



Medical Device Application

Class 1 Status: Under Review

Application Change history

E21-346241 **S22**, 6/08/2021)

Application Progress Date

Date received: 23/07/2021

Review Information

Review flag:

Auto review required: No

Device Product Characteristics

Is the device a single product only? Yes
 Is this medical device presented as a procedure pack? No
 Is the product presented as a system? No
 Is the device, or any form of the device, supplied sterile? No
 Does the device have a measuring function? No
 Is the device, or any form of the device, intended for single use? Yes
 Does the device contain material or ingredients of human origin? No
 Does the device contain materials of recombinant origin? No
 Is the device software or does it incorporate software? No
 Does the device contain materials of animal origin? No
 Is the device intended to be non-invasive? No
 Is the device intended to be invasive via a body orifice? Yes
 Is it to be connected to an active medical device classified as Class IIa or higher? No
 If the device is not intended to be connected to an active medical device, is the device intended to be used continuously for more than 60 minutes? Yes
 Is the device intended to be used in a body orifice other than the oral cavity as far as the pharynx, ear canal up to the ear drum or the nasal cavity? No
 Is the device intended to be used continuously for more than 30 days? No
 Is the device intended to be surgically invasive (i.e. will it penetrate the skin)? No
 Is the device an active device? No
 If the device is a single product does it incorporate a medicine? No
 If the device is a procedure pack does it contain a separate medicine(s)? No
 Is the device intended by the manufacturer to be used for contraception or the prevention of sexually transmitted diseases? No
 Is the device intended by the manufacturer to be used for disinfecting, cleaning, rinsing or hydrating contact lens? No
 Is the device intended by the manufacturer to be used for disinfecting another medical device other than a device used only to clean by means of physical action? No
 Is the device intended by the manufacturer to be non-active and record X-ray diagnostic images? No
 Is the device intended by the manufacturer to be used as a blood bag? No

Application Summary

Application ID: DV-2021-DA-06231-1

Submission ID: DA-2021-06851-1

Sponsor's own reference: **SPL7013** Barrier Nasal Spray

Application for: Medical Device - Included

Will you be applying for listing of this product or procedure in the Medicare Benefit Schedule (MBS)? Yes No

Will you be applying for listing of this product on the Prosthesis List? Yes No

Will you be applying for listing of this product on the Co-dependent or hybrid technology application list? Yes No

Sponsor name: Starpharma Pty Ltd

Sponsor ID: 41979

Agent name:

Contact details: **s22**

Contact email: **s22**@starpharma.com

Is this application supported by EU MDR/IVDR certification?

Manufacturer Information

Manufacturer name: Starpharma Pty Ltd (Australia)[41979]

GMDN code: Nasal moisture barrier dressing[47679]

GMDN description: A substance applied to the nasal passages (nares) to provide a protective moisture barrier to the external environment and to hydrate and soothe the nasal mucosa. It typically contains sodium-based substances, plant oil extracts (e.g., Aloe barbadensis) and purified water and is commonly used to treat dry and irritated nasal passages caused by indoor heat, dry climates, air travel, and oxygen (O2) use. The device is usually provided in the form of a gel or spray and is typically available [non-prescription] over-the-counter (OTC) for use in the home or healthcare facility. After application, this device cannot be reused. See also: Skin moisture barrier dressing 2008.09.09.


Intended purpose:

s47

Device Category Terms

Device category 1: Single-use devices

Attached Documentation

 Declaration of Conformity - AU Declaration of Conformity_22JUL2021.pdf

History

Review Completed - s47G (CN=s22 /OU=TGA/O=Health
24/11/2021)

Record

Date

Fee: Date Paid: 28/07/2021

Start Dates

Finish Dates

Working Days

Application Received	23/07/2021	Payment Received	28/07/2021	3
			Total Working Days	3

From: [Devices Verification Section](#)
To: [s22](#) [@starpharma.com](#)
Subject: s41FH Notice - Non-Compulsory Audit - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679] [SEC=OFFICIAL]
Date: Tuesday, 17 August 2021 8:03:08 AM
Attachments: [image001.png](#)
[image002.png](#)
[image004.png](#)
s41FH Notice - Non-Compulsory Audit - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679].pdf

Dear [s22](#)

Your application DA-2021-06851-1 - Nasal moisture barrier dressing[47679] has been selected for a non-compulsory application audit.

Please refer to the notice for further information.

The information is required by no later than close of business: **16 September 2021**.

Regards

Departmental Officer
Devices Post Market Reforms and Reviews

Medical Devices and Product Quality Division | Health Products Regulation Group
Medical Devices Surveillance Branch
Therapeutic Goods Administration

E: dvs@health.gov.au

Location: FB-51c, 136 Narrabundah Lane, Symonston, ACT, 2609
PO Box 100, Woden ACT 2606, Australia

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

TRIM Reference: E21-346241

Starpharma Pty Ltd
PO Box 2022
PRESTON VIC 3072

Email: **s22** @starpharma.com

Dear **s22**

Notice of selection of application for audit and requirement to provide specified information

Application ID:	DV-2021-DA-06231-1
Submission ID:	DA-2021-06851-1
Classification:	Class I
GMDN:	Nasal moisture barrier dressing[47679]
Sponsor's Reference:	SPL7013 Barrier Nasal Spray

Information is required by no later than close of business: 16 September 2021

I refer to the application identified above in relation to the kind of medical device specified. In accordance with paragraph 41FH(1)(b) of the *Therapeutic Goods Act 1989* (the Act) the Secretary of the Department of Health (the Secretary) has discretion to select any application for ARTG inclusion of a kind of device for audit. As a delegate of the Secretary for the purposes of subsection 41FH(1) of the Act, I have made a decision to select the abovementioned application for audit.

In accordance with paragraph 41FH(2)(a)(i) and (ii) of the Act, I am required to inform you of the selection of the application for audit and to require you to provide information set out in this notice relevant to that audit. I consider that this letter fulfils the requirements of this subsection of the Act.

No audit assessment fee is payable for this audit.

s47G

- That the application was made in accordance with Subdivision A of the Act¹; and
- That all matters in relation to which certifications have been made under section 41FD are correct, including the certification made under:
 - Paragraph 41FD(c) of the Act, that the Device is correctly classified according to the medical device classifications;
 - Paragraph 41FD(j) of the Act, that the information included in or with the application is complete and correct.

s47G

Section 41DB of the Act stipulates that the classifications applying to medical devices or kind of medical devices and related matters are specified in the Regulations. Part 3, Division 3.1 of the Regulations provides the principles for applying the classification rules and states that the classification rules are set out in Schedule 2 of the Regulations.

The manufacturer should take into account the Australian legislation when determining the classification of the Device that is to be supplied in Australia, especially taking into consideration whether there is any difference between the Australian rules and classification rules in different countries.

A medical device is classified having regard to its intended purpose.

The intended purpose is determined from the labelling, instructions for use, advertising material and technical documentation².

The intended purpose you provided in application DV-2021-DA-06231-1 is:

s47

Therefore, based on the above, further clarification is requested about the classification of the Device.

Information to be provided:

- Clarification on the Australian classification rule selected by the manufacturer of the Device based on the intended purpose and justification of the classification rule applied by the manufacturer in accordance with Schedule 2 of the Regulations;
- Instructions for use for the Device (manufacturer's instructions for use or product inserts as supplied in Australia)
- Labels for the Device (copies of the manufacturer's product information as supplied with the Device in Australia);
- A list of all medical devices of the kind that are the subject of this application; and

¹ Part 4-5, Division 1, Subdivision A of the Act - Including medical devices in the Register, Applications

² section 41BD(2) of the Act

- Pictorial images and/or advertising material;
- Technical file including clinical evaluation report/s and clinical trial data supporting the efficacy and mode of action (intended purpose) of the device;
- Evidence that demonstrates compliance with the standards listed in the Declaration of Conformity, specifically:
 - ISO 10993 Biological evaluation of medical devices
 - ICH Q1A(R2), Stability Testing of New Drug Substances and Products
 - ICH Q1E, Evaluation of Stability Data
 - ICH Q6A, Specifications: Test Procedures and Acceptance Criteria for New Drug Substances
 - and New Drug products: Chemical Substances
 - BS EN ISO 14155:2020, Clinical investigations of medical devices for human subjects

Legislation:

Therapeutic Goods Act 1989

<http://www.legislation.gov.au/Series/C2004A03952>

Therapeutic Goods (Medical Devices) Regulations 2002

<http://www.legislation.gov.au/Series/F2002B00237/Compilations>



If information required by this *selection notice* is not received within 10 working days after the end of the period specified in this notice, the abovementioned application will lapse (paragraph 41FK(a) of the Act).

You may withdraw the application at any time prior to a decision being made whether or not to include the devices in the ARTG.

The fee paid for the application is not refundable (<https://www.tga.gov.au/refunds>).

If you decide to withdraw the application, you should advise the TGA of this request in writing, via e-mail: dvs@health.gov.au

If the application lapses or is rejected, you may submit another application at a later date, once all the information is available. Application fees and assessment fees will not be refunded, once an application is lapsed or rejected.

Failure to provide sufficient response may also result in the Delegate making a decision not to include the Device in the ARTG (refer section 41FI(3) of the Act).

Subsection 41FH(2)(a)(ii) of the Act does not limit section 41JA of the Act (further information may be required in relation to this audit)³.

The decision to select an application for audit under section 41FH(1) of the Act is not an 'initial decision' within the meaning of section 60 of the Act. This

³ Subsection 41FH(4) of the Act

means that this decision is not subject to internal review under section 60 of the Act.

How to present the submission

The requested information must be provided as a complete stand-alone submission. Cross-referencing to information submitted in support of previous applications that are already included in the ARTG, or still in process, may not be acceptable and considered or reviewed.

All requested information must be provided in English. Where material is not originally in English a full translation must be submitted, the accuracy of which is the responsibility of the sponsor. All text and pictures must be legible, and pictures must be clearly labelled.

Submissions less than 15MB, can be emailed to dvs@health.gov.au, clearly stating the application ID and the applicant name in the subject line.

Submissions greater than 15MB are to be provided as an electronic copy in the form of a CD, DVD or USB.

The electronic information must be complete and clearly tabulated and titled and should be sent to:

Postal Address

Devices Post Market Reform and Reviews
Medical Devices Surveillance Branch
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

or

Courier Address

Devices Post Market Reform and Reviews
Medical Devices Surveillance Branch
Therapeutic Goods Administration
136 Narrabundah Lane
Symonston ACT 2609

Yours sincerely,

Signed and authorised by

s22

Delegate of the Secretary under s41FH of the Act
Devices Post Market Reform and Reviews
Medical Devices Surveillance Branch
17 August 2021

From: §22
To: [Devices Verification Section](#)
Cc: §22
Subject: RE: TGA reply re sending documents via post - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679] [SEC=OFFICIAL]
Date: Thursday, 16 September 2021 5:20:56 PM
Attachments: [image002.png](#)
[image003.png](#)
[image005.png](#)
[Attach 6 - SPL7013-021 ANNEXES FINAL DRAFT_no refs.pdf](#)

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Hi §22,

I received a bounce back for this email, so am sending Attachment 6 without the cited articles. They are included on the USB.

This is email 5 of 5 and includes the item in bold text.

- Cover letter (also attached to this email)
- Response to application audit request for information, containing links (identified in [blue text](#)) to the supporting information for each response
- Attachment Folder including the following attachments
 - Attachment 1 – Classification Justification – SPL7013 Nasal Spray
 - Attachment 2 – Device Instructions for Use (Draft)
 - Attachment 3 – Device Labels (Draft)
 - Attachment 4 – Technical File – SPL7013 Nasal Spray (a Table of Contents with active links ([blue text](#)) to each section of the Technical File is provided)
 - Attachment 5 – SPL7013-021 Clinical Investigation Report (Final Draft)
 - **Attachment 6 – SPL7013-021 Clinical Investigation Report Annexes (Final Draft) (minus the cited articles)**

Many thanks,

§22

§22

§22

Starpharma Pty Ltd
 4-6 Southampton Crescent, Abbotsford VIC 3067 Australia
 Tel: §22 | Mob: §22
 §22 [@starpharma.com](mailto:§22@starpharma.com) | www.starpharma.com

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From: §22
Sent: Thursday, 16 September 2021 4:54 PM
To: Devices Verification Section <dvs@health.gov.au>
Cc: §22 §22 @starpharma.com) §22 @starpharma.com>
Subject: RE: TGA reply re sending documents via post - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679] [SEC=OFFICIAL]

Hi §22,

This is email 5 of 5 and includes the item in bold text. This is a large file (30MB), I hope it makes it through.

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 - **Attachment 6 – SPL7013-021 Clinical Investigation Report Annexes (Final Draft)**

Many thanks,

§22

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 Starpharma Pty Ltd
 4-6 Southampton Crescent, Abbotsford VIC 3067 Australia
 Tel: §22 | Mob: §22
 §22 @starpharma.com | www.starpharma.com

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From: §22
Sent: Thursday, 16 September 2021 4:51 PM
To: 'Devices Verification Section' <dvs@health.gov.au>
Cc: §22 §22 @starpharma.com §22 @starpharma.com>
Subject: RE: TGA reply re sending documents via post - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679]
 [SEC=OFFICIAL]

Hi §22 ,

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Many thanks,

§22

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 Starpharma Pty Ltd
 4-6 Southampton Crescent, Abbotsford VIC 3067 Australia
 Tel: §22 | Mob: §22
 §22 @starpharma.com | www.starpharma.com

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From: §22
Sent: Thursday, 16 September 2021 4:50 PM
To: 'Devices Verification Section' <dvs@health.gov.au>
Cc: §22 §22 @starpharma.com §22 @starpharma.com>
Subject: RE: TGA reply re sending documents via post - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679]
 [SEC=OFFICIAL]

Hi §22 ,

This is email 3 of 5 and includes the items in bold text.

- Cover letter (also attached to this email)
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2	ESSENTIAL PRINCIPLES CHECKLIST Addendum Essential Principles Checklist – Australia
3	RISK MANAGEMENT TFS3-1 DRR-005 – Risk Management Report – SPL7013 Nasal Spray TFS3-2 DRA-005 – Risk Management Plan & Risk Analysis – SPL7013 Nasal Spray
4	4.1 DEVICE DESIGN AND MANUFACTURING INFORMATION – SPL7013 4.2 DEVICE DESIGN AND MANUFACTURING INFORMATION – SPL7013 NASAL SPRAY TFS4.2-1 Starpharma EN ISO 13485:2016 Certificate
5	5.1 COMPLIANCE WITH STANDARDS 5.2 VALIDATION OF SPL7013 MANUFACTURE 5.3 VALIDATION OF SPL7013 NASAL SPRAY MANUFACTURE 5.4 SPL7013 STABILITY 5.5 SPL7013 NASAL SPRAY STABILITY 5.6 CHEMISTRY AND TOXICOLOGY REVIEW
6	NONCLINICAL INFORMATION (DEVICE PERFORMANCE & BIOCOMPATIBILITY) TFS6-12 BER-001 – Biological Evaluation Report – SPL7013 Nasal Spray TFS6-12-1 Evaluation of Cytotoxicity TFS6-12-2 Assessment of Sensitising Properties TFS6-12-3 Assessment of Intranasal Tolerance
7	CLINICAL EVALUATION Appendix 1 Literature Search Output Appendix 2 Clinical Evaluation Data Appraisal
8	PACKAGING, LABELLING, AND INSTRUCTIONS FOR USE
9	DECLARATION OF CONFORMITY EC Declaration of Conformity AU Declaration of Conformity

- o Attachment 5 – SPL7013-021 Clinical Investigation Report (Final Draft)
- o Attachment 6 – SPL7013-021 Clinical Investigation Report Annexes (Final Draft)

Many thanks,

§22

§22

Starpharma Pty Ltd
4-6 Southampton Crescent, Abbotsford VIC 3067 Australia
Tel: §22 | Mob: §22
§22 @starpharma.com | www.starpharma.com

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From: §22
Sent: Thursday, 16 September 2021 4:48 PM
To: 'Devices Verification Section' <dvs@health.gov.au>
Cc: §22, §22 @starpharma.com, §22 @starpharma.com>
Subject: RE: TGA reply re sending documents via post - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679]
[SEC=OFFICIAL]

Hi §22,

This is email 2 of 5 and includes the items in bold text.

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Many thanks,

§22

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4-6 Southampton Crescent, Abbotsford VIC 3067 Australia
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§22 @starpharma.com | www.starpharma.com

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From: §22

Sent: Thursday, 16 September 2021 4:44 PM

To: Devices Verification Section <dvs@health.gov.au>

Cc: §22, §22 @starpharma.com

Subject: RE: TGA reply re sending documents via post - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679]
[SEC=OFFICIAL]

Hi §22,

I'll be sending the submission in a series of 5 emails.

This is email 1 of 5 and includes the items in bold text.

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Many thanks,

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4-6 Southampton Crescent, Abbotsford VIC 3067 Australia
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§22 [@starpharma.com](mailto:§22@starpharma.com) | www.starpharma.com

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From: Devices Verification Section <dvs@health.gov.au>

Sent: Thursday, 16 September 2021 4:31 PM

To: §22 <§22@starpharma.com>

Subject: TGA reply re sending documents via post - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679]
[SEC=OFFICIAL]

Hi §22

The TGA would prefer PDF documents in emails please.

Regards

§22

Devices Post Market Review and Reform Section
Medical Devices Surveillance Branch

Email: §22 <§22@health.gov.au>

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

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From: §22 <§22@starpharma.com>

Sent: Thursday, 16 September 2021 4:22 PM

To: Devices Verification Section <dvs@health.gov.au>

Cc: §22 <§22@starpharma.com>

Subject: RE: TGA reply re sending documents via post - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679]
[SEC=OFFICIAL]

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Hi §22,

Thanks for your mail.

I'm happy to send the submission as a series of emails, however please note that the interactive links embedded in the documents will no

longer work.

If you're able to download from a link I can provide, the links should remain and you can easily navigate the submission.

Please let me know which you would prefer, the emails or the link, or both.

Many thanks,

s22

[Redacted signature]

Starpharma Pty Ltd
4-6 Southamplon Crescent, Abbotsford VIC 3067 Australia
Tel: s22 | Mob: s22
s22 @starpharma.com | www.starpharma.com

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From: Devices Verification Section <dvs@health.gov.au>

Sent: Thursday, 16 September 2021 4:17 PM

To: s22 s22 @starpharma.com>

Subject: TGA reply re sending documents via post - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679]
[SEC=OFFICIAL]

Hi s22

Is there any chance that you could send all the documents via email as the Department of Health – TGA is very large and your parcel may take some time to be delivered to the appropriate section.

You can send several emails if the size of the files is very large. Additionally considering lockdown in Canberra most staff are not in the office and will not be there to collect the delivery.

Regards

s22

Devices Post Market Review and Reform Section
Medical Devices Surveillance Branch

Email: s22 @health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

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From: s22 s22 @starpharma.com>

Sent: Wednesday, 15 September 2021 2:25 PM

To: Devices Verification Section <dvs@health.gov.au>

Cc: s22 s22 @starpharma.com>

Subject: RE: s41FH Notice - Non-Compulsory Audit - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679]
[SEC=OFFICIAL]

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear s22,

Reference is made to the medical device application audit (TRIM reference E21-346241) for SPL7013 Nasal Spray (Application Ref: DV-2021-DA-06231-1).

We are pleased to advise that the information requested by TGA as part of the Medical Device Application Audit has been couriered to the Devices Post Market Reform and Reviews, Medical Devices Surveillance Branch, and is scheduled to arrive on Thursday 16th September.

The total size of the response in electronic format was larger than 15MB, so we have provided the information electronically on a USB drive.

The USB contains the following files/folders:

- Cover letter (also attached to this email)
- Response to application audit request for information, containing links (identified in blue text) to the supporting information for each response
- Attachment Folder including the following attachments
 - Attachment 1 – Classification Justification – SPL7013 Nasal Spray
 - Attachment 2 – Device Instructions for Use (Draft)
 - Attachment 3 – Device Labels (Draft)
 - Attachment 4 – Technical File – SPL7013 Nasal Spray (a Table of Contents with active links (blue text) to each section of the Technical File is provided)
 - Attachment 5 – SPL7013-021 Clinical Investigation Report (Final Draft)
 - Attachment 6 – SPL7013-021 Clinical Investigation Report Annexes (Final Draft)

We trust the information provided in the submission satisfies the TGA's questions and application audit requirements.

In addition to the above notification, we were hoping you could advise if the application audit is a Level 1 or Level 2 audit?

We look forward to your reply.

Many thanks,

s22

[Redacted Signature]

Starpharma Pty Ltd
4-6 Southampton Crescent, Abbotsford VIC 3067 Australia
Tel: s22 | Mob: s22
s22 @starpharma.com | www.starpharma.com

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From: Devices Verification Section <dvs@health.gov.au>

Sent: Tuesday, 17 August 2021 8:03 AM

To: s22 s22 @starpharma.com>

Subject: s41FH Notice - Non-Compulsory Audit - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679]
[SEC=OFFICIAL]

Dear s22

Your application DA-2021-06851-1 - Nasal moisture barrier dressing[47679] has been selected for a non-compulsory application audit.

Please refer to the notice for further information.

The information is required by no later than close of business: **16 September 2021.**

Regards

Departmental Officer
Devices Post Market Reforms and Reviews

Medical Devices and Product Quality Division | Health Products Regulation Group
Medical Devices Surveillance Branch
Therapeutic Goods Administration
E: dvs@health.gov.au
Location: FB-51c. 136 Narrabundah Lane, Symonston, ACT, 2609
PO Box 100, Woden ACT 2606, Australia



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From: s22
To: [Devices Verification Section](#)
Cc: s22
Subject: RE: TGA reply re sending documents via post - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679] [SEC=OFFICIAL]
Date: Thursday, 16 September 2021 4:55:35 PM
Attachments: [image002.png](#)
[image003.png](#)
[image005.png](#)

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Hi s22,

I've have sent you a series of 5 emails with our application audit response and supporting data.

It would be terrific if you could confirm receipt of all emails, particularly the last email as the attachment was quite large at 30MB.

Many thanks,

[Redacted]

[Redacted]

Starpharma Pty Ltd
4-6 Southampton Crescent, Abbotsford VIC 3067 Australia
Tel: s22 | Mob: s22
s22 @starpharma.com | www.starpharma.com

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From: Devices Verification Section <dvs@health.gov.au>
Sent: Thursday, 16 September 2021 4:31 PM
To: [Redacted] <[Redacted]@starpharma.com>
Subject: TGA reply re sending documents via post - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679] [SEC=OFFICIAL]

Hi [Redacted]

The TGA would prefer PDF documents in emails please.

Regards

s22

s22

Devices Post Market Review and Reform Section
Medical Devices Surveillance Branch

Email: s22 @health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

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From: s22 <s22@starpharma.com>
Sent: Thursday, 16 September 2021 4:22 PM
To: Devices Verification Section <dvs@health.gov.au>
Cc: s22 s22@starpharma.com
Subject: RE: TGA reply re sending documents via post - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679] [SEC=OFFICIAL]

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Hi s22 ,

Thanks for your mail.

I'm happy to send the submission as a series of emails, however please note that the interactive links embedded in the documents will no longer work.

If you're able to download from a link I can provide, the links should remain and you can easily navigate the submission.

Please let me know which you would prefer, the emails or the link, or both.

Many thanks,
s22

s22

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Tel: s22 | Mob: s22
s22@starpharma.com | www.starpharma.com

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From: Devices Verification Section <dvs@health.gov.au>

Sent: Thursday, 16 September 2021 4:17 PM

To: <@starpharma.com>

Subject: TGA reply re sending documents via post - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679] [SEC=OFFICIAL]

Hi s22

Is there any chance that you could send all the documents via email as the Department of Health – TGA is very large and your parcel may take some time to be delivered to the appropriate section.

You can send several emails if the size of the files is very large. Additionally considering lockdown in Canberra most staff are not in the office and will not be there to collect the delivery.


Regards

s22

Devices Post Market Review and Reform Section
Medical Devices Surveillance Branch

Email: s22@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
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Many thanks,

[Redacted]

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From: Devices Verification Section <dvs@health.gov.au>

Sent: Tuesday, 17 August 2021 8:03 AM

To: [Redacted] s22 @starpharma.com>

Subject: s41FH Notice - Non-Compulsory Audit - DW-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679] [SEC=OFFICIAL]

Dear [Redacted] s22

Your application DA-2021-06851-1 - Nasal moisture barrier dressing[47679] has been selected for a non-compulsory application audit.

Please refer to the notice for further information.

The information is required by no later than close of business: **16 September 2021.**

Regards

Departmental Officer
Devices Post Market Reforms and Reviews

Medical Devices and Product Quality Division | Health Products Regulation Group
Medical Devices Surveillance Branch
Therapeutic Goods Administration

E: dvs@health.gov.au

Location: FB-51c, 136 Narrabundah Lane, Symonston, ACT, 2609
PO Box 100, Woden ACT 2606, Australia



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Australian Government
Department of Health
Therapeutic Goods Administration

Medical Devices Program

Internal Form

DPMRRS	Medical Device Application Audit Request and Report – Devices Clinical		
Comes under	DPMRRS DVS - Requesting an assessment for an Application Audit		
Applicable to	Devices Post Market Review and Reforms Section Devices Clinical Section	Authorised by	s22 [REDACTED] s22 [REDACTED], DPMRRS
Date issued	September 2021	Version #	1.0

Application audit details

This section completed by DPMRRS Assessor

Date of request	27/09/2021
Submission ID	DA-2021-06851-1
Application ID	DV-2021-DA-06231-1
Sponsor name	Starpharma Pty Ltd
Manufacturer name	Starpharma Pty Ltd 4-6 Southampton Crescent ABBOTSFORD VIC 3067 Australia
Application audit type	Non-mandatory audit
Reason for clinical review	This application was selected for audit as it was advertising claims for virucidal and antiviral activity against SARS-CoV-2 in vitro. s47 [REDACTED] D21-3139663
Documents provided	<input checked="" type="checkbox"/> IFU and labels - ONLY DRAFTS PROVIDED D21-3124621

Record Details	D21-3133205 Application audit assessment request and report - Clinical (DCS) - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal ~ Starpharma Pty(2).DOCX	Effective Date	27/09/2021
Print Date	29/05/2024 3:48	Page 1 of 11	

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[D21-3124701](#)

For implantable devices (unless excluded*), PIL

For urogynaecological mesh devices, PIC

Advertising material

[D21-3124666](#)

Clinical evaluation report (CER), signed and dated ≤ 2 years [D21-3124637](#)

[D21-3124701](#)

CV of clinical expert [D21-3124637](#)

[D21-3124701](#)

Risk management report, including FMEA [D21-3124717](#)

[D21-3124717](#)

For implantable devices, MRI safety evidence

Comment from DPMRRS Assessor:

Only draft labels and IFU provided

The Zip file in the TRIM folder contains the same documents are the 5 emails labelled the same folder eg.1-5/5 There are some documents in the Zip folder that can't be opened. All the files in the emails can be opened.

Comment from Clinical Section Reviewer:

In addition to the above documents, the sponsor provided cover letters and a number of documents from the technical file for the product:

Request comments

- *Classification Justification* document that includes a discussion of the physical mode of action of the product ([D21-3124621/Attach 1](#))
- *Application Audit Response* document that includes information about ([D21-3124621/02](#)):
 - the use of astodimer sodium in a vaginal gel called Fleurstat BVgel (ARTG 295465) and associated advertising requirements relating to the Poisons Standard
 - biocompatibility
 - product specification
- *Essential Principles Checklist* ([D21-3124717](#))
- *Compliance with Standards* ([D21-3124717](#))
- *Device description* ([D21-3124717](#))
- *Device Design and Manufacturing* ([D21-3124717](#))
- *Validation of SPL7013 Manufacture* ([D21-3124717](#))

Record Details	D21-3133205 Application audit assessment request and report - Clinical (DCS) - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal ~ Starpharma Pty(2).DOCM	Effective Date	27/09/2021
Print Date	29/05/2024 3:48		Page 2 of 11

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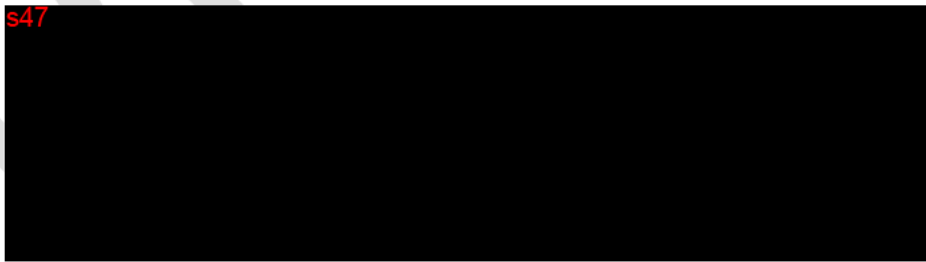
	<ul style="list-style-type: none"> • Validation of SPL7013 Nasal Spray Manufacture (D21-3124717) • SPL7013 Stability (D21-3124717) • SPL7013 Nasal Spray Stability (D21-3124717) • Chemistry and Toxicology Review (D21-3124717) • Nonclinical information (D21-3124701): <ul style="list-style-type: none"> ○ <i>Nonclinical investigations</i> ○ <i>Biological Evaluation Report</i> ○ <i>Assessment of intranasal tolerance</i> ○ <i>Assessment of sensitising properties</i> ○ <i>Evaluation of Cytotoxicity</i> <p>Note that assessments have also been requested from medicines, BIOME and microbiology sections.</p>
Submission TRIM reference	E21-346241

* Excluded devices are sutures, staples, dental filings, dental braces, tooth crowns, general (endosseous) dental implants, screws, wedges, plates, wires, pins, clips, connectors

Device description

Information from eBS device application form

DPMRRS to complete for class other than Class III/AIMD, delete if not applicable. If there are multiple applications in the submission, add and complete a table for each application.

Device name	<p>Sponsor's own reference in eBS application:</p> <ul style="list-style-type: none"> • SPL7013 Barrier Nasal Spray
Intended purpose	<p>s47</p> 
Device classification	Class I
GMDN code and term	Nasal moisture barrier dressing[47679]
Comments	<p><u>Comment from DPMRRS:</u></p> <p>There has been considerable conversation between the Sponsor and the TGA (s22) regarding this device. Initially the sponsor was</p>

wanting to clarify if this device was a medical device or a medicine. [D21-3139649](#), [D21-3139650](#), [D21-3139661](#), [D21-3139662](#), [D21-3139671](#), [D21-3139703](#) and [D21-3139714](#). They received an infringement notice for unlawful advertising on 2/7/21 [D21-3139687](#)

Information provided for the application audit – labels, IFU, advertising, CER etc.

Clinical Reviewer to complete. If there are multiple applications or devices in the submission, add and complete a table for each application or device.

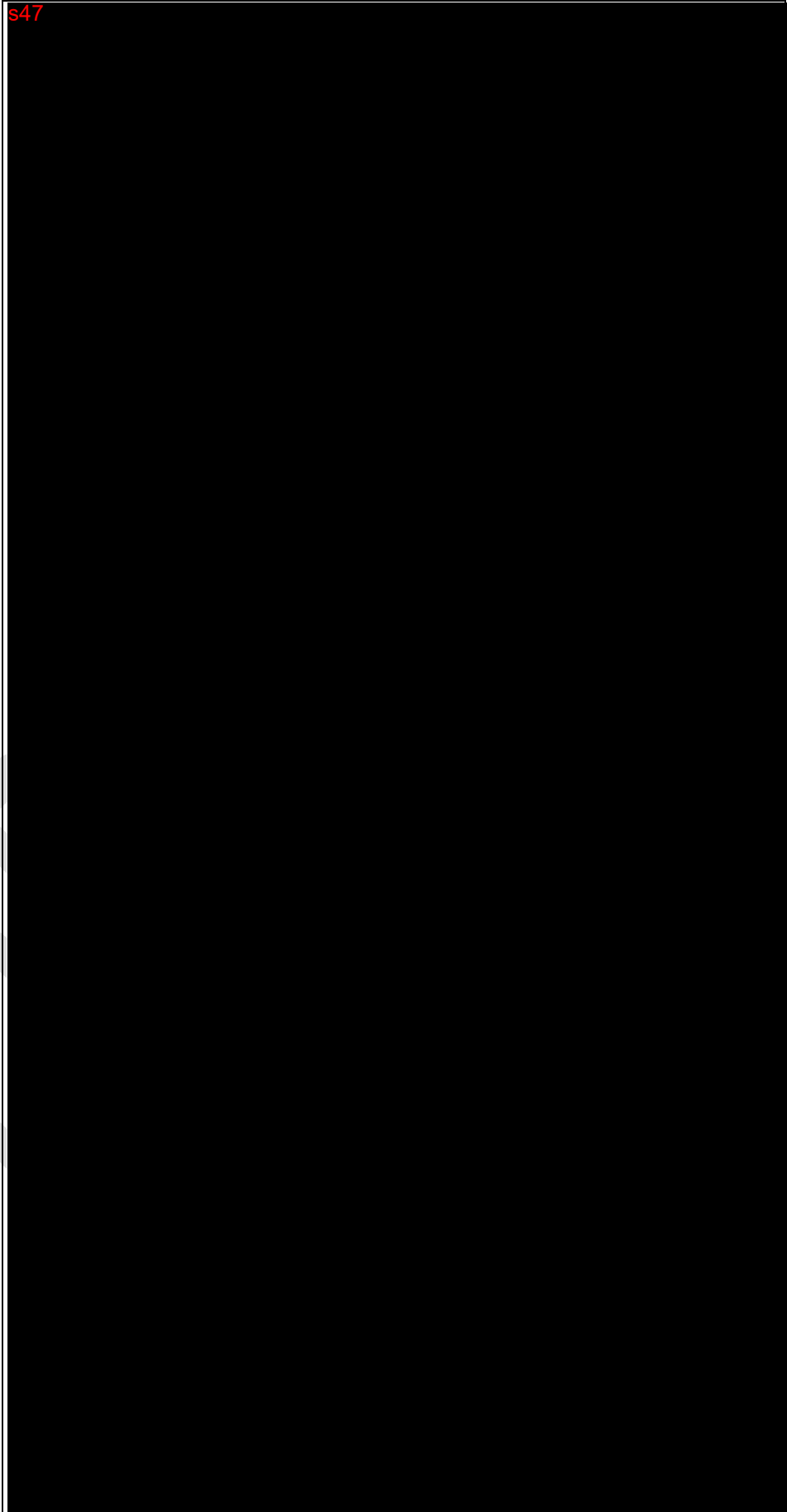
Device name

SPL7013 Barrier Nasal Spray *

Device description

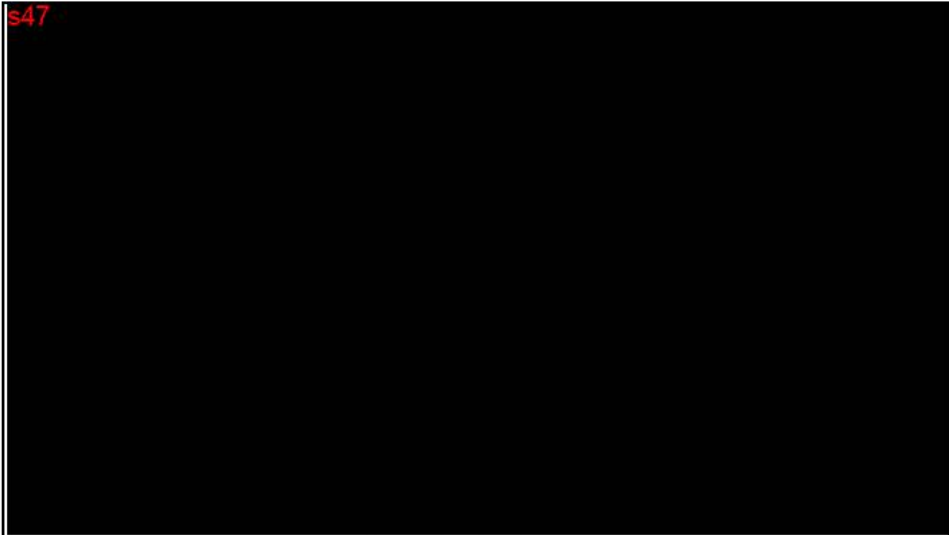
s47

s47



Record Details	D21-3133205 Application audit assessment request and report - Clinical (DCS) - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal ~ Starpharma Pty(2).DOCM	Effective Date	27/09/2021
Print Date	29/05/2024 3:48		Page 5 of 11

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Device configurations & variants

The IFU states:

The carton contains 1 multi-dose plastic bottle with cap, containing 10 mL of SPL7013 Barrier Nasal Spray solution and 1 instruction leaflet.

SPL7013 Nasal Spray consists of a bottle and a nasal pump (actuator) able to deliver a nominal volume of 100 µL per actuation

System or procedure pack

Accessories or compatible devices

Comments

* From the documentation provided for the application audit, it appears that various trade names may be applied to the product.

The draft label and IFU documents ([D21-3124621](#)/ Attach 3 & Attach 2) state:

SPL7013 may be replaced with VivaGel, VIRALEZE, astodimer sodium or other term.

Section 8 of the Technical File on *PACKAGING, LABELLING, AND INSTRUCTIONS FOR USE* ([D21-3124701](#)/ S8.0_v6.0/p.) states:

The following trade names may be used for SPL7013 Nasal Spray labelling:

Trade Names*
VIRALEZE™ or VIRALEZE® Antiviral Nasal Spray
VIRALEZE™ or VIRALEZE® Barrier Nasal Spray

* Trade names are in use or are potential trade names.

Note: **Unique product identifier (UPI)** is only relevant for Class III/AIMD devices as it forms part of the “kind of medical device” by which these devices are entered in the ARTG. The UPI is given to the device by its manufacturer to identify the device and any variants. **Device name** is relevant to devices other than Class III/AIMD. For non-Class

Record Details	D21-3133205 Application audit assessment request and report - Clinical (DCS) - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal ~ Starpharma Pty(2).DOCX	Effective Date	27/09/2021
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III/AIMD devices, the name of the device does not form part of the “kind of medical device” and is not recorded in the ARTG entry.

Application background

Conformity assessment documents accompanying application

These conformity assessment documents are linked to the application as Manufacturer Evidence or attached to the device application form. They were considered satisfactory in relation to the application passing preliminary assessment.

DPMRRS to complete. If there are multiple QMS or product assessment documents, add and complete the relevant table for each document.

QMS Yes No

Product assessment Yes No

Declaration of conformity (Schedule 3) Yes No

Comments

Australian Declaration of Conformity Clause 6.6 Schedule 3:
[D21-2936021](#)

EC Declaration of Conformity

* **First issue/decision date** is the date the document was first issued or a decision was made for the subject device.

^ **Latest issue date/decision date** and **Expiry date** may not be relevant or available, delete if appropriate.

Relevant TGA assessments and regulatory history

Information about whether the device has novel technological features or intended purpose, and whether the device, devices from the same family or related devices in a system/procedure pack (or accessories or compatible devices) have previously been reviewed by the TGA.

Clinical Reviewer to complete. For conformity assessments, review the root file for manufacturer and current and withdrawn rejected applications.

For ARTG inclusions, review current and cancelled ARTG entries (by GMDN, UPI), and current and withdrawn/rejected applications.

For post-market, review SARA database, Qlik IRIS Triage Dev app, and search for device name in TRIM.

If there are multiple certificates or ARTG entries, add and complete the relevant table for each certificate/document. Delete fields that are not relevant. Duplicate fields where necessary.

Novel technological features or intended purpose in Australia?

Yes No

s47

Record Details	D21-3133205 Application audit assessment request and report - Clinical (DCS) - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal ~ Starpharma Pty(2).DOCM	Effective Date	27/09/2021
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TGA conformity assessment certification Yes No

Certificate type	Schedule 3, Part 1.6
Manufacturer	Starpharma Pty Ltd
UPI	Dual Protect Condom
Relevance to subject device	Contains SPL7013 (astodrimmer sodium) as medicine
Certificate number	AU D00387
Issue date	First issue: 7/08/2014 Current issue: 2/07/2019
Expiry date	2/07/2024
TGA clinical assessment	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Comments	<p><u>ARTG inclusion information</u></p> <p>ARTG number: 228796 (start date 02/10/2014, Class III)</p> <p>Sponsor: Starpharma Pty Ltd</p> <p>UPI: Dual Protect Condom</p> <p>Intended purpose from ARTG:</p> <p><i>A medicated Hevea-latex rubber sheath intended to completely cover the penis during coitus, to prevent sperm from gaining access to the female reproductive tract and/or prevent the transmission of sexually transmitted infections. The condom lubricant contains a medicinal substance(astodrimmer sodium), an antiviral agent. This is a single use device.</i></p>
Certificate TRIM reference	D19-5719003
Clinical assessment TRIM reference	Certification report: R14/865155 Clinical assessment: R13/730750

ARTG inclusion Yes No

ARTG number	295465
-------------	--------

Date of ARTG inclusion	24/10/2017
Sponsor name	Starpharma Pty Ltd
Manufacturer	Starpharma Pty Ltd
Name of device/GMDN	<p>Name of device: Fleurstat – VivaGel</p> <p>GMDN: Vaginal flora gel</p> <p>Intended purpose from ARTG:</p> <p><i>Astodrimmer sodium (Fleurstat; VivaGel®), in the form of a gel applied by the user into the vagina: once daily for seven days, for topical treatment and rapid relief of bacterial vaginosis (BV), including unpleasant vaginal odour and discharge, helping to normalise vaginal pH and restore the normal vaginal flora balance; once every second day, for prevention of recurrent BV, including prevention of unpleasant vaginal odour and discharge, helping to maintain normal vaginal pH and vaginal flora balance. After application, the device cannot be reused.</i></p> <p><u>Condition of inclusion:</u></p> <p><i>* This medical device ARTG inclusion is limited to some medical devices of the kind. These devices of the kind are medical devices identified by the manufacturer as: Fleurstat; VivaGel®.</i></p> <p><i>* Other devices of the kind must not be supplied under this ARTG entry in Australia until and unless evidence of compliance of those devices with the essential principles is provided and accepted by the TGA.</i></p> <p><i>* Further the person in relation to whom the kind of device is included in the ARTG (the sponsor) must provide to the Therapeutic Goods Administration, Department of Health, on an annual basis reports similar to a kind referred to in regulation 5.11 of the Therapeutic Goods (Medical Devices) Regulations 2002.</i></p> <p><i>* The reporting periods and the time for providing these reports must be consistent with the time specified in paragraph (4) of this 5.11 regulation. - If the sponsor requires a variation to the ARTG entry to include details of the medical devices that are to be imported, supplied or exported under an entry, the sponsor will need to submit a Device Change Request to the TGA.</i></p>
Device classification	Class IIa
Relevance to subject device	VivaGel has been identified as a possible trade name for the subject device.

Record Details	D21-3133205 Application audit assessment request and report - Clinical (DCS) - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal ~ Starpharma Pty(2).DOCM	Effective Date	27/09/2021
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	In addition, in the <i>Device Design and Manufacturing</i> document provided in the current submission (D21-3124717) it is stated: <i>SPL7013 is included in the formulation of SPL7013 Nasal Spray. SPL7013 is also included in VivaGel Vaginal Gel.</i> <i>SPL7013 for both products is manufactured by the same process and manufacturer.</i>
Application ID	DV-2015-DA-18829-1
Submission ID	DA-2015-08487-1
Comments	Clinical assessment scope was limited to review of the mechanism of action of the product.
Submission TRIM reference	2015/034186
Clinical assessment TRIM reference	Round 1: R16/158208 Round 2: D17-159318

Post-market details Yes No

Comments

A search using the TGA Qlik app IRIS Triage (v2.6) did not reveal any significant post-market issues with ARTG 228796 and 295465.

Other overseas regulator conformity assessment documents representing product assessment

These conformity assessment documents are additional to documents that accompanied the device application form.

Review:

- *Cover letter and information provided for the application audit, including CER.*
- *Relevant market authorisation databases for Health Canada and US FDA documents.*
- *Whether the UPI, variants and intended purpose are the same as the subject device.*

If multiple documents exist for a regulator or there are multiple devices, add and complete the relevant table each document/device. Delete fields that are not relevant.

EC Certification Yes No Not known

In the CER (p.10), it is stated that the product is Class I in the EU. Therefore, third party certification is not required. The draft labels carry a CE mark.

Record Details	D21-3133205 Application audit assessment request and report - Clinical (DCS) - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal ~ Starpharma Pty(2).DOCM	Effective Date	27/09/2021
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Health Canada Yes NoUS FDA Yes NoJapan Yes No Not known

Conclusions and recommendations

Reviewer's conclusion and recommendation

Background information completed.

Sufficient information has been provided for clinical assessment of the SPL7013 Barrier Nasal Spray to proceed.

Sign-Off – Clinical Section Reviewer

Name	s22		
Signature	Signed electronically in TRIM	Date	1 October 2021

Version history

Version	TRIM Reference	Description of change	Author/s	Effective date

Record Details	D21-3133205 Application audit assessment request and report - Clinical (DCS) - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal ~ Starpharma Pty(2).DOCM	Effective Date	27/09/2021
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Medical Devices Program

Internal Form

DPMRRS FORM	Request for assessment - BIOME		
Comes under	Requesting an assessment for an Application Audit		
Applicable to	Devices Applications Section	Authorised by	s22 [REDACTED] DAS
Date issued	September 2021	Version #	1.0

Round 1

DPMRRS to complete details

Attention s22 [REDACTED] - s22 [REDACTED] BIOME

Sponsor's reference SPL7013 Barrier Nasal Spray

GMDN Code

Nasal moisture barrier dressing[47679] - A substance applied to the nasal passages (nares) to provide a protective moisture barrier to the external environment and to hydrate and soothe the nasal mucosa. It typically contains sodium-based substances, plant oil extracts (e.g., Aloe barbadensis) and purified water and is commonly used to treat dry and irritated nasal passages caused by indoor heat, dry climates, air travel, and oxygen (O2) use. The device is usually provided in the form of a gel or spray and is typically available [non-prescription] over-the-counter (OTC) for use in the home or healthcare facility. After application, this device cannot be reused. See also: Skin moisture barrier dressing 2008.09.09.

Sponsor Starpharma Pty Ltd

Manufacturer Starpharma Pty Ltd (Australia)[41979]

Submission ID DA-2021-06851-1 DV-2021-DA-06231-1

Device Classification Class I

Record Details D21-3133218 Application Audit Assessment Request and Report - BIOME Effective Date 21/04/2021

- DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture ~ Starpharma Pty Ltd(2).DOCM

Print Date 29/05/2024 3:51

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Application container [E21-346241](#)

IFU and labels [D21-3124621](#), Only draft labels and IFU provided

Test reports [D21-3124701](#), [D21-3124717](#)

Clinical report [D21-3124666](#), [D21-3124637](#)

Coordinating Assessor [s22](#) Date: 27 September 2021

The request for assessment:

DPMRRS Assessor to complete

This application was selected for audit as it was advertising claims for virucidal and antiviral activity against SARS-CoV-2 in vitro. [D21-3139663](#), [s47](#)

There has been considerable conversation between the Sponsor and the TGA () regarding this device. Initially the sponsor was wanting to clarify if this device was a medical device or a medicine. [D21-3139649](#), [D21-3139650](#), [D21-3139661](#), [D21-3139662](#), [D21-3139671](#), [D21-3139703](#) and [D21-3139714](#). They received an infringement notice for unlawful advertising on 2/7/21 [D21-3139687](#).

The Zip file in the TRIM folder contains the same documents are the 5 emails labelled the same folder eg.1-5/5 There are some documents in the Zip folder that can't be opened. All the files in the emails can be opened.

The sponsor has made claims about compliance with Standards and how they have tested against those Standards - Titles of Documents to be reviewed :

[D21-3124701](#)

1/ 'S6.0_v02-Attach TSF12-3-BER-001-01-Assess of Intranasal Tolerance' study against EN ISO 10993-10:2013 biological evaluation of medical devices part 10: Test for irritation and skin sensitization.

2/ 'S6.0_v02-Attachment TSF12-BER-001-01-SPL7013 Nasal Spray' Biological evaluation report against EN ISO 14971 and ISO 10993-1

3/ 'S6.0_v02-Attach TSF12-2-BER-001-01-Assess of Sensitising Properties' study against the Magnusson and Kligman method and ISO 10993-10 (August 2010) biological evaluations of medical devices: Test for irritation and skin sensitisation.

[D21-3124717](#)

4/ 'S5.1_v03 - Compliance with standards'

5/ 'S5.3_v03 - VALIDATION OF SPL7013 MANUFACTURE'

6/ 'S5.4_v01 - SPL7013 STABILITY'

7/ 'S5.5_v04 - SPL7013 NASAL SPRAY STABILITY'

Record Details D21-3133218 Application Audit Assessment Request and Report - BIOME Effective Date 21/04/2021

- DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture ~ Starpharma Pty Ltd(2).DOCX

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8/ S5.6_v03 - CHEMISTRY AND TOXICOLOGY REVIEW'

Completion date required for assessment (if applicable): 29 October 2021

Assessment from the BIOME Assessor:*BIOME Assessor to complete***Recommendation**

Following the assessment of the Sponsor's supplied information on the 1% SPL7013 Nasal Spray product:

- Sufficient evidence was provided to demonstrate biological safety with compliance to ISO 10993 parts 1, 3, 5, 10, and 11
- No non-clinical chronic toxicity study evaluating the effect of SPL7013 nasal spray via intra-nasal administration was provided
- The chemical and toxicological review according to ISO 10993-18 and -19 deems the constituents of the device to pose an acceptable health risk
- Sufficient evidence was provided in order to establish suitability of the device container closure

See full report at TRIM [D21-3269704](#)**Assessment outcome:***BIOME Assessor to complete*Does the supporting data demonstrate compliance with the relevant essential principles in the *Therapeutic Goods (Medical Devices) Regulations 2002*? Yes No*BIOME Assessor to complete*

Name

s22

Signature

<electronic signature>

Date 1 November 2021

Version history

Version	TRIM Reference	Description of change	Author/s	Effective date
V1.0				

Record Details D21-3133218 Application Audit Assessment Request and Report - BIOME - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture ~ Starpharma Effective Date 21/04/2021

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DPMRRS FORM	Request for assessment - MICRO		
Comes under	Requesting an assessment for an Application Audit		
Applicable to	Devices Applications Section	Authorised by	s22 [REDACTED] DAS
Date issued	September 2021	Version #	1.0

Round 1

DPMRRS to complete details

Attention	s22 [REDACTED] – s22 [REDACTED] Microbiology
Sponsor's reference	SPL7013 Barrier Nasal Spray
GMDN Code	Nasal moisture barrier dressing [47679] - A substance applied to the nasal passages (nares) to provide a protective moisture barrier to the external environment and to hydrate and soothe the nasal mucosa. It typically contains sodium-based substances, plant oil extracts (e.g., Aloe barbadensis) and purified water and is commonly used to treat dry and irritated nasal passages caused by indoor heat, dry climates, air travel, and oxygen (O ₂) use. The device is usually provided in the form of a gel or spray and is typically available [non-prescription] over-the-counter (OTC) for use in the home or healthcare facility. After application, this device cannot be reused. See also: Skin moisture barrier dressing 2008.09.09.
Sponsor	Starpharma Pty Ltd
Manufacturer	Starpharma Pty Ltd (Australia)[41979]
Submission ID	DA-2021-06851-1 DV-2021-DA-06231-1
Device Classification	Class I

Record Details	D21-3145073 Application Audit Assessment Request MICROBIOLOGY - DA-2021-06851-1 - Nasal moisture barrier dressing [47679] - Starpharma Pty ~ JoW(2).DOCM	Effective Date	21/04/2021
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Application container	E21-346241	
IFU and labels	D21-3124621 , Only draft labels and IFU provided	
Test reports	D21-3124701 , D21-3124717	
Clinical report	D21-3124666 , D21-3124637	
Coordinating Assessor	s22 DVS DPMRRS	Date: 28 September 2021

The request for assessment:*DPMRRS Assessor to complete*

<p>This application was selected for audit as it was advertising claims for virucidal and antiviral activity against SARS-CoV-2 in vitro. D21-3139663 s47</p> <p>There has been considerable conversation between the Sponsor and the TGA (s22) regarding this device. Initially the sponsor was wanting to clarify if this device was a medical device or a medicine. D21-3139649, D21-3139650, D21-3139661, D21-3139662, D21-3139671, D21-3139703 and D21-3139714. They received an infringement notice for unlawful advertising on 2/7/21 D21-3139687</p> <p>The Zip file in the TRIM folder contains the same documents as the 5 emails labelled the same folder eg.1-5/5 There are some documents in the Zip folder that can't be opened. All the files in the emails can be opened.</p>

Completion date required for assessment (if applicable): Click or tap to enter a date.**Assessment from the MICRO Assessor:***MICRO Assessor to complete*

<p>The Devices post-market review and reform section (DPMRRS) have requested the Microbiology section to undertake a Round 1 assessment for an application for inclusion in the ARTG, DV-2021-DA-06231-1 - DA-2021-06851-1. Specifically, Microbiology was requested to review the sponsor's documentation for suitability of the microbiological specifications, and compliance with relevant standards.</p> <p>s47</p>

Record Details	D21-3145073 Application Audit Assessment Request MICROBIOLOGY - DA-2021-06851-1 - Nasal moisture barrier dressing [47679] - Starpharma Pty ~ JoW(2).DOCX	Effective Date	21/04/2021
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SPL7013 is the active component in two commercially available products - SPL7013 (or VivaGel) Vaginal Gel, and Condom with SPL7013 Lubricant. The formulation of SPL7013 Nasal Spray is based on SPL7013 Vaginal Gel, the only exception being a reduced amount of s47 present in the nasal spray formulation (s47).

It is noted that the product information includes claims that the product forms a barrier to, physically traps, or inactivates, viruses. This does not represent a virucidal claim, and the microbiological aspects of any virucidal effects of the product have therefore not been assessed. If claims are made that the product is able to kill viruses, or any microorganisms, data to support such claims will need to be provided for review.

Section 4.2 of the submission states that SPL7013 Nasal Spray is supplied as a multi-dose, metered nasal spray that delivers 100 µL of SPL7013 nasal spray formulation per actuation. Each multi-dose container is packaged in an outer carton and accompanied by an approved leaflet containing the instructions for use.

Manufacture of SPL7013 occurs at s47. The SPL7013 Barrier Nasal Spray is manufactured at s47. The company has stated that all subcontracted suppliers are subject to Starpharma's Supplier Management Program. Certificates or licences supporting supplier accreditation are on file at Starpharma.

The SPL7013 specifications include:

s47

The composition of the nasal spray is as follows:

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Table 4.2-2 Batch Composition of SPL7013 Nasal Spray

Component	% w/w	Quantity 1% w/w (kg / 100 kg batch)	Standard*	Function of Ingredient
[Redacted content]				

It appears (Section 5.3 of the submission) that the proposed commercial batch size is 1020kg.

[Redacted content]				
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S47

Development and process validation batches were manufactured as follows (Section 5.3):

Table 1 – Summary of SPL7013 Nasal Spray Batches

Batch	Batch Number	D.O.M. ¹	Scale
Development Batch ²	AJ0469/004	AUG 2020	2 L
Pilot Batch 1	20J05/V10351	OCT 2020	102 kg
Pilot Batch 2	20L17/V11901	DEC 2020	102 kg
Validation / Commercial Batch 1	21A06/V12409	JAN 2021	1020 kg
Validation / Commercial Batch 2	21B02/V12663	FEB 2021	1020 kg
Validation / Commercial Batch 3	21C02/V13255	MAR 2021	1020 kg

¹ D.O.M. = Date of Manufacture; ² This batch manufacture at Intertek Melbourne; all other batches manufactured by Conformia.

The results of microbiological testing of each of the above batches met the acceptance criteria (stated above). For the 3 validation batches, samples were removed from each of the top and bottom of the final solution before filtration, and at the beginning, middle and end of the filtration process.

The assessor is unable to locate information regarding the sterilisation of the packaging components (identified as AeroPump container and applicator). **The company should be asked to provide details regarding the method(s) used to sterilise the product packaging, and confirm validation of the process(es) to demonstrate that a Sterility Assurance Level of 10⁻⁶ is achieved.**

Section 5.5 of the submission contains stability test data for SPL7013 Nasal Spray. It is stated that
The available stability data has been evaluated to support the assigned shelf life for 1% SPL7013 Nasal Spray stored at or below 30°C.

The document also states that the assigned shelf life 'is recorded in FP-009'. However, the assessor is not able to locate a statement of what the proposed product closed shelf-life is. Nor can a statement be found stating the in-use (open) product shelf-life. **The company should be asked to specify the proposed closed product shelf-life, and proposed in-use (open) product shelf-life.**

It is noted that the proposed text for the product IFU does not include a statement regarding the recommended in-use (open) product shelf life. Similarly, the proposed text for the product carton does not include a statement regarding the recommended in-use (open) product shelf life. This information should be added to the IFU and to the product labels.

Record Details	D21-3145073 Application Audit Assessment Request MICROBIOLOGY - DA-2021-06851-1 - Nasal moisture barrier dressing [47679] - Starpharma Pty ~ JoW(2).DOCM	Effective Date	21/04/2021
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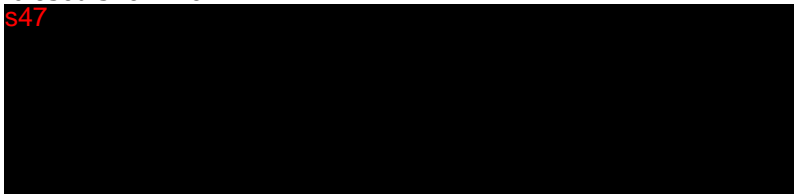
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The proposed formulation contains propyl p-hydroxybenzoate as an antimicrobial preservative. The company has stated (Section 5.5) that the closed shelf life assigned to the commercial product 'will be based on real-time and accelerated stability data from three primary batches of the product as well as supporting data from the early development batch'. The batches used for stability studies are those specified in the table above.

The pilot batches were produced using the same formulation and packaged in the same container closure system as proposed for commercial batches. The manufacturing process used for all primary stability batches was the same as is intended for commercial scale production and each primary batch has met the same specification as that intended for marketed product.

The company states that the stability study program has been designed to meet applicable recommendations of European Medicines Agency (EMA) guideline and ICH guidelines Q1A (R2), Q1D, and Q1E pertaining to the stability conditions, proposed testing frequency, evaluation and analysis methodology, and sample selection.

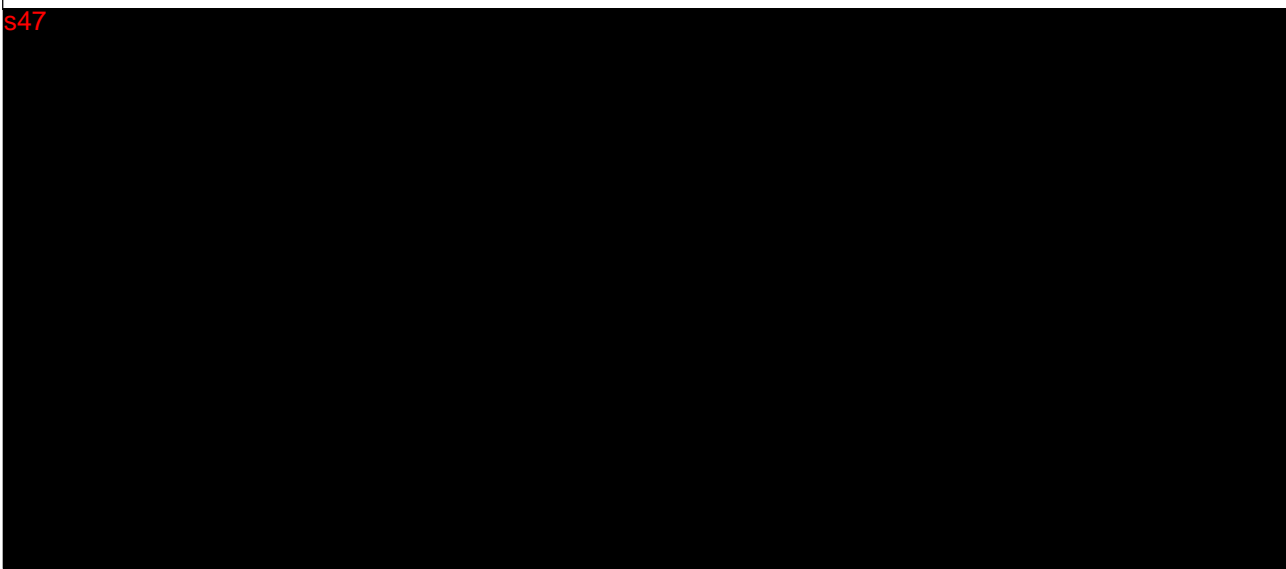
During stability studies, the company applied the batch release microbial content limits to assess the closed shelf life:



Real-Time Stability Studies involved storage of product at 30°C/65% RH. Microbial content testing of the Pilot batches was performed initially, and at 3 month, 4.5 month, 6 month, 12 month, 24 month and 36 month timepoints. Microbial content testing of the Validation batches was performed initially, and at 3 month, 6 month, 9 month, 12 month, 24 month and 36 month timepoints.

Accelerated Stability Studies involved storage of product at 40°C/75% RH. Microbial content testing of the Pilot batches and Validation batches was performed initially, and at 3 month and 6 month timepoints.

Only results up to the 12 month testing timepoints have been provided, with all results meeting the requirements.



The assessor is unable to locate Report AAM40082, MRN 210319-3 in the submission documentation. The company should be asked to provide a copy of this report for review.

The EMA recommends that an in-use stability study be conducted for human medicinal products, to establish a period of time during which a multidose product can be used whilst retaining quality within an accepted specification once the container is opened. The company has stated that SPL7013 Nasal Spray is not intended to be 'opened' during normal use, where 'opened' means the nasal pump is physically unscrewed and removed from the vessel housing the formulation, thereby exposing the formulation to the environment. In this case, the company claims that the combination of the stability data and preservative efficacy data will serve as justification for not conducting an in-use stability study.

This is acknowledged, though container closure integrity testing is also required, to demonstrate that ingress of organisms into an in-use product container does not represent a contamination risk, and that the container is capable of maintaining a barrier to environmental organisms.

To evaluate the efficacy of the container closure system, weight loss testing was conducted on Pilot batches 1 and 2, and Validation batches 1, 2 and 3, at both long-term and accelerated conditions of 30°C/60% RH and 40°C/75% RH, respectively.

Assuming any weight loss is due to the loss of water, the EMA suggests that, for aqueous products stored in semipermeable containers, weight loss is considered significant when it is 5% or more over 3 months under low humidity conditions (40°C/25%RH). At the accelerated conditions employed by Starpharma (40°C/75% RH), the weight loss has been shown to be a maximum of 1% over six months (a weight loss of 0.1 g from 10 mL of product).

The weight loss under low humidity conditions (40°C/25%RH) can be derived from the accelerated data on hand (40°C/75%RH) using the table below, taken from the EMA guideline, Stability Testing of Existing Active Substances and Related Finished Products:

Reference relative humidity	General testing conditions at the same temperature	Ratio of water loss rates at a given temperature
25° C/25 % RH	25° C/60 % RH	1.9 = (100-25) : (100-60)
25° C/40 % RH	25° C/60 % RH	1.5 = (100-40) : (100-60)
40° C/25 % RH	40° C/75 % RH	3.0 = (100-25) : (100-75)

Using this table, the company has determined that the potential weight loss under low humidity conditions would be $3 \times 1\% = 3\%$ over 6 months, which is lower than the EMA's definition of 'significant'. This figure demonstrates that the container closure for SPL7013 Nasal Spray is effective at preventing significant weight loss.

The company has apparently therefore concluded that the product container system is 'integral'. This will be accepted.

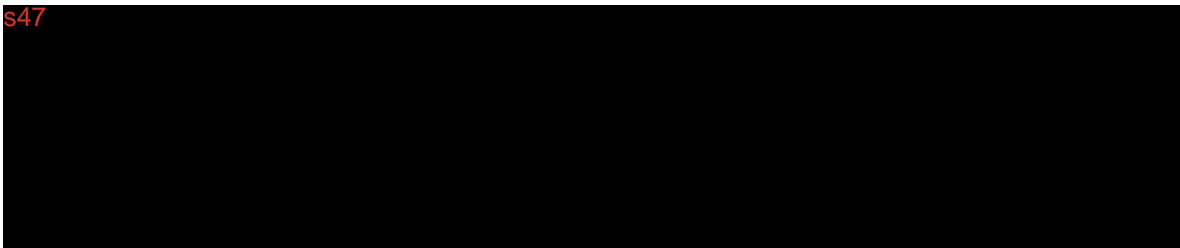
RECOMMENDATIONS

The following questions should be put to the company:

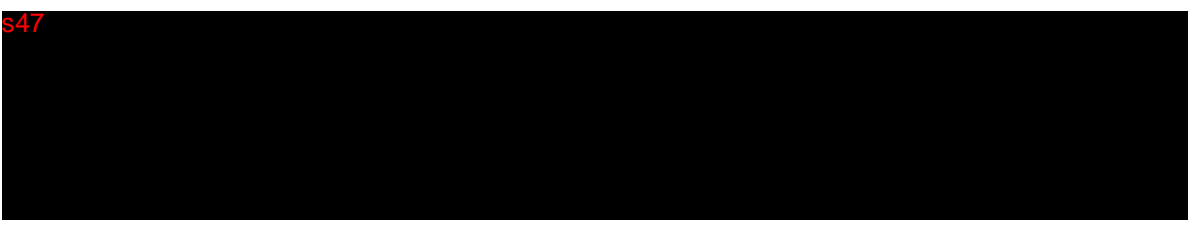
Record Details	D21-3145073 Application Audit Assessment Request MICROBIOLOGY - DA-2021-06851-1 - Nasal moisture barrier dressing [47679] - Starpharma Pty ~ JoW(2).DOCM	Effective Date	21/04/2021
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1. The assessor is unable to locate information regarding the sterilisation of the packaging components (identified as AeroPump container and applicator). You are asked to provide details regarding the method(s) used to sterilise the product packaging, and confirm validation of the process(es) to demonstrate that a Sterility Assurance Level of 10^{-6} is achieved.
2. Section 5.5 of the submission contains stability test data for SPL7013 Nasal Spray. It is stated that
The available stability data has been evaluated to support the assigned shelf life for 1% SPL7013 Nasal Spray stored at or below 30°C.
The document also states that the assigned shelf life 'is recorded in FP-009'. However, the assessor is not able to locate a statement of what the proposed product closed shelf-life is. Nor can a statement be found stating the in-use (open) product shelf-life. You are asked to specify the proposed closed product shelf-life, and proposed in-use (open) product shelf-life.
3. It is noted that the proposed text for the product IFU does not include a statement regarding the recommended in-use (open) product shelf life. Similarly, the proposed text for the product carton does not include a statement regarding the recommended in-use (open) product shelf life. This information should be added to the IFU and to the product labels.

4. s47 

To date, the 6-month accelerated and 12-month real-time results have been received and comply with the specification. Please provide this data for review.

5. s47 

The assessor is unable to locate Report AAM40082, MRN 210319-3 in the submission documentation. Please provide a copy of this report for review.

Assessment outcome:

MICRO Assessor to complete

Record Details	D21-3145073 Application Audit Assessment Request MICROBIOLOGY - DA-2021-06851-1 - Nasal moisture barrier dressing [47679] - Starpharma Pty ~ JoW(2).DOCM	Effective Date	21/04/2021
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Does the supporting data demonstrate compliance with the relevant essential principles in the <i>Therapeutic Goods (Medical Devices) Regulations 2002</i> ?	s47G
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MICRO Assessor to complete

Name	Microbiology Assessor		
Signature	Signed in TRIM	Date	1 August 2022

Version history

Version	TRIM Reference	Description of change	Author/s	Effective date
V1.0				



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Medical Devices Program

Internal Form

DPMRRS FORM	Request for assessment - MEDICINES		
Comes under	Requesting an assessment for an Application Audit		
Applicable to	Devices Applications Section	Authorised by	s22 [REDACTED] DAS
Date issued	September 2021	Version #	1.0

Round 1

DPMRRS to complete details

Attention	s22 [REDACTED] – [REDACTED] Medicines
Sponsor's reference	SPL7013 Barrier Nasal Spray
GMDN Code	Nasal moisture barrier dressing[47679] - A substance applied to the nasal passages (nares) to provide a protective moisture barrier to the external environment and to hydrate and soothe the nasal mucosa. It typically contains sodium-based substances, plant oil extracts (e.g., Aloe barbadensis) and purified water and is commonly used to treat dry and irritated nasal passages caused by indoor heat, dry climates, air travel, and oxygen (O2) use. The device is usually provided in the form of a gel or spray and is typically available [non-prescription] over-the-counter (OTC) for use in the home or healthcare facility. After application, this device cannot be reused. See also: Skin moisture barrier dressing 2008.09.09.
Sponsor	Starpharma Pty Ltd
Manufacturer	Starpharma Pty Ltd (Australia)[41979]
Submission ID	DA-2021-06851-1 DV-2021-DA-06231-1
Device Classification	Class I

Record Details	D21-3145877 Application Audit Assessment Request MEDICINES~ DA-2021-06851-1 - Nasal moisture barrier dressing [47679] - Starpharma Pty Ltd(2).DOCX	Effective Date	21/04/2021
Print Date	29/05/2024 4:00	Page 1 of 3	

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Application container	E21-346241	
IFU and labels	D21-3124621 , Only draft labels and IFU provided	
Test reports	D21-3124701 , D21-3124717	
Clinical report	D21-3124666 , D21-3124637	
Coordinating Assessor	s22 DVS DPMRRS	Date: 28 September 2021

The request for assessment:*DPMRRS Assessor to complete*

This application was selected for audit as it was advertising claims for virucidal and antiviral activity against SARS-CoV-2 in vitro. [D21-3139663](#) **s47**

There has been considerable conversation between the Sponsor and the TGA (**s22**) regarding this device. Initially the sponsor was wanting to clarify if this device was a medical device or a medicine. [D21-3139649](#), [D21-3139650](#), [D21-3139661](#), [D21-3139662](#), [D21-3139671](#), [D21-3139703](#) and [D21-3139714](#). They received an infringement notice for unlawful advertising on 2/7/21 [D21-3139687](#)

The Zip file in the TRIM folder contains the same documents are the 5 emails labelled the same folder eg.1-5/5 There are some documents in the Zip folder that can't be opened. All the files in the emails can be opened.

Completion date required for assessment (if applicable): Click or tap to enter a date.**Assessment from the Medicines Assessor:***Medicines Assessor to complete*

--

Assessment outcome:*Medicines Assessor to complete*

Does the supporting data demonstrate compliance with the relevant essential principles in the <i>Therapeutic Goods (Medical Devices) Regulations 2002</i> ?	<input type="checkbox"/> Yes <input type="checkbox"/> No
---	--

Medicines Assessor to complete

Record Details	D21-3145877 Application Audit Assessment Request MEDICINES~ DA-2021-06851-1 - Nasal moisture barrier dressing [47679] - Starpharma Pty Ltd(2).DOCM	Effective Date	21/04/2021
Print Date	29/05/2024 4:00	Page 2 of 3	
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Name			
Signature		Date	Click or tap to enter a date.

Version history

Version	TRIM Reference	Description of change	Author/s	Effective date
V1.0				

DRAFT



Australian Government
Department of Health
 Therapeutic Goods Administration

Medical Devices Program

Internal Form

DCS FORM 1.a	Application Audit Clinical Assessment Report		
Comes under	DCDS SOP 1 Clinical assessment of application audit		
Applicable to	Devices Clinical Section	Authorised by	Simon Singer Director and Principal Medical Advisor, DCS
Date issued	13 January 2021	Version #	1.0

Application details

To be completed by Clinical Section Reviewer

Submission ID	DA-2021-06851-1
Application ID	DV-2021-DA-06231-1
Sponsor name	Starpharma Pty Ltd
Manufacturer name	Starpharma Pty Ltd 4-6 Southampton Crescent ABBOTSFORD VIC 3067 Australia
Device classification	Class I
GMDN code and term	Nasal moisture barrier dressing[47679]
Name of device(s)	SPL7013 Barrier Nasal Spray
Submission TRIM reference	E21-346241
Comments	See initial clinical review for background: D21-3133205

Device description

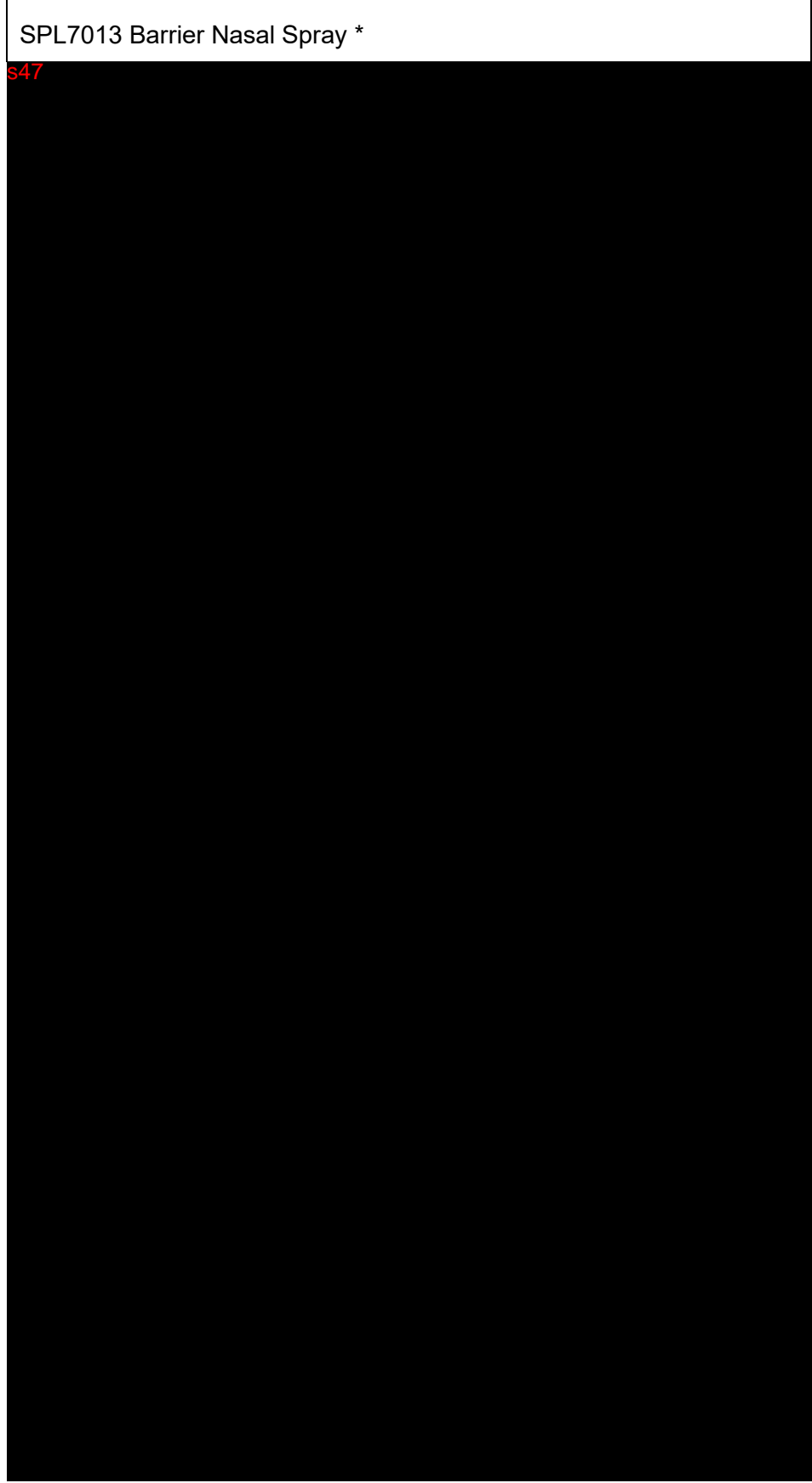
To be completed by Clinical Section Reviewer.

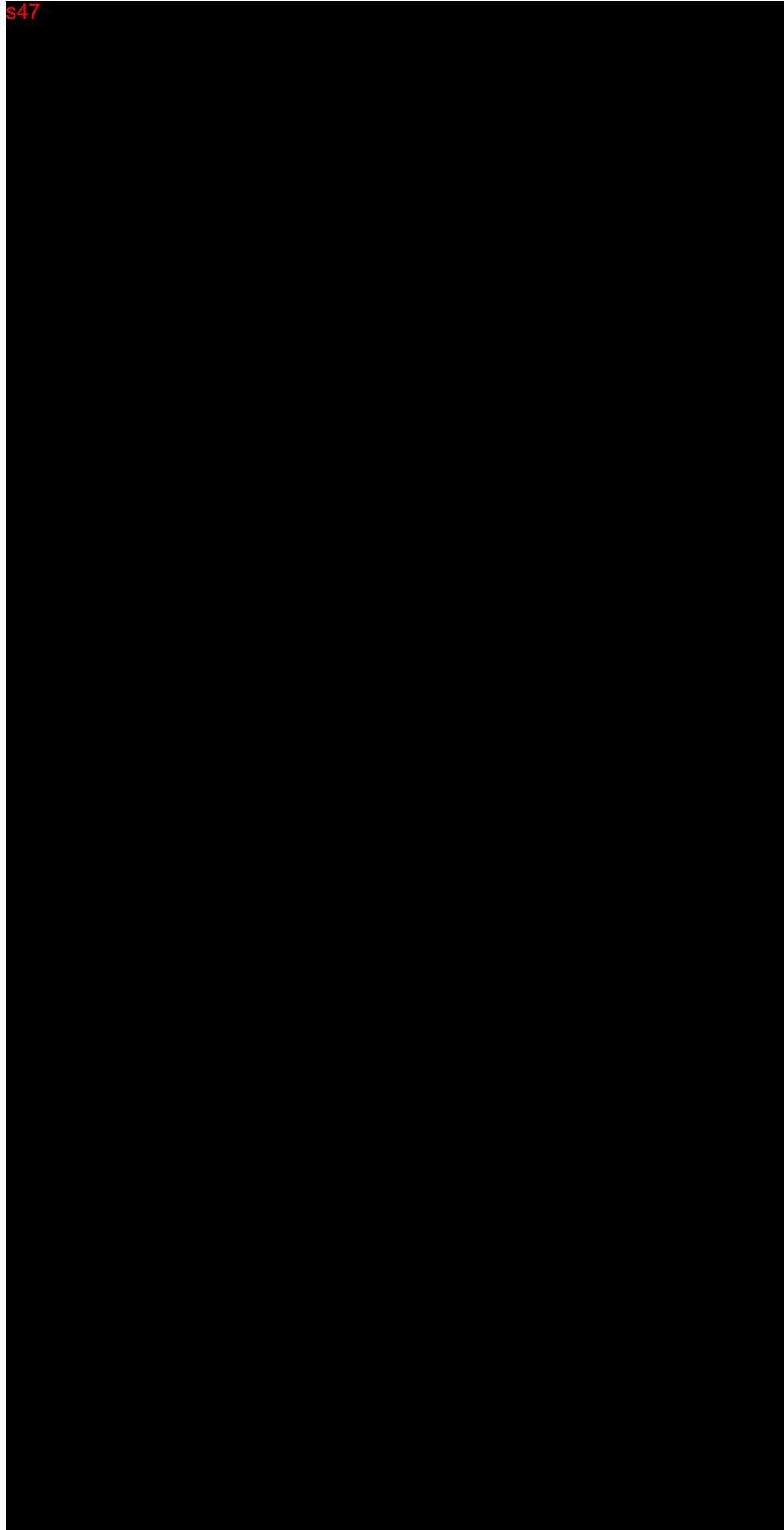
Device name

SPL7013 Barrier Nasal Spray *

s47

Device description

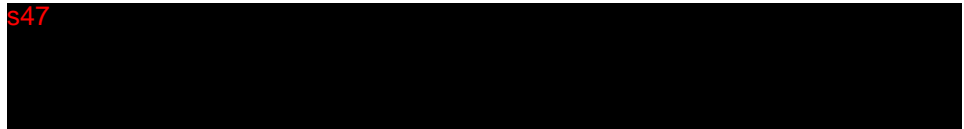




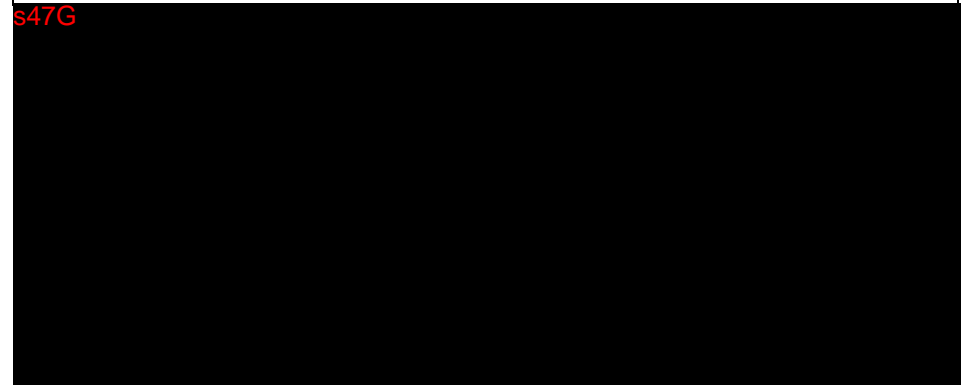
s47

Record Details	D21-3159714 Application Audit Clinical Assessment Report - DA-2021-06851-1(2).DOCM	Effective Date	13/01/2021
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Clinical assessor comments



Device configurations & variants

The IFU states:

The carton contains 1 multi-dose plastic bottle with cap, containing 10 mL of SPL7013 Barrier Nasal Spray solution and 1 instruction leaflet.

SPL7013 Nasal Spray consists of a bottle and a nasal pump (actuator) able to deliver a nominal volume of 100 µL per actuation

System or procedure pack

Accessories or compatible devices

* From the documentation provided for the application audit, it appears that various trade names may be applied to the product.

The draft label and IFU documents ([D21-3124621](#)/ Attach 3 & Attach 2) state:

SPL7013 may be replaced with VivaGel, VIRALEZE, astodrimer sodium or other term.

Section 8 of the Technical File on *PACKAGING, LABELLING, AND INSTRUCTIONS FOR USE* ([D21-3124701](#)/ S8.0_v6.0/p.) states:

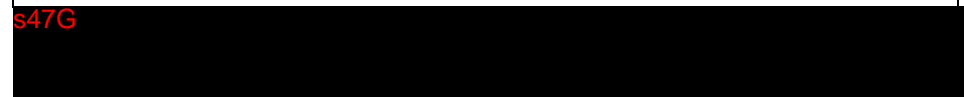
Comments

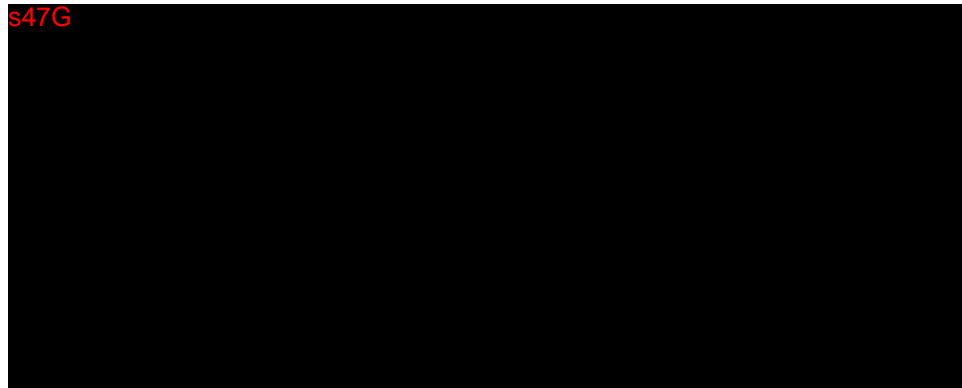
The following trade names may be used for SPL7013 Nasal Spray labelling:

Trade Names*
VIRALEZE™ or VIRALEZE® Antiviral Nasal Spray
VIRALEZE™ or VIRALEZE® Barrier Nasal Spray

* Trade names are in use or are potential trade names.

Clinical assessor comments





Scope of assessment

The aim of this assessment is to verify whether SPL7013 Barrier Nasal Spray complies with essential principles (EPs) 1, 3, 6, 13 and 14 from a clinical perspective.

Assessment

Clinical evidence report (CER)

Competency of CER author	<p>The CER was signed by Professor s22. He is a retired Physician with experience in infectious diseases.</p> <p>A CV was not provided for Professor s22</p> <p><i>It should be requested that the sponsor provide a CV for Dr s22 or a CV from a suitable clinical expert that has reviewed and endorsed the CER.</i></p>
Comments	<p><i>Comment on whether the CER includes evaluation of the clinical data.</i></p>

Demonstration of equivalence Yes No

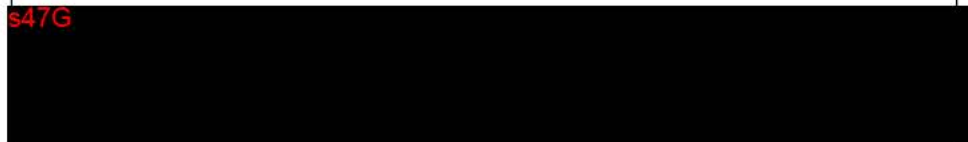
Comparator device	<p><i>Enter device name, and manufacturer if different</i></p>
Can the comparator device be considered substantially equivalent to the subject device based on clinical, technical and biological aspects?	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Claimed mechanism of action (CER p13/77)</p> <p>The CER states that “The mechanism of action of SPL7013 in achieving its intended purpose has been demonstrated to be dependent on physical means and is not considered to be pharmacological, metabolic, nor chemical in nature.”</p> <p>“Numerous in vitro and in vivo studies, including peer-reviewed published studies, have shown that SPL7013 physically blocks a broad spectrum of viruses from infecting, including:</p>

- HIV (Dezzutti et al., 2004; Jiang et al., 2005; Lackman-Smith et al., 2008; Tyssen et al., 2010; Telwatte et al., 2011),
- HSV (Bernstein et al., 2003; Gong et al., 2005; Tyssen et al., 2010),
- Adenoviruses (Romanowski et al., 2021), and
- SARS-CoV-2 (Paull et al., 2021a; Paull et al., 2021b)."

"Extensive investigations have shown that positively charged regions of viral attachment proteins result in viruses being physically trapped by the large, negatively charged branches of SPL7013 (Tyssen et al., 2010) (see Figure 1). These trapped viruses are unable to infect cells."

"In contrast to systemic antiviral drugs that enter a host cell to pharmacologically inhibit viral replication, a large negatively charged substance such as SPL7013 physically blocks the initial generic interaction of the virus with cell surface structures that eventually leads to specific receptor-mediated viral attachment and fusion, to inhibit viral replication."

Clinical assessor comments



Substantial equivalence

As per CER p27/77:

"While strict substantial equivalence to a predicate device is not claimed, the clinical evaluation does rely to some extent on indirect clinical data based on the comparability of SPL7013 Nasal Spray to other nasal sprays already in the market; this determination of comparability is discussed below."

A comparison of formulation characteristics between nasal spray products, including a moisturising nasal spray product with and without hyaluronic acid is provided in the table below.

Table 4-1. Comparison of Formulation Characteristics Between SPL7013 Nasal Spray and Other Nasal Spray Products

Formulation Characteristic:	iota-Carrageenan Nasal Sprays	HPAC Nasal Spray	Hyaluronic Acid Nasal Spray	Saline Sprays
Claims	Shorten the duration of a cold and help reduce the severity of cold symptoms. Forms a barrier in the nasal passage that traps cold viruses, helping to reduce their multiplication and spread, allowing your body's natural defenses to sweep viruses away from the nasal lining.	- Trap, inactivate and remove cold viruses before a cold develops - Reduces chances of a full-blown cold	- The saline spray forms a protective film over the mucosa and restores the natural barriers of the mucous membrane. - It is ideal for the prevention and treatment of dryness. It hydrates and promotes nasal mucosa regeneration.	- Saline solution restores moisture to dry nasal passages and sinuses, and curbs inflammation of mucous membranes.
Isotonic / saline solution	Yes	Low pH formulation	Yes	Yes
Virus blocking polymer	Yes - Iota-carrageenan	Yes - hydroxypropyl methylcellulose	No	No
Muco / Bioadhesive polymer	Yes - Iota-carrageenan	Yes - hydroxypropyl methylcellulose	Yes - hyaluronic acid	No
Delivery	Nasal Spray Pump	Nasal Spray Pump	Nasal Spray Pump	Nasal Spray Pump
Marketed Brands (examples)	- Mucicare® Cold Defence - Algover® - Erkältungsspray - Colomam® - Profens Nasen-Spray - Schrotzand - Flo® Travel Nasal Spray	- Vick® First Defence	- Hysat Hyaluron Spray - Hyla Mist - NasoGEL - Free nose	- Fess nasal spray - Flo nasal spray

The CER also presented a comparability analysis of SPL7013 Nasal Spray and a carrageenan containing nasal spray, Mundicare® Cold Defence Nasal. The comparability analysis (see Table 4-2) considered the clinical, technical, and biological characteristics of both devices.

Table 4-2. Comparability of SPL7013 Nasal Spray and Iota-Carrageenan (e.g., Mundicare® Cold Defence) Nasal Spray

Evidence Discussed	SPL7013 Nasal Spray	Mundicare® Cold Defence Nasal Spray	Impact of Difference on Safety and Performance
Clinical Characteristics			
Intended purpose, and the clinical condition being targeted	s47	Used supportively for the treatment of common cold caused by viruses. It can be used additionally as prophylaxis based on the continuous moistening of the nasal mucous membrane. Forms a protective barrier in the nasal lining to trap common cold viruses, helping to stop their multiplication and spread. To help prevent a cold by forming a protective barrier in the nasal lining to trap common cold viruses. Clinical condition: colds/respiratory virus Adults and children over the age of 1 year. Can be used during pregnancy and breastfeeding.	s47G
Target population			
Site of application to/in the body		The nasal mucosa of the septum, turbinates, vestibule, and as far as the nasopharynx.	

Table 4-2. Comparability of SPL7013 Nasal Spray and Iota-Carrageenan (e.g., Mundicare® Cold Defence) Nasal Spray

Evidence Presented	SPL7013 Nasal Spray	Mundicare® Cold Defence Nasal Spray	Impact of Difference on Safety and Performance
Type of contact and duration of use/contact with the body	s47	Product application is 3 times daily when displaying symptoms, and maximum exposure is expected to be over a 12-16 hour period. Device exposure would occur for a period of 8-11 hours overnight or during sleep. Product application may also be intermittent when used for prevention.	s47G
Environment of use		At the first signs of a cold, within 48 hours of symptoms appearing, to help shorten its duration and lessen the severity of symptoms. It can also be used when not experiencing a cold to provide moisturisation of the nasal lining and to also help prevent a cold by forming a protective barrier in the nasal lining to trap common cold viruses.	
Intended user (e.g., healthcare professional or layperson)		Healthcare professionals and lay persons.	
Recommended dosing regimen		1 spray (140µl) into each nostril, 3 times a day, as needed.	

Table 4-2. Comparability of SPL7013 Nasal Spray and Iota-Carrageenan (e.g., Mundicare® Cold Defence) Nasal Spray

Evidence Presented	SPL7013 Nasal Spray	Mundicare® Cold Defence Nasal Spray	Impact of Difference on Safety and Performance
Technical Characteristics			
Design (e.g., dimensions, design tolerances etc.)	s47	A nasal pump (actuator) able to deliver a nominal volume of 140 µl per actuation for adults, and 50 µl per actuation for children.	s47G
Material (e.g., chemical formulation, additives etc.)		Iota-carrageenan (1.2 mg/ml) Other ingredients: Saline solution (purified water, sodium chloride 0.9%)	
Specifications and properties		Very low viscosity, clear, colourless liquid formulation, with pH in neutral range.	

Table 4-2. Comparability of SPL7013 Nasal Spray and Iota-Carrageenan (e.g., Mundicare® Cold Defence) Nasal Spray

Evidence Presented	SPL7013 Nasal Spray	Mundicare® Cold Defence Nasal Spray	Impact of Difference on Safety and Performance
Deployment methods	s47	Formulation delivered via an actuator and pump. Clean nostrils before use. Before first use, pump a few times if necessary, until spray is discharged.	s47G
Critical performance requirements		Store between 5 and 30°C. Keep away from light.	
Principles of operation		The principle of operation is a moistening barrier between viruses and nasal mucosa. The barrier contains a substance that traps and blocks virus thereby inactivating the virus.	
Biological Characteristics			
Biocompatibility of materials in contact with the body		Carrageenan is a naturally derived compound, commonly used in food preparation, while saline is of no biological concern to the body. Clinical data indicate the product is safe and well-tolerated.	
Biological action		The device forms a physical moisture barrier that traps and inactivates extracellular virus via a physical mechanism of action.	
Degradation mechanism and profile		Following application, the device shall be evacuated from the body via the digestive system.	
Biological response (e.g., inflammatory/immune response, tissue integration etc.)		The device utilizes a physical mechanism of action to achieve its intended purpose.	

The CER, p34/77, stated:

“Based on the evaluation of comparability in Table 4-2, SPL7013 Nasal Spray is considered comparable to Iota-carrageenan (Mundicare® Cold Defence) nasal sprays. Where differences have been identified, these do not impact the safety and/or performance of SPL7013 Nasal Spray with respect to Mundicare® Cold Defence.”

Clinical assessor comments

s47G

Formulation

The composition of the SPL7013 Nasal Spray is shown below.

Table 6.2-1 Composition of SPL7013 Nasal Spray

Ingredient	% w/w	Quantity 1% w/w (kg / 100 kg batch)	Standard*	Function of Ingredient
[Redacted content]				

Clinical assessor comments

[Redacted content]

Manufacturer’s clinical investigations

Has the manufacturer conducted clinical investigations?

Yes No

If no, what is the rationale and is this acceptable?

Comment on rationale and its acceptability

Pre-market or post-market clinical investigations?

Pre-market Post-market

Randomised controlled trial

Device Predicate Nil

Comments: *Include details of trial and outcomes*

Single-arm trial

Device Predicate Nil

Comments: *Include details of trial and outcomes*

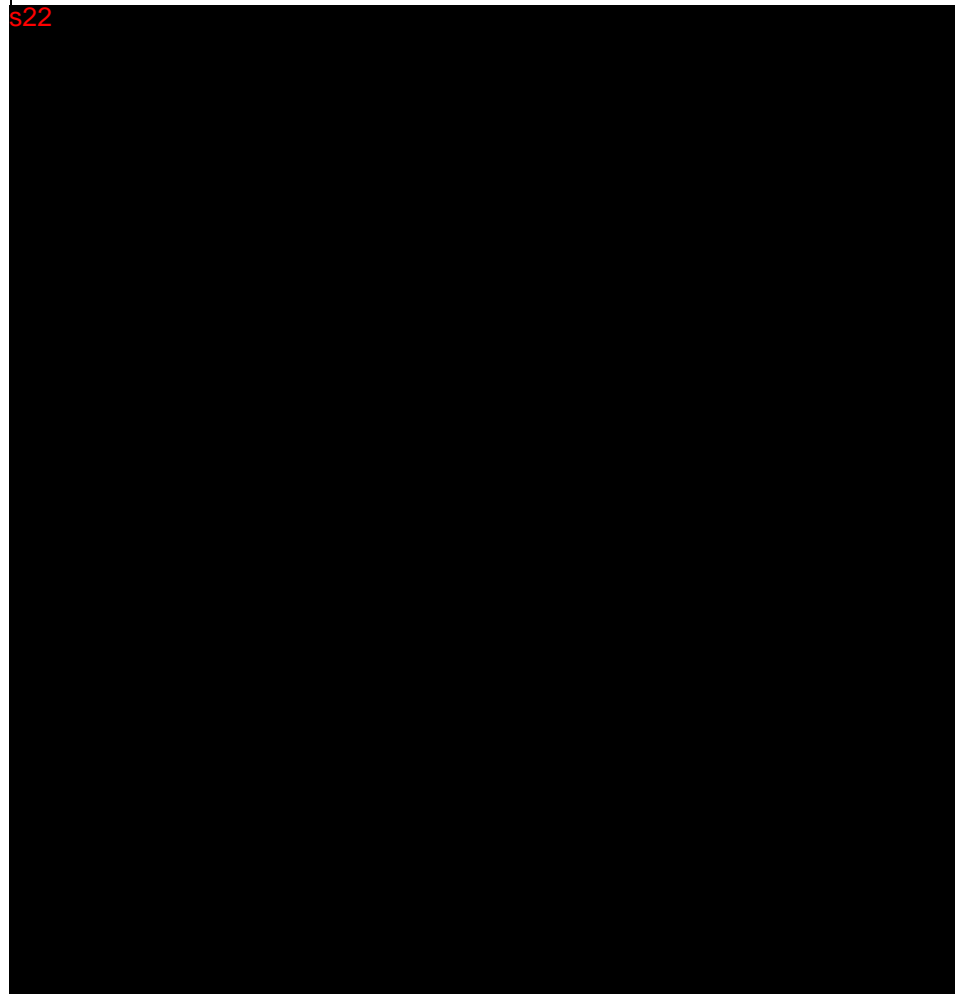
Other

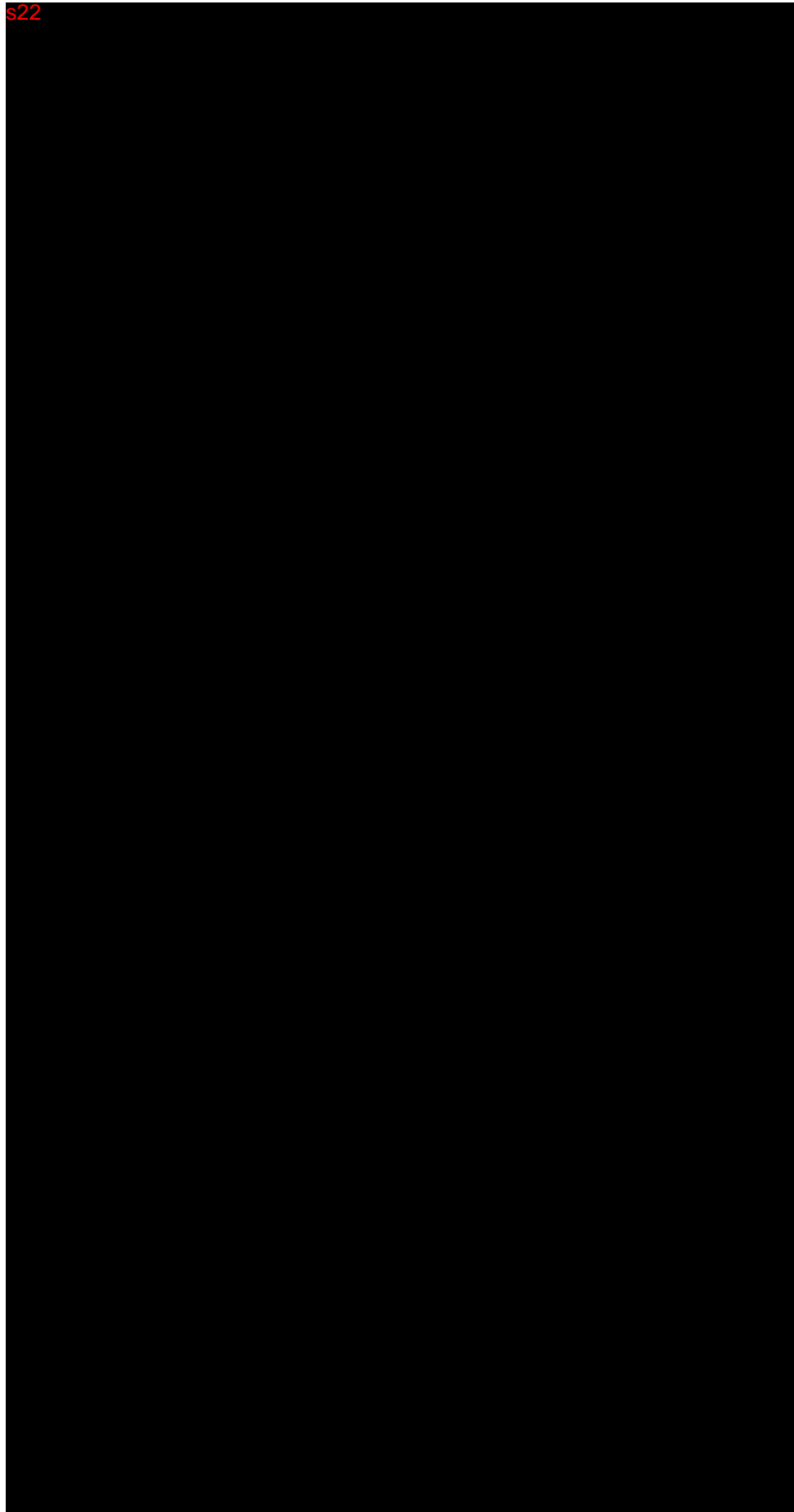
Device Predicate Nil

Comments: *Include details of investigation and outcomes, e.g. registry based PMCF*

s22

Investigation scope and design





s22

s22



Clinical assessor comments

s47G



Clinical literature review

Yes No

Literature search protocol provided

Yes No

Comments:

Selection criteria of the literature review

Device Predicate Similar marketed

Addresses all device variants (if any) in the device application

Addresses the same clinical condition

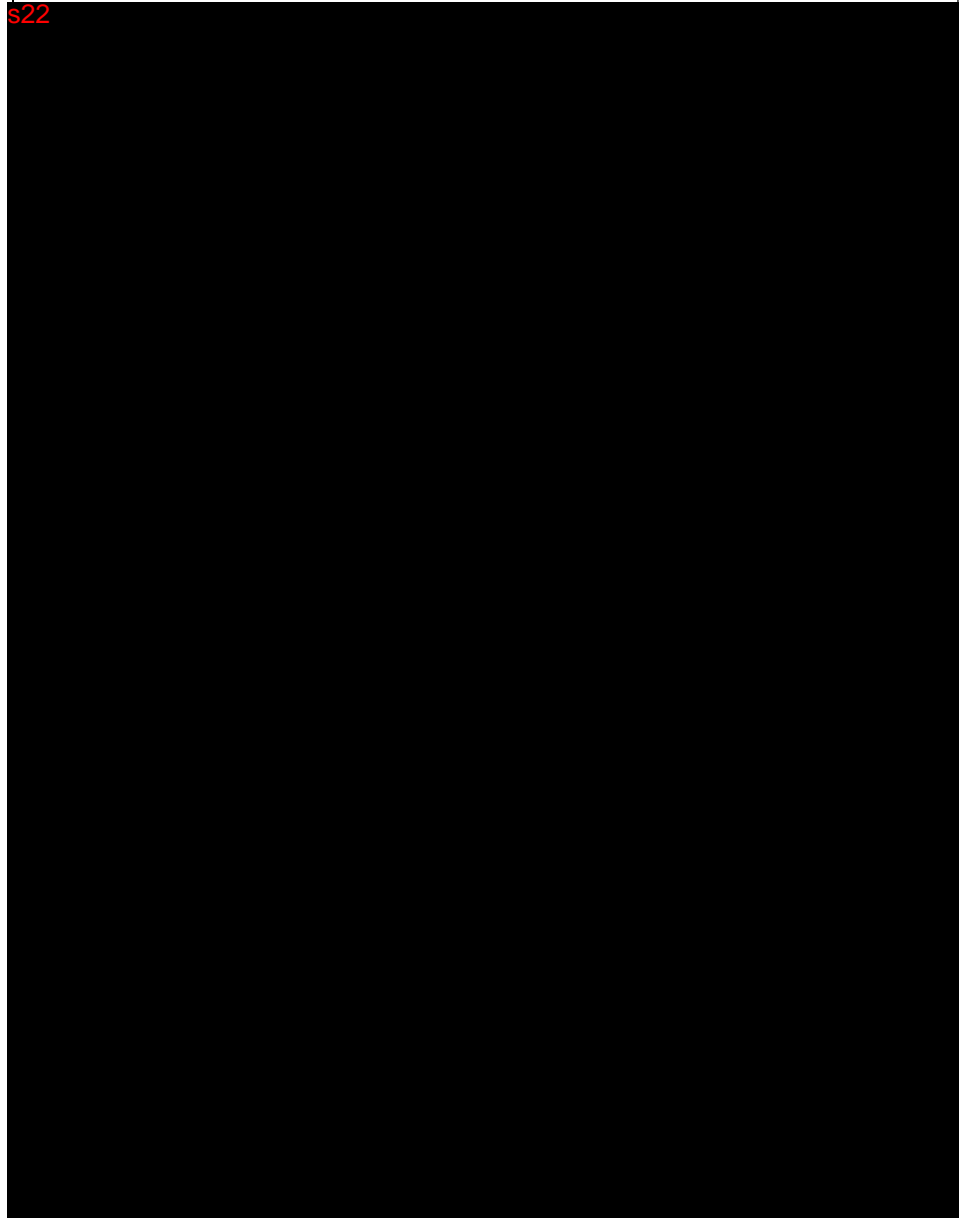
Literature type

Published literature

Unpublished literature

Other

s22



Data appraisal

s22



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s22



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s22

TGA clinical assessor comments

s47G

Other clinical experience **Yes** **No**

Adverse events with complaint rates

Device Predicate Nil

Comment: *Describe data/information and any significant issues.*

Public adverse event databases

Device Predicate Similar marketed Nil

Comment: *Describe data/information and any significant issues.*

Recalls (or actions such as market withdrawals, field corrections, safety alerts)

Device Predicate Similar marketed Nil

Comment: *Describe data/information and any significant issues.*

Corrective and preventative actions (CAPAs)

Device Predicate Nil

Comment: *Describe data/information and any significant issues.*

Registry data

Device Predicate Similar marketed Nil

Comment: *Describe data/information and any significant issues.*

Other

Device Predicate Similar marketed Nil

Comment: *Describe data/information and any significant issues.*

The CER stated that the subject device is currently in production after initial launch of the product in the UK in March 2021 (p62/77).

Post-market surveillance/vigilance data covering the period from launch (March 2021) to 3 September 2021 have been provided (see Table 4-16 below). To date, over 100,000 units of the device have been released to the market in the UK.

Table 4-16. Vigilance/PMS Data for SPL7013 Nasal Spray Since Launch

Vigilance/PMS activity	Total	Summary
Recalls	0	No recalls for the product
Reportable Incidents	0	No reportable incidents
Complaints/Incidents		
Quality related	0	No quality related complaints/incidents
Safety related	1	1 x vomiting following use

Comments

TGA clinical assessor comments

Post-market data are limited.

The sponsor should be requested to provide:

- i) *An update on the regulatory status of the subject device, including the approved intended purpose in each jurisdiction.*
- ii) *An update on the current marketing status of the subject device, including whether the subject device has been withdrawn from sale in any jurisdiction, and the reason/s why.*

Risk management

From a clinical perspective, does the report/FMEA include the risks arising from the use of the device for its intended purpose, and

Yes No

A Risk Management Plan Risk Analysis document was provided. This included a risk matrix.

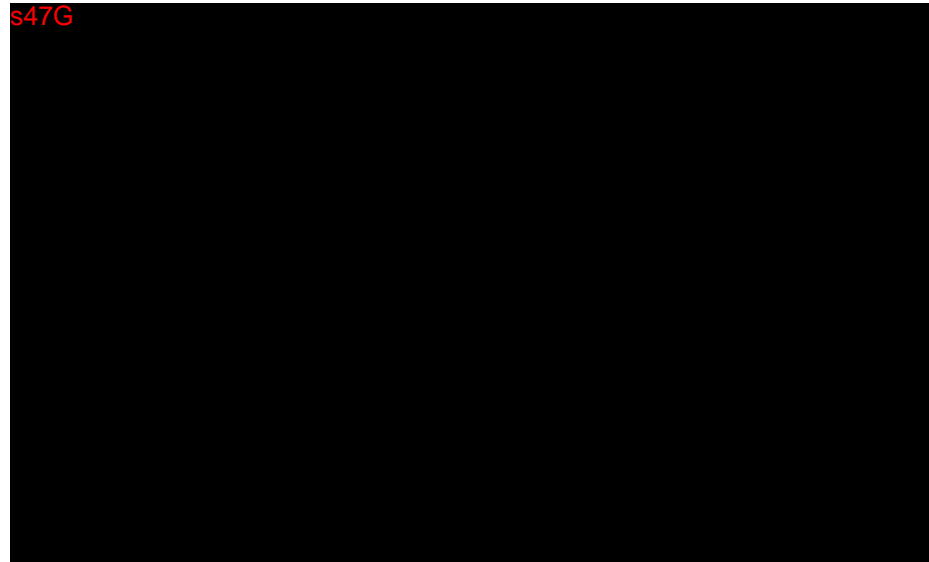
No risks were considered above the level of “minimal”.

foreseeable misuse of the device?

The following hazardous situations had a Residual Risk Code of "minimal":

- Assigned dose, or concentration of SPL7013 in the formulation, is insufficient to inactivate virus
- Product used continuously for longer than 30 days
- User gains a false sense of security during use and doesn't employ other accepted methods for prevention of infection

TGA clinical assessor comments



Do the risks associated with the use of the device appear to have been adequately mitigated?

Yes No

Comments: *Comment if risks not adequately mitigated*

Are the residual risks appropriately documented in the IFU/labels/PIL?

Yes No

Comments: *Comment if residual risks not appropriately documented*

Safety in Magnetic Resonance (MR) environment

Active implant Passive implant Not implantable

MR safety labelling claim

Choose an item.

If MR Conditional, specified conditions of use:

State conditions of use as per labelling

Overall, does the evidence provided support the MR safety

Yes No

Comments: *Consider the following: clinical data to confirm computer modelling capability of manufacturer (or: any similar devices approved*

claims in the IFU/labels/PIL?

by FDA for similar MR conditions/claims); image artefact dimensions, acceptance criteria, warnings and precautions in IFU/labels/PIL, hazards considered in risk management documents.

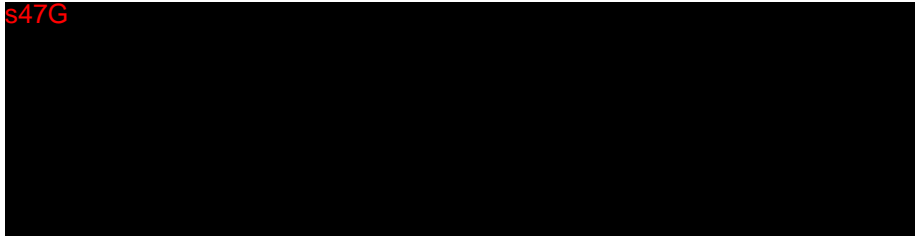
IFU, labels and other information provided with the device

From a clinical perspective, does the information provided with the device (IFU, labels, PIL, etc.) provide adequate information on the intended purpose, proper use, and warnings about risks to patients and users?

Yes No

The IFU contained information on what the nasal spray is, how it works, and directions for use. There is no maximum time period for continuous use stated.

s47G

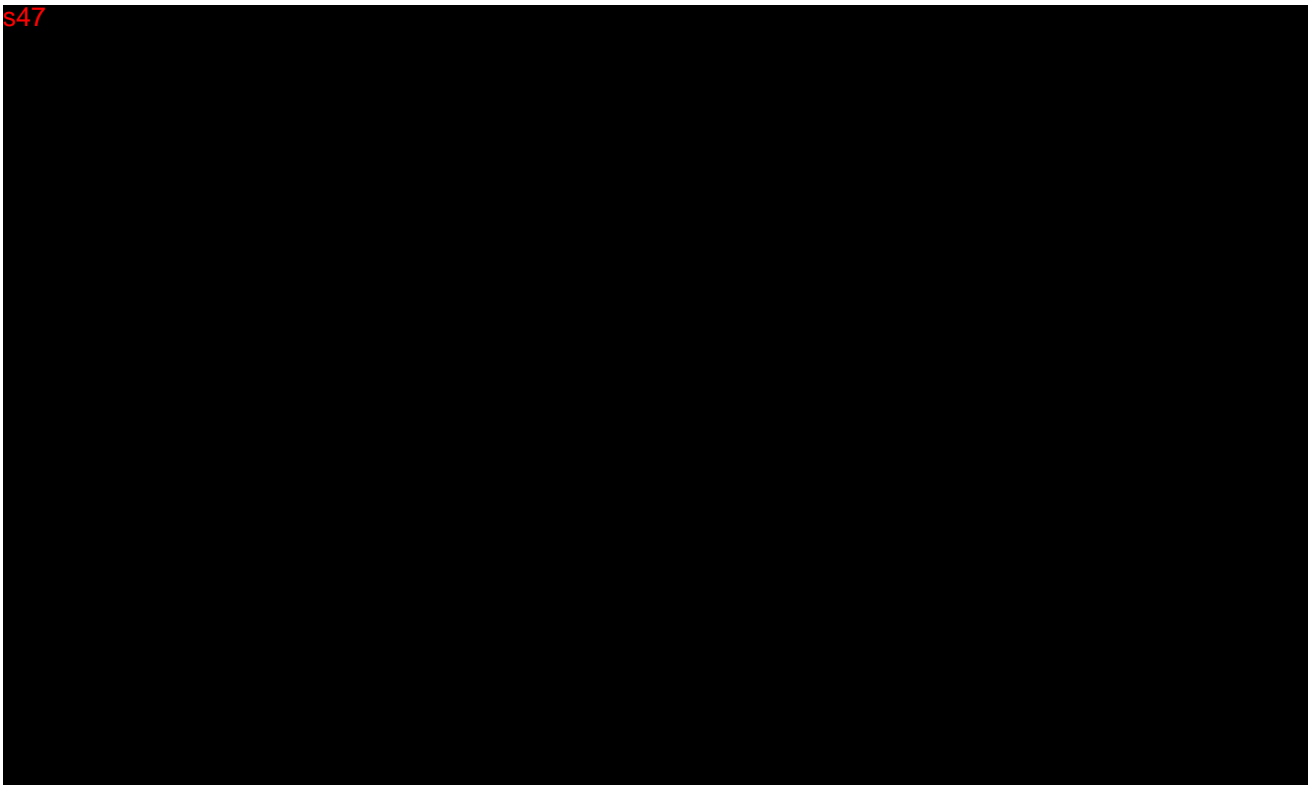


The IFU may need to be reviewed again upon provision of further data.

Assessment summary

Product Description

s47



Clinical Expert

The CER was signed by Professor s22. He is a retired Physician with experience in infectious diseases. A CV for Professor s22 has not been provided and this should be requested.

Formulation

s47

Clinical Data

Non-clinical data were provided which is beyond the scope of clinical assessment and is not directly relevant to informing on safety and performance of the subject device.

Data were provided from one double-blind, single-centre, randomised, placebo-controlled clinical investigation of the safety, tolerability and absorption of single and multiple applications of SPL7013 Nasal Spray in healthy volunteers. The primary endpoint was the frequency and severity of treatment emergent adverse events (TEAEs) and serious adverse events (SAEs).

Pharmacokinetic data were collected for the first 7 days of the study. There were no deaths, SAEs or AEs leading to withdrawal of treatment. All AEs experienced were of mild intensity and self-limiting.

Blood plasma levels of SPL7013 were not detected above the lower limit of quantitation of the bioanalytical assay.

It is unusual for pharmacokinetic (PK) data to be collected in a clinical study examining a medical device. It is unclear as to why the study collected PK data up to 7 days only and not for the full duration of study treatment, 14 days.

It is also not clear as to why only one dose level of the SPL7013 Nasal Spray was studied.

There is no clinical evidence that the SPL 7013 Nasal Spray traps and inactivates cold viruses in humans.

There is no explanation as to whether there would be any effect on viruses that enter beyond the nose, for example the nasopharynx or lungs, that may result in infection.

It is noted that the Clinical Investigation Report provided summary tables and listings for a number of parameters. No summary tables or listings were provided for the PK parameters. It is therefore not possible to assess whether there were any trends observed, or evidence of accumulation of the SPL 7013 in blood, over the 7 days.

Literature Review

The literature search strategy aimed to capture key clinical data related to the subject device and comparable devices as well as SPL7013-related non-clinical and clinical data. Search dates were limited to the period 2010 to 2021. The literature review data does not support the clinical claims made in relation to prevention of respiratory viral infections, including SARS-CoV-2. In vitro data and data from animal studies are insufficient to support claims of clinical performance and safety in humans.

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The pre-clinical data indicate that the logical next step in establishing effectiveness of the SPL7013 Nasal Spray would be to conduct a clinical efficacy study in humans.

Post-market Data

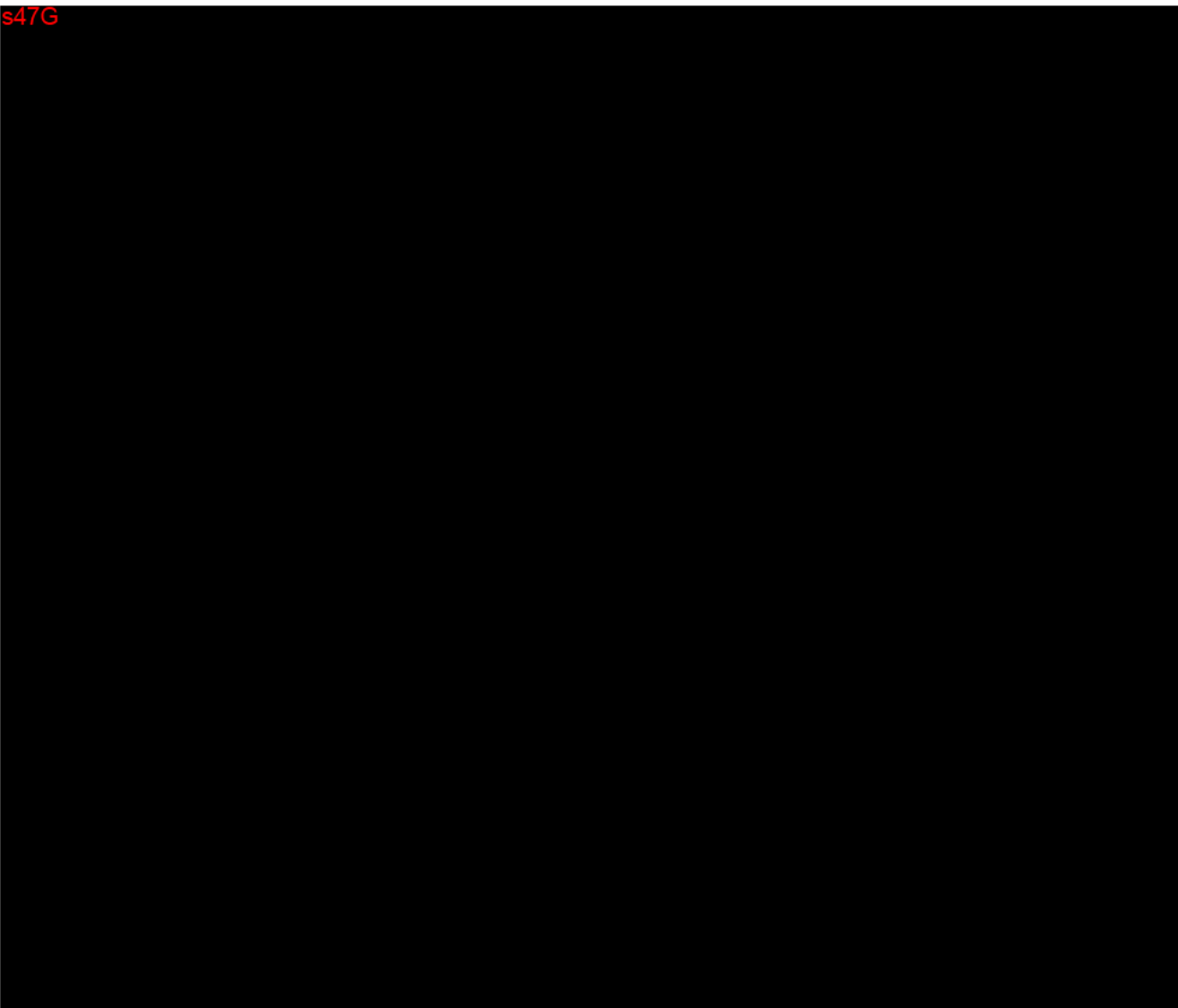
Post-market data are limited; March 2021 to 3 September 2021.

Instructions for Use

The IFU contained information on what the nasal spray is, how it works, and directions for use. There is no maximum time period for continuous use stated.

Overall the SPL7013 Nasal Spray cannot be seen to comply with Essential Principle 14 at this time.

Conclusions and recommendations



s47G [redacted] then it is recommended that the following information should be requested from the sponsor:

1. In relation to the Clinical Investigation Study in healthy volunteers provide:

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- a. A clinically reasoned rationale and justification for why blood samples were only collected for 7 days in the Clinical Investigation Study when the treatment duration was 14 days
- b. Detailed pharmacokinetic data for the blood samples that were collected, including summary tables and listings

Note is made that summary tables and listings have been provided for a number of other study parameters but not for pharmacokinetic results.

2. Provide clinical evidence that demonstrates that the subject device is safe and performs as intended for the proposed indication, and for the “Claims and assertions associated with the product” as stated in the CER, p12/77. Clinical evidence could be provided in the form of clinical studies, a literature review, and post-market data that involves use of the subject device or substantially equivalent devices that are used according to the subject device’s indication for use.

For evidence provided in the form of clinical studies, the following information is required for each clinical study:

- The complete study protocol, including the primary/secondary study endpoints, inclusion/exclusion criteria, and information regarding duration and frequency of use of the subject device
- All results obtained from the study including statistical analysis and reporting of statistical significance

For evidence provided in the form of a literature review, the following information is required:

- The date the search was performed
- Inclusion of the subject device name in the search terms
- Clearly show the number of articles retrieved from each search and the determination of the final number of studies included in the literature analysis

Discussion regarding how the results of each clinical study inform the safety and performance of the subject device should be provided.

Note is made that in vitro data and data from animal studies have been provided, however these data are insufficient to support claims of clinical performance and safety in humans.

3. Provide an update on the regulatory status of the subject device, including the approved intended purpose in each jurisdiction.
4. Provide an update on the current marketing status of the subject device, including whether the subject device has been withdrawn from sale in any jurisdiction, and the reason/s why.
5. Provide a clinically reasoned justification as to why there is no maximum duration of treatment stated in the IFU.

Note is made that the duration of treatment in the Clinical Investigation Study in healthy volunteers was 14 days. Safety of the subject device beyond this duration has not been established.

6. Provide a curriculum vitae for the clinical expert who has reviewed and endorsed the CER, namely Professor s22,

OR

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Provide the following information relating to a suitable clinical expert that has reviewed and endorsed the clinical evidence for the subject device:

- a. Evidence that the clinical expert is a competent clinical expert, in accordance with Schedule 3 Part 8.6 of the Therapeutic Goods (Medical Devices) Regulations 2002. As outlined in the Clinical Evidence Guidelines (Medical Devices), a 'competent clinical expert' is someone with relevant medical qualifications and direct clinical experience in the use of the device or device type in a clinical setting. The curriculum vitae of the clinical expert should be included in the submission.
- b. Provide a signed and dated endorsement of the CER from the competent clinical expert.

Sign-Off – Medical Advisor

Name	s22		
Signature	Signed electronically in TRIM	Date	12 October 2021

Senior Medical Advisor's comments

Sign-Off – Senior Medical Advisor

Name			
Signature	Signed electronically in TRIM	Date	Click or tap to enter a date.

Clinical review Round 2

Information provided in response to questions from previous round of assessment

To be completed by DAS: document title and TRIM reference

Comments

Include summary assessment of the information provided in response to questions from the previous round of clinical assessment.

Detail any issues with the clinical data or IFU/labels/PIL in relation to the safety and performance of the device. Issues should be detailed in terms of compliance with the applicable essential principle(s).

Clinical assessor's conclusion and recommendation

Following assessment of the information provided for this application audit in relation to the SPL7013 Barrier Nasal Spray, it is recommended that the sponsor be requested to provide the following:

1.

OR

Based on assessment of the information provided for this application audit, the *UPI/Device Name* complies with essential principles 1, 2, 3, 4, 6, 13 and 14 from a clinical perspective.

OR

It is recommended that *UPI/Device Name* be considered for referral to ACMD.

OR

Based on assessment of the information provided for this application audit, the *UPI/Device Name* does not comply with essential principles *Enter EP numbers here* from a clinical perspective.

Provide reasons if it is concluded that there is non-compliance with an EP

IF NECESSARY

It is recommended that the following condition be imposed (under s41FO of the *Therapeutic Goods Act*) if *UPI/Device Name* is included in the ARTG

-

Sign-Off – Medical Advisor

Name

--

Signature

Signed electronically in TRIM

Date

Click or tap to enter a date.

Senior Medical Advisor's comments

Record Details	D21-3159714 Application Audit Clinical Assessment Report - DA-2021-06851-1(2).DOCM	Effective Date	13/01/2021
Print Date	29/05/2024 4:01		Page 24 of 26
Once printed or copied from the Master, this is no longer a controlled document; check validity before use			

Sign-Off – Senior Medical Advisor

Name			
Signature	Signed electronically in TRIM	Date	Click or tap to enter a date.

Version history

Version	TRIM Reference	Description of change	Author/s	Effective date
V1.0	D20-3667497	New FORM	s22	13 Jan 2021

Appendix 1 – Documentation provided by the sponsor

To be completed by Clinical Section Reviewer

Type of documentation	Document name, version number/reference & date	TRIM location
Labels		
IFU		
Patient information leaflet (PIL)		
Patient information card (PIC)		
Advertising		
Clinical evaluation report (CER)		
CV of clinical expert		
Risk management report		
FMEA		
MRI information		
(Other documents)		

From: [Devices Verification Section](#)
To: s22
Subject: TGA reply re status update - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679] [SEC=OFFICIAL]
Date: Sunday, 24 October 2021 3:45:13 PM
Attachments: [image002.png](#)
[image003.png](#)
[image005.png](#)

Hi s22

Thank you for your email below. Regarding your application DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679] it remains under assessment by the TGA with the aim of completing this by early November.

At that time the TGA will be in contact with you if further information is required.

Regards

s22

Devices Post Market Review and Reform Section
 Medical Devices Surveillance Branch

Email: s22@health.gov.au

Therapeutic Goods Administration
 Department of Health
 PO Box 100
 Woden ACT 2606
www.tga.gov.au

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From: s22 s22@starpharma.com>
Sent: Friday, 15 October 2021 10:06 AM
To: Devices Verification Section <dvs@health.gov.au>
Cc: s22 s22@starpharma.com>
Subject: RE: TGA reply re sending documents via post - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679] [SEC=OFFICIAL]

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear s22,

I hope this email finds you well.

We were hoping you could provide an update on the progress of the medical device application audit (TRIM reference E21-346241) for SPL7013 Nasal Spray (Application Ref: DV-2021-DA-06231-1).

Many thanks,

s22

Starpharma Pty Ltd
 4-6 Southampton Crescent, Abbotsford VIC 3067 Australia
 Tel: s22 | Mob: s22

s22@starpharma.com | www.starpharma.com

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From: s22
Sent: Thursday, 16 September 2021 5:21 PM

To: Devices Verification Section

Cc: s22 [REDACTED] s22 [REDACTED] @starpharma.com)

Subject: RE: TGA reply re sending documents via post - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679]
[SEC=OFFICIAL]

Hi s22 [REDACTED],

I received a bounce back for this email, so am sending Attachment 6 without the cited articles. They are included on the USB.

This is email 5 of 5 and includes the item in bold text.

- Cover letter (also attached to this email)
- Response to application audit request for information, containing links (identified in blue text) to the supporting information for each response
- Attachment Folder including the following attachments
 - Attachment 1 – Classification Justification – SPL7013 Nasal Spray
 - Attachment 2 – Device Instructions for Use (Draft)
 - Attachment 3 – Device Labels (Draft)
 - Attachment 4 – Technical File – SPL7013 Nasal Spray (a Table of Contents with active links (blue text) to each section of the Technical File is provided)
 - Attachment 5 – SPL7013-021 Clinical Investigation Report (Final Draft)
 - **Attachment 6 – SPL7013-021 Clinical Investigation Report Annexes (Final Draft) (minus the cited articles)**

Many thanks,

s22 [REDACTED]

[REDACTED]
[REDACTED]

Starpharma Pty Ltd

4-6 Southampton Crescent, Abbotsford VIC 3067 Australia

Tel: s22 [REDACTED] | Mob: s22 [REDACTED]

s22 [REDACTED] @starpharma.com | www.starpharma.com

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From: s22 [REDACTED]

Sent: Thursday, 16 September 2021 4:54 PM

To: Devices Verification Section <dvs@health.gov.au>

Cc: s22 [REDACTED] s22 [REDACTED] @starpharma.com) s22 [REDACTED] @starpharma.com>

Subject: RE: TGA reply re sending documents via post - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679]
[SEC=OFFICIAL]

Hi s22 [REDACTED],

This is email 5 of 5 and includes the item in bold text. This is a large file (30MB), I hope it makes it through.

- Cover letter (also attached to this email)
- Response to application audit request for information, containing links (identified in blue text) to the supporting information for each response
- Attachment Folder including the following attachments
 - Attachment 1 – Classification Justification – SPL7013 Nasal Spray
 - Attachment 2 – Device Instructions for Use (Draft)
 - Attachment 3 – Device Labels (Draft)
 - Attachment 4 – Technical File – SPL7013 Nasal Spray (a Table of Contents with active links (blue text) to each section of the Technical File is provided)
 - Attachment 5 – SPL7013-021 Clinical Investigation Report (Final Draft)
 - **Attachment 6 – SPL7013-021 Clinical Investigation Report Annexes (Final Draft)**

Many thanks,

s22 [REDACTED]

[REDACTED]
[REDACTED]

Starpharma Pty Ltd

4-6 Southampton Crescent, Abbotsford VIC 3067 Australia

Tel: s22 [REDACTED] | Mob: s22 [REDACTED]

s22 [REDACTED] @starpharma.com | www.starpharma.com

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From: s22 [REDACTED]

Sent: Thursday, 16 September 2021 4:51 PM

To: 'Devices Verification Section' <dvs@health.gov.au>

Cc: s22 [REDACTED] s22 [REDACTED] @starpharma.com) s22 [REDACTED] @starpharma.com>

Subject: RE: TGA reply re sending documents via post - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679]
[SEC=OFFICIAL]

Hi **s22**

This is email 4 of 5 and includes the item in bold text.

- Cover letter (also attached to this email)
- Response to application audit request for information, containing links (identified in [blue text](#)) to the supporting information for each response
- Attachment Folder including the following attachments
 - Attachment 1 – Classification Justification – SPL7013 Nasal Spray
 - Attachment 2 – Device Instructions for Use (Draft)
 - Attachment 3 – Device Labels (Draft)
 - Attachment 4 – Technical File – SPL7013 Nasal Spray (a Table of Contents with active links ([blue text](#)) to each section of the Technical File is provided)
 - **Attachment 5 – SPL7013-021 Clinical Investigation Report (Final Draft)**
 - Attachment 6 – SPL7013-021 Clinical Investigation Report Annexes (Final Draft)

Many thanks,

s22

Starpharma Pty Ltd

4-6 Southampton Crescent, Abbotsford VIC 3067 Australia

Tel: **s22** | Mob: **s22**

s22 @starpharma.com | www.starpharma.com

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From: **s22**

Sent: Thursday, 16 September 2021 4:50 PM

To: 'Devices Verification Section' <dvs@health.gov.au>

Cc: **s22**, **s22** @starpharma.com, **s22** @starpharma.com>

Subject: RE: TGA reply re sending documents via post - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679]
[SEC=OFFICIAL]

Hi **s22**,

This is email 3 of 5 and includes the items in bold text.

- Cover letter (also attached to this email)
- Response to application audit request for information, containing links (identified in [blue text](#)) to the supporting information for each response
- Attachment Folder including the following attachments
 - Attachment 1 – Classification Justification – SPL7013 Nasal Spray
 - Attachment 2 – Device Instructions for Use (Draft)
 - Attachment 3 – Device Labels (Draft)
 - **Attachment 4 – Technical File – SPL7013 Nasal Spray (a Table of Contents with active links ([blue text](#)) to each section of the Technical File is provided)**

Section	Contents
1	DEVICE DESCRIPTION
2	ESSENTIAL PRINCIPLES CHECKLIST Addendum Essential Principles Checklist – Australia
3	RISK MANAGEMENT TFS3-1 DRR-005 – Risk Management Report – SPL7013 Nasal Spray TFS3-2 DRA-005 – Risk Management Plan & Risk Analysis – SPL7013 Nasal Spray
4	4.1 DEVICE DESIGN AND MANUFACTURING INFORMATION – SPL7013 4.2 DEVICE DESIGN AND MANUFACTURING INFORMATION – SPL7013 NASAL SPRAY TFS4.2-1 Starpharma EN ISO 13485:2016 Certificate
5	5.1 COMPLIANCE WITH STANDARDS 5.2 VALIDATION OF SPL7013 MANUFACTURE 5.3 VALIDATION OF SPL7013 NASAL SPRAY MANUFACTURE 5.4 SPL7013 STABILITY 5.5 SPL7013 NASAL SPRAY STABILITY 5.6 CHEMISTRY AND TOXICOLOGY REVIEW
6	NONCLINICAL INFORMATION (DEVICE PERFORMANCE & BIOCOMPATIBILITY) TFS6-12 BER-001 – Biological Evaluation Report – SPL7013 Nasal Spray TFS6-12-1 Evaluation of Cytotoxicity TFS6-12-2 Assessment of Sensitising Properties TFS6-12-3 Assessment of Intranasal Tolerance

7	CLINICAL EVALUATION Appendix 1 Literature Search Output Appendix 2 Clinical Evaluation Data Appraisal
8	PACKAGING, LABELLING, AND INSTRUCTIONS FOR USE
9	DECLARATION OF CONFORMITY EC Declaration of Conformity AU Declaration of Conformity

- o Attachment 5 – SPL7013-021 Clinical Investigation Report (Final Draft)
- o Attachment 6 – SPL7013-021 Clinical Investigation Report Annexes (Final Draft)

Many thanks,

s22

Starpharma Pty Ltd
4-6 Southampton Crescent, Abbotsford VIC 3067 Australia
Tel: s22 | Mob: s22
s22@starpharma.com | www.starpharma.com

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From: s22

Sent: Thursday, 16 September 2021 4:48 PM

To: 'Devices Verification Section' <dvs@health.gov.au>

Cc: s22, s22@starpharma.com, s22@starpharma.com

Subject: RE: TGA reply re sending documents via post - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679]
[SEC=OFFICIAL]

Hi s22,

This is email 2 of 5 and includes the items in bold text.

- Cover letter (also attached to this email)
- Response to application audit request for information, containing links (identified in blue text) to the supporting information for each response
- Attachment Folder including the following attachments
 - o Attachment 1 – Classification Justification – SPL7013 Nasal Spray
 - o Attachment 2 – Device Instructions for Use (Draft)
 - o Attachment 3 – Device Labels (Draft)
 - o **Attachment 4 – Technical File – SPL7013 Nasal Spray (a Table of Contents with active links (blue text) to each section of the Technical File is provided)**

Section	Contents
1	DEVICE DESCRIPTION
2	ESSENTIAL PRINCIPLES CHECKLIST Addendum Essential Principles Checklist – Australia
3	RISK MANAGEMENT TFS3-1 DRR-005 – Risk Management Report – SPL7013 Nasal Spray TFS3-2 DRA-005 – Risk Management Plan & Risk Analysis – SPL7013 Nasal Spray
4	4.1 DEVICE DESIGN AND MANUFACTURING INFORMATION – SPL7013 4.2 DEVICE DESIGN AND MANUFACTURING INFORMATION – SPL7013 NASAL SPRAY TFS4.2-1 Starpharma EN ISO 13485:2016 Certificate
5	5.1 COMPLIANCE WITH STANDARDS 5.2 VALIDATION OF SPL7013 MANUFACTURE 5.3 VALIDATION OF SPL7013 NASAL SPRAY MANUFACTURE 5.4 SPL7013 STABILITY 5.5 SPL7013 NASAL SPRAY STABILITY 5.6 CHEMISTRY AND TOXICOLOGY REVIEW
6	NONCLINICAL INFORMATION (DEVICE PERFORMANCE & BIOCOMPATIBILITY) TFS6-12 BER-001 – Biological Evaluation Report – SPL7013 Nasal Spray TFS6-12-1 Evaluation of Cytotoxicity TFS6-12-2 Assessment of Sensitising Properties TFS6-12-3 Assessment of Intranasal Tolerance
7	CLINICAL EVALUATION Appendix 1 Literature Search Output Appendix 2 Clinical Evaluation Data Appraisal
8	PACKAGING, LABELLING, AND INSTRUCTIONS FOR USE
9	DECLARATION OF CONFORMITY EC Declaration of Conformity

	AU Declaration of Conformity
--	------------------------------

- o Attachment 5 – SPL7013-021 Clinical Investigation Report (Final Draft)
- o Attachment 6 – SPL7013-021 Clinical Investigation Report Annexes (Final Draft)

Many thanks,

s22

Starpharma Pty Ltd

4-6 Southampton Crescent, Abbotsford VIC 3067 Australia

Tel: **s22** | Mob: **s22**

s22 @starpharma.com | www.starpharma.com

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From: **s22**

Sent: Thursday, 16 September 2021 4:44 PM

To: Devices Verification Section <dvs@health.gov.au>

Cc: **s22** <**s22** @starpharma.com>

Subject: RE: TGA reply re sending documents via post - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679]
[SEC=OFFICIAL]

Hi **s22**,

I'll be sending the submission in a series of 5 emails.

This is email 1 of 5 and includes the items in bold text.

- **Cover letter (also attached to this email)**
- **Response to application audit request for information, containing links (identified in blue text) to the supporting information for each response**
- Attachment Folder including the following attachments
 - o **Attachment 1 – Classification Justification – SPL7013 Nasal Spray**
 - o **Attachment 2 – Device Instructions for Use (Draft)**
 - o **Attachment 3 – Device Labels (Draft)**
 - o Attachment 4 – Technical File – SPL7013 Nasal Spray (a Table of Contents with active links (blue text) to each section of the Technical File is provided)
 - o Attachment 5 – SPL7013-021 Clinical Investigation Report (Final Draft)
 - o Attachment 6 – SPL7013-021 Clinical Investigation Report Annexes (Final Draft)

Many thanks,

s22

Starpharma Pty Ltd

4-6 Southampton Crescent, Abbotsford VIC 3067 Australia

Tel: **s22** | Mob: **s22**

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From: Devices Verification Section <dvs@health.gov.au>

Sent: Thursday, 16 September 2021 4:31 PM

To: **s22** <**s22** @starpharma.com>

Subject: TGA reply re sending documents via post - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679]
[SEC=OFFICIAL]

Hi **s22**,

The TGA would prefer PDF documents in emails please.

Regards

s22

Devices Post Market Review and Reform Section

Medical Devices Surveillance Branch

Email: **s22** @health.gov.au

Therapeutic Goods Administration

Department of Health

PO Box 100

Woden ACT 2606

www.tga.gov.au

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From: s22 <s22@starpharma.com>

Sent: Thursday, 16 September 2021 4:22 PM

To: Devices Verification Section <dvs@health.gov.au>

Cc: s22 <s22@starpharma.com>

Subject: RE: TGA reply re sending documents via post - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679] [SEC=OFFICIAL]

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Hi s22,

Thanks for your mail.

I'm happy to send the submission as a series of emails, however please note that the interactive links embedded in the documents will no longer work.

If you're able to download from a link I can provide, the links should remain and you can easily navigate the submission.

Please let me know which you would prefer, the emails or the link, or both.

Many thanks,

s22

[Redacted]

[Redacted]

Starpharma Pty Ltd

4-6 Southampton Crescent, Abbotsford VIC 3067 Australia

Tel: s22 | Mob: s22

s22@starpharma.com | www.starpharma.com

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From: Devices Verification Section <dvs@health.gov.au>

Sent: Thursday, 16 September 2021 4:17 PM

To: s22 <s22@starpharma.com>

Subject: TGA reply re sending documents via post - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679] [SEC=OFFICIAL]

Hi s22

Is there any chance that you could send all the documents via email as the Department of Health – TGA is very large and your parcel may take some time to be delivered to the appropriate section.

You can send several emails if the size of the files is very large. Additionally considering lockdown in Canberra most staff are not in the office and will not be there to collect the delivery.

Regards

s22

[Redacted]

Devices Post Market Review and Reform Section

Medical Devices Surveillance Branch

Email: s22@health.gov.au

Therapeutic Goods Administration

Department of Health

PO Box 100

Woden ACT 2606

www.tga.gov.au

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From: s22 <s22@starpharma.com>

Sent: Wednesday, 15 September 2021 2:25 PM

To: Devices Verification Section <dvs@health.gov.au>

Cc: s22 <s22@starpharma.com>

Subject: RE: s41FH Notice - Non-Compulsory Audit - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679] [SEC=OFFICIAL]

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and

know the content is safe.

Dear s22,

Reference is made to the medical device application audit (TRIM reference E21-346241) for SPL7013 Nasal Spray (Application Ref: DV-2021-DA-06231-1).

We are pleased to advise that the information requested by TGA as part of the Medical Device Application Audit has been couriered to the Devices Post Market Reform and Reviews, Medical Devices Surveillance Branch, and is scheduled to arrive on Thursday 16th September.

The total size of the response in electronic format was larger than 15MB, so we have provided the information electronically on a USB drive.

The USB contains the following files/folders:

- Cover letter (also attached to this email)
- Response to application audit request for information, containing links (identified in blue text) to the supporting information for each response
- Attachment Folder including the following attachments
 - Attachment 1 – Classification Justification – SPL7013 Nasal Spray
 - Attachment 2 – Device Instructions for Use (Draft)
 - Attachment 3 – Device Labels (Draft)
 - Attachment 4 – Technical File – SPL7013 Nasal Spray (a Table of Contents with active links (blue text) to each section of the Technical File is provided)
 - Attachment 5 – SPL7013-021 Clinical Investigation Report (Final Draft)
 - Attachment 6 – SPL7013-021 Clinical Investigation Report Annexes (Final Draft)

We trust the information provided in the submission satisfies the TGA's questions and application audit requirements.

In addition to the above notification, we were hoping you could advise if the application audit is a Level 1 or Level 2 audit?

We look forward to your reply.

Many thanks,

s22

Starpharma Pty Ltd

4-6 Southampton Crescent, Abbotsford VIC 3067 Australia

Tel: s22 | Mob: s22

s22 @starpharma.com | www.starpharma.com

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From: Devices Verification Section <dvs@health.gov.au>

Sent: Tuesday, 17 August 2021 8:03 AM

To: s22 s22 @starpharma.com>

Subject: s41FH Notice - Non-Compulsory Audit - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679]
[SEC=OFFICIAL]

Dear s22

Your application DA-2021-06851-1 - Nasal moisture barrier dressing[47679] has been selected for a non-compulsory application audit.

Please refer to the notice for further information.

The information is required by no later than close of business: **16 September 2021.**

Regards

Departmental Officer

Devices Post Market Reforms and Reviews

Medical Devices and Product Quality Division | Health Products Regulation Group

Medical Devices Surveillance Branch

Therapeutic Goods Administration

E: dvs@health.gov.au

Location: FB-51c. 136 Narrabundah Lane, Symonston, ACT, 2609

PO Box 100, Woden ACT 2606, Australia



The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

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From: [Devices Verification Section](#)
To: s22
Subject: RE: Request for round 1 review - MEDICINES -DV-2021-DA-06231-1 DA-2021-06851-1 - Nasal moisture barrier dressing [47679] - Viraleze - Starpharma Pty Ltd [SEC=OFFICIAL]
Date: Thursday, 21 October 2021 2:57:20 PM

Hi s22

Yes please we would love to have OTCMES input as they are still debating if this product is a medicine or a medical device.

Regards

s22

Devices Post Market Review and Reform Section
Medical Devices Surveillance Branch

Email: s22@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

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-----Original Message-----

From: s22@health.gov.au
Sent: Thursday, 14 October 2021 3:54 PM
To: Devices Verification Section <dvs@health.gov.au>
Subject: RE: Request for round 1 review - MEDICINES -DV-2021-DA-06231-1 DA-2021-06851-1 - Nasal moisture barrier dressing [47679] - Viraleze - Starpharma Pty Ltd [SEC=OFFICIAL]

Hi s22

I must apologise, I haven't had a chance to look at this yet. Were you still requiring input from OTCMES?

Thanks

s22

OTC Medicines Evaluation Section
Complementary and OTC Medicines Branch
Medicines Regulation Division

Phone: s22
Email: s22@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

This information is given to you without prejudice and is not binding on the TGA. It is the responsibility of the sponsor to ensure that all of the legislative requirements are met.

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-----Original Message-----

From: Devices Verification Section <dvs@health.gov.au>

Sent: Tuesday, 28 September 2021 3:23 PM

To: s22@health.gov.au; s22
s22@health.gov.au

Cc: s22@health.gov.au

Subject: Request for round 1 review - MEDICINES -DV-2021-DA-06231-1 DA-2021-06851-1 - Nasal moisture barrier dressing [47679] - Viraleze - Starpharma Pty Ltd [SEC=OFFICIAL]

Dear Medicines team,

Following on from our meeting on the 5 August 2021 where the premarket medical device application Viraleze - Starpharma was discussed regarding evidence required to support inclusion the following information has been provided with a request for medicines assessment of this device.

DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing [47679] - Viraleze - Starpharma Pty request for medicines assessment - [Round 1] TRIM link to the request above.

I am not sure that the request/review form attached is in a format that you are familiar with however as I was sending the same request to Micro, BIOME and Clinical I kept the format the same. I hope this is OK?

Kind regards,

s22

Devices Post Market Review and Reform Section Medical Devices Surveillance Branch

Email: s22@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

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-----< HPE Content Manager record Information >-----

Record Number : D21-3145877

Title : Application Audit Assessment Request MEDICINES~ DA-2021-06851-1 - Nasal moisture barrier dressing [47679] - Starpharma Pty Ltd



Australian Government
Department of Health
 Therapeutic Goods Administration

Biomaterials and Engineering Assessment

TRIM link: [D21-3269704](#)

Device information

Sponsor	Starpharma Pty Ltd
Device	Nasal moisture barrier dressing (Viraleze)
Manufacturer	Starpharma Pty Ltd (Australia)[41979]
Classification	Class I medical device
GMDN code	Nasal moisture barrier dressing [47679] - A substance applied to the nasal passages (nares) to provide a protective moisture barrier to the external environment and to hydrate and soothe the nasal mucosa. It typically contains sodium-based substances, plant oil extracts (e.g., Aloe barbadensis) and purified water and is commonly used to treat dry and irritated nasal passages caused by indoor heat, dry climates, air travel, and oxygen (O ₂) use. The device is usually provided in the form of a gel or spray and is typically available [non-prescription] over-the-counter (OTC) for use in the home or healthcare facility. After application, this device cannot be reused. See also: Skin moisture barrier dressing 2008.09.09.
Reason for Evaluation	Assessment for an Application Audit

Material assessed

#	Title	Location
1	S6.0_v02-Attach TSF12-3-BER-001-01-Assess of Intranasal Tolerance	D21-3124701
2	S6.0_v02-Attachment TSF12-BER-001-01-SPL7013 Nasal Spray	
3	S6.0_v02-Attach TSF12-2-BER-001-01-Assess of Sensitising Properties	
4	S5.1_v03 - Compliance with standards	D21-3124717
5	S5.3_v03 - VALIDATION OF SPL7013 MANUFACTURE	
6	S5.4_v01 - SPL7013 STABILITY	
7	S5.5_v04 - SPL7013 NASAL SPRAY STABILITY	
8	S5.6_v03 - CHEMISTRY AND TOXICOLOGY REVIEW	

Background

The Devices post-market review and reform section (DPMRRs) have requested the Biomaterials and Engineering (BiomE) section to undertake a Round 1 assessment for an application for inclusion in the ARTG, DV-2021-DA-06231-1 - DA-2021-06851-1. Specifically, BiomE was requested to review the sponsor's documentation outlined in [D21-3133218](#) (sections 5 and 6; [D21-3201729](#)) for suitability of the device container closure and compliance with biocompatibility testing standards.

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Declaration of Conformity

The sponsor supplied the Australian Declaration of conformity for the SPL7013 Nasal Spray product, made under clause 6.6 of Schedule 3 of the Therapeutic Goods (Medical Devices) Regulations 2002. A European Declaration of conformity for *VIRALEZE™ Antiviral Nasal Spray* was also supplied, showing compliance with *BS EN ISO 15223-1, Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements* and the EU Medical Devices Directive 93/42/EEC. The design, development, and realisation processes were established in line with the requirements of *EN ISO 13485:2016 – Medical devices – Quality management systems – Requirements for regulatory purposes*. The risk management system is in line with the requirements of *BS EN ISO 14971:2019 – Medical devices – Application of risk management to medical devices*.

Biological Risk Analysis

The sponsor submitted a report against EN ISO 14971 and ISO 10993-1 where they carried out a risk analysis of the product according to ISO 14971:2019.

The sponsor states that nonclinical study reports on SPL7013, SPL7013 Vaginal Gel and Condom with SPL7013 Lubricant, and Extractable and leachable studies have previously been conducted on the SPL7013 Vaginal Gel product.

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Summary of Biological safety evidence provided:

Endpoint	Standard	Evidence
Cytotoxicity	ISO 10993-5	Yes
Sensitisation	ISO 10993-10	Yes
Irritation/Intracutaneous Reactivity	ISO 10993-10	Yes
Acute Systemic Toxicity/Subacute Toxicity	ISO 10993-11	Yes
Subchronic/Chronic Toxicity	ISO 10993-11	Not in the nasal cavity
Genotoxicity	ISO 10993-3	Yes
Chemistry and Physical toxicity	ISO 10993-18 and -19	Yes

Cytotoxicity testing

Sample preparation was conducted on the SPL7013 Nasal Spray formulation to assess the cytotoxicity potential on cells according to ISO 10993-5. The results of the study demonstrated that at 5000 µg/mL, the formulation is not cytotoxic.

Irritation/Intracutaneous Reactivity

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Acute Systemic Toxicity/Subacute Toxicity

Several studies were carried out to evaluate acute systemic toxicity using various modes of administrations, such as into the mucosal membrane (nasal and vaginal), intravenously or orally. To summarise:

- s47
-
-

Subchronic/Chronic Toxicity

s47

Genotoxicity

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Chemistry and Toxicology review

A review of the characteristics of the components of the device, the possible interactions between the device and the primary packaging, and a review of the toxicological implications from all identified chemicals present in accordance with ISO 10993 Part 18: *Chemical Characterisation of Materials* was supplied. The sponsor provided information to determine whether SPL7013 Nasal Spray is biologically equivalent, in configuration, composition, manufacturing, processing and intended use, to a clinically established medical device.

As per ISO 10993-18, physical equivalence is where the physical characteristics of two materials or medical devices are sufficiently similar, such that the configuration, morphology, and topography

(per ISO/TS 10993-19:2020, Biological evaluation of medical devices – Part 19 – *Physico-chemical, morphological and topographical characterization of materials*) do not result in additional or different biocompatibility concerns.

s47

A large black rectangular redaction box covers the majority of the page content below the first paragraph.

Container Closure

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A large black rectangular redaction box covers the entire section titled 'Container Closure'.

Validation of SPL7013 Manufacture

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Stability

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Conclusion

BiomE evaluated the documentation provided by the sponsor in relation to the biological safety and of the suitability of the container closure system for the SPL7013 Nasal Spray device and formulation.

In summary, the sponsor adequately performed a biological risk analysis as per ISO 10993-1 for the device, treating it as a long-term device by taking into account the potential of misuse. For this, evidence of various *in vitro* and *in vivo* studies for cytotoxicity, sensitisation, irritation, systemic toxicity (acute and chronic) were provided, varying in formulation (VivaGel or SPL7013 nasal spray), animal model, and route of administration. Sufficient biological safety evidence was provided to cover all relevant end-point parameters, apart from not having carried out a chronic toxicity study to evaluate the effect of SPL7013 nasal spray on the nasal cavity.

The SPL7013 nasal spray device was deemed to have chemical and physical equivalence, and as a result, materially equivalent container closure systems.

The sponsor provided information on manufacture validation and quality control for the 1% SPL7013 nasal spray, supported by acceptable device performance data, validated by uniformity of mass and droplet size distribution.

Lastly, long-term and accelerated stability studies were carried out thus far for 36 and 3 months, respectively, demonstrating evidence supporting the device's shelf-life and storage conditions.

Recommendations

Following the assessment of the Sponsor's supplied information on the 1% SPL7013 Nasal Spray product:

- Sufficient evidence was provided to demonstrate biological safety with compliance to ISO 10993 parts 1, 3, 5, 10, and 11
- **No non-clinical chronic toxicity study evaluating the effect of SPL7013 nasal spray via intra-nasal administration was provided**
- The chemical and toxicological review according to ISO 10993-18 and -19 deems the constituents of the device to pose an acceptable health risk
- Sufficient evidence was provided in order to establish suitability of the device container closure

Assessed by:

Biomaterials and Engineering Section
Laboratories Branch
Medical Devices and Product Quality Division
Therapeutic Goods Administration

<signed electronically>

1 November 2021

From: s22
To: s22
Cc: s22
Subject: RE: Request for round 1 review due 30 October 2021 - BIOME - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing [47679] - Viraleze - Starpharma Pty Ltd [SEC=OFFICIAL]
Date: Monday, 1 November 2021 2:58:42 PM
Attachments: [image001.png](#)
[image002.png](#)
[image004.png](#)

Dear s22,

Please find Biome's assessment of the Starpharma SPL7013 Nasal spray: [D21-3269704](#)

Request form for reference: [D21-3133218](#)

Best,

s22

s22 – Biomaterials and Engineering Section

Medical Devices & Product Quality Division | Health Products Regulation Group
Laboratories Branch
Australian Government Department of Health
E: s22@health.gov.au
Location: TGA Symonston
PO Box 100, Woden ACT 2606, Australia



The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: s22
Sent: Thursday, 28 October 2021 3:33 PM
To: s22@health.gov.au
Cc: s22@health.gov.au; s22@health.gov.au
Subject: RE: Request for round 1 review due 30 October 2021 - BIOME - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing [47679] - Viraleze - Starpharma Pty Ltd [SEC=OFFICIAL]

Hi s22,

I just wanted to give you a heads up that Biome's assessment of Starpharma SPL7013 Nasal spray will be complete by your proposed deadline of 30 October. So far there is nothing of concern to report, however, we will only have the report reviewed and finalised by the start of next week. Would we be able to get a few days extension to the deadline?

Draft report at: [D21-3269704](#)

Apologies for the inconvenience.

All the best,

s22

s22 – Biomaterials and Engineering Section

Medical Devices & Product Quality Division | Health Products Regulation Group
Laboratories Branch
Australian Government Department of Health
E: s22@health.gov.au
Location: TGA Symonston
PO Box 100, Woden ACT 2606, Australia



The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: s22 [redacted] <[redacted]@Health.gov.au>
Sent: Monday, 11 October 2021 5:02 PM
To: s22 [redacted] <[redacted]@health.gov.au>
Subject: FW: Request for round 1 review due 30 October 2021 - BIOME - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing [47679] - Viralze - Starpharma Pty Ltd [SEC=OFFICIAL]

s22 [redacted],

Can you or team take a look at this one? If it's for s22 [redacted] and we can answer it for them (to help with their workload), please ask s22 [redacted] if he's happy with that.

s22 [redacted]

s22 [redacted]
 [redacted] | Biomaterials and Engineering Section
 Laboratories Branch | Medical Devices and Product Quality Division
 Health Products Regulation Group
 Australian Government Department of Health
 T: s22 [redacted] | M: s22 [redacted] | E: s22 [redacted]@health.gov.au
 136 Narrabundah Lane, Symonston ACT 2609
 PO Box 100, Woden ACT 2606, Australia

s22 [redacted]

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: s22 [redacted]
Sent: Monday, 11 October 2021 5:00 PM
To: s22 [redacted] <[redacted]@health.gov.au>
Cc: BIOME - s22 [redacted] <[redacted]@health.gov.au>
Subject: RE: Request for round 1 review - BIOME - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing [47679] - Viralze - Starpharma Pty Ltd [SEC=OFFICIAL]

Thanks s22 [redacted],

This helps and we're all learning, so no worries there. I'll check with my subject matter experts if **Section 6** below is for us or for the biotherapeutics section, but we can refer this part on and let you know if it's better answered by biotherapeutics.

For the request part of the TRIM document ([D21-3133218](#)) would you mind if I added something at the start to the affect of "DPMRRS would like BiomE to assess **Section 6** of the sponsor's documentation available at TRIM link <TRIM link> for suitability of and compliance with biocompatibility testing standards. Further background is below."

Cheers,

s22 [redacted]
 [redacted] | Biomaterials and Engineering Section
 Laboratories Branch | Medical Devices and Product Quality Division
 Health Products Regulation Group
 Australian Government Department of Health
 T: s22 [redacted] | M: s22 [redacted] | E: s22 [redacted]@health.gov.au
 136 Narrabundah Lane, Symonston ACT 2609
 PO Box 100, Woden ACT 2606, Australia

s22 [redacted]

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: s22 [redacted] <[redacted]@health.gov.au>
Sent: Monday, 11 October 2021 4:46 PM
To: s22 [redacted] <[redacted]@Health.gov.au>
Cc: BIOME - s22 [redacted] <[redacted]@health.gov.au>
Subject: Request for round 1 review - BIOME - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing [47679] - Viralze - Starpharma Pty Ltd [SEC=OFFICIAL]

Dear s22 [redacted]

In the table of contents provided by the sponsor below it was Section 5 and 6 that have reference to compliance with standards.

Apologies for not completing the request for review by BIOME sufficiently as I am not familiar with this process and I adapted a forms I have taken from DAS.

I think I have updated the request but please let me know if I have not hit the mark again as this is a learning process for me. The due date, after I spoke with §22 is the end of this month (30/10/21).

Section	Contents
1	DEVICE DESCRIPTION
2	ESSENTIAL PRINCIPLES CHECKLIST Addendum Essential Principles Checklist – Australia
3	RISK MANAGEMENT TFS3-1 DRR-005 – Risk Management Report – SPL7013 Nasal Spray TFS3-2 DRA-005 – Risk Management Plan & Risk Analysis – SPL7013 Nasal Spray
4	4.1 DEVICE DESIGN AND MANUFACTURING INFORMATION – SPL7013 4.2 DEVICE DESIGN AND MANUFACTURING INFORMATION – SPL7013 NASAL SPRAY TFS4.2-1 Starpharma EN ISO 13485:2016 Certificate
5	5.1 COMPLIANCE WITH STANDARDS 5.2 VALIDATION OF SPL7013 MANUFACTURE 5.3 VALIDATION OF SPL7013 NASAL SPRAY MANUFACTURE 5.4 SPL7013 STABILITY 5.5 SPL7013 NASAL SPRAY STABILITY 5.6 CHEMISTRY AND TOXICOLOGY REVIEW
6	NONCLINICAL INFORMATION (DEVICE PERFORMANCE & BIOCOMPATIBILITY) TFS6-12 BER-001 – Biological Evaluation Report – SPL7013 Nasal Spray TFS6-12-1 Evaluation of Cytotoxicity TFS6-12-2 Assessment of Sensitising Properties TFS6-12-3 Assessment of Intranasal Tolerance
7	CLINICAL EVALUATION Appendix 1 Literature Search Output Appendix 2 Clinical Evaluation Data Appraisal
8	PACKAGING, LABELLING, AND INSTRUCTIONS FOR USE
9	DECLARATION OF CONFORMITY EC Declaration of Conformity AU Declaration of Conformity

From: §22 @Health.gov.au
Sent: Wednesday, 6 October 2021 2:29 PM
To: Devices Verification Section <dvs@health.gov.au>; §22 @health.gov.au
Cc: BIOME <§22 @health.gov.au>
Subject: RE: Request for round 1 review - BIOME - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing [47679] - Viraleze - Starpharma Pty Ltd [SEC=OFFICIAL]

§22,

Thank you for your email and request for Round 1 review at [D21-3133218](#).

Before I can accept the request, are you able to update the document to specify what you would like my Section to look at? If the sponsor/manufacturer has made claims about compliance with Standards and how they have tested against those Standards, we may be able to review the suitability of that aspect of their response for you. If the product is considered a medicine (rather than a medical device), or if you want claims about viricidal performance assessed, this is probably not my Section, but I'm happy to help you refer it to the right area. Finally, when would you like the Round 1 completed by?

Feel free to reach out if you have any questions.

Kind regards,

§22
§22 | Biomaterials and Engineering Section

Laboratories Branch | Medical Devices and Product Quality Division
Health Products Regulation Group
Australian Government Department of Health
T: §22 | M: §22 | E: §22 @health.gov.au
136 Narrabundah Lane, Symonston ACT 2609
PO Box 100, Woden ACT 2606, Australia

s22

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-----Original Message-----

From: Devices Verification Section <dvs@health.gov.au>

Sent: Tuesday, 28 September 2021 3:04 PM

To: BIOME <s22@health.gov.au>

Cc: s22@Health.gov.au

Subject: Request for round 1 review - BIOME - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing [47679] - Viraleze - Starpharma Pty Ltd [SEC=OFFICIAL]

Dear BIOME team,

Please see the following details for a request for BIOME assessment for an application for inclusion in the ARTG.

DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing [47679] - Viraleze - Starpharma Pty Ltd for BIOME assessment - [Round 1] TRIM link to the request attached

Kind regards,

s22

Devices Post Market Review and Reform Section Medical Devices Surveillance Branch

Email: s22@health.gov.au

Therapeutic Goods Administration

Department of Health

PO Box 100

Woden ACT 2606

www.tga.gov.au

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-----< HPE Content Manager record Information >-----

Record Number : D21-3133218

Title : Application Audit Assessment Request and Report - BIOME - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing [47679] - Starpharma Pty Ltd

From: s22
To: s22
Subject: StarPharma meeting information 1 November 2021 [SEC=OFFICIAL]
Date: Monday, 1 November 2021 11:55:21 AM

Hi s22 and s22

Here is the TRIM links for StarPharma information.

Folder: E21-346241

D21-3269704 **BIOME - Technical Assessment** - DV-2021-DA-06231-1 - DA-2021-06851-1 - Starpharma Pty Ltd - SPL7013 Nasal spray

- Sufficient evidence was provided to demonstrate biological safety with compliance to ISO 10993 parts 1, 3, 5, 10, and 11
- **No non-clinical chronic toxicity study evaluating the effect of SPL7013 nasal spray via intra-nasal administration was provided**
- The chemical and toxicological review according to ISO 10993-18 and -19 deems the constituents of the device to pose an acceptable health risk
- Sufficient evidence was provided in order to establish suitability of the device container closure

D21-3159714 **Clinical Assessment Report** - DA-2021-06851-1

s47G

D21-3145073 **MICRO** - DA-2021-06851-1 - Nasal moisture barrier dressing [47679] - Starpharma Pty Ltd

sent to Mirco s22 Microbiology on 28/9/21 DVS has not received a report back from Micro yet.

D21-3145877 **MEDICINES** DA-2021-06851-1 - Nasal moisture barrier dressing [47679] - Starpharma Pty Ltd

Sent to Medicines s22 Medicines 28/9/21 DVS has not received a report back from Medicines yet.

Regards

s22

Devices Post Market Review and Reform Section

Medical Devices Surveillance Branch

Email: s22 [@health.gov.au](mailto:s22@health.gov.au)

Therapeutic Goods Administration

Department of Health

PO Box 100

Woden ACT 2606

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From: s22
To: s22; SINGER, Simon; s22
 s22
 s22
Cc: s22
Subject: RE: StarPharma Viraleze discussion [SEC=OFFICIAL]
Date: Monday, 1 November 2021 3:13:40 PM
Attachments: [image003.png](#)

Just thought of sharing this. Viraleze retails in India for equivalent of \$70 AUD per bottle.

<https://www.indiamart.com/proddetail/viraleze-antiviral-nasal-spray-against-sars-cov-2-23488864797.html>



Viraleze Antiviral Nasal Spray, Against Sars Cov-2, Packaging Size: 10ml

Seller: 3G Chemist
₹ 3,995 / Piece [Get Latest Price](#)

Brand	Starpharma
Packaging Type	Nasal Spray
Usage/Application	Personal
Packaging Size	10ml
Strength	10ml
Grade Standard	Astodimer Sodium

[View Complete Data](#)

Fill the quantity to get latest price!

Quantity Piece

[Get Latest Price](#)
Request a quote

3G Chemist
 3.3/5 ★★★★★ (120)
 Defence Colony Market,
 New Delhi
 TrustSEAL Verified Retailer

[View Mobile Number](#)
56% Response Rate
[Contact Seller](#)

-----Original Appointment-----

From: s22 @health.gov.au>
Sent: Sunday, 31 October 2021 3:32 PM
To: s22; SINGER, Simon; s22;
 s22; s22; OH,
 s22
Cc: s22
Subject: StarPharma Viraleze discussion [SEC=OFFICIAL]
When: Monday, 1 November 2021 3:30 PM-4:30 PM (UTC+10:00) Canberra, Melbourne, Sydney.
Where: via webex

Hi all

This meeting is to discuss the way forward regarding StarPharma – Viraleze. DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing [47679] - Viraleze - Starpharma Pty.

TRIM folder: E21-346241

It is an opportunity for each section to present and discuss their finding from the review of the documents provided by the sponsor that was sent to each section around 11th or 12th October 2021.

Thank you for your input. If I have forgotten to invite anyone please forward the meeting invite onto them.

s22

-- Do not delete or change any of the following text. --

When it's time, join your Webex meeting here.

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<https://health-au.webex.com/health-au/j.php?MTID=m440cd5799e3453557e6406ced575a89a>

Join by meeting number

Meeting number (access code): 2654 419 3320

Meeting password: gJJ45GXHCA6

Tap to join from a mobile device (attendees only)

[+61-2-9338-2221,26544193320###](tel:+61-2-9338-2221,26544193320###) Australia Toll

Join by phone

+61-2-9338-2221 Australia Toll

[Global call-in numbers](#)

Join from a video system or application

Dial [26544193320@health-au.webex.com](tel:26544193320@health-au.webex.com)

You can also dial 210.4.202.4 and enter your meeting number.

Join using Microsoft Lync or Microsoft Skype for Business

Dial [26544193320.health-au@lync.webex.com](tel:26544193320.health-au@lync.webex.com)

If you are a host, [click here](#) to view host information.

Need help? Go to <https://help.webex.com>

From: s22
 To: s22; SINGER, Simon; s22
 Cc: s22
 Subject: RE: StarPharma Viraleze discussion [SEC=OFFICIAL]
 Date: Monday, 1 November 2021 3:29:45 PM
 Attachments: [image003.png](#)

s47

<https://starpharma.com/assets/asxannouncements/211026%20VIRALEZE%E2%84%A2%20distribution%20and%20supply%20to%20Vietnam.pdf>



VIRALEZE™ distribution and supply to Vietnam

- Starpharma has received its first orders of approximately 100,000 units of VIRALEZE™ antiviral nasal spray to Vietnam, with product expected to arrive in Vietnam in November
- Registration of VIRALEZE™ in Vietnam is already well advanced
- Vietnam is experiencing a widespread Delta outbreak with ~20% of its population fully vaccinated
- A portion of VIRALEZE™ from these initial orders will be donated to hospitals and healthcare organisations in Vietnam
- VIRALEZE™ is a broad-spectrum antiviral nasal spray that contains SPL7013, which has been shown to have potent antiviral and virucidal activity in multiple respiratory viruses, including inactivation of >99.9% of the Delta variant of SARS-CoV-2, in laboratory studies

Melbourne, Australia; 26 October 2021: Starpharma (ASX: SPL, OTCQX: SPHRY) today announced it has signed an initial supply contract for VIRALEZE™ antiviral nasal spray in Vietnam and first delivery into Vietnam is expected in early November. In parallel with completing registration, Starpharma is finalising an ongoing distribution agreement for VIRALEZE™ in Vietnam which will allow subsequent larger orders and ongoing supply.

Vietnam, which has a population of approximately 97 million, is experiencing a significant Delta outbreak with ~20 per cent of its population fully vaccinated¹. According to figures from the World Health Organisation, the death toll in Vietnam from COVID-19 exceeds 21,000².

Starpharma's initial orders committed for purchase under this initial supply distribution contract for VIRALEZE™ to Vietnam total approximately 100,000 units of VIRALEZE™ with further larger orders expected upon signing of an ongoing distribution agreement, which is currently being finalised. The distribution arrangements for Vietnam include Australian-based Healthco Australia Pty Ltd (**HealthCo**), with Truong Bao Land International Investment Company Limited (**TBL**) responsible for importation, sales, marketing, and distribution in Vietnam. TBL will also utilise the local medical distribution networks in Vietnam of associated company Nam Thanh Trade and Medical Services Company Limited³. The initial supply contract for the first shipments of VIRALEZE™ has a maximum three-month term and will be replaced by an ongoing distribution arrangement, which is currently being finalised. These arrangements are exclusive for retail, pharmacies, clinics, and hospitals in Vietnam.

The first shipment of VIRALEZE™ is expected in Vietnam in early November 2021 and launch preparations for the product are already well advanced with promotions to start shortly. A portion of VIRALEZE™ from these orders will be donated to hospitals and other healthcare organisations in Vietnam.

-----Original Appointment-----

From: s22 [redacted]@health.gov.au>
Sent: Sunday, 31 October 2021 3:32 PM
To: s22 [redacted]; SINGER, Simon; s22 [redacted],
s22 [redacted];
s22 [redacted]
Cc: s22 [redacted]
Subject: StarPharma Viraleze discussion [SEC=OFFICIAL]
When: Monday, 1 November 2021 3:30 PM-4:30 PM (UTC+10:00) Canberra, Melbourne, Sydney.
Where: via webex

Hi all

This meeting is to discuss the way forward regarding StarPharma – Viraleze. DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing [47679] - Viraleze - Starpharma Pty.

TRIM folder: E21-346241

It is an opportunity for each section to present and discuss their finding from the review of the documents provided by the sponsor that was sent to each section around 11th or 12th October 2021.

Thank you for your input. If I have forgotten to invite anyone please forward the meeting invite onto them.

s22 [redacted]

-- Do not delete or change any of the following text. --

When it's time, join your Webex meeting here.

[Join meeting](#)

More ways to join:

Join from the meeting link

<https://health-au.webex.com/health-au/j.php?MTID=m440cd5799e3453557e6406ced575a89a>

Join by meeting number

Meeting number (access code): 2654 419 3320

Meeting password: gJJ45GXHCA6

Tap to join from a mobile device (attendees only)

[+61-2-9338-2221,26544193320](tel:+61-2-9338-2221,26544193320)## Australia Toll

Join by phone

+61-2-9338-2221 Australia Toll

[Global call-in numbers](#)

Join from a video system or application

Dial [26544193320@health-au.webex.com](tel:26544193320@health-au.webex.com)

You can also dial 210.4.202.4 and enter your meeting number.

Join using Microsoft Lync or Microsoft Skype for Business

Dial [26544193320.health-au@lync.webex.com](tel:26544193320.health-au@lync.webex.com)

If you are a host, [click here](#) to view host information.

Need help? Go to <https://help.webex.com>

From: [Devices Verification Section](#)
To: s22
Cc: s22
Bcc: s22
Subject: s47G - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679] [SEC=OFFICIAL]
Date: Wednesday, 24 November 2021 1:57:59 PM
Attachments: [image002.png](#)
[image003.png](#)
[image005.png](#)
s47G - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing [47679] - Starpharma Pty.pdf

Dear s22

RE: Application: DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679] – Starpharma Pty.

Please find attached the Notice under s47G

Regards

s22

Devices Post Market Review and Reform Section
Medical Devices Surveillance Branch

Email: s22@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

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From: s22 <s22@starpharma.com>
Sent: Friday, 15 October 2021 10:06 AM
To: Devices Verification Section <dvs@health.gov.au>
Cc: s22 <s22@starpharma.com>
Subject: RE: TGA reply re sending documents via post - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679] [SEC=OFFICIAL]

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear s22,

I hope this email finds you well.

We were hoping you could provide an update on the progress of the medical device application audit (TRIM reference E21-346241) for SPL7013 Nasal Spray (Application Ref: DV-2021-DA-06231-1).

Many thanks,

s22

Starpharma Pty Ltd
4-6 Southampton Crescent, Abbotsford VIC 3067 Australia
Tel: s22 | Mob: s22
s22@starpharma.com | www.starpharma.com

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From: s22
Sent: Thursday, 16 September 2021 5:21 PM
To: Devices Verification Section
Cc: s22; s22 @starpharma.com
Subject: RE: TGA reply re sending documents via post - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679]
[SEC=OFFICIAL]

Hi s22,

I received a bounce back for this email, so am sending Attachment 6 without the cited articles. They are included on the USB.
This is email 5 of 5 and includes the item in bold text.

- Cover letter (also attached to this email)
- Response to application audit request for information, containing links (identified in blue text) to the supporting information for each response
- Attachment Folder including the following attachments
 - Attachment 1 – Classification Justification – SPL7013 Nasal Spray
 - Attachment 2 – Device Instructions for Use (Draft)
 - Attachment 3 – Device Labels (Draft)
 - Attachment 4 – Technical File – SPL7013 Nasal Spray (a Table of Contents with active links (blue text) to each section of the Technical File is provided)
 - Attachment 5 – SPL7013-021 Clinical Investigation Report (Final Draft)
 - **Attachment 6 – SPL7013-021 Clinical Investigation Report Annexes (Final Draft) (minus the cited articles)**

Many thanks,

s22

Starpharma Pty Ltd
4-6 Southampton Crescent, Abbotsford VIC 3067 Australia
Tel: s22 | Mob: s22
s22 @starpharma.com | www.starpharma.com

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From: s22
Sent: Thursday, 16 September 2021 4:54 PM
To: Devices Verification Section <dvs@health.gov.au>
Cc: s22; s22 @starpharma.com; s22 @starpharma.com
Subject: RE: TGA reply re sending documents via post - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679]
[SEC=OFFICIAL]

Hi s22,

This is email 5 of 5 and includes the item in bold text. This is a large file (30MB), I hope it makes it through.

- Cover letter (also attached to this email)
- Response to application audit request for information, containing links (identified in blue text) to the supporting information for each response
- Attachment Folder including the following attachments
 - Attachment 1 – Classification Justification – SPL7013 Nasal Spray
 - Attachment 2 – Device Instructions for Use (Draft)
 - Attachment 3 – Device Labels (Draft)
 - Attachment 4 – Technical File – SPL7013 Nasal Spray (a Table of Contents with active links (blue text) to each section of the Technical File is provided)
 - Attachment 5 – SPL7013-021 Clinical Investigation Report (Final Draft)
 - **Attachment 6 – SPL7013-021 Clinical Investigation Report Annexes (Final Draft)**

Many thanks,

s22

Starpharma Pty Ltd
4-6 Southampton Crescent, Abbotsford VIC 3067 Australia
Tel: s22 | Mob: s22
s22 @starpharma.com | www.starpharma.com

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From: s22

Sent: Thursday, 16 September 2021 4:51 PM

To: 'Devices Verification Section' <dvs@health.gov.au>

Cc: s22 s22 @starpharma.com s22 @starpharma.com>

Subject: RE: TGA reply re sending documents via post - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679]
[SEC=OFFICIAL]

Hi s22,

This is email 4 of 5 and includes the item in bold text.

- Cover letter (also attached to this email)
- Response to application audit request for information, containing links (identified in blue text) to the supporting information for each response
- Attachment Folder including the following attachments
 - Attachment 1 – Classification Justification – SPL7013 Nasal Spray
 - Attachment 2 – Device Instructions for Use (Draft)
 - Attachment 3 – Device Labels (Draft)
 - Attachment 4 – Technical File – SPL7013 Nasal Spray (a Table of Contents with active links (blue text) to each section of the Technical File is provided)
 - **Attachment 5 – SPL7013-021 Clinical Investigation Report (Final Draft)**
 - Attachment 6 – SPL7013-021 Clinical Investigation Report Annexes (Final Draft)

Many thanks,

s22

s22

s22

Starpharma Pty Ltd

4-6 Southampton Crescent, Abbotsford VIC 3067 Australia

Tel: s22 | Mob: s22

s22 @starpharma.com | www.starpharma.com

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From: s22

Sent: Thursday, 16 September 2021 4:50 PM

To: 'Devices Verification Section' <dvs@health.gov.au>

Cc: s22 s22 @starpharma.com s22 @starpharma.com>

Subject: RE: TGA reply re sending documents via post - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679]
[SEC=OFFICIAL]

Hi s22,

This is email 3 of 5 and includes the items in bold text.

- Cover letter (also attached to this email)
- Response to application audit request for information, containing links (identified in blue text) to the supporting information for each response
- Attachment Folder including the following attachments
 - Attachment 1 – Classification Justification – SPL7013 Nasal Spray
 - Attachment 2 – Device Instructions for Use (Draft)
 - Attachment 3 – Device Labels (Draft)
 - **Attachment 4 – Technical File – SPL7013 Nasal Spray (a Table of Contents with active links (blue text) to each section of the Technical File is provided)**

Section	Contents
1	DEVICE DESCRIPTION
2	ESSENTIAL PRINCIPLES CHECKLIST Addendum Essential Principles Checklist – Australia
3	RISK MANAGEMENT TFS3-1 DRR-005 – Risk Management Report – SPL7013 Nasal Spray TFS3-2 DRA-005 – Risk Management Plan & Risk Analysis – SPL7013 Nasal Spray
4	4.1 DEVICE DESIGN AND MANUFACTURING INFORMATION – SPL7013 4.2 DEVICE DESIGN AND MANUFACTURING INFORMATION – SPL7013 NASAL SPRAY TFS4.2-1 Starpharma EN ISO 13485:2016 Certificate
5	5.1 COMPLIANCE WITH STANDARDS 5.2 VALIDATION OF SPL7013 MANUFACTURE 5.3 VALIDATION OF SPL7013 NASAL SPRAY MANUFACTURE 5.4 SPL7013 STABILITY 5.5 SPL7013 NASAL SPRAY STABILITY 5.6 CHEMISTRY AND TOXICOLOGY REVIEW
6	NONCLINICAL INFORMATION (DEVICE PERFORMANCE & BIOCOMPATIBILITY) TFS6-12 BER-001 – Biological Evaluation Report – SPL7013 Nasal Spray

	TFS6-12-1 Evaluation of Cytotoxicity TFS6-12-2 Assessment of Sensitising Properties TFS6-12-3 Assessment of Intranasal Tolerance
7	CLINICAL EVALUATION Appendix 1 Literature Search Output Appendix 2 Clinical Evaluation Data Appraisal
8	PACKAGING, LABELLING, AND INSTRUCTIONS FOR USE
9	DECLARATION OF CONFORMITY EC Declaration of Conformity AU Declaration of Conformity

- o Attachment 5 – SPL7013-021 Clinical Investigation Report (Final Draft)
- o Attachment 6 – SPL7013-021 Clinical Investigation Report Annexes (Final Draft)

Many thanks,

§22

§22

§22

Starpharma Pty Ltd

4-6 Southampton Crescent, Abbotsford VIC 3067 Australia

Tel: +§22 | Mob: +§22

§22@starpharma.com | www.starpharma.com

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From: §22

Sent: Thursday, 16 September 2021 4:48 PM

To: 'Devices Verification Section' <dvs@health.gov.au>

Cc: §22, §22@starpharma.com, §22@starpharma.com

Subject: RE: TGA reply re sending documents via post - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679]
[SEC=OFFICIAL]

Hi §22,

This is email 2 of 5 and includes the items in bold text.

- Cover letter (also attached to this email)
- Response to application audit request for information, containing links (identified in blue text) to the supporting information for each response
- Attachment Folder including the following attachments
 - o Attachment 1 – Classification Justification – SPL7013 Nasal Spray
 - o Attachment 2 – Device Instructions for Use (Draft)
 - o Attachment 3 – Device Labels (Draft)
 - o **Attachment 4 – Technical File – SPL7013 Nasal Spray (a Table of Contents with active links (blue text) to each section of the Technical File is provided)**

Section	Contents
1	DEVICE DESCRIPTION
2	ESSENTIAL PRINCIPLES CHECKLIST Addendum Essential Principles Checklist – Australia
3	RISK MANAGEMENT TFS3-1 DRR-005 – Risk Management Report – SPL7013 Nasal Spray TFS3-2 DRA-005 – Risk Management Plan & Risk Analysis – SPL7013 Nasal Spray
4	4.1 DEVICE DESIGN AND MANUFACTURING INFORMATION – SPL7013 4.2 DEVICE DESIGN AND MANUFACTURING INFORMATION – SPL7013 NASAL SPRAY TFS4.2-1 Starpharma EN ISO 13485:2016 Certificate
5	5.1 COMPLIANCE WITH STANDARDS 5.2 VALIDATION OF SPL7013 MANUFACTURE 5.3 VALIDATION OF SPL7013 NASAL SPRAY MANUFACTURE 5.4 SPL7013 STABILITY 5.5 SPL7013 NASAL SPRAY STABILITY 5.6 CHEMISTRY AND TOXICOLOGY REVIEW
6	NONCLINICAL INFORMATION (DEVICE PERFORMANCE & BIOCOMPATIBILITY) TFS6-12 BER-001 – Biological Evaluation Report – SPL7013 Nasal Spray TFS6-12-1 Evaluation of Cytotoxicity TFS6-12-2 Assessment of Sensitising Properties TFS6-12-3 Assessment of Intranasal Tolerance
7	CLINICAL EVALUATION Appendix 1 Literature Search Output Appendix 2 Clinical Evaluation Data Appraisal

8	PACKAGING, LABELLING, AND INSTRUCTIONS FOR USE
9	DECLARATION OF CONFORMITY EC Declaration of Conformity AU Declaration of Conformity

- o Attachment 5 – SPL7013-021 Clinical Investigation Report (Final Draft)
- o Attachment 6 – SPL7013-021 Clinical Investigation Report Annexes (Final Draft)

Many thanks,

s22

[Redacted]

[Redacted]

Starpharma Pty Ltd

4-6 Southampton Crescent, Abbotsford VIC 3067 Australia

Tel: +s22 | Mob: +s22

s22@starpharma.com | www.starpharma.com

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From: s22

Sent: Thursday, 16 September 2021 4:44 PM

To: Devices Verification Section <dvs@health.gov.au>

Cc: s22, s22@starpharma.com

Subject: RE: TGA reply re sending documents via post - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679]
[SEC=OFFICIAL]

Hi s22,

I'll be sending the submission in a series of 5 emails.

This is email 1 of 5 and includes the items in bold text.

- **Cover letter (also attached to this email)**
- **Response to application audit request for information, containing links (identified in blue text) to the supporting information for each response**
- Attachment Folder including the following attachments
 - o **Attachment 1 – Classification Justification – SPL7013 Nasal Spray**
 - o **Attachment 2 – Device Instructions for Use (Draft)**
 - o **Attachment 3 – Device Labels (Draft)**
 - o Attachment 4 – Technical File – SPL7013 Nasal Spray (a Table of Contents with active links (blue text) to each section of the Technical File is provided)
 - o Attachment 5 – SPL7013-021 Clinical Investigation Report (Final Draft)
 - o Attachment 6 – SPL7013-021 Clinical Investigation Report Annexes (Final Draft)

Many thanks,

s22

[Redacted]

[Redacted]

Starpharma Pty Ltd

4-6 Southampton Crescent, Abbotsford VIC 3067 Australia

Tel: +s22 | Mob: +s22

s22@starpharma.com | www.starpharma.com

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From: Devices Verification Section <dvs@health.gov.au>

Sent: Thursday, 16 September 2021 4:31 PM

To: s22, s22@starpharma.com

Subject: TGA reply re sending documents via post - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679]
[SEC=OFFICIAL]

Hi s22

The TGA would prefer PDF documents in emails please.

Regards

s22

[Redacted]

Devices Post Market Review and Reform Section

Medical Devices Surveillance Branch

Email: s22, s22@health.gov.au

Therapeutic Goods Administration

Department of Health
 PO Box 100
 Woden ACT 2606
www.tga.gov.au

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From: s22 s22 @starpharma.com>

Sent: Thursday, 16 September 2021 4:22 PM

To: Devices Verification Section <dvs@health.gov.au>

Cc: s22 s22 @starpharma.com>

Subject: RE: TGA reply re sending documents via post - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679] [SEC=OFFICIAL]

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Hi s22,

Thanks for your mail.

I'm happy to send the submission as a series of emails, however please note that the interactive links embedded in the documents will no longer work.

If you're able to download from a link I can provide, the links should remain and you can easily navigate the submission.

Please let me know which you would prefer, the emails or the link, or both.

Many thanks,

s22

Starpharma Pty Ltd
 4-6 Southampton Crescent, Abbotsford VIC 3067 Australia
 Tel: s22 | Mob: s22

s22 @starpharma.com | www.starpharma.com

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From: Devices Verification Section <dvs@health.gov.au>

Sent: Thursday, 16 September 2021 4:17 PM

To: s22 s22 @starpharma.com>

Subject: TGA reply re sending documents via post - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679] [SEC=OFFICIAL]

Hi s22

Is there any chance that you could send all the documents via email as the Department of Health – TGA is very large and your parcel may take some time to be delivered to the appropriate section.

You can send several emails if the size of the files is very large. Additionally considering lockdown in Canberra most staff are not in the office and will not be there to collect the delivery.

Regards

s22

Devices Post Market Review and Reform Section
 Medical Devices Surveillance Branch

Email: s22 @health.gov.au

Therapeutic Goods Administration
 Department of Health
 PO Box 100
 Woden ACT 2606
www.tga.gov.au

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From: s22 s22 @starpharma.com>

Sent: Wednesday, 15 September 2021 2:25 PM

To: Devices Verification Section <dvs@health.gov.au>

Cc: s22 s22 @starpharma.com>

Subject: RE: s41FH Notice - Non-Compulsory Audit - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679]
[SEC=OFFICIAL]

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear s22,

Reference is made to the medical device application audit (TRIM reference E21-346241) for SPL7013 Nasal Spray (Application Ref: DV-2021-DA-06231-1).

We are pleased to advise that the information requested by TGA as part of the Medical Device Application Audit has been couriered to the Devices Post Market Reform and Reviews, Medical Devices Surveillance Branch, and is scheduled to arrive on Thursday 16th September.

The total size of the response in electronic format was larger than 15MB, so we have provided the information electronically on a USB drive.

The USB contains the following files/folders:

- Cover letter (also attached to this email)
- Response to application audit request for information, containing links (identified in blue text) to the supporting information for each response
- Attachment Folder including the following attachments
 - Attachment 1 – Classification Justification – SPL7013 Nasal Spray
 - Attachment 2 – Device Instructions for Use (Draft)
 - Attachment 3 – Device Labels (Draft)
 - Attachment 4 – Technical File – SPL7013 Nasal Spray (a Table of Contents with active links (blue text) to each section of the Technical File is provided)
 - Attachment 5 – SPL7013-021 Clinical Investigation Report (Final Draft)
 - Attachment 6 – SPL7013-021 Clinical Investigation Report Annexes (Final Draft)

We trust the information provided in the submission satisfies the TGA's questions and application audit requirements.

In addition to the above notification, we were hoping you could advise if the application audit is a Level 1 or Level 2 audit?

We look forward to your reply.

Many thanks,

s22

[Redacted]

[Redacted]

Starpharma Pty Ltd

4-6 Southampton Crescent, Abbotsford VIC 3067 Australia

Tel: +s22 | Mob: +s22

s22@starpharma.com | www.starpharma.com

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From: Devices Verification Section <dvs@health.gov.au>

Sent: Tuesday, 17 August 2021 8:03 AM

To: s22 s22@starpharma.com

Subject: s41FH Notice - Non-Compulsory Audit - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal moisture barrier dressing[47679]
[SEC=OFFICIAL]

Dear s22,

Your application DA-2021-06851-1 - Nasal moisture barrier dressing[47679] has been selected for a non-compulsory application audit.

Please refer to the notice for further information.

The information is required by no later than close of business: **16 September 2021.**

Regards

Departmental Officer

Devices Post Market Reforms and Reviews

[Redacted]

Medical Devices and Product Quality Division | Health Products Regulation Group

Medical Devices Surveillance Branch

Therapeutic Goods Administration

E: dvs@health.gov.au

Location: FB-51c. 136 Narrabundah Lane, Symonston, ACT, 2609

PO Box 100, Woden ACT 2606, Australia



The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

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Australian Government
Department of Health
 Therapeutic Goods Administration

TGA Reference number: E21-346241

Starpharma Pty Ltd
 PO Box 2022
 PRESTON VIC 3072

Email address: s22 [REDACTED] [@starpharma.com](mailto:s22@starpharma.com)

Dear s22 [REDACTED],

s47G [REDACTED]

Application ID:	DV-2021-DA-06231-1
Submission ID:	DA-2021-06851-1
Classification:	Class I
GMDN¹:	Nasal moisture barrier dressing[47679]
Sponsor's Reference:	SPL7013 Barrier Nasal Spray
Manufacturer:	Starpharma Pty Ltd (Australia)[41979]

s47G [REDACTED]

I have made this decision because following evaluation of the information provided to the Therapeutic Goods Administration (TGA) in relation to this application, s47G [REDACTED]

s47G [REDACTED].

s47G [REDACTED]

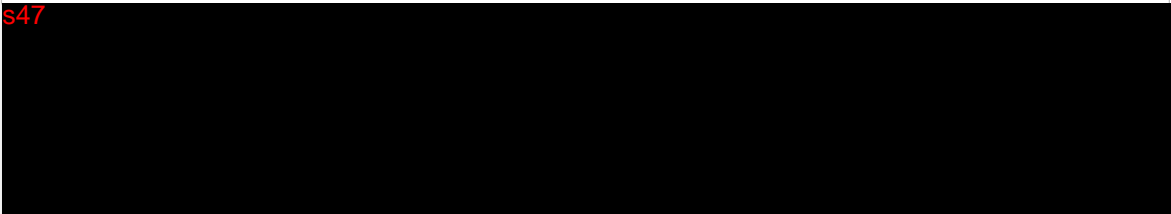
s47G [REDACTED]

s47G

s47G

Background

1.	Application for inclusion received by the TGA on:	23 July 2021
2.	Prescribed application fee was received by the TGA on:	28 July 2021
3.	<p>Notice under section 41FH(1)(b) of the Act notifying you that the application was selected for audit and information was required to enable the audit to be conducted was sent on:</p> <p>This notification required the following information:</p> <ul style="list-style-type: none"> • Clarification on the Australian classification rule selected by the manufacturer of the Device based on the intended purpose and justification of the classification rule applied by the manufacturer in accordance with Schedule 2 of Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations); • Instructions for use for the Device (manufacturer's instructions for use or product inserts as supplied in Australia) • Labels for the Device (copies of the manufacturer's product information as would be supplied with the Device in Australia); • A list of all medical devices of the kind that are the subject of this application; and • Pictorial images and/or advertising material; • Technical file including clinical evaluation report/s and clinical trial data supporting the efficacy and mode of action (intended purpose) of the device; • Evidence that demonstrates compliance with the standards listed in the Declaration of Conformity, specifically: <ul style="list-style-type: none"> ISO 10993 Biological evaluation of medical devices; ICH Q1A(R2), Stability Testing of New Drug Substances and Products; ICH Q1E, Evaluation of Stability Data; 	17 August 2021

	<p>ICH Q6A, Specifications: Test Procedures and Acceptance Criteria for New Drug Substances;</p> <p>and New Drug products: Chemical Substances; and</p> <p>BS EN ISO 14155:2020, Clinical investigations of medical devices for human subjects.</p>	
4.	<p>The intended purpose of the product, as stated in the application, is:</p> <p>s47</p> 	
5.	<p>Evidence of the application of appropriate conformity assessment procedures to the Device was provided with the application in the form of an Australian Declaration of Conformity made under clause 6.6 of Schedule 3 of the Regulations dated 22 July 2021.</p>	
6.	<p>Information in response to section 41FH request was provided to the TGA on:</p> <p>This included:</p> <ul style="list-style-type: none"> • Cover letter; • A folder containing the following documents: <ul style="list-style-type: none"> ○ Attachment 1 – Classification Justification – SPL7013 Nasal Spray; ○ Attachment 2 – Device Instructions for Use (Draft); ○ Attachment 3 – Device Labels (Draft); ○ Attachment 4 – Technical File – SPL7013 Nasal Spray (a Table of Contents with active links to each section of the Technical); ○ Attachment 5 – SPL7013-021 Clinical Investigation Report (Final Draft); and ○ Attachment 6 – SPL7013-021 Clinical Investigation Report Annexes (Final Draft). 	16 September 2021
7.	<p>An assessment of the evidence to support the application was undertaken; a copy of the report is attached to this notification letter.</p>	

s47G

This statement of reason does not repeat the entirety of the report (see Attachment) but highlights the key reasons for the Decision.

s47 [Redacted]

Decision

s47G [Redacted]

Relevant Legislation

Paragraph 41FH(1)(b) of the Act stipulates that a delegate of the Secretary may select for auditing any other application for a kind of medical device to be included in the ARTG. s47G [Redacted]

[Redacted]

- s47G [Redacted]
- s47G [Redacted]

Legislation

Therapeutic Goods Act 1989

<https://www.legislation.gov.au/Series/C2004A03952>

Therapeutic Goods (Medical Devices) Regulations 2002

<https://www.legislation.gov.au/Series/F2002B00237>



The fee paid for the application is not refundable (<https://www.tga.gov.au/refunds>).

Your review rights are attached.

s47G [Redacted]

Review of the decision under section 60 of the Act

s47G



Yours sincerely,

s22



[Signed electronically]

Delegate of the Secretary under sections s47G and s47G of the Act
Devices Applications Section

Medical Device Review and Reforms Section

Surveillance Branch

24 November 2021

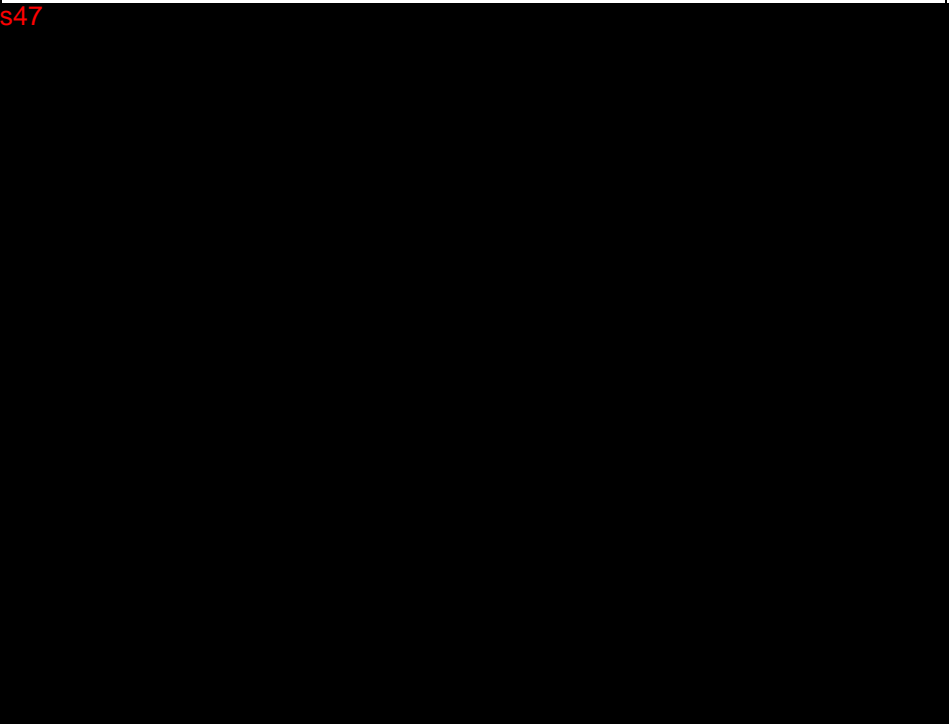
Application details

To be completed by Clinical Section Reviewer

Submission ID	DA-2021-06851-1
Application ID	DV-2021-DA-06231-1
Sponsor name	Starpharma Pty Ltd
Manufacturer name	Starpharma Pty Ltd 4-6 Southampton Crescent ABBOTSFORD VIC 3067 Australia
Device classification	Class I
GMDN code and term	Nasal moisture barrier dressing[47679]
Name of device(s)	SPL7013 Barrier Nasal Spray

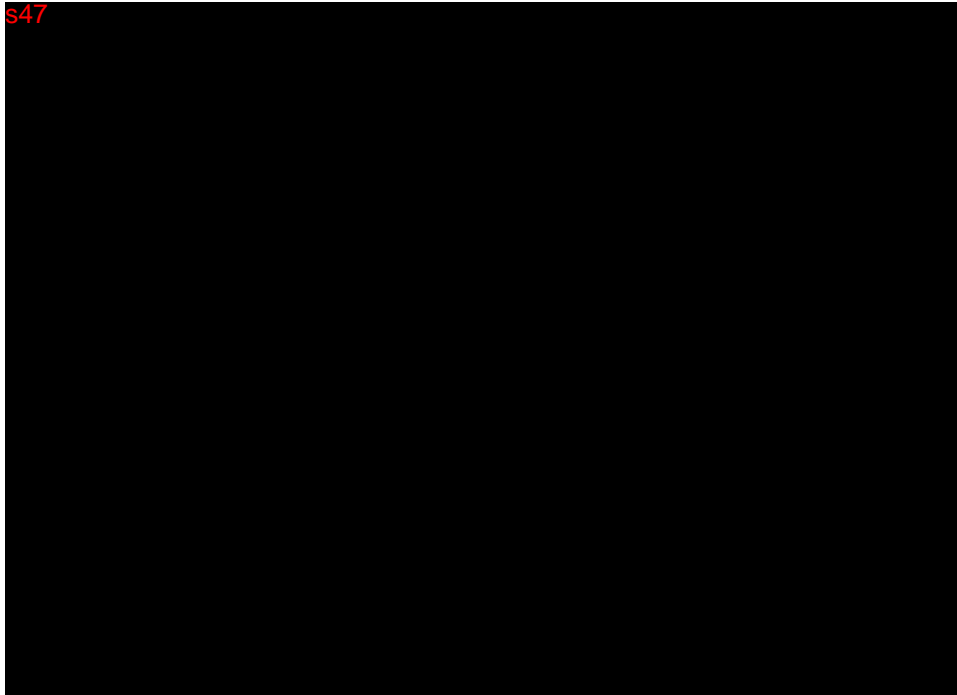
Device description

To be completed by Clinical Section Reviewer.

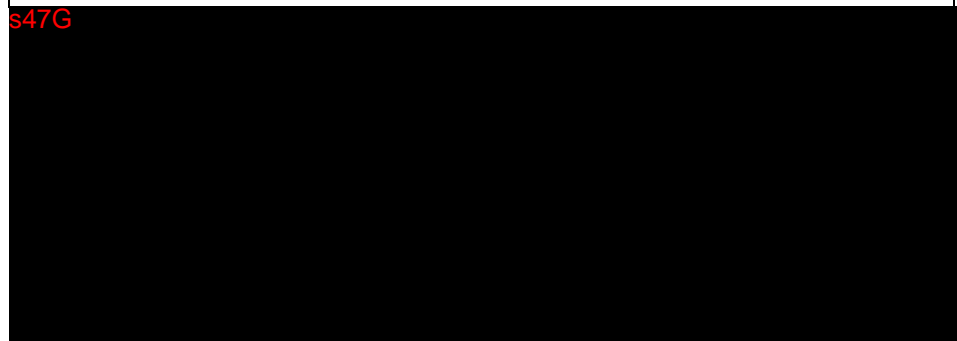
Device name	SPL7013 Barrier Nasal Spray *
Device description	 s47

S47





Clinical assessor comments



Device configurations & variants

The IFU states:

The carton contains 1 multi-dose plastic bottle with cap, containing 10 mL of SPL7013 Barrier Nasal Spray solution and 1 instruction leaflet.

SPL7013 Nasal Spray consists of a bottle and a nasal pump (actuator) able to deliver a nominal volume of 100 µL per actuation

Comments

* From the documentation provided for the application audit, it appears that various trade names may be applied to the product.

The draft label and IFU documents (Attach 3 & Attach 2) state:

SPL7013 may be replaced with VivaGel, VIRALEZE, astodrimer sodium or other term.

Section 8 of the Technical File on *PACKAGING, LABELLING, AND INSTRUCTIONS FOR USE* (S8.0_v6.0/p.) states:

The following trade names may be used for SPL7013 Nasal Spray labelling:

Trade Names*
VIRALEZE™ or VIRALEZE® Antiviral Nasal Spray
VIRALEZE™ or VIRALEZE® Barrier Nasal Spray

* Trade names are in use or are potential trade names.

Clinical assessor comments

s47G

Scope of assessment

The aim of this assessment is to verify whether SPL7013 Barrier Nasal Spray complies with essential principles (EPs) 1, 3, 6, 13 and 14 from a clinical perspective.

Assessment

Clinical evidence report (CER)

Competency of CER author	<p>The CER was signed by Professor s22. He is a retired Physician with experience in infectious diseases.</p> <p>A CV was not provided for Professor s22</p> <p><i>It should be requested that the sponsor provide a CV for Dr s22 or a CV from a suitable clinical expert that has reviewed and endorsed the CER.</i></p>
Comments	<p><i>Comment on whether the CER includes evaluation of the clinical data.</i></p>

Demonstration of equivalence Yes No

Comparator device	<p><i>Enter device name, and manufacturer if different</i></p>
Can the comparator device be considered substantially equivalent to the subject device based on clinical, technical and biological aspects?	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Claimed mechanism of action (CER p13/77)</p> <p>The CER states that “The mechanism of action of SPL7013 in achieving its intended purpose has been demonstrated to be dependent on physical means and is not considered to be pharmacological, metabolic, nor chemical</p>

in nature.”

“Numerous in vitro and in vivo studies, including peer-reviewed published studies, have shown that SPL7013 physically blocks a broad spectrum of viruses from infecting, including:

- HIV (Dezzutti et al., 2004; Jiang et al., 2005; Lackman-Smith et al., 2008; Tyssen et al., 2010; Telwatte et al., 2011),
- HSV (Bernstein et al., 2003; Gong et al., 2005; Tyssen et al., 2010),
- Adenoviruses (Romanowski et al., 2021), and
- SARS-CoV-2 (Paull et al., 2021a; Paull et al., 2021b).”

“Extensive investigations have shown that positively charged regions of viral attachment proteins result in viruses being physically trapped by the large, negatively charged branches of SPL7013 (Tyssen et al., 2010) (see Figure 1). These trapped viruses are unable to infect cells.”

“In contrast to systemic antiviral drugs that enter a host cell to pharmacologically inhibit viral replication, a large negatively charged substance such as SPL7013 physically blocks the initial generic interaction of the virus with cell surface structures that eventually leads to specific receptor-mediated viral attachment and fusion, to inhibit viral replication.”

Clinical assessor comments

s47G

Substantial equivalence

As per CER p27/77:

“While strict substantial equivalence to a predicate device is not claimed, the clinical evaluation does rely to some extent on indirect clinical data based on the comparability of SPL7013 Nasal Spray to other nasal sprays already in the market; this determination of comparability is discussed below.”

A comparison of formulation characteristics between nasal spray products, including a moisturising nasal spray product with and without hyaluronic acid is provided in the table below.

Table 4-1. Comparison of Formulation Characteristics Between SPL7013 Nasal Spray and Other Nasal Spray Products

Formulation Characteristic	SPL7013 Nasal Spray	Iota-Carrageenan Nasal Sprays	HMPC Nasal Spray	Hyaluronic Acid Nasal Spray	Saline Sprays
Claims	S47	<ul style="list-style-type: none"> Shorten the duration of a cold and help reduce the severity of cold symptoms Forms a barrier in the nasal passage that traps cold viruses, helping to reduce their multiplication and spread, slowing your body's natural defenses to sweep viruses away from the nasal lining. 	<ul style="list-style-type: none"> Trap, inactivate and remove cold viruses before a cold develops Reduces chances of a full-blown cold 	<ul style="list-style-type: none"> The saline spray forms a protective film over the mucosa and restores the natural barriers of the mucous membrane. It is ideal for the prevention and treatment of dryness. It hydrates and promotes nasal mucosa regeneration. 	<ul style="list-style-type: none"> Saline solution restores moisture to dry nasal passages and sinuses, and curbs inflammation of mucous membranes.
Isotonic / saline solution	Yes	Yes	Low pH formulation	Yes	Yes
Virus blocking polymer	Yes - Iota-carrageenan	Yes - Iota-carrageenan	Yes - hydroxypropyl methylcellulose	No	No
Muco / Bioadhesive polymer	Yes - Iota-carrageenan	Yes - Iota-carrageenan	Yes - hydroxypropyl methylcellulose	Yes - hyaluronic acid	No
Delivery	Nasal Spray Pump	Nasal Spray Pump	Nasal Spray Pump	Nasal Spray Pump	Nasal Spray Pump
Marketed brands (examples)	<ul style="list-style-type: none"> Mundicare® Cold Defence Algolair® Erkältungspray Coldamair® ProSens Nasen-Spray Schützend Hi® Travel Nasal Spray 	<ul style="list-style-type: none"> Viclo® First Defence 	<ul style="list-style-type: none"> HySan Hyaluronspray Hyla Mist Nasogel Free nose 	<ul style="list-style-type: none"> Fos nasal spray Flo nasal spray 	

The CER also presented a comparability analysis of SPL7013 Nasal Spray and a carrageenan containing nasal spray, Mundicare® Cold Defence Nasal. The comparability analysis (see Table 4-2) considered the clinical, technical, and biological characteristics of both devices.

Table 4-2. Comparability of SPL7013 Nasal Spray and Iota-Carrageenan (e.g., Mundicare® Cold Defence) Nasal Spray

Evidence Presented	SPL7013 Nasal Spray	Mundicare® Cold Defence Nasal Spray	Impact of Difference on Safety and Performance
Clinical Characteristics	S47	<ul style="list-style-type: none"> Used specifically for the treatment of common cold caused by viruses, it can be used additionally as prophylaxis based on the sustainable moistening of the nasal mucous membrane. Forms a protective barrier in the nasal lining to trap common cold viruses, helping to stop their multiplication and spread. To help prevent a cold by forming a protective barrier in the nasal lining to trap common cold viruses. Clinical condition: colds/respiratory virus 	S47G
Intended purpose, and the clinical condition being targeted	S47	<ul style="list-style-type: none"> Used specifically for the treatment of common cold caused by viruses, it can be used additionally as prophylaxis based on the sustainable moistening of the nasal mucous membrane. Forms a protective barrier in the nasal lining to trap common cold viruses, helping to stop their multiplication and spread. To help prevent a cold by forming a protective barrier in the nasal lining to trap common cold viruses. Clinical condition: colds/respiratory virus 	S47G
Target population		<ul style="list-style-type: none"> Adults and children over the age of 1 year. Can be used during pregnancy and breastfeeding. 	
Site of application (s)/in the body		<ul style="list-style-type: none"> The nasal mucosa of the septum, turbinates, vestibule, and as far as the nasopharynx. 	

Table 4-2. Comparability of SPL7013 Nasal Spray and Iota-Carrageenan (e.g., Mundicare® Cold Defence) Nasal Spray

Evidence Presented	SPL7013 Nasal Spray	Mundicare® Cold Defence Nasal Spray	Impact of Difference on Safety and Performance
Type of contact and duration of use/contact with the body	s47	Product application is 3 times daily when displaying symptoms, and maximum exposure is expected to be over a 12-16 hour period. Device exposure would cease for a period of 8-12 hours overnight or during sleep. Product application may also be intermittent when used for prevention.	s47G
Environment of use		At the first signs of a cold, within 48 hours of symptoms appearing, to help shorten its duration and lessen the severity of symptoms. It can also be used when not experiencing a cold to provide moisturization of the nasal lining and to also help prevent a cold by forming a protective barrier in the nasal lining to trap common cold viruses.	
Intended user (e.g., healthcare professional or lay person)		Healthcare professionals and lay persons.	
Recommended dosing regimen		1 spray (140 µl) into each nostril, 3 times a day, as needed.	

Table 4-2. Comparability of SPL7013 Nasal Spray and Iota-Carrageenan (e.g., Mundicare® Cold Defence) Nasal Spray

Evidence Presented	SPL7013 Nasal Spray	Mundicare® Cold Defence Nasal Spray	Impact of Difference on Safety and Performance
Technical Characteristics			
Design (e.g., dimensions, design tolerances etc.)	s47	A nasal pump (actuator) able to deliver a nominal volume of 140 µl per actuation for adults, and 50 µl per actuation for children.	s47G
Material (e.g., chemical formulation, additives etc.)		Iota-carrageenan (1.2 mg/ml) Other ingredients: saline solution (purified water, sodium chloride [Eg1])	
Specifications and properties		Very low viscosity, clear, colourless liquid formulation, with pH in neutral range.	

Table 4-2. Comparability of SPL7013 Nasal Spray and Iota-Carrageenan (e.g., Mundicare® Cold Defence) Nasal Spray

Evidence Presented	SPL7013 Nasal Spray	Mundicare® Cold Defence Nasal Spray	Impact of Difference on Safety and Performance
Deployment methods	s47	Formulation delivered via an actuator and pump. Clean nostrils before use. Before first use, pump a few times if necessary, until spray is discharged.	s47G
Critical performance requirements		Store between 5 and 30°C. Keep away from light.	
Principle of operation		The principle of operation is a moistening barrier between sinuses and nasal mucosa. The barrier contains a substance that traps and blocks virus thereby inactivating the virus.	
Biological Characteristics			
Biocompatibility of materials in contact with the body		Carrageenan is a naturally derived compound, commonly used in food preparation, while saline is of no biological concern to the body. Clinical data indicate the product is safe and well-tolerated.	
Biological action		The device forms a physical moisture barrier that traps and inactivates extracellular virus via a physical mechanism of action.	
Degradation mechanism and profile		Following application, the device shall be exhaled from the body via the digestive system.	
Biological response (e.g., inflammatory/immune response, tissue integration etc.)		The device utilizes a physical mechanism of action to achieve its intended purpose.	

The CER, p34/77, stated:

“Based on the evaluation of comparability in Table 4-2, SPL7013 Nasal Spray is considered comparable to Iota-carrageenan (Mundicare® Cold Defence) nasal sprays. Where differences have been identified, these do not impact the safety and/or performance of SPL7013 Nasal Spray with respect to Mundicare® Cold Defence.”

Clinical assessor comments

s47G

Formulation

The composition of the SPL7013 Nasal Spray is shown below.

Table 6.2-1 Composition of SPL7013 Nasal Spray

Ingredient	% w/w	Quantity 1% w/w (kg / 100 kg batch)	Standard'	Function of Ingredient
s47				

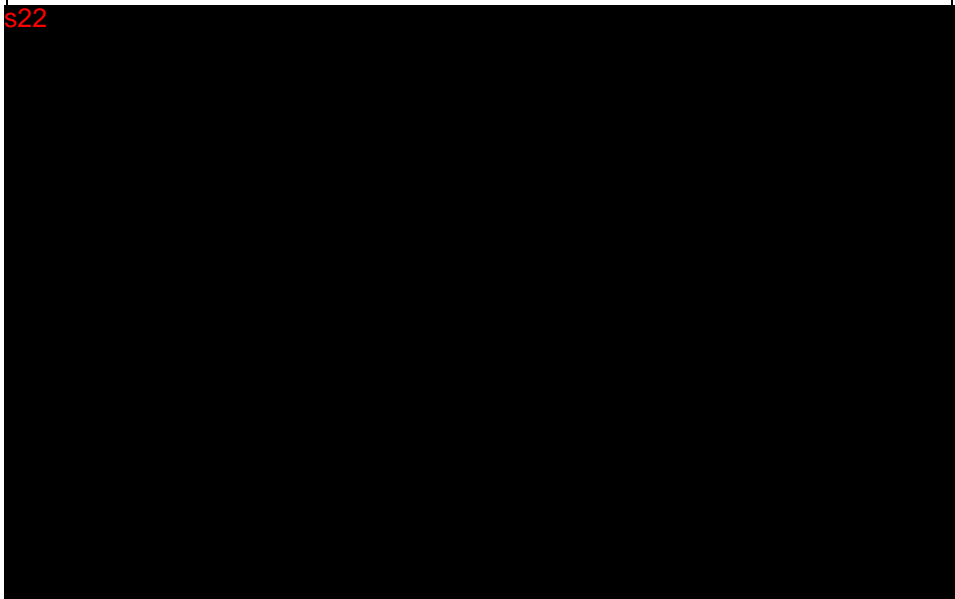
Clinical assessor comments

s47G



Manufacturer's clinical investigations

<p>Has the manufacturer conducted clinical investigations?</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If no, what is the rationale and is this acceptable?</p> <p><i>Comment on rationale and its acceptability</i></p>
<p>Pre-market or post-market clinical investigations?</p>	<p><input checked="" type="checkbox"/> Pre-market <input checked="" type="checkbox"/> Post-market</p>
<p>Randomised controlled trial</p>	<p><input checked="" type="checkbox"/> Device <input type="checkbox"/> Predicate <input type="checkbox"/> Nil</p> <p>Comments: <i>Include details of trial and outcomes</i></p>
<p>Single-arm trial</p>	<p><input type="checkbox"/> Device <input type="checkbox"/> Predicate <input type="checkbox"/> Nil</p> <p>Comments: <i>Include details of trial and outcomes</i></p>
<p>Other</p>	<p><input checked="" type="checkbox"/> Device <input type="checkbox"/> Predicate <input type="checkbox"/> Nil</p> <p>Comments: <i>Include details of investigation and outcomes, e.g. registry based PMCF</i></p>



Investigation scope and design

s22



s22



Clinical assessor comments

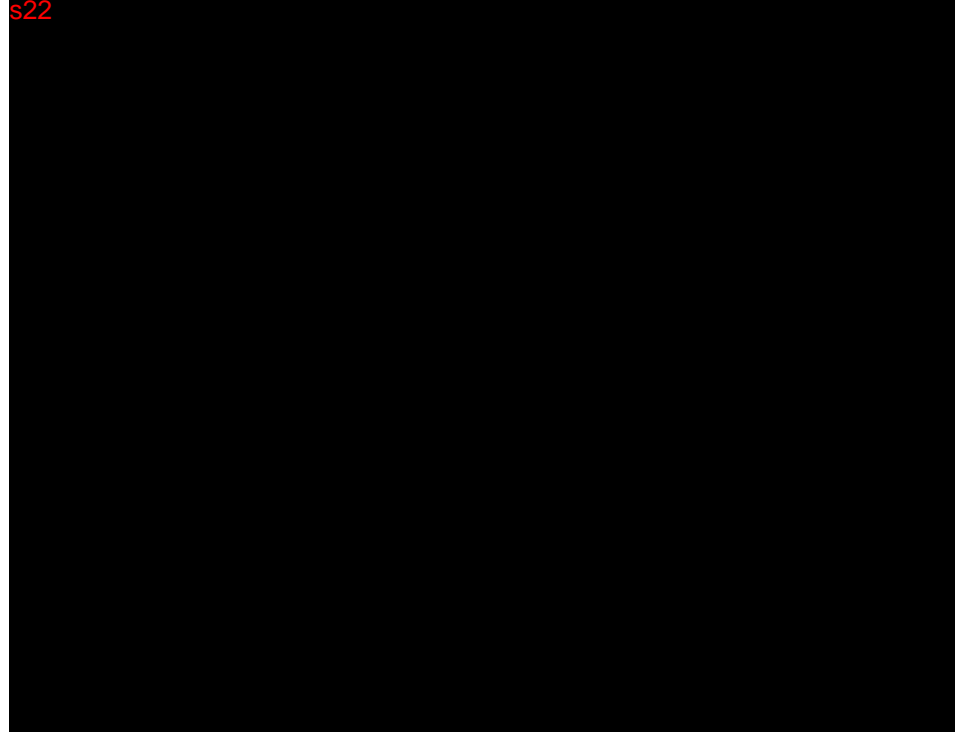
s47G





Clinical literature review **Yes** **No**

Literature search protocol provided	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Comments:
Selection criteria of the literature review	<input checked="" type="checkbox"/> Device <input type="checkbox"/> Predicate <input checked="" type="checkbox"/> Similar marketed <input type="checkbox"/> Addresses all device variants (if any) in the device application <input type="checkbox"/> Addresses the same clinical condition
Literature type	<input checked="" type="checkbox"/> Published literature <input type="checkbox"/> Unpublished literature <input type="checkbox"/> Other



Data appraisal

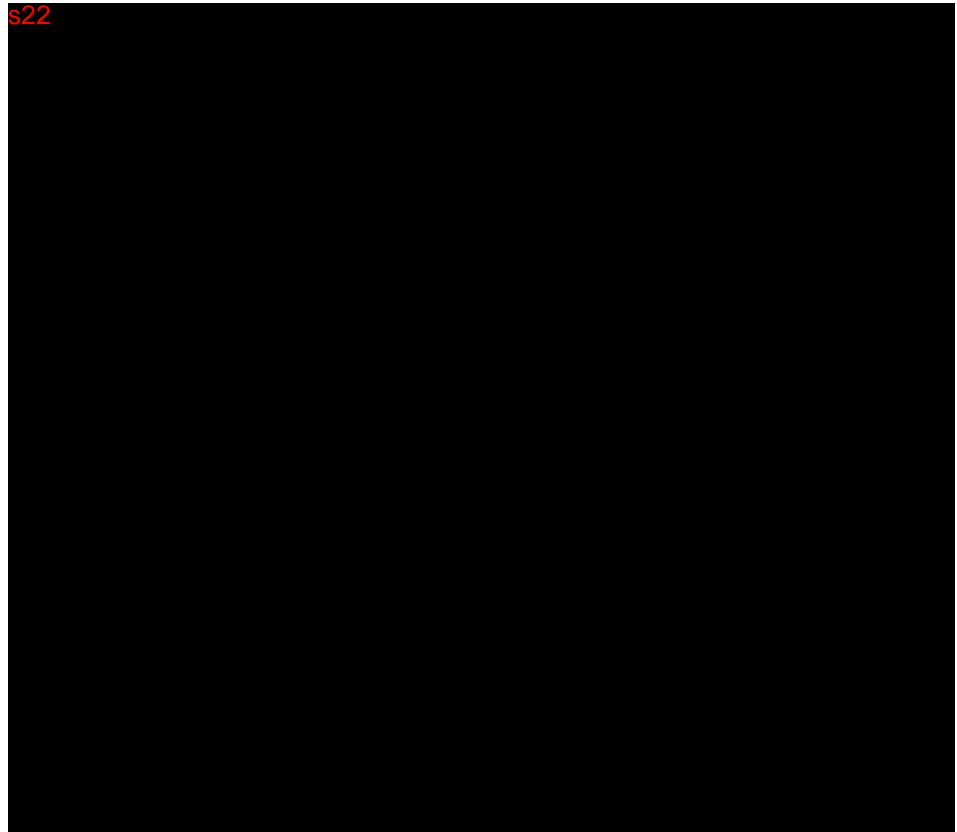
s22



s22

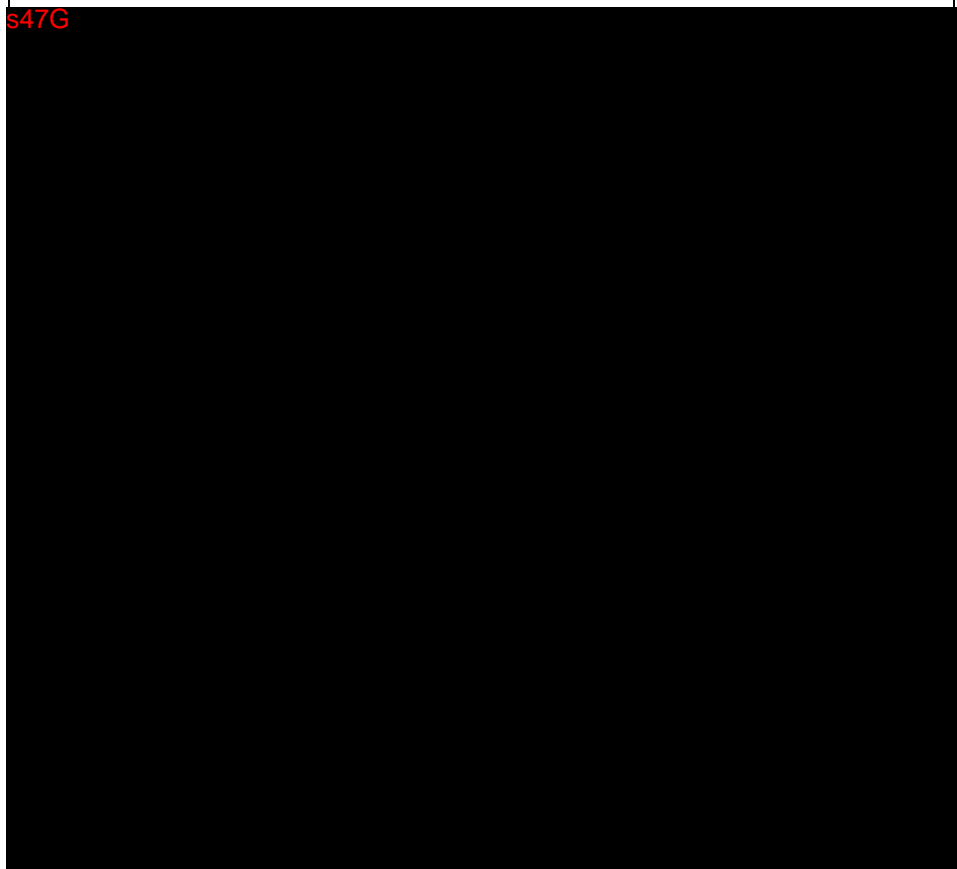


s22



TGA clinical assessor comments

s47G



Other clinical experience Yes No

Adverse events with complaint rates

Device Predicate Nil

Comment: *Describe data/information and any significant issues.*

Public adverse event databases

Device Predicate Similar marketed Nil

Comment: *Describe data/information and any significant issues.*

Recalls (or actions such as market withdrawals, field corrections, safety alerts)

Device Predicate Similar marketed Nil

Comment: *Describe data/information and any significant issues.*

Corrective and preventative actions (CAPAs)

Device Predicate Nil

Comment: *Describe data/information and any significant issues.*

Registry data

Device Predicate Similar marketed Nil

Comment: *Describe data/information and any significant issues.*

Other

Device Predicate Similar marketed Nil

Comment: *Describe data/information and any significant issues.*

The CER stated that the subject device is currently in production after initial launch of the product in the UK in March 2021 (p62/77).

Post-market surveillance/vigilance data covering the period from launch (March 2021) to 3 September 2021 have been provided (see Table 4-16 below). To date, over 100,000 units of the device have been released to the market in the UK.

Table 4-16. Vigilance/PMS Data for SPL7013 Nasal Spray Since Launch

Vigilance/PMS activity	Total	Summary
Recalls	0	No recalls for the product
Reportable Incidents	0	No reportable incidents
Complaints/Incidents		
Quality related	0	No quality related complaints/incidents
Safety related	1	1 x vomiting following use

Comments

TGA clinical assessor comments

Post-market data are limited.

The sponsor should be requested to provide:

- i) *An update on the regulatory status of the subject device, including the approved intended purpose in each jurisdiction.*
- ii) *An update on the current marketing status of the subject device, including whether the subject device has been withdrawn from sale in any jurisdiction, and the reason/s why.*

Risk management

From a clinical perspective, does the report/FMEA include the risks arising from the use of the device for its intended purpose, and foreseeable misuse of the device?

Yes No

A Risk Management Plan Risk Analysis document was provided. This included a risk matrix.

No risks were considered above the level of "minimal".

The following hazardous situations had a Residual Risk Code of "minimal":

- Assigned dose, or concentration of SPL7013 in the formulation, is insufficient to inactivate virus
- Product used continuously for longer than 30 days
- User gains a false sense of security during use and doesn't employ other accepted methods for prevention of infection

TGA clinical assessor comments

There have been no clinical studies conducted to assess the efficacy of the subject device, therefore it is possible that users may have expectations of efficacy that cannot be met by the product. This may also have serious consequences if the user becomes less diligent in employing other methods to prevent infection.

Non-clinical studies are not considered to be adequate in mitigating such risks, and the Residual Risk Code of "minimal" is not considered appropriate.

The duration of treatment in the clinical study conducted in healthy volunteers was 14 days and there are no safety data for the subject device beyond this period. In addition there are no safety data available in the target population.

It is therefore not acceptable that the hazard of continuous use beyond 30 days is "minimal".

Do the risks associated with the use of the device appear to have been adequately mitigated?

Yes No

Comments: *Comment if risks not adequately mitigated*

Are the residual risks appropriately documented in the IFU/labels/PIL?

Yes No

Comments: *Comment if residual risks not appropriately documented*

IFU, labels and other information provided with the device

From a clinical perspective, does the information provided with the device (IFU, labels, PIL, etc.) provide adequate information on the intended purpose, proper use, and warnings about risks to patients and users?

Yes No

The IFU contained information on what the nasal spray is, how it works, and directions for use. There is no maximum time period for continuous use stated.

The sponsor should be requested to provide a clinically reasoned justification as to why there is no maximum duration of treatment stated in

the IFU.

Note is made that the duration of treatment in the clinical investigation study in healthy volunteers was 14 days. Safety beyond this duration has not been established.

The IFU may need to be reviewed again upon provision of further data.

Assessment summary

Product Description

s47



Clinical Expert

The CER was signed by Professor s22 . He is a retired Physician with experience in infectious diseases. A CV for Professor s22 has not been provided and this should be requested.

Formulation

s47



Clinical Data

Non-clinical data were provided which is beyond the scope of clinical assessment and is not directly relevant to informing on safety and performance of the subject device.

Data were provided from one double-blind, single-centre, randomised, placebo-controlled clinical investigation of the safety, tolerability and absorption of single and multiple applications of SPL7013 Nasal Spray in healthy volunteers. The primary endpoint was the frequency and severity of treatment emergent adverse events (TEAEs) and serious adverse events (SAEs). Pharmacokinetic data were collected for the first 7 days of the study. There were no deaths, SAEs or AEs leading to withdrawal of treatment. All AEs experienced were of mild intensity and self-limiting.

Blood plasma levels of SPL7013 were not detected above the lower limit of quantitation of the bioanalytical assay.

It is unusual for pharmacokinetic (PK) data to be collected in a clinical study examining a medical device. It is unclear as to why the study collected PK data up to 7 days only and not for the full duration of study treatment, 14 days.

It is also not clear as to why only one dose level of the SPL7013 Nasal Spray was studied.

There is no clinical evidence that the SPL 7013 Nasal Spray traps and inactivates cold viruses in humans.

There is no explanation as to whether there would be any effect on viruses that enter beyond the nose, for example the nasopharynx or lungs, that may result in infection.

It is noted that the Clinical Investigation Report provided summary tables and listings for a number of parameters. No summary tables or listings were provided for the PK parameters. It is therefore not possible to assess whether there were any trends observed, or evidence of accumulation of the SPL 7013 in blood, over the 7 days.

Literature Review

The literature search strategy aimed to capture key clinical data related to the subject device and comparable devices as well as SPL7013-related non-clinical and clinical data. Search dates were limited to the period 2010 to 2021. The literature review data does not support the clinical claims made in relation to prevention of respiratory viral infections, including SARS-CoV-2. In vitro data and data from animal studies are insufficient to support claims of clinical performance and safety in humans.

The pre-clinical data indicate that the logical next step in establishing effectiveness of the SPL7013 Nasal Spray would be to conduct a clinical efficacy study in humans.

Post-market Data

Post-market data are limited; March 2021 to 3 September 2021.

Instructions for Use

The IFU contained information on what the nasal spray is, how it works, and directions for use. There is no maximum time period for continuous use stated.

Overall the SPL7013 Nasal Spray cannot be seen to comply with Essential Principle 14 at this time.

Conclusions and recommendations

s47G



Sign-Off – Medical Advisor

Name			
Signature	Signed electronically in TRIM	Date	12 October 2021

Review Rights

Request for reconsideration of an initial decision

This decision is a reviewable initial decision under section 60 of the Act. Under section 60, a person whose interests are affected by a 'reviewable' initial decision, can seek reconsideration of the initial decision.

As this document constitutes written notice of the making of an initial decision being given by the Secretary, a request for reconsideration of this initial decision must be given to the Minister within 90 days and be accompanied by any information that you wish to have considered. A request for reconsideration given to the Minister outside the statutory 90 day reconsideration period cannot be accepted.

The Minister may either personally undertake a request for reconsideration of an initial decision or delegate to an officer of the Department with the appropriate delegation.

Under section 60(3A) of the Act, the Minister (or the Minister's delegate) is not able to consider any information provided after the notification is made of a request for reconsideration of an initial decision unless the information is provided in response to a request from the Minister (or the Minister's delegate), or it is information that indicates that the quality, safety or efficacy of the relevant therapeutic goods is unacceptable.

Guidelines for requesting reconsideration of an initial decision

A request for reconsideration should be made in writing, signed and dated by the person requesting reconsideration, should be titled "<insert person/company name> - Request for Reconsideration Under Section 60 of the *Therapeutic Goods Act 1989*" and should include the following:

- a copy of the initial decision notification letter (or other evidence of notification);
- identify, and describe with as much specificity as possible, which component(s) of the initial decision should be reconsidered and set out the reasons why reconsideration is requested;
- any information/documentation in support of the request, clearly labelled to correspond with (any or each of) the reasons why reconsideration is requested; and
- an email address nominated for the purposes of receiving correspondence in relation to the request for reconsideration.

All requests for reconsideration should be given to the Minister by email:

Email: 'minister.hunt.DLO@health.gov.au' and copied to 'decision.review@health.gov.au'

Requests for reconsideration that include dossiers (or similar bulk material) that cannot easily be attached to the request given first by email, may then be submitted on a USB drive or CD sent by express post or registered mail to:

Mail: **Minister for Health**
Suite M1 40
c/- Parliament House
CANBERRA ACT 2600

Subject to the *Administrative Appeals Tribunal Act 1975* (AAT Act), if you are dissatisfied with the decision upon reconsideration by the Minister (or the Minister's delegate), you can apply to the Administrative Appeals Tribunal (AAT) for a review of that decision upon reconsideration.

NOTE: This initial decision remains in effect unless and until it is revoked or revoked and substituted by the Minister (or the Minister's delegate) as a result of a request for reconsideration under section 60 of the Act OR is set aside, varied or remitted by the AAT or is otherwise overturned or stayed.

From: s22 s22 on behalf of [Devices Verification Section](#)
To: s22
Cc: s22
Bcc: s22
Subject: TGA reply re : Application DV-2021-DA-06231-1 - DA-2021-06851-1 - Starpharma - viraleze [SEC=OFFICIAL]
Date: Thursday, 23 December 2021 2:12:49 PM
Attachments: [image006.png](#)
[image007.png](#)
[image009.png](#)


Dear s22,

Thank you for your email and feedback regarding application DV-2021-DA-06231-1 - DA-2021-06851-1 - Starpharma viraleze

s47G



As you indicate that this ingredient astodimer sodium has been demonstrated to be an effective virucidal agent in *in-vitro* studies, this action *in-vivo* is pharmacological. This, combined with the product's pharmacokinetics are responsible for the product's claimed benefit, if indeed this can be proven *in-vivo*. s47G



s47G



Additionally, you noted that the CER provided intended to cover the evaluation of the product for safety and performance to support registration in multiple jurisdictions. Generally, the TGA expects that all documents provided meet the TGA's requirements. They are reviewed in full and all claims are considered against the product in the application for inclusion. Therefore all

the claims in the CER were assessed against the product as intended to be sold on the Australian market.

Regarding the brand name 'Viraleze' and the labels provided these were requested in the s41FH as:

- Instructions for use for the Device (manufacturer's instructions for use or product inserts as supplied in Australia)
- Labels for the Device (copies of the manufacturer's product information as supplied with the Device in Australia);

Therefore the submitted documents were considered in the application to be the labels to be used when sold onto the Australian market and the name Viraleze thus considered to be the name of the product.

For further information, please refer to the notification letter dated 24 November 2021.

Regards

s22

Devices Post Market Review and Reform Section
Medical Devices Surveillance Branch

Email: s22@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

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From: s22

Sent: Friday, 3 December 2021 4:37 PM

To: s22@starpharma.com>

Cc: s22@starpharma.com>

Subject: RE: Application DV-2021-DA-06231-1 - DA-2021-06851-1 [SEC=OFFICIAL]

Dear s22

Thank you for providing your concerns in the email below. This has been provided to the relevant areas who will review and provide me with feedback.

I will be in touch with you again next week.

Best wishes

s22

s22

s22 – Devices Post Market Reforms & Reviews Section

Medical Devices and Product Quality Division | Health Products Regulation Group

Medical Devices Surveillance Branch

Australian Government Department of Health

T: s22 M: s22 | E: s22@health.gov.au

Location: Perth 87

PO Box 100, Woden ACT 2606, Australia



The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: s22@starpharma.com>

Sent: Thursday, 2 December 2021 4:48 PM

To: s22@health.gov.au>

Cc: s22@starpharma.com>

Subject: RE: Application DV-2021-DA-06231-1 - DA-2021-06851-1

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear s22,

Thanks again for agreeing to consider some feedback from us on the recent communication from TGA regarding our application.

We submitted a Class I medical device application, which is accompanied by a declaration of conformity. An extensive amount of information was then requested by the TGA when the application was selected for audit, and we compiled that information and submitted it to TGA for consideration. We are concerned that, contrary to our own experiences, our understanding of the typical review processes, and our previous discussion with you in May, no opportunity was provided subsequent to TGA's review of that body of information to provide clarification of any issues raised or assumptions that were made by the reviewers, or to respond.

Issues that we would wish to discuss and clarify with TGA, if given the opportunity, include:

- s47. We note that other medical device products that are marketed in Australia, and that are presumably accepted

to act physically, refer to “s47” of viruses in their packaging/claims. Therefore, we assumed this description would be acceptable and used this nomenclature in the intended purpose, and were surprised that this description resulted in astodimer being considered by TGA to act pharmacologically. The mechanism of action of astodimer is essentially identical to that of carrageenan, which is included in a marketed medical device to s47 and available data indicate an identical fundamental mechanism of action against viruses. “s47” is a descriptor of the consequence of an action, and does not necessarily describe the mechanism of action. s47. We would appreciate the opportunity to discuss this more fully.

- comparability with the carrageenan-containing nasal spray marketed in Australia was dismissed as being irrelevant by the reviewer, without any comment on the specifics of the evaluation we provided. Our analysis of comparability identified differences between the products and, as per the relevant TGA guidances, we evaluated these differences for impact on relevance, safety and performance. We would like the opportunity to discuss and defend this analysis of comparability, as we believe it is scientifically and technically relevant and valid.
- the CER is intended to cover the evaluation of the product for safety and performance to support registration in multiple jurisdictions. In Australia, we do not intend to make a number of the claims listed in the CER in relation to the product. However, for completeness, all data were included in the CER. We would appreciate the opportunity to discuss and clarify the proposed claims for the product in Australia.
- we would appreciate the opportunity to discuss and clarify the TGA’s position on the inclusion of parabens in our product and implications for its classification. Parabens do not contribute to the intended purpose of the product and are included in numerous products where they are not considered to be medicinal. Globally, these substances are considered to be GRAS ingredients, food additives, and non-medicinal ingredients. Non-sterile products, including nasal sprays, typically include preservatives, which by definition have antimicrobial activity, but they are not, to our knowledge, considered to be medicinal substances or Class III devices. We are not aware of data showing that parabens have antiviral activity.
- the rationale for inclusion of evaluation of PK (extent of absorption of astodimer sodium) in the clinical study in healthy volunteers. There are extensive data supporting the design of the sampling time points, including the numerous nonclinical and clinical studies showing lack of systemic absorption of astodimer following topical application to a wide range of mucosal membranes. As systemic absorption is a key factor in determining mode of action and classification of a product, we considered it highly relevant to assess extent of absorption of the product in the clinical study.
- the identified potential “serious consequences” a user may experience “if the user becomes less diligent in employing other methods to prevent infection”. s47G, we would like to discuss and clarify the TGA’s interpretation of intended purpose and the implications for the risk:benefit assessment for the product, and the possible serious consequences that are foreseen.
- the target population and intended use, to clarify that the product is indeed intended for use in healthy people, consistent with the clinical study, and is not intended for continuous use for greater than 30 days.
- the reference to the brandname, “Viraleze”. We appreciate this name was referenced in

the draft label/IFU as a potential brandname that may be used in place of SPL7013 Barrier Nasal Spray. However, we would like to clarify that we never intended to use this brandname for the product in Australia, given the different claims made for the product branded as Viraleze in other jurisdictions.

We would greatly appreciate the opportunity to discuss these issues with you and the relevant team members at TGA, to determine a way forward.

We would also like to seek clarification that these discussions, which you have suggested, are separate to a potential formal request for reconsideration of an initial decision under the Therapeutic Goods Act, and that such a course of action will still be available to Starpharma.

Thanks again for your consideration and we look forward to hearing from you and potentially discussing these matters with you.

Regards,

s22

s22

s22

Starpharma Pty Ltd

4-6 Southampton Crescent, Abbotsford, VIC 3067, Australia

Tel: +s22 | Mob: +s22

s22 @starpharma.com | www.starpharma.com

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From: s22

Sent: Thursday, 25 November 2021 10:29 PM

To: s22 @health.gov.au>

Subject: Application DV-2021-DA-06231-1 - DA-2021-06851-1

Dear s22,

Thank you for your time and the discussion on Thursday morning regarding our application. We appreciate your offer for the opportunity for us to provide to you via email our concerns, and some clarifications and positions in response to the notice provided by the TGA on our application, so that you may discuss these with s22 and the clinical team. We appreciate the potential opportunity to discuss or present the information. I will send a further email within the next few days.

Thanks again and regards,

s22

s22

Starpharma Pty Ltd
4-6 Southampton Crescent, Abbotsford, VIC 3067, Australia
Tel: +s22 | Mob: +s22
s22@starpharma.com | www.starpharma.com

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SPL7013 NASAL SPRAY



Australian Government

Department of Health

Therapeutic Goods Administration

Medical Devices Program

Internal Form

DAS FORM 6.2.a	Medical Device Application Audit Request and Report - Clinical		
Comes under	DAS WI 6.2 Requesting an assessment for an Application Audit		
Applicable to	Devices Applications Section Devices Clinical Section	Authorised by	s22 [REDACTED] DAS
Date issued	13 January 2021	Version #	1.0

Application audit details

Date of request	12/07/2022	
Submission ID	DA-2021-06851-1	
Application ID	DV-2021-DA-06231-1	
Sponsor name	Starpharma Pty Ltd	
Manufacturer name	Starpharma Pty Ltd (Australia)[41979]	
Application audit type	Non-mandatory audit If mandatory, choose prescribed device type	
Reason for clinical review	To request for your advice as to whether the applicant has sufficient information to substantiate the compliance with the essential principles, in particular, EP 1, 3, 6 and 14.	
Documents provided	<input checked="" type="checkbox"/> IFU and labels	TF5S8 within D22-5643748
	<input type="checkbox"/> For implantable devices (unless excluded*), PIL	TRIM reference
	<input type="checkbox"/> For urogynaecological mesh devices, PIC	TRIM reference

Record Details	D22-5684008 Application audit assessment request and report - Clinical (DCS) - DV-2021-DA-06231-1 - DA-2021-06851-1 - ~ Starpharma Pty Ltd(3).DOCX	Effective Date	13/01/2021
Print Date	29/05/2024 4:20		Page 1 of 35
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	<p><input type="checkbox"/> Advertising material TRIM reference</p> <p><input checked="" type="checkbox"/> Clinical evaluation report (CER), signed and dated ≤ 2 years TF5S7 within D22-5643748</p> <p><input checked="" type="checkbox"/> CV of clinical expert TF5S7 within D22-5643748</p> <p><input checked="" type="checkbox"/> Risk management report, including FMEA TF5S3 within D22-5643748</p> <p><input type="checkbox"/> For implantable devices, MRI safety evidence TRIM reference</p>
Request comments	<p>The full submission for your consideration is located in D22-5643748; the full submission also includes the summary, cover letters containing the applicant’s response to concerns raised during the previous review, and the information on device design and non-clinical evaluation.</p>
Submission TRIM reference	<p>D22-5643748</p>

* Excluded devices are sutures, staples, dental filings, dental braces, tooth crowns, general (endosseous) dental implants, screws, wedges, plates, wires, pins, clips, connectors

Device description

Information from eBS device application form

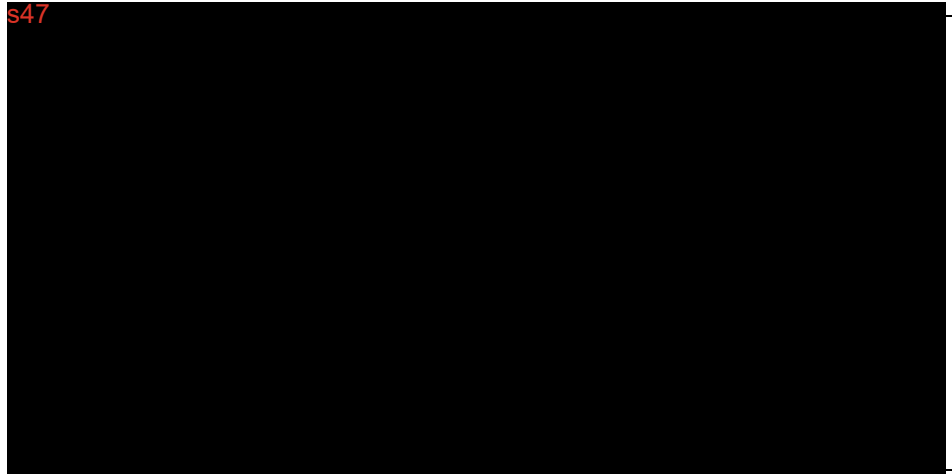
Device name	SPL7013 nasal spray
Intended purpose	<div style="background-color: black; color: red; padding: 5px;">s47</div>



Device classification	Choose a classificationClass I
GMDN code and term	Nasal moisture barrier dressing[47679]
Comments	<i>Provide comments if the details in the device application form do not appropriately cover the device(s) for which information has been provided for the application audit.</i>

Information provided for the application audit – labels, IFU, advertising, CER etc.

Device name	SPL7013 Nasal Spray
Device description	



Device configurations & variants



Figure 4.1-1.
Presentation of
SPL7013 Nasal Spray.

There are no variants in the application.

System or procedure pack

none

Accessories or compatible devices

none

Comments

Provide comments if the details in the device application form (as specified above under Information from device application form) do not appropriately reflect/cover the information provided for the application audit.

Note: **Unique product identifier (UPI)** is only relevant for Class III/AIMD devices as it forms part of the “kind of medical device” by which these devices are entered in the ARTG. The UPI is given to the device by its manufacturer to identify the device and any variants. **Device name** is relevant to devices other than Class III/AIMD. For non-Class III/AIMD devices, the name of the device does not form part of the “kind of medical device” and is not recorded in the ARTG entry.

Record Details	D22-5684008 Application audit assessment request and report - Clinical (DCS) - DV-2021-DA-06231-1 - DA-2021-06851-1 - ~ Starpharma Pty Ltd(3).DOCX	Effective Date	13/01/2021
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Application background

Conformity assessment documents accompanying application

These conformity assessment documents are linked to the application as Manufacturer Evidence or attached to the device application form. They were considered satisfactory in relation to the application passing preliminary assessment.

Comment: The application is for a Class I medical device, which relies on the manufacturer's self-declaration. The manufacturer's declaration made under clause 6.6 of Schedule 3 of the Therapeutic Goods (Medical Devices) Regulations 2002 has been provided ([D21-2936021](#)). The declaration states "Each kind of medical device to which the technical documentation applies complies with the applicable provisions of the essential principles and the classification rules before being supplied" and listed the standards that have been applied. No evidence of approval by overseas regulators has been provided. However, from the manufacturer's website, VIRALEZE™ is registered for sale in more than 30 countries, including in Europe, Asia, and the Middle East. VIRALEZE™ launched in the UK through LloydsPharmacy, [as announced on 25 March 2021](#) and then in Europe via Starpharma's webstore, [as announced on 6 May 2021](#). VIRALEZE™ has also launched in Vietnam [as announced on 3 December 2021](#).

QMS Yes No

Regulatory authority

Choose an item.

Type of document

Choose an item.

Issuer

Name of body who issued document

Document identification

e.g. certificate number

Issue/decision date

Click here to enter a date.

Expiry date

Click here to enter a date.

Product assessment

Yes No

Regulatory authority

Choose an item.

Type of document

Choose an item.

Issuer

Name of body who issued document

Document identification

e.g. certificate number, licence number

First issue/decision date*

Click here to enter a date.

Record Details	D22-5684008 Application audit assessment request and report - Clinical (DCS) - DV-2021-DA-06231-1 - DA-2021-06851-1 - ~ Starpharma Pty Ltd(3).DOCX	Effective Date	13/01/2021
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Latest issue/decision date^

Click here to enter a date.

Expiry date

Click here to enter a date.

Comments

Document scope comments, device class for HC licence, PMA supplement information, whether device intended purpose aligns with subject device

Declaration of conformity (Schedule 3, clause 7.5 only)

 Yes No

Comments

* **First issue/decision date** is the date the document was first issued or a decision was made for the subject device.

^ **Latest issue date/decision date** and **Expiry date** may not be relevant or available, delete if appropriate.

Relevant TGA assessments and regulatory history

Information about whether the device has novel technological features or intended purpose, and whether the device, devices from the same family or related devices in a system/procedure pack (or accessories or compatible devices) have previously been reviewed by the TGA.

Reviewer to complete. For conformity assessments, review the root file for manufacturer and current and withdrawn/rejected applications.

For ARTG inclusions, review current and cancelled ARTG entries (by GMDN, UPI), and current and withdrawn/rejected applications.

For post-market, review SARA database, Qlik IRIS Triage Dev app, and search for device name in TRIM.

If there are multiple certificates or ARTG entries, add and complete the relevant table for each certificate/document. Delete fields that are not relevant. Duplicate fields where necessary.

Novel technological features or intended purpose in Australia?

 Yes No

Whilst the application of nasal spray applied to nasal mucosa providing physical barrier or to hydrate the mucosa is not novel, the main ingredient of this device for the claimed intended purpose, the SPL7013, may be considered as novel features.

TGA conformity assessment certification

 Yes No

Certificate type

Choose an item.

Record Details	D22-5684008 Application audit assessment request and report - Clinical (DCS) - DV-2021-DA-06231-1 - DA-2021-06851-1 - ~ Starpharma Pty Ltd(3).DOCX	Effective Date	13/01/2021
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Manufacturer	
UPI	
Relevance to subject device	
Certificate number	<i>Certificate number (or Sub ID)</i>
Issue date	Click or tap to enter a date.
Expiry date	Click or tap to enter a date.
TGA clinical assessment	<input type="checkbox"/> Yes <input type="checkbox"/> No
Comments	<i>Comment on scope of clinical assessment already undertaken, including documents reviewed, withdrawal or rejection of application and any device/manufacture differences</i>
Certificate TRIM reference	
Clinical assessment TRIM reference	

ARTG inclusion Yes No

ARTG number	
Date of ARTG inclusion	Click or tap to enter a date.
Sponsor name	
Manufacturer	
Name of device/GMDN	
Device classification	Choose an item.
Relevance to subject device	Choose an item.
Application ID	
Submission ID	

Comments	<i>Comment on scope of clinical assessment already undertaken, including documents reviewed, withdrawal or rejection of application and any device/matrix differences</i>
Submission TRIM reference	
Clinical assessment TRIM reference	

Post-market details Yes No

Comments	<i>Details of significant post-market actions/issues in Australia, including removal/suspension from ARTG, suspension or revocation of TGA CA certificate, and recalls/DIRs/PMRs</i>
----------	--

Other overseas regulator conformity assessment documents representing product assessment

These conformity assessment documents are additional to documents that accompanied the device application form.

Review:

- Cover letter and information provided for the application audit, including CER.
- Relevant market authorisation databases for Health Canada and US FDA documents.
- Whether the UPI, variants and intended purpose are the same as the subject device.

If multiple documents exist for a regulator or there are multiple devices, add and complete the relevant table each document/device. Delete fields that are not relevant.

EC Certification Yes No Not known

Certificate type	Choose an item.
Device name	
Notified body	
First issue date	Click or tap to enter a date.
Latest issue date	Click or tap to enter a date.
Expiry date	Click or tap to enter a date.

Comments	
TRIM reference:	

Health Canada Yes No

Active licence number	
Device name	
Device class	Choose an item.
Device first issue date	Click or tap to enter a date.
Comments	
TRIM reference	<i>Copy and save in TRIM container if not provided by sponsor</i>

US FDA Yes No

Approval type & number	Choose an item.
Device name:	
First decision date:	Click or tap to enter a date.
Latest PMA supplement decision date:	Click or tap to enter a date.
Comments:	
TRIM reference:	<i>Copy and save in TRIM container if not provided by sponsor</i>

Japan Yes No Not known

Approval type & number	Choose an item.
Device name:	
First issue date:	Click or tap to enter a date.

Latest issue date:

Comments:

TRIM reference:

Clinical review documentation

Clinical evidence report (CER)

Document identification & date

D22-5643748 (CER-003A-01) dated May 2022

Competency of CER Clinical expert

The CER author is §22 who is the §22 §22, Starpharma Pty Ltd.

The CER has been reviewed by Prof. §22, a retired genitourinary physician. The curriculum vitae (CV) indicates that he received his medical degree in 1972 and practiced as consultant physician in genitourinary (GU) medicine till 2013. The CV does not show evidence of direct experience with this device type in a clinical setting. He is, therefore, not considered an appropriate clinical expert for the purpose of this report.

According to the TGA Clinical Evidence Guidelines, “A competent clinical expert is generally someone with relevant medical qualifications and direct clinical experience in the use of the device or device type in a clinical setting.”

Clinical standards or solutions applied

A document provided by the applicant (TF5S5.1_v04: Compliance with standards) outlines that the following clinical standard was applied by the applicant:

- BS EN ISO 14155:2020, Clinical investigation of medical devices for human subjects. Good clinical practice

Are the UPI/device name, any variants and intended purpose in the CER consistent with information provided with the device (IFU, labels etc)?

Yes No

Comments: In the CER, the device is referred to as SPL7013 Nasal Spray while in the Instructions for use (IFU) and carton it is referred to as SPL7013 Barrier Nasal Spray.

Does the CER include an evaluation of the clinical data?

Yes No

Comments: The CER includes clinical data. However, critique of the clinical data by the clinical expert is not evident in this CER.

Substantial equivalence claim

Yes No

Comparable device:

Mundicare Cold Defence Nasal spray

Comparable device type

Predicate device Similar marketed device

Comments:

Has evidence to demonstrate substantial equivalence of the comparable device to the subject device been provided?

Yes No

Comments: The applicant asserts in the CER that SPL7013 Nasal Spray and Mundicare Cold Defence Nasal Spray are comparable and “where differences have been identified, these do not impact the safety and/or performance of SPL7013 Nasal Spray with respect to Mundicare Cold Defence”. Section 6.2 of the CER outlines the applicant’s reasoning behind these claims.

Clinical characteristics

Intended purpose: The applicant states that the two devices have the same intended purpose. According to the TGA clinical assessor, the intended purpose of the two devices is broadly similar however there are differences.

SPL7013 Nasal Spray	Mundicare Cold defence nasal spray
s47	s47
	intended purpose specifies that it can be used “supportively” for the treatment of common cold.
	does not include this phrase

Intended population: Different

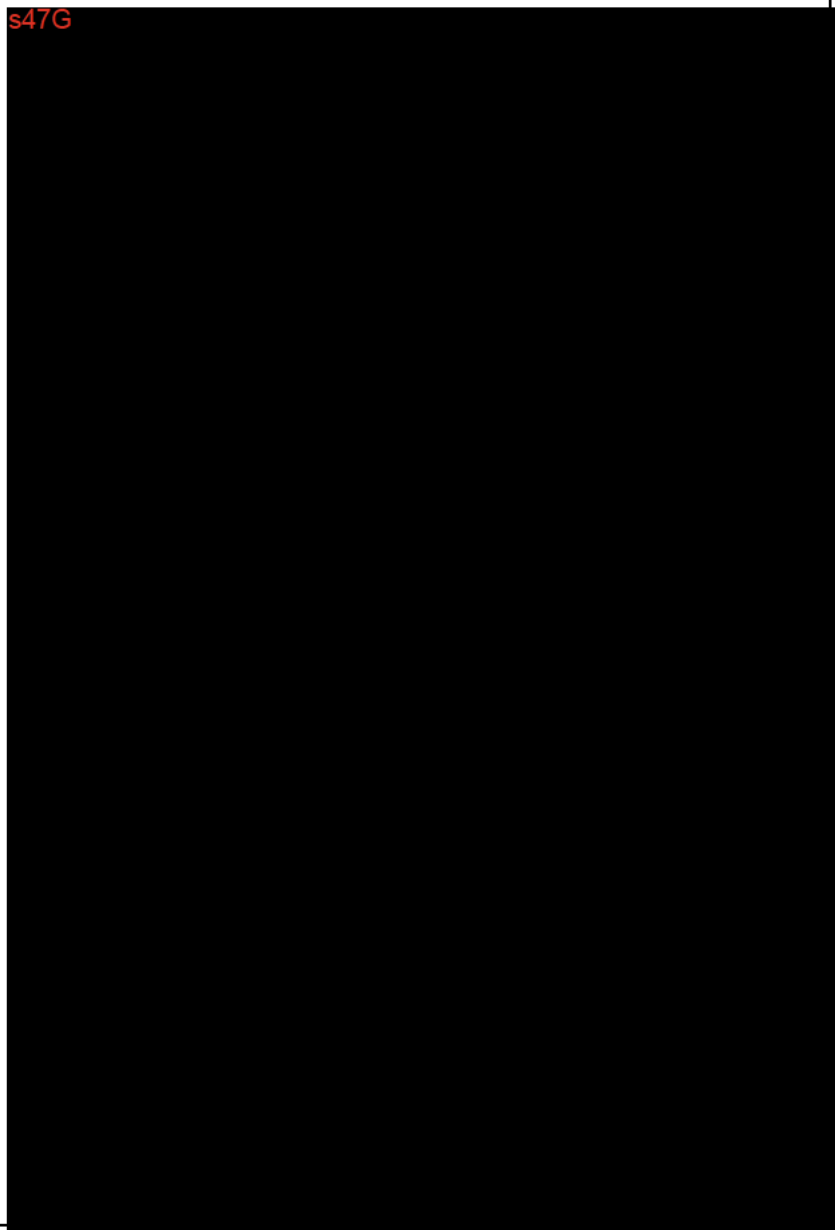
SPL7013 Nasal Spray	Mundicare Cold defence nasal spray
s47	adults and children from one year of age

The applicant states that the intended population for the subject device is narrower. The rationale for this difference in intended population has not been provided.

Environment of use: Different but acceptable

Type of contact and duration of use/contact with the body: The applicant states that both devices are to be used intermittently and the device exposure would cease overnight during sleep.

SPL7013 Nasal Spray	Mundicare Cold defence nasal spray
s47	Anticipated exposure duration not specified

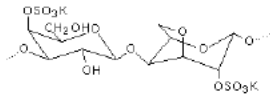


s47G

Technical characteristics

Material: An important point of technical difference is in the chemical formulation:

SPL7013 Nasal Spray	Mundicare Cold defence nasal spray
s47	Component purified water sodium chloride lota-carrageenan
Key component: Astodrimer sodium	Key component: lota-carrageenan

high molecular weight polymer that carries significant negative charge	high molecular weight polymer that carries significant negative charge
s47	<p>Linear polymer terminating in sulphate groups</p> 
Synthetic	Naturally occurring
Lysine based dendrimer	polysaccharide
isotonic	isotonic

These structural /chemical differences could translate into different biological characteristics. For instance, in the non-clinical study report QR-514-01 provided by the applicant, it is reported that s47

[Redacted text block]

The applicant has not provided biological, clinical and technical characteristics of any of the “other ingredients”. In this report the word ‘ingredients’ is used interchangeably with ‘components’ and ‘excipients’:

- The applicant states that these components together form a solution that is technically capable of delivering an equivalent level of moisturisation as Mundicare Cold Defence Nasal Spray. s47G

[Redacted text block]

- s41 [Redacted text block]

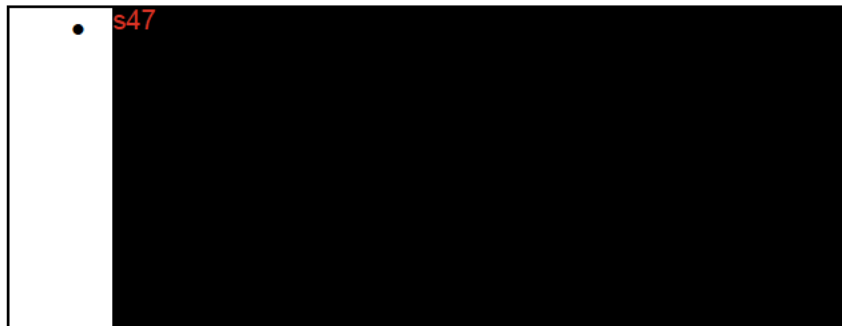
s47 | s47G

- s47
-
- s47G
- s47
-

s47

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Design and Deployment methods: Identical

Principle of operation: The applicant states that both devices operate as a moisturising barrier between viruses and nasal mucosa.

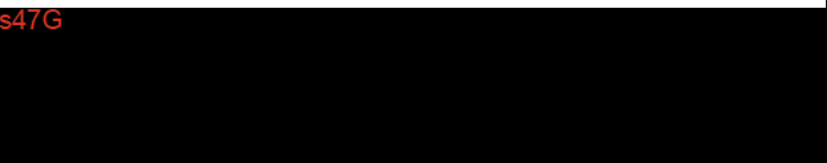
Storage conditions: Dissimilar

The subject device does not require protection from light unlike the claimed equivalent device. Therefore, the TGA Clinical Assessor states that this suggests that the two devices may have different chemical or degradation profile.

In summary, based on the available information, the two devices have important clinical, biological and technical differences that can result in clinically significant difference in clinical safety and performance. s47G



Comment



Comparable device's regulatory history in Australia

ARTG number:
Date of ARTG inclusion: 21/03/2018
Comments: ARTG no 301123; as Class IIa device
No significant post market issues or recalls.
Currently in purview of a post market review (yet to be concluded).

Clinical investigations

Yes No

Clinical trial/study protocol, results and analysis provided?

Yes No

Comments:

Pre-market or post-market clinical investigations for subject device?

Pre-market Post-market Nil

Record Details	D22-5684008 Application audit assessment request and report - Clinical (DCS) - DV-2021-DA-06231-1 - DA-2021-06851-1 - ~ Starpharma Pty Ltd(3).DOCX	Effective Date	13/01/2021
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Device Predicate Nil

Comments: One phase I safety and tolerability healthy volunteer study has been presented for the subject device (SPL7013-021). The study is mentioned under Section 7.2 of the CER (Clinical Data Generated and Held by the Manufacturer) but the applicant detailed this study under Literature section of the CER (**Castellarnau et al, 2022**). The TGA clinical assessor obtained the publication of this study online.

The study protocol and full clinical study report have not been provided.

Randomised controlled trial

Type of study	double-blind, single-center, randomized, placebo-controlled clinical investigation																		
Population	<p>Forty healthy volunteers, 18 to 65 years, no clinically significant nasal cavity examination findings.</p> <p>Randomized 3:1 to astodrimmer sodium nasal spray (N = 30) or placebo (N = 10) in an Australian clinical trials facility.</p> <p>Exclusion criteria included (amongst others):</p> <ul style="list-style-type: none"> Abnormal and/or clinically significant findings in nasal cavity examination, Usage of any kind of nasal product within 7 days prior to the start of the investigation <p>Inclusion criteria:</p> <ul style="list-style-type: none"> Non-smoker, in good general health, with no significant medical history, no clinically significant abnormalities on physical examination. 																		
Devices	<p>The components of the device and placebo were as tabulated below:</p> <table border="1"> <thead> <tr> <th>Device</th> <th>Placebo</th> </tr> </thead> <tbody> <tr> <td>Purified water</td> <td>Purified water</td> </tr> <tr> <td>Astodrimmer sodium (SPL7013)</td> <td>Propylene glycol</td> </tr> <tr> <td>Propylene glycol</td> <td>Glycerol</td> </tr> <tr> <td>Glycerol</td> <td>Methyl p-hydroxybenzoate</td> </tr> <tr> <td>Methyl p-hydroxybenzoate</td> <td>Carbomer homopolymer type B</td> </tr> <tr> <td>Carbomer homopolymer type B</td> <td>Propyl p-hydroxybenzoate</td> </tr> <tr> <td>Propyl p-hydroxybenzoate</td> <td>Disodium edetate, dihydrate</td> </tr> <tr> <td>Disodium edetate, dihydrate</td> <td></td> </tr> </tbody> </table> <p>Placebo contains every substance in device but NOT astodrimmer sodium</p>	Device	Placebo	Purified water	Purified water	Astodrimmer sodium (SPL7013)	Propylene glycol	Propylene glycol	Glycerol	Glycerol	Methyl p-hydroxybenzoate	Methyl p-hydroxybenzoate	Carbomer homopolymer type B	Carbomer homopolymer type B	Propyl p-hydroxybenzoate	Propyl p-hydroxybenzoate	Disodium edetate, dihydrate	Disodium edetate, dihydrate	
Device	Placebo																		
Purified water	Purified water																		
Astodrimmer sodium (SPL7013)	Propylene glycol																		
Propylene glycol	Glycerol																		
Glycerol	Methyl p-hydroxybenzoate																		
Methyl p-hydroxybenzoate	Carbomer homopolymer type B																		
Carbomer homopolymer type B	Propyl p-hydroxybenzoate																		
Propyl p-hydroxybenzoate	Disodium edetate, dihydrate																		
Disodium edetate, dihydrate																			
Outcome measures	<p>The primary outcome: safety and tolerability of astodrimmer sodium nasal spray,</p> <p>The secondary outcome: absorption of astodrimmer sodium into blood following application to the nasal mucosa of healthy volunteers.</p>																		
Results	32 treatment emergent adverse events (TEAEs) were recorded in 19 (63.3%) participants randomized to																		

	<p>astodimer, and 15 were recorded in 8 (80.0%) participants randomized to placebo.</p> <p>23 TEAEs were deemed by the investigator to be potentially related to the study product. The most commonly experienced TEAE was headache.</p> <table border="1" data-bbox="790 369 1380 683"> <thead> <tr> <th rowspan="2"></th> <th colspan="2">Astodimer nasal spray (N = 30)</th> <th colspan="2">Placebo nasal spray (N = 10)</th> </tr> <tr> <th>Participants (%)</th> <th>Events</th> <th>Participants (%)</th> <th>Events</th> </tr> </thead> <tbody> <tr> <td>Headache</td> <td>4 (13.3%)</td> <td>5</td> <td>1 (10.0%)</td> <td>1</td> </tr> <tr> <td>Epistaxis</td> <td>3 (10.0%)</td> <td>3</td> <td>1 (10.0%)</td> <td>1</td> </tr> <tr> <td>Nasal discomfort</td> <td>3 (10.0%)</td> <td>3</td> <td>1 (10.0%)</td> <td>1</td> </tr> <tr> <td>Nasal congestion</td> <td>2 (6.7%)</td> <td>2</td> <td>2 (20.0%)</td> <td>2</td> </tr> <tr> <td>Nausea</td> <td>1 (3.3%)</td> <td>1</td> <td>0 (0.0%)</td> <td>0</td> </tr> <tr> <td>Rhinorrhoea</td> <td>1 (3.3%)</td> <td>1</td> <td>0 (0.0%)</td> <td>0</td> </tr> <tr> <td>Nasal pruritus</td> <td>0 (0.0%)</td> <td>0</td> <td>1 (10.0%)</td> <td>1</td> </tr> <tr> <td>Paranasal sinus discomfort</td> <td>0 (0.0%)</td> <td>0</td> <td>1 (10.0%)</td> <td>1</td> </tr> <tr> <td>Throat irritation</td> <td>0 (0.0%)</td> <td>0</td> <td>1 (10.0%)</td> <td>1</td> </tr> </tbody> </table> <p>The applicant states that the incidence of adverse events (AEs), including those considered to be potentially causally related to product use, was similar or lower in participants allocated to SPL7013 Nasal Spray as compared to those allocated to placebo.</p> <p>No clinically significant findings on nasal cavity examinations, and no clinically relevant laboratory abnormalities, vital signs or electrocardiography alterations, or physical examination findings were recorded during the investigation.</p> <p>Astodimer sodium was not detected in any of the collected plasma samples.</p>		Astodimer nasal spray (N = 30)		Placebo nasal spray (N = 10)		Participants (%)	Events	Participants (%)	Events	Headache	4 (13.3%)	5	1 (10.0%)	1	Epistaxis	3 (10.0%)	3	1 (10.0%)	1	Nasal discomfort	3 (10.0%)	3	1 (10.0%)	1	Nasal congestion	2 (6.7%)	2	2 (20.0%)	2	Nausea	1 (3.3%)	1	0 (0.0%)	0	Rhinorrhoea	1 (3.3%)	1	0 (0.0%)	0	Nasal pruritus	0 (0.0%)	0	1 (10.0%)	1	Paranasal sinus discomfort	0 (0.0%)	0	1 (10.0%)	1	Throat irritation	0 (0.0%)	0	1 (10.0%)	1
	Astodimer nasal spray (N = 30)		Placebo nasal spray (N = 10)																																																				
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Throat irritation	0 (0.0%)	0	1 (10.0%)	1																																																			
<p>Limitations</p>	<ul style="list-style-type: none"> • Since the “placebo” included all components of the subject device except astodimer sodium, the related AEs from both arms should be considered as side effects of the device and included in the IFU. • Systemic absorption of excipients was not tested. • Since the duration of product application was 14 days, safety beyond this period cannot be ascertained based on this trial. • Being a healthy volunteer study, the safety profile of the device may be different when it is used in the target population (for example, during rhinorrhoea (as often occurs in common cold). • The safety and tolerability results from the study are applicable to the subset of population representative of included subjects. 																																																						
<p>Single-arm trial</p> <p><input type="checkbox"/> Device <input type="checkbox"/> Predicate <input checked="" type="checkbox"/> Nil</p>																																																							

Other

Comments: *Comment on whether pre- or post-market study, number of patients, duration of study, primary outcome measure*

Device Predicate Nil

Comments: *Comment on whether pre- or post-market study, number of patients, duration of study, primary outcome measure*

s47G

Comments

Literature review

Yes No

Literature review including search protocol & search results provided?

Yes No

Literature review scope

Device Predicate Similar marketed

Comments

Castellarnau et al, 2022: (Study no. SPL7013-021).

Discussed under "Clinical investigation" section (See above)

s47

SPL7013 vaginal gel

A list of Phase I, II and III studies conducted with the vaginal gel have been presented as supportive of the subject device's assessment. The applicant states that the two formulations are identical except for carbomer type and concentration.

Limitations: The TGA clinical assessor notes that (a) the site of application for the vaginal gel is different to the subject

device, (b) the intended purpose and the targeted pathogens are different (bacterial vaginosis in case of vaginal gel) and (c) Different consistency may result in different technical characteristics. These studies are therefore not applicable to this assessment.

Iota-Carrageenan nasal spray

Summary of i-carrageenan nasal spray studies were provided by the applicant.

Limitations: In the absence of substantial equivalence, the results of i-carrageenan nasal spray studies and publications cannot be utilised for this assessment.

low-pH hypromellose nasal powder spray

While similarly marketed, this is a low pH device and the results of the studies for this nasal spray are not applicable to the current assessment.

Other similarly marketed nasal sprays

Hahn et al., 2013. In an observational study in patients suffering from rhinitis sicca, three isotonic formulations showed significant improvements for all single items tested. The duration of the moistening effect was assessed by most of the patients as lasting longer than 30 min for all treatments.

Limitations: The TGA clinical assessor notes that the condition being treated (rhinitis sicca) is not the targeted condition for the subject medical device.

Other clinical experience, including post-market data Yes No

World-wide distribution (sales) numbers for device provided?

Yes No

Comments:

Clinical experience data provided?

Yes No

Adverse events with complaint rates

Device Predicate Nil

Post-market data is provided by the applicant is for the subject device for the period March 2021 to 31 Dec 2021.

3 safety related AEs were reported – vomiting following use, nasal discomfort following use, nasal irritation and bleeding following use. It is stated that the complaints were investigated. The safety related complaints were deemed to be non-reportable incidents based on the clinical data held by the manufacturer and will continue to be monitored.”

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Reproductive toxicity studies in rats and rabbits with vaginal administration

Carcinogenicity studies in mice and rats with vaginal administration

Biocompatibility studies

Balb/c 3T3 clone A31 cells	In vitro
Guinea Pigs	Topical
Sprague-Dawley Rats	Nasal
L-929 cells	In vitro
Guinea Pigs	Topical
New Zealand White Rabbits	Vaginal
Guinea Pigs	Topical
New Zealand White Rabbits	Vaginal
L-929 cells	In vitro
L-929 cells	In vitro

Mechanism of action studies

Studies to demonstrate the mode of action for SPL7013 were presented.

Limitations: The TGA clinical assessor notes that for the above performance, toxicology, biocompatibility and mechanism of action studies, there is no clinical data to show how these studies apply to humans.

Comments

TGA clinical assessor also notes the absence of direct non-clinical studies on mucociliary clearance of the device.

Risk management

Document identification & date

Risk management report: D22-5643748
 TFS3-2_DR4_Risk_Management_Plan_&_Risk_Analysis-SPL7013_Nasal_Spray Dated 30-May-2022
 Risk matrices/FMEA: provided – Risk matrices hyperlinked within risk management file; FMEA tables have not been provided.

Are the report and risk matrices/FMEA relevant to the device and its use

Yes No

Comments

The applicant states that risk management activities were performed in accordance with BS EN ISO 14971:2019, Medical Devices –Application of risk management to medical devices, that all potential risks fell into an acceptable risk category after controls were applied and that the overall residual risk was acceptable and exceeded by benefits to the patient.

Limitations: Not all risks were identified and not all risks have been justified.

p.8/14 of the Risk management plan and risk analysis: Risk score was calculated as the product of severity and frequency.

Risk Score	Required Response	Number of Risk Scores Identified in Each Category
1 – 4	Action must be considered to reduce risk	81
5 – 9	Action must be taken to reduce risk	89
10 – 25	Action must be taken to reduce risk	0
Total:		170

Following implementation of controls, applicant states the risks were reduced as under:

Risk Score	Required Response	Number of Risk Scores Identified in Each Category	Number of Risk Scores Following Implementation of Control
1 – 4	Action must be considered to reduce risk	81	170
5 – 9	Action must be taken to reduce risk	89	0
10 – 25	Action must be taken to reduce risk	0	0
Total:		170	170

The TGA clinical assessor highlights the following risks from the applicant’s Risk Matrix table and highlights their limitations:


(In this section, the text in bold is as stated in the Risk management documents provided by the applicant. The text not in bold is the TGA clinical assessor commentary).

- Hazardous situation: Formulation has a deleterious local effect; Hazard: Mucociliary function is adversely affected, resulting in exposure to viral pathogens; Harms: exacerbation of respiratory/cold symptoms if infected.** s47G

[Redacted]

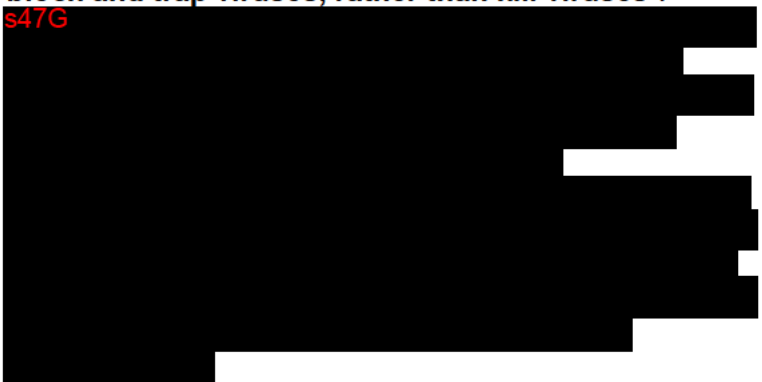
[Redacted]

s47G




- **Hazardous situation: Formulation interferes with diagnostic test for disease caused by respiratory pathogens (such as viruses); Hazard: consumer being unaware that he/she is already infected and unknowingly continues to interact with others; Harms: spreading the infectious disease to others.** The mitigation is described as “Product designed as a medical device with a physical mode of action to block and trap viruses, rather than kill viruses”.


s47G



- **Harms: Systemic toxicity (e.g., organ, blood or general toxicity due to absorption of toxic substance into bloodstream):** s47G



- **Hazardous situation: SPL7013 or ingredients in formulation disrupt the normal nasal flora; Hazard: user experiencing reduced resistance to bacterial or viral infection; Harms: Exacerbation of respiratory/ cold symptoms if infected due to new bacterial infection:** s47G



³ Macchi, A., Gallo, S. & Montrasio, G. Analysis of mucociliary clearance: a new diagnostic method and a therapeutical proposal. *Clin Transl Allergy* 5, P16 (2015). <https://doi.org/10.1186/2045-7022-5-S4-P16>

- **Hazardous situation: User gains a false sense of security during use and doesn't employ other accepted methods for prevention of infection; Hazard: User exposed to viral pathogens; Harms: Viral respiratory infection** ^{s47G}

[Redacted]

- **Hazardous situation: Used intentionally with other products, e.g., hay fever/allergy nasal sprays; Hazard: Product negatively impacts the efficacy of another product); Harms: exacerbation of symptoms of condition for which other product being used.** ^{s47G}

[Redacted]

In addition, the following risk has not been identified in the risk management documents:

Safety in prolonged use: The safety and tolerability study in healthy volunteers studied 14-day exposure only. IFU does not include any guidance around the duration of use.

In summary, there is inadequate identification and mitigation of all hazards and associated risks. Therefore, compliance with Essential Principles (EP) 2 and 6 is not demonstrated.

Safety in Magnetic Resonance (MR) environment

- Active implant Passive implant Not implantable

IFU, labels and other information provided with the device

From a clinical perspective, does the information provided with the device (IFU, labels, PIL, etc.) provide adequate information on the intended purpose, proper use, and warnings about risks to patients and users?

- Yes No

Comments:

IFU

The device name in the IFU is 'SPL7013 Barrier nasal Spray' whereas in the CER it is 'SPL7013 Nasal Spray'.

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(The applicant's statements in IFU are in bold. TGA's clinical assessment is presented in non-bold statements)

The TGA clinical assessor notes the following statements included in the IFU:

s47G
[Redacted]

- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]

[Redacted]

- [Redacted]

[Redacted]

- [Redacted]

[Redacted]

- [Redacted]

[Redacted]

- [Redacted]

[Redacted]


- [Redacted]

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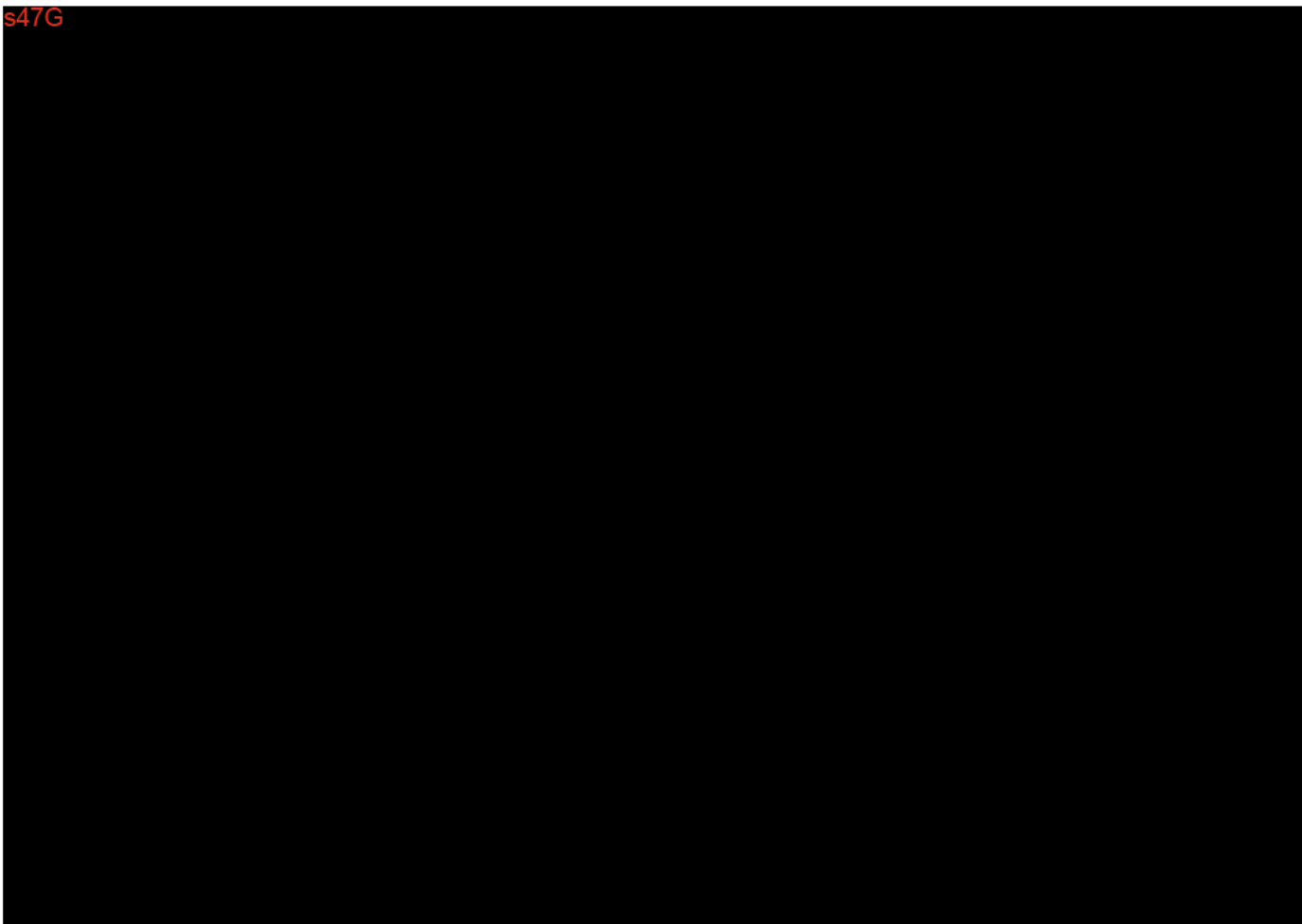
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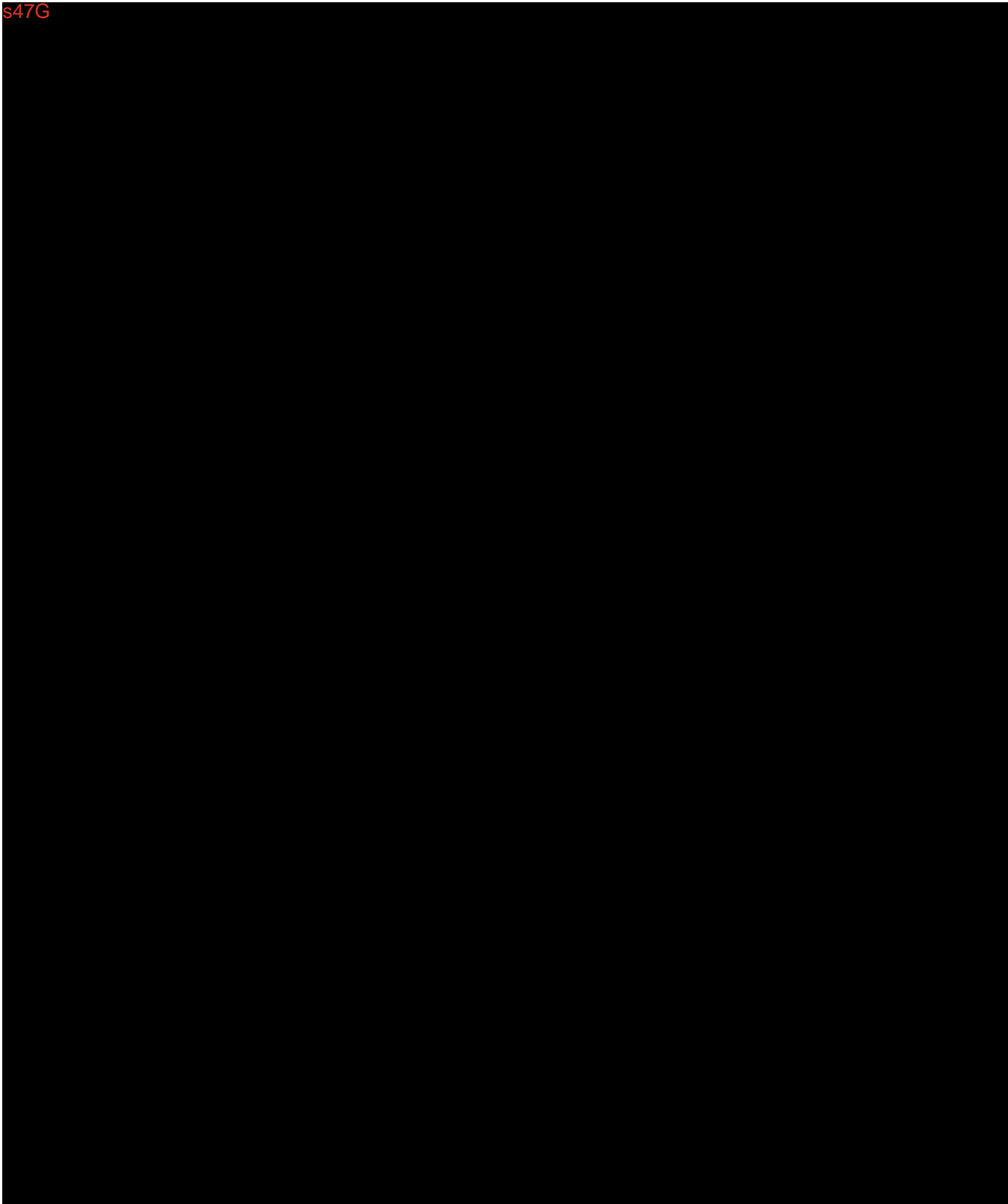
Comments	<p>s47G</p>  <p><u>Carton</u></p> <p>Pertinent points mentioned by the TGA clinical assessor in the IFU section (see above) also apply to the carton.</p> <p>Compliance with EP 13 is not demonstrated.</p>
	<p>IFU can only be fully assessed once the other concerns regarding performance and safety of all the device components have been addressed adequately.</p>

Conclusions and recommendations

Reviewer's conclusion and recommendation



s47G



Sign-Off – Clinical Section Reviewer and Medical Advisor

Name	Dr s22 [REDACTED]		
Signature	Signed electronically in TRIM	Date	26 August 2022

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Sign-Off – Senior Medical Advisor

Name	Dr s22		
Signature	Signed electronically in TRIM	Date	26 August 2022

Clinical review on further evidence

Information provided in response to questions from previous round of review

Submission as attachments in the email [D23-5034027](#)

Comments

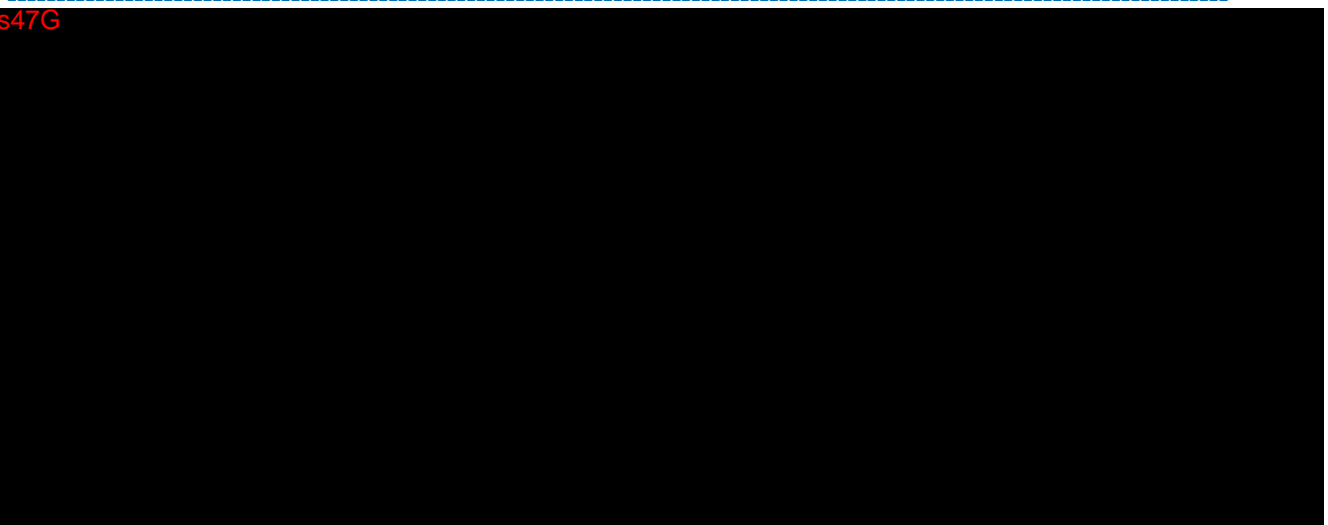
Where necessary for context, excerpts from applicant's Clinical Evaluation Report, CER-003A-01 (**CER**) or the applicant's response (**Response**; dated 13 Jan 2023) to the Clinical Assessment Report (**CAR**) are quoted and italicised.

The applicant has responded specifically to the following aspects of CAR:

- *“The conclusion that the two devices are not substantially equivalent”* (referred to by the applicant as *“Issue 1”*).
- *“Based on the unsubstantiated substantially equivalent claims, there are insufficient direct clinical data to support the claimed intended purpose”* (referred to by the applicant as *“Issue 2”*).

In addition, Applicant has also addressed more specific comments in the CAR including those on risk management, IFU, clinical investigations pertaining to compliance with Essential principles (**EP**).

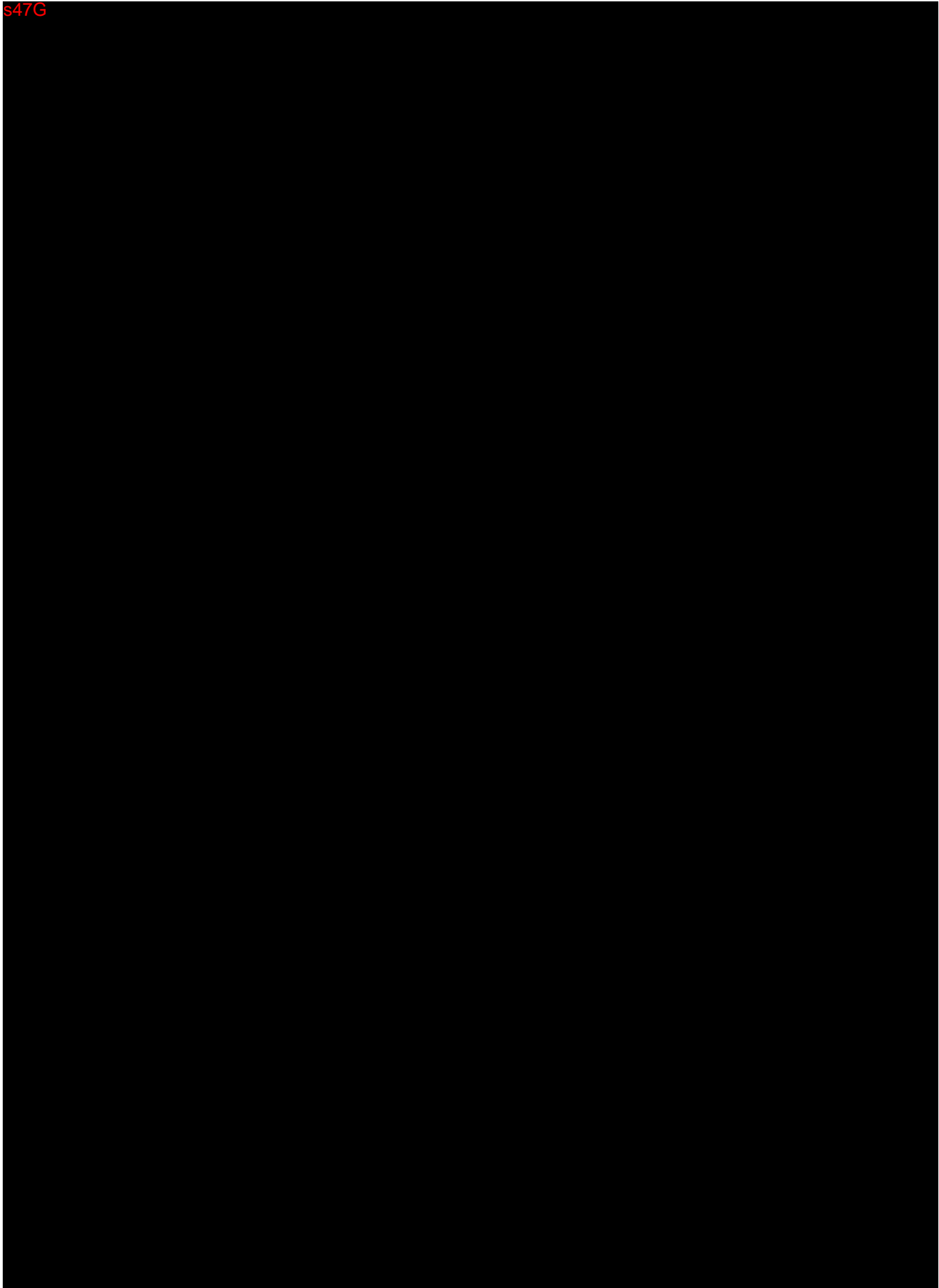
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Reviewer's conclusion and recommendation

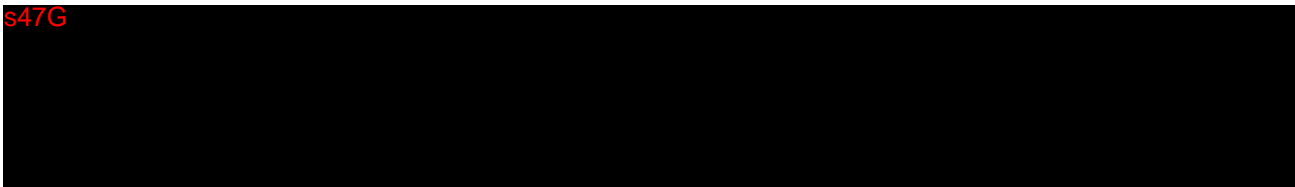
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Sign-Off – Clinical Section Reviewer

Name	s22		
Signature	Signed electronically in TRIM	Date	17 April 2023

Sign-Off – Senior Medical Advisor

Name	Dr s22		
Signature	Signed electronically in TRIM	Date	Click or tap to enter a date.

Additional Submission received 4 August

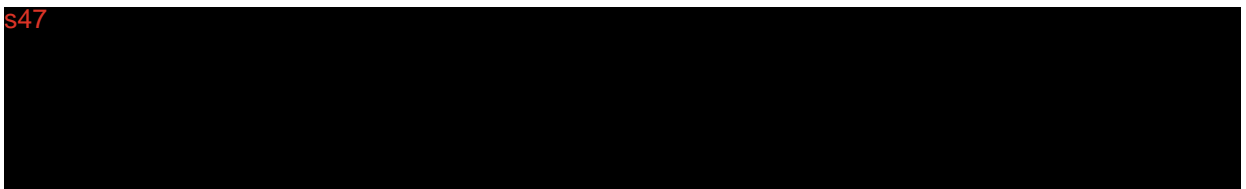
A submission was received on 4 August, containing the Applicant’s response to the letter from the TGA dated 4 May, and after further meetings, in June and July. The submission includes:

- (1) a revised proposed intended purpose for the Product;
- (2) additional justification for the application of the term “well established technology” to the Product; and
- (3) responses to the specific concerns raised by the delegate in the TGA’s letter dated 4 May 2023.

Additional stability data has been provided to address concerns about biomaterials in an attachment.

Revised Intended Purpose

The Applicant has revised the product’s intended purpose to:



This is stated to be consistent with other similar products that have been identified, including two with the same GMDN code. A search of the ARTG on the TGA website confirms the applicant’s finding of nine products listed when the term “s47” is searched, although review of intended purposes reveals that a majority

(5/9) only make statements regarding moisturising and soothing the nasal passages/ mucous membranes. One further product's intended purpose includes a statement that it is intended to relieve nasal dryness and irritation, whose causes may include cold/ flu. Two of the products' intended purposes include statements in addition to moisturising the nasal passages such as: that they may relieve, give symptomatic relief, or shorten the duration of colds. One product's intended purpose included a statement about protecting the nasal mucosa from airborne contaminants, including viruses. No product intended purpose could be found matching that which is cited for Mundicare Cold Defence; this product itself is not included in the ARTG – it cannot be assumed that this is an intended purpose that has been accepted by the TGA.

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“Well Established Technology”

The applicant seeks to justify their approach to the clinical evaluation, justifying that the product is a “well established technology”, citing a statement in the TGA’s Clinical Evidence Guidelines v3.1 June 2022 under the heading “Direct and indirect evidence”:

Evidence from comparable devices that are not substantially equivalent may support or supplement direct or indirect clinical evidence. However, it will not generally constitute sufficient clinical evidence for substantiating compliance with the EPs (except for certain low risk, well established technologies).

A similar statement is contained in the same guidance document under the heading “Comparable devices” but does not make use of the words “well established technologies”. Instead, this paragraph refers to “lower risk devices, whose clinical effects are well understood and characterised”. It is challenging to assert that this should be applied in the context of SPL7013 Barrier Nasal Spray, as there is limited experience of astrodrimer sodium’s usage in the human nasal cavity for therapeutic purposes. The circumstances under which it is reasonable to employ such a strategy, relying on evidence obtained with comparable devices, are not laid out in further detail.

Considering the following factors:

s47


Response to Assessor’s Comments

The applicant has responded to 6 concerns outlined in the assessment of this product as follows:

a) *The intended purpose has been amended, as described above, thus addressing concerns relating to the lack of clinical evidence for the device preventing or treating common colds.*

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b) *Intended purpose included a proposed warning against continuous usage for more than 14 days.*

Accepted.

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c) **Concerns about safety potentially being different in a population with cold symptoms (e.g. rhinorrhoea) addressed by removal of claims related to treating a cold.**

Accepted.

d) **Claims related to use in children removed from IFU and product information to address concerns related to lack of clinical evidence of safety in children.**

Accepted.

e) **No claims related to nasal residence time are included in the product label.**

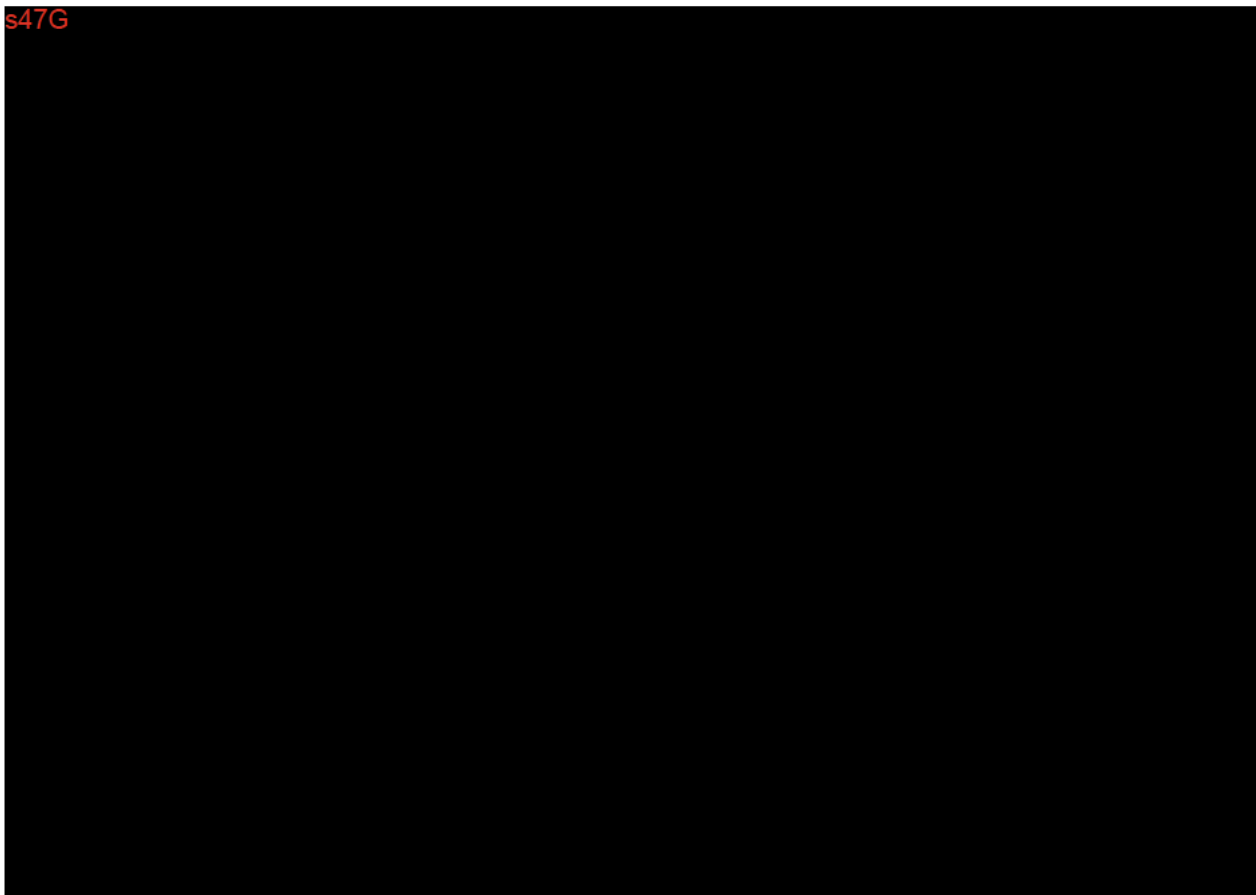
Although no product claims are included citing a residence time for the device and this in itself is reasonable considering the precedent of an identified comparable product, s47

This in turn related directly to how clinical data obtained with a comparable product might reliably inform on the safety and performance of this product.

f) **Concerns about disruption of nasal flora are not borne out by clinical observations; nasal flora is multifactorial and the product is not intended to disrupt bacterial flora.**

Although this is a legitimate concern, considering the same chemical compound, astodrimer sodium is intended to affect bacteria flora in another product, in the vagina, the response is acceptable, and could reasonably be addressed in the longer term through post market surveillance.

Compliance with Essential Principles



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Biomaterials review and Attachments

Outside scope of clinical review.

Conclusion

Save for stability data, no new data has been supplied on the product's safety and performance. Although the intended purpose has been amended and some of the arguments stated by the applicant are reasonable, concerns remain that this product does not have a benefit that has been substantiated with clinical evidence. Although the applicant argues that the product is a "well established technology", a search of the ARTG revealed few products with similar claims contained in the intended purpose; owing to fact that this product consists of a different chemical compound that is stated to achieve the claimed benefit, it is reasonable to expect that any claimed benefit must be substantiated with clinical data obtained with use of this compound.

s47

Sign-Off – Senior Medical Advisor

Name	Simon Leon Singer		
Signature	Signed electronically in TRIM	Date	10 October 2023

Version history

Version	TRIM Reference	Description of change	Author/s	Effective date
V1.0	D20-3667495	New FORM	s22	13 Jan 2021

Record Details	D22-5684008 Application audit assessment request and report - Clinical (DCS) - DV-2021-DA-06231-1 - DA-2021-06851-1 - ~ Starpharma Pty Ltd(3).DOCX	Effective Date	13/01/2021
Print Date	29/05/2024 4:20	Page 37 of 37	
Once printed or copied from the Master, this is no longer a controlled document; check validity before use			

From: s22
To: s22
Cc: s22; s22 @starpharma.com; s22; s22
Subject: RE: Submission Number: DV-2021-DA-06231-1; ARTG Class 1 device application: SPL7013 barrier nasal spray [SEC=OFFICIAL]
Date: Wednesday, 31 May 2023 10:18:02 AM
Attachments: [image001.png](#)
[image002.png](#)
Importance: High

Dear Ms s22

I have received a response from Ms Duffy with the offer of a conference call to discuss the issues with respect my client's application.

I will try and arrange that call as soon as possible, following which I will seek instructions in relation to the application (viz whether my client wishes to withdraw the application or proceed to a decision).

I would be grateful if you could continue to pause on any decision with respect to the application until I convey my client's instructions.

Please do not hesitate to contact me if you have any questions, or wish to discuss the matter.

Yours sincerely

s22

s22

From: s22
Sent: Monday, 29 May 2023 10:09 PM
To: s22 @health.gov.au>
Cc: s22 @starpharma.com>; s22 @starpharma.com; s22 @starpharma.com>; s22 s22
Subject: RE: Submission Number: DV-2021-DA-06231-1; ARTG Class 1 device application: SPL7013 barrier nasal spray [SEC=OFFICIAL]

Dear Ms s22

Just letting you know that I am still waiting to hear from Ms Duffy but will revert as soon as I receive a response and have obtained my client's instructions.

Kind regards

s22

s22



From: s22
Sent: Friday, 26 May 2023 4:19 PM
To: s22 @health.gov.au>
Cc: s22 @starpharma.com>; s22 @starpharma.com; s22 s22 @starpharma.com>; s22 <s22 s22
Subject: RE: Submission Number: DV-2021-DA-06231-1; ARTG Class 1 device application: SPL7013 barrier nasal spray [SEC=OFFICIAL]

Dear Ms s22

I confirm that I have written to Tracey Duffy to request a conference call with her to discuss the extension to the EU MDR transition period and its impact on the transition period and reclassification reforms in Australia.

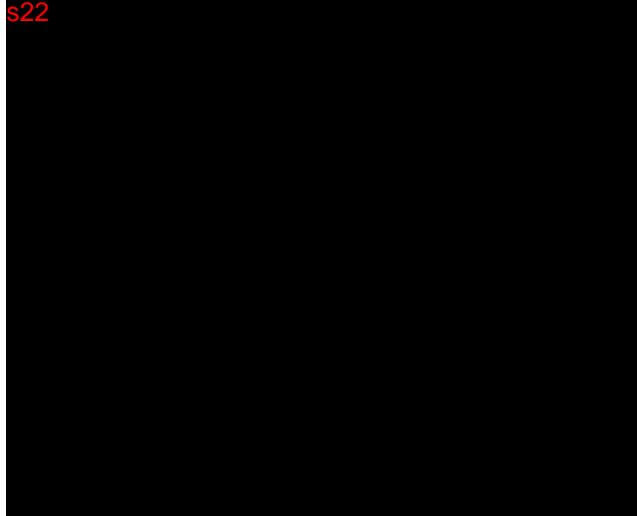
I will revert to you once I have received a response.

Kind regards

s22

s22





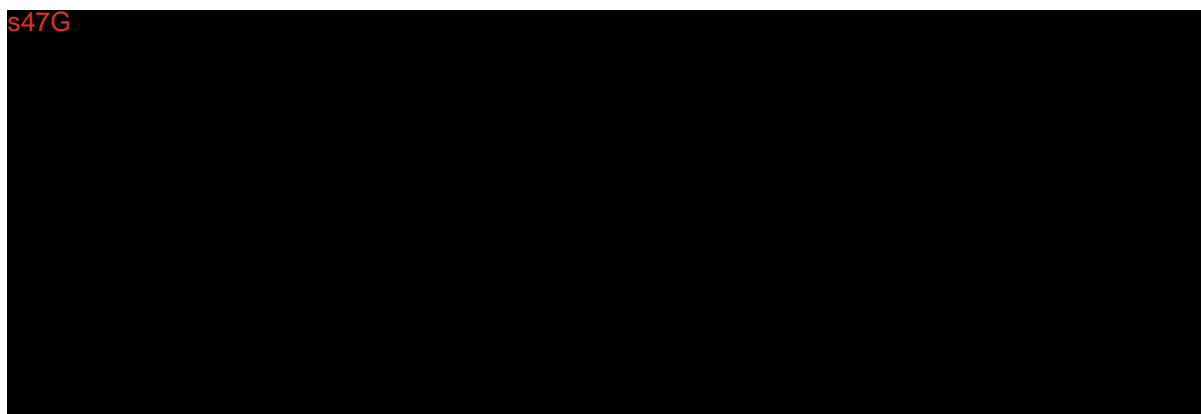
From: s22
Sent: Wednesday, 24 May 2023 3:56 PM
To: s22 @health.gov.au
Cc: s22 starpharma.com>, s22 @starpharma.com; s22
s22 starpharma.com>; s22 <s22 s22
Subject: RE: Submission Number: DV-2021-DA-06231-1; ARTG Class 1 device application:
SPL7013 barrier nasal spray [SEC=OFFICIAL]

Dear Ms s22

Thank you for your email and prompt response to our email.

We note that the TGA website, at <https://www.tga.gov.au/how-we-regulate/supply-therapeutic-good/supply-medical-device/eu-mdr-transition/eu-mdr-transition-extension>, states that “The TGA is considering the impact of the EU MDR transition extension on Australia’s reclassification and personalised medical device reforms and will provide advice to the Government about whether changes to the transition timeframes will be needed.”

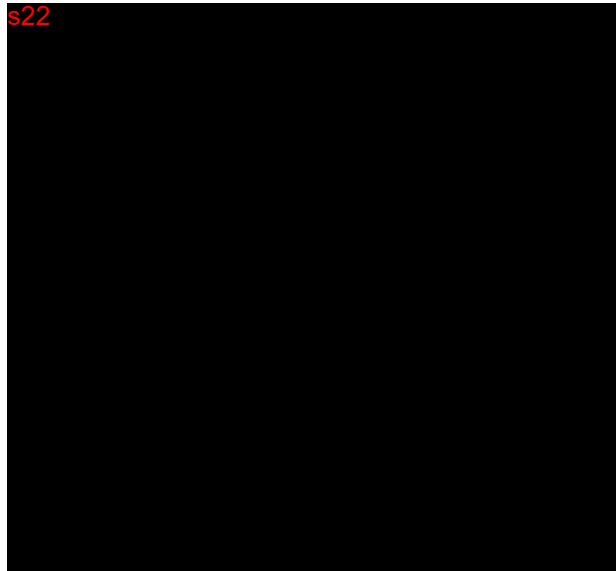
As there has been no formal advice to sponsors confirming the position stated in your email below, or any “informal” advice by way of an update at the website link above, our client has asked us to write to Mr John Jamieson, as the new Head of the Medical Devices Authorisations Branch, to request formal written confirmation that changes to the transition period in Australia will not be made to align with the extension to the MDR transition period, despite the negative impact that this will have on sponsors whose products are affected by the extension.



If you have any questions or concerns regarding our email, please do not hesitate to contact me.

Kind regards

s22



From: s22 [redacted] <[redacted]@health.gov.au>
Sent: Tuesday, 23 May 2023 10:52 AM
To: s22 [redacted] <[redacted] s22 [redacted]>
Cc: s22 [redacted] s22 [redacted] <[redacted]@starpharma.com>; s22 [redacted] <[redacted]@starpharma.com>; s22 [redacted] <[redacted]@starpharma.com>; s22 [redacted] <[redacted] s22 [redacted]>
Subject: RE: Submission Number: DV-2021-DA-06231-1; ARTG Class 1 device application: SPL7013 barrier nasal spray [SEC=OFFICIAL]

Dear s22 [redacted]

Thank you for your email.

I can confirm that any new applications will need to be lodged at the higher classification. This has been in place since 25 November 2021 and is not changing. For existing ARTG entries that the sponsors have notified the TGA before 25 May 2022 or within 2 months of the start date of the ARTG entry, we are looking at extending transitional timeframes beyond 1 November 2024, but this will be subject to Government decision. Further information will be made available on the TGA website when any decisions are made.

Please let me know if you have any further question.

Kind Regards,

s22 [redacted]
s22 [redacted]



Devices Applications Section | Medical Devices Authorisation Branch

Australian Government, Department of Health and Aged Care
Therapeutic Goods Administration

27 Scherger Drive, Fairbairn ACT 2609, Australia

Phone: 1800 141 144

PO Box 100, Woden ACT 2606

www.tga.gov.au

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From: s22 <s22 s22>
Sent: Monday, 22 May 2023 7:01 PM
To: s22 @health.gov.au
Cc: s22 @starpharma.com>; s22 @starpharma.com; s22 s22 @starpharma.com>; s22 s22
Subject: FW: Submission Number: DV-2021-DA-06231-1; ARTG Class 1 device application: SPL7013 barrier nasal spray [SEC=OFFICIAL]

Dear Ms s22

Thank you for your email below. We note your explanation regarding the clinical and biomaterial assessment reports.

We are currently in discussions with our client regarding their response to your email below and your letter of 4 May 2023. Before our client submits their response, we wish to seek clarification from the TGA as to how the extension granted by the European Union (EU) on 15 March 2023 regarding the Medical Device Regulation (MDR) transition period will affect the MDR transition period in Australia.

The TGA website (<https://www.tga.gov.au/how-we-regulate/supply-therapeutic-good/supply-medical-device/eu-mdr-transition/eu-mdr-transition-extension>) states that for Class IIb and lower risk devices, the transition period has been extended to 31 December 2028. The website further states that the “The TGA will recognise the extended transition for the European Union Medical Device Regulation (EU MDR)”, but advice has not been provided on whether changes to the transition period in Australia will be made to align with the extension to the MDR transition period. In this regard, we note that the TGA website still states, in relation to the impact on reclassification reforms, that “Sponsors must lodge any new applications at the higher classification, and sponsors of existing ARTG entries who notified the TGA before 25 May 2022, must apply for their device to be included at the higher classification before 1 November 2024, failing which their ARTG entries at the lower classification will be cancelled.”

As you will appreciate, a natural consequence of the extension to the EU MDR transition period is that Australian sponsors reliant on EU evidence to support ‘applications at higher classifications’ will be impacted by the extension. We would therefore appreciate confirmation of the TGA’s position regarding the extension to the EU MDR transition period, and particular whether a similar extension will flow in respect of the transition timeframes as they relate to reclassification reforms in Australia.

s47G



Kind regards

s22



s22



From: s22 <[redacted]@health.gov.au>
Sent: Wednesday, 10 May 2023 12:46 PM
To: s22 <[redacted]> <[redacted] s22 [redacted]>
Cc: s22 <[redacted]@starpharma.com>; s22 <[redacted]@starpharma.com>; s22 <[redacted]@starpharma.com>; s22 <[redacted] s22 [redacted]>
Subject: RE: Submission Number: DV-2021-DA-06231-1; ARTG Class 1 device application: SPL7013 barrier nasal spray [SEC=OFFICIAL]

Dear s22 [redacted],

Thank you for your email below.

Contrary to your belief, the redacted clinical and biomaterial assessment reports I provided to you in my previous letter of 5 May 2023 as Attachments 1 and 2 were not excerpts, but are indeed the full assessment reports (with evaluator names redacted).

As you had already been provided with the full assessments reports (with evaluator names redacted) but was under the impression that you had not, I will allow for a two-week period from today, with an additional extension of one week, for you to respond.

If Starpharma Pty Ltd would like to provide any comments in response to the clinical or biomaterials assessments, please do so by **31 May 2023**. After this date, I will finalise the outcome of the application. If your client wishes to submit new data or evidence, they may withdraw the current application and submit a new application for inclusion when they are

ready.

Please note that application fees are non-refundable following receipt by the TGA. You can refer to the TGA website for more information on fees and payments:

<https://www.tga.gov.au/refunds>.

Kind Regards,

s22
 [Redacted]



Devices Applications Section | Medical Devices Authorisation Branch
 Australian Government, Department of Health and Aged Care
 Therapeutic Goods Administration

27 Scherger Drive, Fairbairn ACT 2609, Australia
 Phone: 1800 141 144

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From: s22 <s22 s22>
Sent: Tuesday, 9 May 2023 3:48 PM
To: s22 @health.gov.au>
Cc: s22 @starpharma.com>; s22 @starpharma.com; s22 s22 @starpharma.com>; s22 <s22 s22>
Subject: RE: Submission Number: DV-2021-DA-06231-1; ARTG Class 1 device application: SPL7013 barrier nasal spray [SEC=OFFICIAL]

Dear Ms s22

We refer to your email below that attached your letter, received on 5 May 2023, regarding our client's application for inclusion of its product, SPL7013 Nasal Spray in the ARTG. We note that your letter provided, at Attachments 1 and 2, what you refer to as 'redacted' versions of the most recent clinical and biomaterial assessments of our client's application. However, it seems to us that Attachments 1 and 2 contain what appear to be 'excerpts' of the relevant assessments, rather than redacted copies of the assessment reports themselves.

We note that your letter states that if our client would like to 'provide any comments in response to the clinical or biomaterials assessment', it should do so by 18 May 2023. However, we first request that you provide us with copies of the actual assessment reports, so that our client can review the reports in their totality, and understand them in their correct context, before preparing a response. It is not

possible for our client to make submissions '*in response to the clinical or biomaterials assessment*' if you do not provide them with copies of the actual assessments, and we note that it is highly irregular from a procedural perspective to only provide our client with 'excerpts' of those assessments. In this regard, our client considers that the information provided is insufficiently detailed to enable them to prepare a complete and considered response.

Further to our request above, we would be grateful for an extension of another 6 weeks from the date we receive the actual assessment reports, so that our client has the opportunity to consult with and obtain advice from their clinical experts (who are based overseas) and then has the opportunity to confer with us after receiving that clinical expert advice, and obtain our assistance in preparing a response.

We note that there is no prejudice to the TGA in granting the extension requested and no apparent urgency in finalising the application, noting that it has taken the TGA almost 4 months to revert following the response we submitted on 13 January 2023 (on behalf of our client) to the previous clinical and biomaterials assessments.

We look forward to hearing from you.

Kind regards

s22

s22

From: s22 <[redacted]@health.gov.au>
Sent: Thursday, 4 May 2023 11:59 AM
To: s22 <[redacted] s22 [redacted]>
Cc: s22 <[redacted]@starpharma.com>; s22 <[redacted]@starpharma.com>; s22 <[redacted]@starpharma.com>; s22 <[redacted] s22 [redacted]>
Subject: RE: Submission Number: DV-2021-DA-06231-1; ARTG Class 1 device application: SPL7013 barrier nasal spray [SEC=OFFICIAL]

Dear s22

Thank you for your submission dated 13 January 2023 on behalf of Starpharma Pty Ltd in relation to the application DV-2021-DA-06231-1.

Please refer to the attached correspondence including the redacted further clinical and

biomaterials assessment report.

If Starpharma Pty Ltd would like to provide any comments in response to the clinical or biomaterials assessments, please do so by **18 May 2023**. (Note: This is an invitation to provide a written response to the assessments of the evidence and data you have submitted in support of your application. If your client wishes to submit new data or evidence, they may withdraw the current application and submit a new application for inclusion when they are ready.)

Kind Regards,

s22

Devices Applications Section | Medical Devices Authorisation Branch

Australian Government, Department of Health and Aged Care
Therapeutic Goods Administration

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Phone: 1800 141 144

PO Box 100, Woden ACT 2606

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From: s22 <s22 s22>
Sent: Friday, 13 January 2023 2:08 PM
To: s22 @health.gov.au>
Cc: s22 @starpharma.com>; s22 @starpharma.com; s22 s22 starpharma.com>; s22 <s22 s22>
Subject: Submission Number: DV-2021-DA-06231-1; ARTG Class 1 device application: SPL7013 barrier nasal spray
Importance: High

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear Ms s22

Please find attached a cover letter from s22 along with Starpharma's response to the clinical and biomaterials assessment of Starpharma's application (**Application**) to include

SPL7013 barrier nasal spray in the ARTG as a Class I medical device (Submission Number: DV-2021-DA-06231-1). Starpharma's response also includes seven (7) attachments, which have been provided separately.

Please do not hesitate to contact us if there are any issues with the attachments or if you require any further information in relation to the Application.

Yours sincerely

s47



s22



s22



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transmission."

This email has been scanned for spam and viruses by Proofpoint Essentials. Click [here](#) to report this email as spam.

From: [JAMIESON, John](#)
To: s22, s22
Cc: s22, s22
Subject: FW: Starpharma Pty Ltd: Application for inclusion of SPL7013 barrier nasal spray in the ARTG (Submission Number: DV-2021-DA-06231-1) [SEC=OFFICIAL]
Date: Thursday, 8 June 2023 10:05:04 AM
Attachments: [image002.png](#)
[image003.png](#)

Hi s22

Please add Tracey's email to the file for this application.

Please also note the follow up steps noted in the email.

Regards

John

From: DUFFY, Tracey <Tracey.Duffy@health.gov.au>
Sent: Wednesday, 7 June 2023 2:31 PM
To: s22 <s22 s22>
Cc: s22 <s22 s22 @starpharma.com>; s22 <s22 s22 @starpharma.com>; s22 <s22 s22>; s22 <s22 s22 @starpharma.com>; JAMIESON, John <John.JAMIESON@Health.gov.au>; s22, s22 <s22 s22 @health.gov.au>; s22, s22 <s22 s22 @health.gov.au>
Subject: RE: Starpharma Pty Ltd: Application for inclusion of SPL7013 barrier nasal spray in the ARTG (Submission Number: DV-2021-DA-06231-1) [SEC=UNOFFICIAL]

Dear s22

Thankyou and Starpharma for your time earlier today.

As discussed, the TGA will organise for a follow up meeting with your client to better clarify:

- Comparability vs
- Substantially equivalent vs
- Well established technology.

In the context of low risk (Class 1) devices.

In addition, if needed and based on the outcome of the first discussion (above), we are happy to further canvass potential terminology changes (to instructions for use, intended purpose or other documentation) that may be useful to consider.

After that, if needed, there may be a third discussion regarding your client's options if they choose to withdraw their current application.

At our meeting today, John Jamieson took the lead in organising the meetings outlined above.

Kind regards
Tracey

From: s22 <s22 s22>
Sent: Thursday, 1 June 2023 9:44 AM
To: DUFFY, Tracey <Tracey.Duffy@health.gov.au>
Cc: s22 <s22 s22 @starpharma.com>; s22

<s22 s22 @starpharma.com>; s22 <s22 s22 s22 s22>
<s22 s22 @starpharma.com>; JAMIESON, John <John.JAMIESON@Health.gov.au>; s22 ,
s22 <s22 s22 @health.gov.au>

Subject: RE: Starpharma Pty Ltd: Application for inclusion of SPL7013 barrier nasal spray in the ARTG (Submission Number: DV-2021-DA-06231-1) [SEC=UNOFFICIAL]

Thank you Ms Duffy. I appreciate your prompt response.

Kind regards

s22

s22

From: DUFFY, Tracey <Tracey.Duffy@health.gov.au>

Sent: Wednesday, 31 May 2023 5:21 PM

To: s22 <s22 s22 s22 s22>

Cc: s22 <s22 s22 @starpharma.com>; s22
<s22 s22 @starpharma.com>; s22 <s22 s22 s22 s22> s22
<s22 s22 @starpharma.com>; JAMIESON, John <John.JAMIESON@Health.gov.au>; s22 ,
s22 <s22 s22 @health.gov.au>

Subject: RE: Starpharma Pty Ltd: Application for inclusion of SPL7013 barrier nasal spray in the ARTG (Submission Number: DV-2021-DA-06231-1) [SEC=UNOFFICIAL]

Dear s22

I have asked my EA (s22 – copied) to find some suitable time.

In the meantime, I have also asked John Jamieson (Head of the Authorisation Branch) to discuss where the delegate is up to in consideration – given this meeting will be held.

Kind regards

Tracey

Tracey Duffy
Acting Deputy Secretary

Health Products Regulation Group
Australian Government, Department of Health and Aged Care
T: +61 2 6289 4200 | E: Tracey.Duffy@health.gov.au

Location: 27 Scherger Drive, Fairbairn, ACT, 2609, Australia
PO Box 100, Woden ACT 2606, Australia

Executive Assistant s22 T: s22 | E: s22 s22@health.gov.au
Executive Officer s22 T: s22 | E: s22 s22@health.gov.au

I may send emails out of hours due to travel and other commitments. If this e-mail requires a response, I look forward to receiving it during your normal working hours.

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From: s22 <s22 s22>
Sent: Wednesday, 31 May 2023 4:17 PM
To: DUFFY, Tracey <Tracey.Duffy@health.gov.au>
Cc: s22 <s22 s22@starpharma.com>; s22 <s22 s22@starpharma.com>; s22 <s22 s22>; s22 <s22 s22@starpharma.com>; JAMIESON, John <John.JAMIESON@Health.gov.au>
Subject: RE: Starpharma Pty Ltd: Application for inclusion of SPL7013 barrier nasal spray in the ARTG (Submission Number: DV-2021-DA-06231-1) [SEC=UNOFFICIAL]

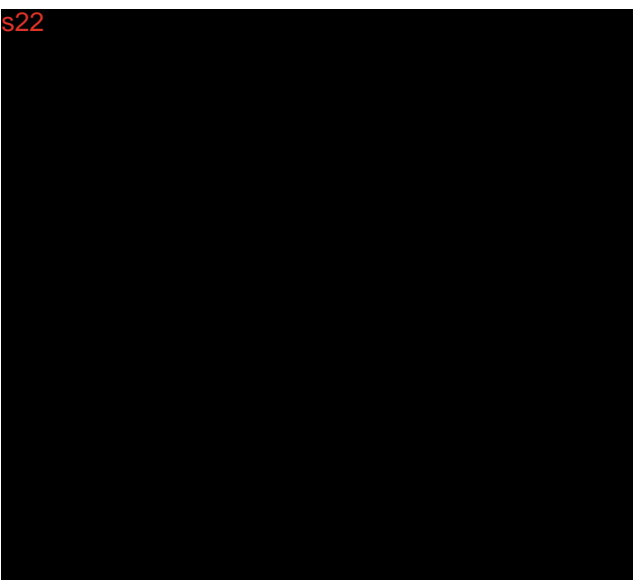
Thank you for your reply Ms Duffy. My client greatly appreciates, and would like to take up, your offer of a meeting, as they remain concerned that the position in which they find themselves with respect to the Application has arisen because the Delegate has potentially applied the wrong criteria in assessing whether the clinical evidence submitted in respect of the Product adequately established the safety and performance. Starpharma would also like to discuss the clinical and biomaterials assessments *per se*, specifically in the context of what due process would require.

I look forward to hearing from you further. As a courtesy, I wrote to the Delegate to inform her that I had written to you and asked her to pause on a decision with respect to the Application until we have had the opportunity to speak.

Kind regards

s22

s22



s22

From: DUFFY, Tracey <Tracey.Duffy@health.gov.au>

Sent: Wednesday, 31 May 2023 9:33 AM

To: s22 <s22 s22

Cc: s22 <s22 s22 @starpharma.com>; s22 s22 @starpharma.com; s22

s22 <s22 s22 @starpharma.com>; s22 <s22 s22

JAMIESON, John <John.JAMIESON@Health.gov.au>

Subject: RE: Starpharma Pty Ltd: Application for inclusion of SPL7013 barrier nasal spray in the ARTG (Submission Number: DV-2021-DA-06231-1) [SEC=UNOFFICIAL]

Dear s22

Sorry for the delay. I note the information you provided below about Starpharma's application to include its SPL7013 Nasal Spray in the Australian Register of Therapeutic Goods. I will leave the consideration of the decision about the application to the relevant TGA delegate, noting that you have asked me specifically about the impact of the EU MDR transition extension on Australia's reclassification reforms.

As outlined in your email, the EU extended its transition for medical device manufacturers to comply with its new Medical Device Regulation (EU MDR), and the TGA recently announced that we would continue to accept EU certification for medical devices under the previous Medical Device Directive as evidence for Australian regulatory purposes, in line with the EU extension.

The Starpharma application, for a class I medical device, does not rely on EU certification as evidence, so the EU extension is not immediately relevant.

However, I appreciate that if the application is decided or withdrawn, any subsequent application from Starpharma for the SPL7103 Nasal Spray would need to demonstrate compliance with the regulatory requirements and classification rules that apply at that time, including the reclassification reforms that are in our Regulations.

I would like to emphasise that the TGA administers the relevant parts of the Act and Regulations, but does not set those Regulations. Our website statement about the impact of the EU extension on Australian reclassification reforms states that we will consider the impact and advise the Government. It will be up to the Government to decide any extension, and the TGA cannot decide Government policy or Regulation.

I look forward to our meeting if you still wish to meet.

Regards

Tracey

Tracey Duffy
Acting Deputy Secretary

Health Products Regulation Group
Australian Government, Department of Health and Aged Care
T: +61 2 6289 4200 | E: Tracey.Duffy@health.gov.au
Location: 27 Scherger Drive, Fairbairn, ACT, 2609, Australia
PO Box 100, Woden ACT 2606, Australia

Executive Assistant s22 T: s22 | E: s22 s22@health.gov.au
 Executive Officer s22 T: s22 | E: s22 s22@health.gov.au

I may send emails out of hours due to travel and other commitments. If this e-mail requires a response, I look forward to receiving it during your normal working hours.

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From: DUFFY, Tracey
Sent: Tuesday, 30 May 2023 2:07 PM
To: s22 <s22 s22>
Cc: s22 <s22 s22@starpharma.com>; s22 s22@starpharma.com; s22 s22 <s22 s22@starpharma.com>; s22 s22 <s22 s22>
 JAMIESON, John <John.JAMIESON@Health.gov.au>
Subject: RE: Starpharma Pty Ltd: Application for inclusion of SPL7013 barrier nasal spray in the ARTG (Submission Number: DV-2021-DA-06231-1) [SEC=UNOFFICIAL]

Dear s22
 Thank you for your email and I apologise for the delay in responding.
 I would be happy to organise a virtual meeting to discuss the matter.
 In the interim I have asked John Jamieson to provide some written information so that it can inform our discussions.
 Kind regards
 Tracey

From: s22 <s22 s22>
Sent: Friday, 26 May 2023 4:18 PM
To: DUFFY, Tracey <Tracey.Duffy@health.gov.au>
Cc: s22 <s22 s22@starpharma.com>; s22 s22@starpharma.com; s22 s22 <s22 s22@starpharma.com>; s22 s22 <s22 s22>
Subject: Starpharma Pty Ltd: Application for inclusion of SPL7013 barrier nasal spray in the ARTG (Submission Number: DV-2021-DA-06231-1)

Dear Ms Duffy


I hope this email finds you well.

I understand that yesterday you met with members of s22 s22 in relation to which s22 from Starpharma Pty Ltd, for whom we act, is a member.

I know that you have previous knowledge of Starpharma's application (**Application**) for inclusion of its product, SPL7013 Nasal Spray (**Product**), in the ARTG, s47G

s47G, the Application was reinstated and has been subjected to a protracted clinical and biomaterials assessment since that time.

The Delegate is now at the point of wanting to make a decision with respect to the Application and Starpharma is, in turn, s47G



Leaving that issue aside, over the course of the Application's somewhat protracted and complex history, the European Union Medical Device Regulation (**EU MDR**) transition period for MDR-certified devices was extended from May 2024, and the TGA website (<https://www.tga.gov.au/how-we-regulate/supply-therapeutic-good/supply-medical-device/eu-mdr-transition/eu-mdr-transition-extension>) states that for Class IIb and lower risk devices, the transition period has been extended to 31 December 2028. The TGA website further states that the "The TGA will recognise the extended transition for the EU MDR", but advice has not been provided on whether changes to the transition period in Australia will flow through to the timing of the reclassification reforms to align with the extension to the MDR transition period. We note, in this regard, that the TGA website still states, in relation to the impact on reclassification reforms, that "Sponsors must lodge any new applications at the higher classification, and sponsors of existing ARTG entries who notified the TGA before 25 May 2022, must apply for their device to be included at the higher classification before 1 November 2024, failing which their ARTG entries at the lower classification will be cancelled." However, the TGA website also states that "The TGA is considering the impact of the EU MDR transition extension on Australia's reclassification and personalised medical device reforms and will provide advice to the Government about whether changes to the transition timeframes will be needed."

A natural consequence of the extension to the EU MDR transition period is that Australian sponsors reliant on EU evidence to support 'applications at higher classifications' will be impacted by the extension and how the TGA aligns with that, and may not be able to obtain the required evidence to support inclusion in the ARTG at the higher classification, without first undergoing Australian conformity assessment, which will add burden to sponsors and the TGA.

As stated above, Starpharma is considering its position regarding the Application, but respectfully requests a conference call with you as soon as possible to discuss its concerns about

s47G



As Starpharma would like to make an informed decision as soon as practicable, we would be grateful if you could indicate your availability for a call as soon as possible.

Kind regards

s22

A small black rectangular redaction box covering the text 's22'.

s22

A large black rectangular redaction box covering the text 's22' and the majority of the page's content.

s22

A wide black rectangular redaction box covering the text 's22' and a significant portion of the page's content.

This email has been scanned for spam and viruses by Proofpoint Essentials. Click [here](#) to report this email as spam.

From: s22
To: s22, s22
Cc: s22; s22, s22@starpharma.com; s22; s22; JAMIESON, John; s22; s22; DUFFY, Tracey
Subject: RE: Starpharma application (Submission ID: DV-2021-DA-06231-1) for the SPL7013 barrier nasal spray [SEC=OFFICIAL]
Date: Tuesday, 27 June 2023 2:10:36 PM
Attachments: [image001.png](#)
[image002.png](#)

Dear s22

We acknowledge your email below dated 21 June 2023, which ostensibly seeks to clarify the TGA's interpretation of the terms "*well-established technology*", "*comparability*" and "*substantial equivalence*" (**Terms**) in the context of low-risk devices (including devices such as our client's device, SPL7013 barrier nasal spray (**Device**)). As you are aware, it was agreed that the TGA would provide such clarification following a meeting (**Meeting**) held between us, our client and the TGA on 7 June 2023 regarding the assessment of our client's application for inclusion of the Device in the ARTG.

We note that Ms Duffy's email on 7 June 2023, which summarised the discussion during the Meeting held on that day, stated that "*the TGA will organise for a follow up meeting with [our] client to better clarify the above terms in the context of low risk (Class 1 devices)*". Additionally, Ms Duffy noted the discussion during the Meeting about the potential for amendments to the intended purpose for the Device '*based on the outcome of the first discussion*'. We understand that Ms Duffy's reference to the '*first discussion*' is a reference to the follow-up meeting still to be held with our client.

Having regard to the discussion held during the Meeting, our client is somewhat confused by your email below, as our understanding from the Meeting was that the TGA would further consider the Terms and then arrange a further meeting with us and our client to discuss their interpretation, and also discuss any proposed amendments to the Device's intended purpose.

Noting our and our client's understanding of the Meeting, we are instructed to raise our client's concerns regarding the content of your email below, and the essential paraphrasing in it of the wording and sentiment from the Clinical Assessor's report, such that there appears to be no independent, objective consideration as to how the Terms ought to be interpreted. As you may recall, one of the key concerns raised during the Meeting was that there is no legislative provision, and otherwise no guidance, that provides an objective definition of '*well-established technology*', and our understanding was that – for that reason – the TGA would give some considered thought to objective criteria that could be applied to determine whether or not a technology could be regarded as "*well-established*".

Our understanding from the Meeting (which is shared by our client) was that the TGA would revert to our client to arrange a follow-up meeting to discuss what the TGA proposed as objective criteria to define a "*well-established technology*", and allow our client the opportunity to provide feedback on those proposed criteria given the bearing they have on our client's pending application. Notably, it was not our understanding from the Meeting that the TGA would simply go about finding excerpts from our client's website and the (previously supplied) Clinical Assessor's report to maintain its previous (subjective) position that the technology underpinning our client's Device is not "*well-established*". This is not what we had understood would be an

independent, objective consideration by the TGA of the definition of “*well-established technology*”, and our client believes there needs to be alignment on that definition before a proper assessment of whether our client’s clinical evidence is adequate can be made.

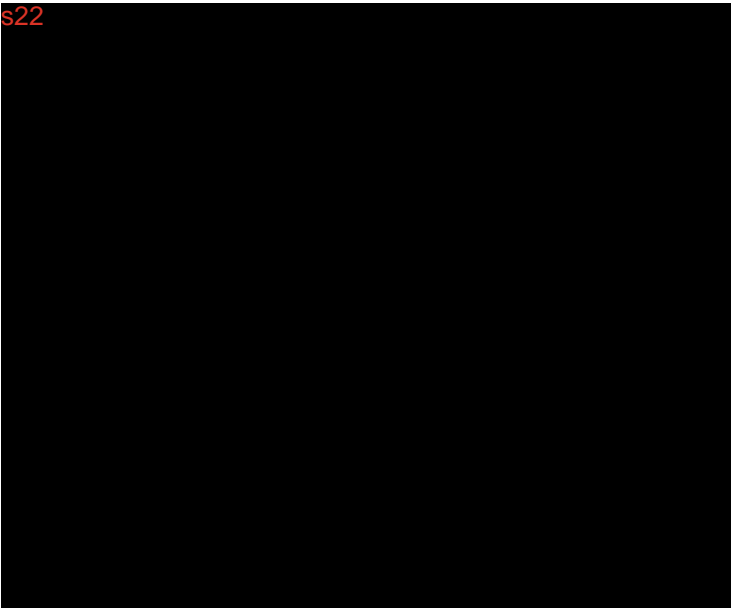
Noting the issues we have raised, we are instructed to arrange a conference call to discuss the criteria that the TGA proposes to apply in determining whether a technology can be regarded to be “*well-established*”. Our client would also like to take the opportunity during that conference call to discuss a proposed amended intended purpose, which our client has given careful consideration to, hopefully as a means of facilitating ARTG approval.

We look forward to hearing from you further about your availability for a follow-up conference call.

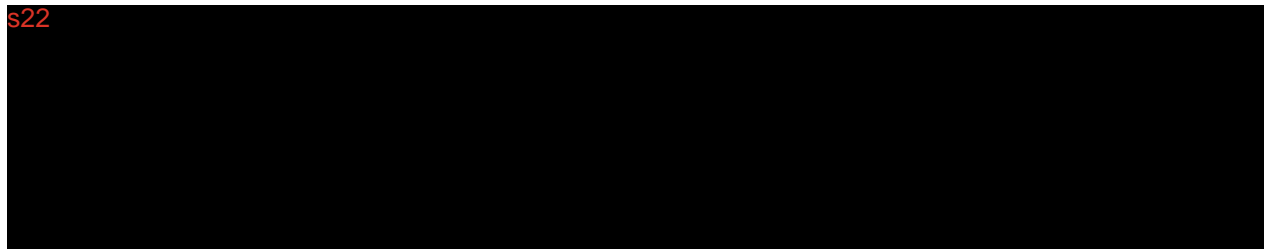
Kind regards

s22

s22



s22



From: s22, s22 <s22, s22@health.gov.au>
Sent: Wednesday, 21 June 2023 10:47 AM
To: s22 <s22, s22>
Cc: s22 <s22, s22@starpharma.com>; s22, s22@starpharma.com; s22
s22 <s22, s22@starpharma.com>; s22 <s22, s22>
JAMIESON, John <John.JAMIESON@Health.gov.au>; s22, s22
<s22, s22@health.gov.au>

Subject: Re: Starpharma application (Submission ID: DV-2021-DA-06231-1) for the SPL7013

barrier nasal spray [SEC=OFFICIAL]

Dear S22,

I hope this email finds you well.

I'm writing in relation to the Starpharma application (Submission ID: DV-2021-DA-06231-1) for the SPL7013 barrier nasal spray.

As discussed during our meeting on 7 June 2023, it came to our attention that you required clarification on the "Well-established Technology", "Comparability" and "Substantial Equivalence" in the context of low risk devices.

In response, I reached out to our clinical assessment team, who has provided the following information for your reference.

In context of the subject device, dendrimer based nasal sprays that are medical devices claiming virucidal actions are not a well-established technology for the following reasons:

a) Other than the subject device there is no precedent for the use of dendrimers in the nose for prevention and treatment of cold viruses. On the contrary, at present, this is novel technology as also evidenced through the applicant's websites and literature publication.

- o Starpharma describes SPL7013 as an "innovative proprietary dendrimer that is antiviral and blocks bacteria." (<https://starpharma.com/spl7013> accessed 16 Jun 2023)
- o Authors Castellarnau et al., 2022 in their publication of the subject device's phase I clinical investigation also refer to astodrimer sodium as a "...promising innovation warranting further investigation..."
- o In the ASX announcement "Starpharma awarded \$1M MRFF funding for COVID-19 spray", it is stated "\$1 million awarded to Starpharma by the Medical Research Future Fund (MRFF) to expedite development and commercialisation of its novel SPL7013 nasal spray for COVID-19"

b) More broadly, nasal sprays claiming virucidal actions that are medical devices as a group are also not a well-established technology.

- o These are not considered standard of care for treatment or prevention of common cold.
- o This group of devices is heterogenous and therefore not automatically comparable simply by the action of spraying a product into a nostril.

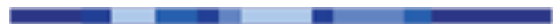
As stated in the Clinical Evidence Guidelines, "Evidence from comparable devices that are not substantially equivalent may support or supplement direct or indirect clinical evidence. However, it will not generally constitute sufficient clinical evidence for substantiating compliance with the EPs (except for certain low risk, well established technologies)."

Thus, indirect clinical evidence from such comparable devices for substantiating compliance with the Essential Principles is relevant only for certain low risk, well established technologies. SPL7013 by Starpharma is not well-established technology, as explained above. Therefore, this does not apply.

I trust the above information adequately addresses your concerns and clarifies our understanding of those terms for you and your client to consider your position about the application. However, should you have any further questions or require additional clarification, I am more than happy to arrange a follow-up meeting. If you find it necessary, please inform me of your availability for the upcoming week.

Kind Regards,

s22
[Redacted]



Devices Applications Section | Medical Devices Authorisation Branch

Australian Government, Department of Health and Aged Care
Therapeutic Goods Administration

27 Scherger Drive, Fairbairn ACT 2609, Australia
Phone: 1800 141 144

PO Box 100, Woden ACT 2606

www.tga.gov.au

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From: s22
To: s22
Subject: RE: Starpharma application (Submission ID: DV-2021-DA-06231-1) for the SPL7013 barrier nasal spray [SEC=OFFICIAL]
Date: Friday, 1 September 2023 8:51:07 AM
Attachments: [image002.png](#)
[image003.png](#)
Importance: High

Dear s22,

I hope this email finds you well. I'm writing to touch base regarding the scheduling of a discussion about the application status.

Since my last email, some of the previously proposed dates and times have become unavailable. I apologize for any inconvenience this may cause and appreciate your flexibility.

Below are some new potential time slots for our meeting:

September

Thursday 21 9:00 -10:00

October

Wednesday 4 1:30 – 2:30

Friday 6 9:00 – 11:00

Please let me know your preferred time. If none of these options work for you, please let me know your availability and we can work together to find a suitable time.

If you have any questions, please feel free to let me know.

Kind Regards,

s22

From: s22 @health.gov.au>

Sent: Monday, 28 August 2023 1:51 PM

To: s22 <s22 s22

Subject: RE: Starpharma application (Submission ID: DV-2021-DA-06231-1) for the SPL7013 barrier nasal spray [SEC=OFFICIAL]

Dear s22,

I hope this email finds you well.

Thank you for your submission.

I wanted to take a moment to update you on the status of your application. While a final decision has not been made, I believe it's important to keep you informed about the current direction.

Below are some potential time slots for our meeting:

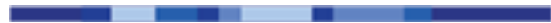
Thursday 14 10:00 – 11:00
3:00 – 4:00
Friday 15 2:00 – 3:00
Thursday 21 9:00 -10:00

Please let me know your preferred time. If none of these options work for you, please let me know your availability and we can work together to find a suitable time.

If you have any questions, please feel free to let me know.

Kind Regards,

s22
[Redacted]



Devices Applications Section | Medical Devices Authorisation Branch

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Therapeutic Goods Administration

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From: s22 <s22 s22>
Sent: Friday, 4 August 2023 4:21 PM
To: s22 @health.gov.au>
Cc: s22 s22 @starpharma.com>; s22 @starpharma.com; s22 s22 @starpharma.com>; DUFFY, Tracey <Tracey.Duffy@health.gov.au>; JAMIESON, John <John.JAMIESON@Health.gov.au>; s22 s22 @health.gov.au>; SINGER, Simon <simon.singer@health.gov.au>; s22 s22 @health.gov.au>; s22 s22 s22 s22
Subject: FW: Starpharma application (Submission ID: DV-2021-DA-06231-1) for the SPL7013 barrier nasal spray [SEC=OFFICIAL]

Dear s22

Further to my email below, I attach Starpharma's submission (including stability data in Attachment 1) in response to the Webex meeting on 12 July 2023 (**Conference**) attended by Starpharma, s22 and the TGA, during which we discussed the status of Starpharma's

application for inclusion of its product, SPL7013 barrier nasal spray (**Product**), in the Australian Register of Therapeutic Goods.

We look forward to your review of the information provided by Starpharma and to hearing from you further to arrange another Webex meeting, as was agreed during the Conference, in case there are any matters requiring further clarification and so that the TGA can verbally inform Starpharma of the decision it proposes to make with respect to the Application.

Please do not hesitate to contact us if you require any further information or you have any questions about the submission and attached stability data.

Yours sincerely

s22

s22

From: s22 <s22@health.gov.au>
Sent: Wednesday, 2 August 2023 4:52 PM
To: s22 <s22 s22>
Cc: s22 s22 <s22@starpharma.com>; s22 <s22@starpharma.com>; s22 s22 <s22@starpharma.com>; s22 <s22 s22>
Subject: RE: Starpharma application (Submission ID: DV-2021-DA-06231-1) for the SPL7013 barrier nasal spray [SEC=OFFICIAL]

Thanks, s22. Look forward to receiving the information.

Kind Regards,

s22

From: s22 <s22 s22>
Sent: Wednesday, 2 August 2023 4:42 PM
To: s22 <s22@health.gov.au>
Cc: s22 s22 <s22@starpharma.com>; s22 <s22@starpharma.com>; s22

s22 [redacted]@starpharma.com>; s22 [redacted] <s22 [redacted] s22 [redacted]>

Subject: RE: Starpharma application (Submission ID: DV-2021-DA-06231-1) for the SPL7013 barrier nasal spray [SEC=OFFICIAL]

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear s22 [redacted]

Thanks for your email. I am well and hope you are too.

We are just working through the draft that Starpharma sent through today and we hope to provide our input to them tomorrow. I anticipate that Starpharma will be able to send the information through to you by the end of the week.

Kind regards

s22 [redacted]

s22 [redacted]

s22 [redacted]

From: s22 [redacted]@health.gov.au>

Sent: Wednesday, 2 August 2023 3:07 PM

To: s22 [redacted] <s22 [redacted] s22 [redacted]>

Subject: RE: Starpharma application (Submission ID: DV-2021-DA-06231-1) for the SPL7013 barrier nasal spray [SEC=OFFICIAL]

Dear s22 [redacted],

Hope the email finds you well. I'm writing in relation to the Starpharma application DV-2021-DA-06231-1.

As discussed at our last meeting on 12 July 2023, you indicated Starpharma would send more information about the safety, performance and intended purpose of the device in support of the application.

I'd like to enquire if you have any update or an estimated timeline for providing that information?

Please let me know if you have any question.

Thank you.

Kind Regards,

s22

Devices Applications Section | Medical Devices Authorisation Branch

Australian Government, Department of Health and Aged Care
Therapeutic Goods Administration

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Phone: 1800 141 144

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From: s22, s22
To: s22
Cc: DUFFY, Tracey; JAMIESON, John; s22; s22; s22; s22; s22
Subject: RE: Starpharma Pty Ltd - Medical Device Application (DV-2021-DA-06231-1) [SEC=OFFICIAL]
Date: Friday, 29 September 2023 5:53:56 PM
Attachments: image001.png
Letter to s22 - Device Application DV-2021-DA-06231-1 - DA-2021-06851-1, SPL7013 Barrier Nasal Spray 20230929.pdf

Dear s22,

Thank you for your email.

Please find the attached letter in response to your latest correspondence.

Kind Regards,

s22
[Redacted]

Devices Application & Triage Section | Medical Devices Authorisation Branch
Australian Government, Department of Health and Aged Care
Therapeutic Goods Administration

27 Scherger Drive, Fairbairn ACT 2609, Australia
Phone: 1800 141 144

PO Box 100, Woden ACT 2606

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From: s22 <s22 s22>
Sent: Wednesday, 27 September 2023 5:15 PM
To: s22, s22 <s22 s22@health.gov.au>
Cc: DUFFY, Tracey <Tracey.Duffy@health.gov.au>; JAMIESON, John <John.JAMIESON@Health.gov.au>; s22 <s22 s22> s22 <s22 s22>
Subject: Starpharma Pty Ltd - Medical Device Application (DV-2021-DA-06231-1)
Importance: High

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear s22,

Please see **attached** correspondence for your consideration.

Kind regards,

s22

s22



s22



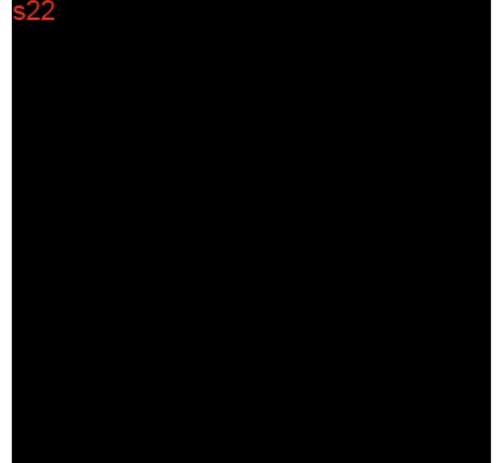
27 September 2023

s22



Devices Applications Section
Medical Devices Authorisation Branch
Therapeutic Goods Administration
PO BOX 100
Woden ACT 2000

s22



Email: s22@health.gov.au

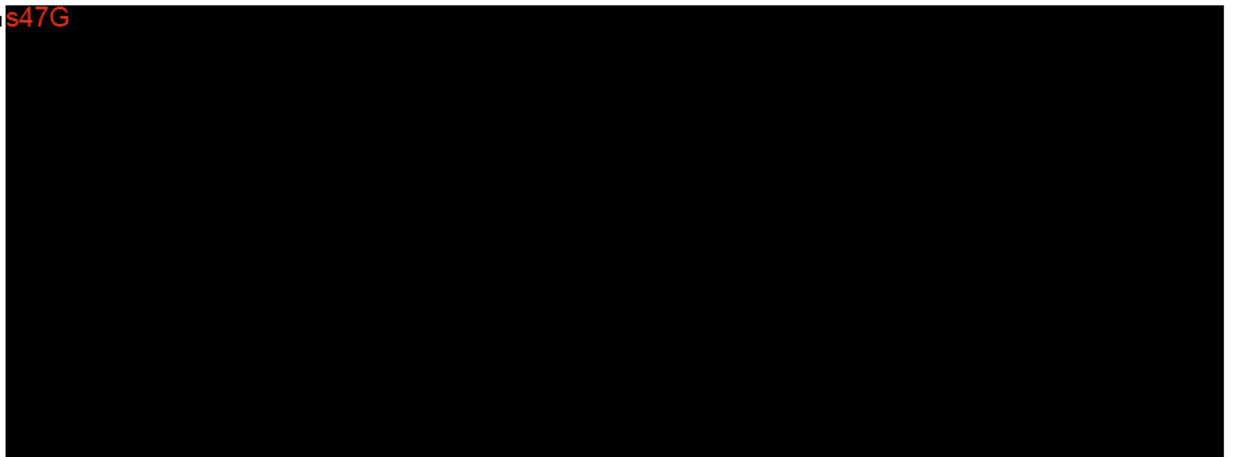
Copy: tracey.duffy@health.gov.au
john.jamieson@health.gov.au

Dear s22

**Inclusion of SPL7013 Barrier Nasal Spray in Australian Register of Therapeutic Goods:
Medical Device Application (DV-2021-DA-06231-1)**

1. We are writing to you in anticipation of our upcoming Webex meeting on 6 October 2023 (**Meeting**) regarding the TGA's assessment of our client's application (**Application**; DV-2021-DA-06231-1) for inclusion of SPL7013 Barrier Nasal Spray (**Product**) in the Australian Register of Therapeutic Goods (**ARTG**).
2. We understand that the intention of the Meeting is to inform our client of the current direction of the TGA's assessment with respect to the Application, having considered our client's data, all previous correspondence and our client's last submission dated 4 August 2023 (**Submission**), which included responses to additional technical questions posed by the TGA and a proposed revised intended purpose for the Product.

3. s47G



4.

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s22



5.

s47G

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9.

s47G

10. Noting the date of the Meeting, we would be grateful if you could please respond to our letter prior to the Meeting so that our client understands the TGA's position prior to the Meeting.
11. If you have any questions or require further information, please do not hesitate to contact me on s22 or s22

Yours faithfully

s22

s22



Dear s22,

Submission Number: DV-2021-DA-06231-1
ARTG Class I device application: SPL7013 barrier nasal spray

Thank you for your letter.

We note the contents of your letter and confirm that the purpose of the upcoming meeting on 6 October is to inform your client of the delegate's position following the meeting of 12 July and consideration of your client's submission of 4 August.

We do not consider it appropriate to pre-empt the outcome of the meeting before it takes places, as the meeting will provide an opportunity to discuss the application in light of the submissions provided. Further, in relation to your client's request for a consolidated clinical assessment report, we do not consider that this is necessary to enable your client to consider whether to withdraw the application if the delegate indicates that it is intending to reject the application. This is because, in our view, your client has been provided with all the relevant information that the delegate will consider if they proceed to make a decision on this application. In addition, the delegate has received and taken into account your submissions on this point, including in your letter of 13 January as well as your latest submission of 4 August.

We look forward to speaking next week.

Yours sincerely,

s22



Devices Application & Triage Section
Medical Devices Authorisation Branch
Therapeutic Goods Administration

From: s22
To: s22, s22
Cc: s22, s22@starpharma.com; s22; DUFFY, Tracey; JAMIESON, John; SINGER, Simon; s22.
Subject: FW: EMAIL 2 of 2: Starpharma application (Submission ID: DV-2021-DA-06231-1) for SPL7013 Nasal Spray
Date: Wednesday, 31 January 2024 2:33:09 PM
Attachments: [image001.png](#)
[CFR-003A-02 - Appendix 3 - CV s22 .pdf](#)
[CFR-003A-02 - Appendix 4 - Initial Literature Search Output.pdf](#)
[CFR-003A-02 - Appendix 5 - Data Appraisal.pdf](#)
[CFR-003A-02 - Appendix 6 - Subsequent Literature Search Output.pdf](#)
[Attachment 2_DRA-4_Risk Management Plan & Risk Analysis - SPL7013 Nasal Spray_v3.0.pdf](#)
[Attachment 2_DRA-4_v3.0_1_DRA-4 v3.0 - Risk Matrix - SPL7013 Nasal Spray.pdf](#)
[Attachment 3_DRR-5_Risk Management Report - SPL7013 Nasal Spray_v3.0.pdf](#)

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Dear s22

Just resending the second email with the correct recipients.

Kind regards

s22

s22



From: s22

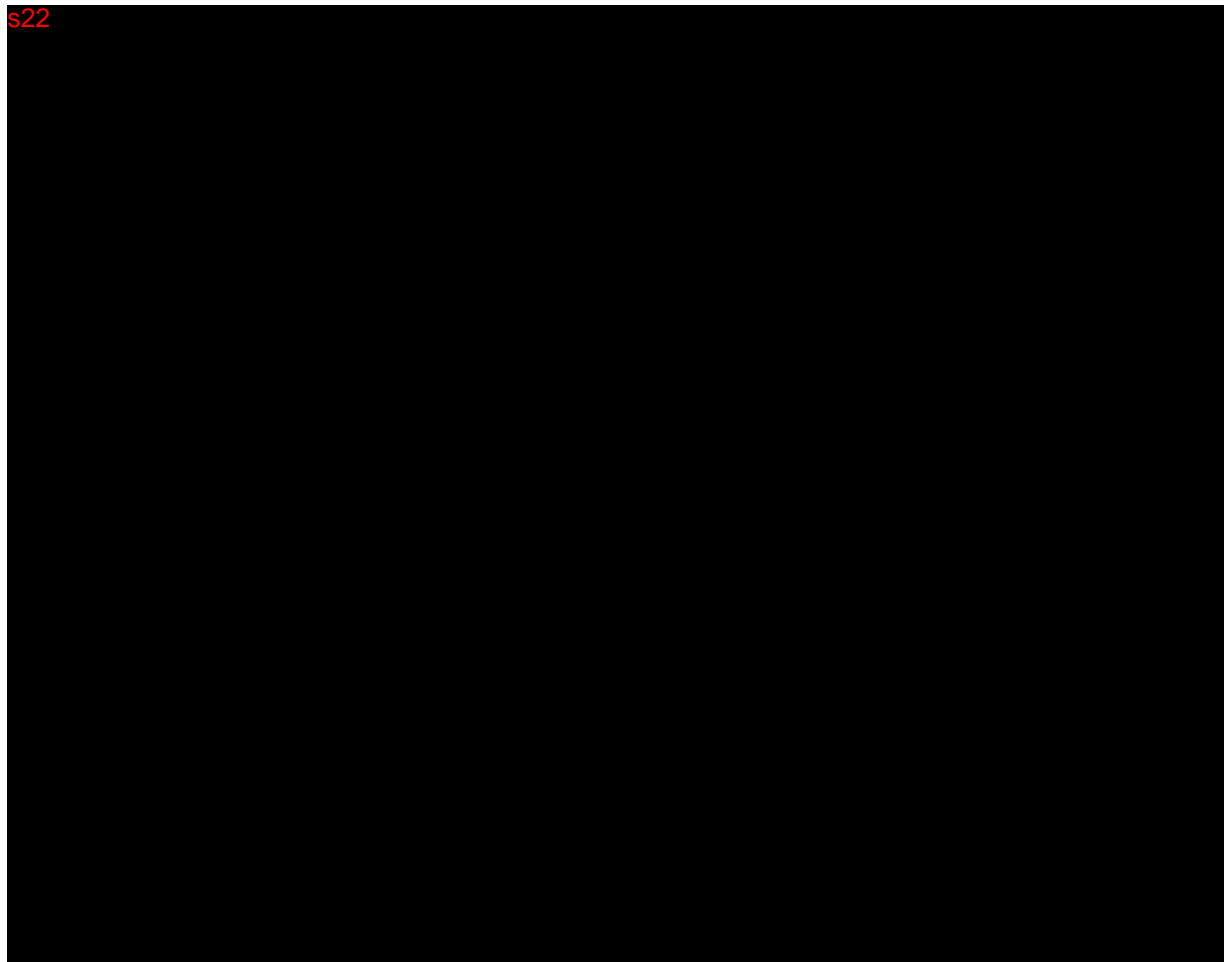
Sent: Wednesday, 31 January 2024 2:23 PM

To: s22, s22 <s22, s22@health.gov.au>
Cc: s22, s22@starpharma.com; s22 <s22, s22@starpharma.com>; DUFFY, Tracey <Tracey.Duffy@health.gov.au>; JAMIESON, John <John.JAMIESON@Health.gov.au>; SINGER, Simon <simon.singer@health.gov.au>; s22, s22 <s22, s22@Health.gov.au>;

Subject: EMAIL 2 of 2: Starpharma application (Submission ID: DV-2021-DA-06231-1) for SPL7013 Nasal Spray

Dear s22

Please find in this email the further documents referred to in EMAIL 1 of 2, sent prior to this one.





Australian Government
Department of Health
 Therapeutic Goods Administration

Medical Devices Program

Internal Form

DAS FORM 6.2.a	Medical Device Application Audit Request and Report - Clinical		
Comes under	DAS WI 6.2 Requesting an assessment for an Application Audit		
Applicable to	Devices Applications Section Devices Clinical Section	Authorised by	s22 [REDACTED] DAS
Date issued	13 January 2021	Version #	1.0

Application audit details

This section completed by **DAS Assessor**

Date of request	1/02/2024		
Submission ID	DA-2021-06851-1		
Application ID	DV-2021-DA-06231-1		
Sponsor name	Starpharma Pty Ltd		
Manufacturer name	Starpharma Pty Ltd (Australia)[41979]		
Application audit type	Non-mandatory audit If mandatory, choose prescribed device type		
Reason for clinical review	To request for your advice as to whether the applicant has sufficient information to substantiate the compliance with the essential principles, in particular, EP 1, 3, 6 and 14.		
Documents provided	<input type="checkbox"/> IFU and labels		TRIM reference
	<input type="checkbox"/> For implantable devices (unless excluded*), PIL		TRIM reference

Record Details	D24-413419 Application audit assessment request and report - Clinical (DCS) - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal ~ Starpharma Pty Ltd(2).DOCX	Effective Date	13/01/2021
Print Date	30/05/2024 3:25		Page 1 of 11

Once printed or copied from the Master, this is no longer a controlled document; check validity before use

For urogynaecological mesh devices, PIC TRIM reference

Advertising material TRIM reference

Clinical evaluation report (CER), signed and dated ≤ 2 years Lit review and data appraisal also in [D24-400580](#)
[D24-400591](#)

CV of clinical expert [D24-400580](#)
[D24-400591](#)

Risk management report, including FMEA [D24-400591](#)

For implantable devices, MRI safety evidence TRIM reference

The application was first made by the applicant in July 2021.

s47G



There were multiple correspondence with the applicant since then, with the previous data submissions in [D22-5643748](#) and [D23-5034027](#).

No IFU/label was provided on 31 Jan 2024, the newly proposed intended purpose is available in the updated CER.

Request comments

Submission TRIM reference

[D24-400580](#)

[D24-400591](#)

Additional data submitted ([D24-901234](#)): updated IFU

Additional data submitted ([D24-1381489](#)):

- Response to TGA
- Clinical Investigation Report
- Clinical Investigation Report - Annexes

* Excluded devices are sutures, staples, dental filings, dental braces, tooth crowns, general (endosseous) dental implants, screws, wedges, plates, wires, pins, clips, connectors

Application background

Conformity assessment documents accompanying application

These conformity assessment documents are linked to the application as Manufacturer Evidence or attached to the device application form. They were considered satisfactory in relation to the application passing preliminary assessment.

DAS to complete. If there are multiple QMS or product assessment documents, add and complete the relevant table for each document.

Comment: The application is for a Class I medical device, which relies on the manufacturer's self-declaration. The manufacturer's declaration made under clause 6.6 of Schedule 3 of the Therapeutic Goods (Medical Devices) Regulations 2002 has been provided ([D21-2936021](#)).

No evidence of approval by overseas regulators has been provided or found available.

Device description

Information from eBS device application form

DAS to complete for class other than Class III/AIMD, delete if not applicable. If there are multiple applications in the submission, add and complete a table for each application.

Device name

SPL7013 Nasal Spray

s47

Intended purpose

Record Details	D24-413419 Application audit assessment request and report - Clinical (DCS) - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal ~ Starpharma Pty Ltd(2).DOCX	Effective Date	13/01/2021
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	s47
Device classification	Choose a classification Class I
GMDN code and term	Nasal moisture barrier dressing[47679]
Comments	<i>Provide comments if the details in the device application form do not appropriately cover the device(s) for which information has been provided for the application audit.</i>

Information provided for the application audit – labels, IFU, advertising, CER etc.

Clinical Reviewer to complete. If there are multiple applications or devices in the submission, add and complete a table for each application or device.

Choose an item.	<i>As represented on labels, IFU, PIL etc.</i>
Device description	<p><i>Describe the device and intended purpose, including:</i></p> <ul style="list-style-type: none"> •<i>The intended patient population and medical conditions to be diagnosed, treated and/or monitored.</i> •<i>A general description of the key functional elements: its parts/components (including software if appropriate), its formulation, its composition, its functionality and, where relevant, its qualitative and quantitative composition.</i> •<i>The principles of operation of the device and its mode of action; explanation of any novel features.</i>
Device configurations & variants	<p><i>Include the manufacturer’s description of the sizes, differences in design features, different configurations etc.</i></p> <p><i>Include an image of the device where possible.</i></p> <p><i>Where relevant, include the manufacturer’s description of the reason for differences in variants with illustrative images where possible.</i></p>
System or procedure pack	<p><i>Include component devices in case of system/procedure pack, otherwise state “none”.</i></p> <p><i>e.g. pacemaker and leads, or component of a joint replacement system.</i></p>
Accessories or compatible devices	<i>Describe any accessories or compatible devices if any, or state “none”.</i>

Comments

If the use of accessories or compatible devices has an impact on clinical safety or performance or the scope or validity of the clinical evaluation, identify this here.

If it is necessary to understand the usage of the device, include images or other relevant information such as diagrams.

Provide comments if the details in the device application form (as specified above under Information from device application form) do not appropriately reflect/cover the information provided for the application audit.

Note: **Unique product identifier (UPI)** is only relevant for Class III/AIMD devices as it forms part of the “kind of medical device” by which these devices are entered in the ARTG. The UPI is given to the device by its manufacturer to identify the device and any variants. **Device name** is relevant to devices other than Class III/AIMD. For non-Class III/AIMD devices, the name of the device does not form part of the “kind of medical device” and is not recorded in the ARTG entry.

Clinical review documentation

Clinical evidence report (CER)

Document identification & date

Document id, revision number and number of pages

Competency of CER author

Comment on competency of the clinical data evaluator(s) with respect to the subject device and their relevant clinical qualifications and clinical experience as documented in the CV

Clinical standards or solutions applied

List any clinical standard or solution applied by the manufacturer.

Are the UPI/device name, any variants and intended purpose in the CER consistent with information provided with the device (IFU, labels etc)?

Yes No

Comments:

Does the CER include an evaluation of the clinical data?

Yes No

Comments:

Record Details	D24-413419 Application audit assessment request and report - Clinical (DCS) - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal ~ Starpharma Pty Ltd(2).DOCX	Effective Date	13/01/2021
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Substantial equivalence claim

Yes No

Comparator device:

Enter device name, and manufacturer if different

Comparator type

Predicate device Similar marketed device

Comments:

Has evidence to demonstrate substantial equivalence of the comparator to the subject device been provided?

Yes No

Comments:

Comparator device's regulatory history in Australia

Choose an item.

Date of ARTG inclusion: Click or tap to enter a date.

Comments:

Details of any significant post-market actions/issues, including removal/suspension from ARTG, suspension or revocation of TGA CA certificate, and recalls/DIRs/PMRs

Clinical investigations

Yes No

Clinical trial/study protocol, results and analysis provided?

Yes No

Comments:

Pre-market or post-market clinical investigations for subject device?

Pre-market Post-market Nil

Device Predicate Nil

Randomised controlled trial

Comments: *Comment on whether pre- or post-market study, number of patients, duration of study, primary outcome measure*

Device Predicate Nil

Single-arm trial

Comments: *Comment on whether pre- or post-market study, number of patients, duration of study, primary outcome measure*

Device Predicate Nil

Other

Comments: *Comment on whether pre- or post-market study, number of patients, duration of study, primary outcome measure*

Literature review

Yes No

Literature review including search protocol & search results provided?

Yes No

Literature review scope

Device Predicate Similar marketed

Comments

Document number of articles included in literature review

Other clinical experience, including post-market data

Yes No

World-wide distribution (sales) numbers for device provided?

Yes No

Comments:

Clinical experience data provided?

Yes No

Adverse events with complaint rates

Device Predicate Nil

Public adverse event databases

Device Predicate Similar marketed Nil

Recalls (or actions such as market withdrawals, field corrections, safety alerts)

Device Predicate Similar marketed Nil

Corrective and preventative actions (CAPAs)

Device Predicate Nil

Registry data

Device Predicate Similar marketed Nil

Other

Device Predicate Similar marketed Nil

Type of data:

Comments

Comment if relevant data has not been provided

Risk management

Document identification & date

Risk management report:

Risk matrices/FMEA:

Are the report and risk matrices/FMEA relevant to the device and its use

Yes No

Comments

Comment if relevant information has not been provided

Safety in Magnetic Resonance (MR) environment

Active implant Passive implant Not implantable

MR safety labelling claim

Choose an item.

If MR Conditional, specified conditions of use:

State conditions of use as per labelling.

Description of evidence provided

Comments

Comment if claims in any information provided with the device (e.g. IFU, labels, user manual, brochure, PIL) is not consistent or differs from that in MR safety evidence, CER etc. Comment if any significant issues with evidence identified.

Conclusions and recommendations

Reviewer’s conclusion and recommendation

Include concluding remarks necessary to support the recommendation.

Following a review of the information provided for this application audit in relation to the *UPI/Device Name*, it is recommended that the sponsor be requested to provide the following:

- 1.
- 2.
- 3.

OR

Based on the review of a previous clinical assessment undertaken by the TGA for *relevant application/UPI/Device Name* and the supporting information provided for this application audit, further clinical review of *UPI/Device Name* is not required, for the following reasons:

-

OR

Record Details	D24-413419 Application audit assessment request and report - Clinical (DCS) - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal ~ Starpharma Pty Ltd(2).DOCX	Effective Date	13/01/2021
Print Date	30/05/2024 3:25		Page 8 of 11

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Sufficient information has been provided for clinical assessment of the *UPI/Device Name* to proceed.

Based on the review of previous clinical assessment undertaken by the TGA for *relevant application/UPI/Device Name* and the supporting information provided for this application audit, it is recommended that further clinical review of *UPI/Device Name* be focused on the following:

-

OR

- Sufficient information has been provided for clinical assessment of the *UPI/Device Name* to proceed.

OR

Based on the review of *information held by the TGA* and the supporting information provided for this application audit, it is recommended that further clinical review of the *UPI/Device Name* be focused on the following:

-

Sign-Off – Clinical Section Reviewer

Name			
Signature	Signed electronically in TRIM	Date	Click or tap to enter a date.

Senior Medical Advisor's comments

Sign-Off – Senior Medical Advisor

Name			
Signature	Signed electronically in TRIM	Date	Click or tap to enter a date.

Record Details	D24-413419 Application audit assessment request and report - Clinical (DCS) - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal ~ Starpharma Pty Ltd(2).DOCX	Effective Date	13/01/2021
Print Date	30/05/2024 3:25		Page 9 of 11
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Clinical review Round 2

Information provided in response to questions from previous round of review

To be completed by DAS: document title and TRIM reference

Comments

Reviewer's conclusion and recommendation

Include concluding remarks necessary to support the recommendation.

Following a review of the information provided for this application audit in relation to the *UPI/Device Name*, it is recommended that the sponsor be requested to provide the following:

1.

OR

Based on the review of a previous clinical assessment undertaken by the TGA for *relevant application/UPI/Device Name* and the supporting information provided for this application audit, clinical assessment of *UPI/Device Name* is not required, for the following reasons:

-

OR

Sufficient information has been provided for clinical assessment of *UPI/Device Name* to proceed.

Based on the review of previous clinical assessment undertaken by the TGA for *relevant application/UPI/Device Name* and the supporting information provided for this application audit, it is recommended that the clinical assessment of *UPI/Device Name* be focused on the following:

-

OR

- Sufficient information has been provided for clinical assessment of *UPI/Device Name* to proceed.

OR

Based on the review of *information held by the TGA* and the supporting information provided for this application audit, it is recommended that the clinical assessment of *UPI/Device Name* be focused on the following:

Record Details	D24-413419 Application audit assessment request and report - Clinical (DCS) - DV-2021-DA-06231-1 - DA-2021-06851-1 - Nasal ~ Starpharma Pty Ltd(2).DOCX	Effective Date	13/01/2021
Print Date	30/05/2024 3:25		Page 10 of 11
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•

Sign-Off – Clinical Section Reviewer

Name			
Signature	Signed electronically in TRIM	Date	Click or tap to enter a date.

Senior Medical Advisor’s comments

Sign-Off – Senior Medical Advisor

Name			
Signature	Signed electronically in TRIM	Date	Click or tap to enter a date.

Version history

Version	TRIM Reference	Description of change	Author/s	Effective date
V1.0	D20-3667495	New FORM	s22	13 Jan 2021

From: s22
To: s22
Cc: s22 @starpharma.com; s22; JAMIESON, John; DUFFY, Tracey; SINGER, Simon; s22.
s22; s22
Subject: RE: Starpharma application (Submission ID: DV-2021-DA-06231-1) for SPL7013 Nasal Spray [SEC=OFFICIAL]
Date: Friday, 8 March 2024 3:58:05 PM
Attachments: [image003.png](#)
[image006.png](#)
[image007.png](#)
[image008.png](#)
[image009.png](#)

Dear s22,

Thank you and your clients for your time earlier.

We appreciate your interest in receiving preliminary feedback on the clinical data and the revised intended purpose.

Clinical data

The clinical trial SPL7013-022 (ISRCTN70449927) seems to relate directly to the revised intended purpose. The data submitted on the clinical trial is not complete and in order for recommendations to be made that are based on that data, more information is needed including: the full clinical investigation report, statistical analysis plan and the study protocol. I anticipate the clinical investigation report you plan to provide to us will contain the full write up of the clinical study and be final *i.e.* signed and dated.

The primary concern identified with the clinical data is that the study did not meet its primary endpoint. You presented further post-hoc analyses which indicated a potential benefit in a sub-group of the study population. As you acknowledged, this is not a usual approach for drawing robust conclusions from clinical trial findings. While we do not propose to dismiss this approach off-hand, we require more detail (as can be expected to be contained in the above documents) to be convinced of its validity and merits. I additionally expect to see a sound scientific rationale that is supportive of any findings of age-related effect.

Revised Intended Purpose

Although the revised intended purpose is related to outcomes studied in SPL7013-022, the correlation between the claimed reduction in viral load and therapeutic benefit should be addressed. This should be discussed in your further submission.

I understand that the report is on track to be available by the end of March but you expect delays in obtaining signatures given the Easter break. I confirm my preference to receive the final, signed and dated version of the full clinical investigation. If you have an updated expected availability date for the report, please let me know. Otherwise, I will follow up with you by 31 March 2024.

Kind Regards,

s22

s22

Devices Application & Triage Section | Medical Devices Authorisation Branch
Australian Government, Department of Health and Aged Care
Therapeutic Goods Administration

27 Scherger Drive, Fairbairn ACT 2609, Australia
Phone: 1800 141 144

PO Box 100, Woden ACT 2606

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From: s22 <s22>
Sent: Thursday, March 7, 2024 12:35 PM
To: JAMIESON, John <John.JAMIESON@Health.gov.au>; s22
s22@health.gov.au
Cc: s22@starpharma.com; s22 <s22 s22@starpharma.com>; DUFFY, Tracey <Tracey.Duffy@health.gov.au>; SINGER, Simon <simon.singer@health.gov.au>; s22, s22 s22@Health.gov.au; s22 s22@starpharma.com
Subject: Re: Starpharma application (Submission ID: DV-2021-DA-06231-1) for SPL7013 Nasal Spray [SEC=OFFICIAL]

Understood John. Let's go ahead with tomorrow as is.

Thanks for getting back to me so promptly.

Kind regards

s22

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From: JAMIESON, John <John.JAMIESON@Health.gov.au>
Sent: Thursday, March 7, 2024 12:29:46 PM
To: s22 <s22 s22@health.gov.au>
Cc: s22@starpharma.com s22@starpharma.com; s22 s22@starpharma.com; DUFFY, Tracey <Tracey.Duffy@health.gov.au>; SINGER, Simon <simon.singer@health.gov.au>; s22@Health.gov.au; s22@starpharma.com
Subject: RE: Starpharma application (Submission ID: DV-2021-DA-06231-1) for SPL7013 Nasal Spray [SEC=OFFICIAL]

Hi s22

Unfortunately Tracey Duffy is unavailable for this meeting as she is travelling internationally, and she has asked me to chair the meeting from the TGA side. We would prefer to proceed with the meeting as planned, given that this will likely be a largely technical discussion about the proposed intended purpose and the clinical data, but please let us know if you would rather not proceed with tomorrow's meeting.

Regards
John

John Jamieson

Assistant Secretary, Medical Devices Authorisation Branch

Medical Devices and Product Quality Division

Australian Government, Department of Health and Aged Care

s22

From: s22 <s22 s22>
Sent: Thursday, March 7, 2024 12:03 PM
To: s22 @health.gov.au>
Cc: JAMIESON, John <John.JAMIESON@Health.gov.au>; s22 @starpharma.com; s22 s22 @starpharma.com>; DUFFY, Tracey <Tracey.Duffy@health.gov.au>; SINGER, Simon <simon.singer@health.gov.au>; s22 s22 @Health.gov.au>; s22 @starpharma.com>
Subject: RE: Starpharma application (Submission ID: DV-2021-DA-06231-1) for SPL7013 Nasal Spray [SEC=OFFICIAL]

Dear s22

I confirm that the attendees for the scheduled conference call tomorrow are myself and s22 s22 (s22), s22, s22 and s22 s22 (s22, Quality and Regulatory) from Starpharma.

I also note that Ms Duffy was not included in the meeting invitation, and would like to confirm whether she will be attending, as her insight and guidance has been invaluable in previous meetings we have had. If Ms Duffy is unavailable for the meeting tomorrow, my client would be happy to postpone it and work around her availability to attend as well.

I would be grateful if you could get back to me today on the issue of Ms Duffy's availability.

Many thanks and kind regards

s22

s22

s22

From: s22 <s22 s22>
Sent: Thursday, 29 February 2024 6:02 PM
To: s22 @health.gov.au>
Cc: JAMIESON, John <John.JAMIESON@Health.gov.au>; s22 @starpharma.com; s22 @starpharma.com>; DUFFY, Tracey <Tracey.Duffy@health.gov.au>; SINGER, Simon <simon.singer@health.gov.au>; s22 @Health.gov.au>
Subject: Re: Starpharma application (Submission ID: DV-2021-DA-06231-1) for SPL7013 Nasal Spray [SEC=OFFICIAL]

Dear s22

My client has confirmed their availability on either 7 or 8 March at 12-1 pm.

Kind regards

s22

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From: s22 @health.gov.au>
Sent: Wednesday, February 28, 2024 2:03 pm
To: s22 <s22 s22>
Cc: JAMIESON, John <John.JAMIESON@Health.gov.au>; s22 @starpharma.com @starpharma.com>; s22 @starpharma.com>; DUFFY, Tracey <Tracey.Duffy@health.gov.au>; SINGER, Simon <simon.singer@health.gov.au>; s22 ,

s22 [REDACTED]@Health.gov.au>

Subject: RE: Starpharma application (Submission ID: DV-2021-DA-06231-1) for SPL7013 Nasal Spray [SEC=OFFICIAL]

Dear s22 [REDACTED],

Thank you for your email and the updated IFU.

Thank you for providing the expected availability date of the final clinical investigation report. As mentioned, the clinical investigation report is crucial for a thorough assessment of the submission. Please provide the report for further review by 31 March 2024.

We appreciate your interest in receiving preliminary feedback on the additional clinical data and proposed modified intended purpose. We would be happy to arrange a meeting with you to discuss this further.

Here are a few potential time slots for the meeting:

7 or 8 March 2024: 12-1pm

19, 21 or 22 March 2024: 1-2 pm

Please let me know which time slot works best for you, and I will arrange the meeting accordingly.

Thank you.

Kind Regards,

s22 [REDACTED]
[REDACTED]

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From: s22 <s22 s22>
Sent: Tuesday, February 13, 2024 5:52 PM
To: s22 @health.gov.au>
Cc: JAMIESON, John <John.JAMIESON@Health.gov.au>; s22 @starpharma.com; s22 s22 @starpharma.com>; DUFFY, Tracey <Tracey.Duffy@health.gov.au>; SINGER, Simon <simon.singer@health.gov.au>; s22 s22 @Health.gov.au>
Subject: RE: Starpharma application (Submission ID: DV-2021-DA-06231-1) for SPL7013 Nasal Spray [SEC=OFFICIAL]

Dear s22

As requested, please find a copy of our client's updated IFU, which includes the modified intended purpose proposed in our client's response and our cover letter.

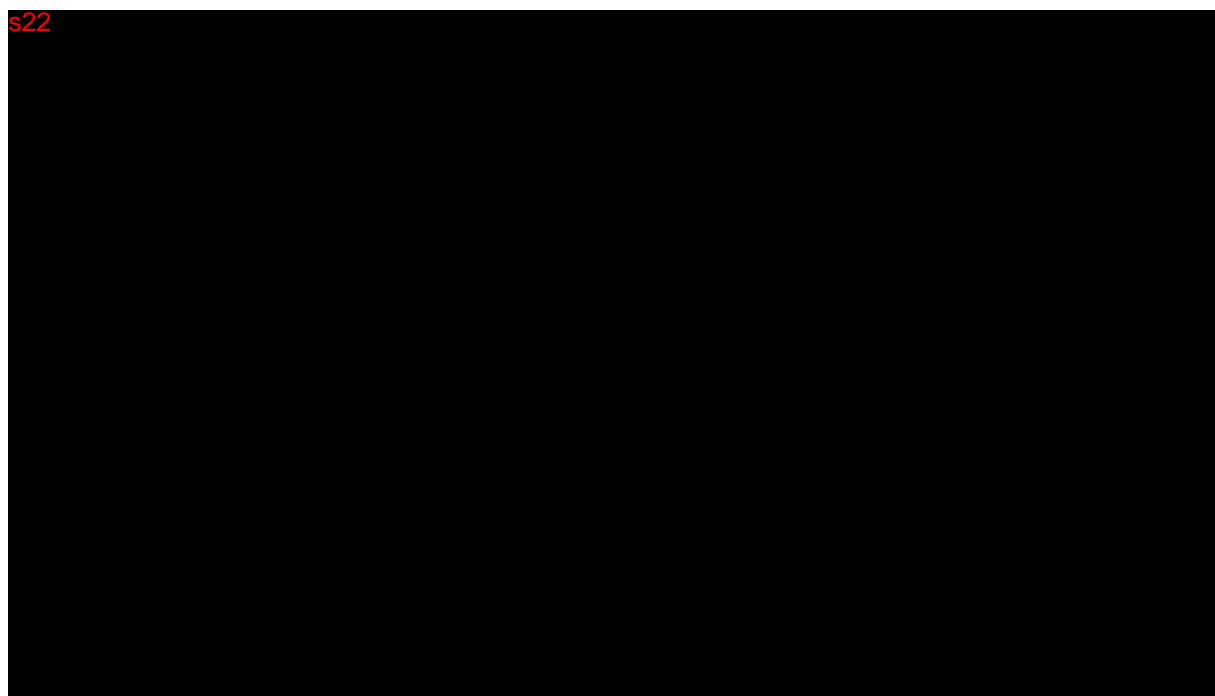
In relation to the clinical investigation report, we are instructed that the final investigation report is expected to be available by 31 March 2024. Our client is, of course, more than happy to submit the final investigation report to the TGA for review at that time, but was hoping to get the TGA's preliminary feedback beforehand on the additional clinical data submitted and the proposed modified intended purpose.

We look forward to hearing from you further.

Yours sincerely

s22

s22



s22



From: s22

Sent: Friday, 9 February 2024 5:49 PM

To: s22@health.gov.au>

Cc: JAMIESON, John <John.JAMIESON@Health.gov.au>; s22@starpharma.com; s22

s22@starpharma.com>; DUFFY, Tracey <Tracey.Duffy@health.gov.au>;

SINGER, Simon <simon.singer@health.gov.au>; s22

s22@Health.gov.au>

Subject: RE: Starpharma application (Submission ID: DV-2021-DA-06231-1) for SPL7013 Nasal Spray [SEC=OFFICIAL]

Dear s22

Thank you for your email. I have sought instructions from my client and will revert on Monday, after my client has consulted the relevant stakeholders.

Kind regards

s22



s22



s22

From: s22 [redacted] <[redacted]@health.gov.au>
Sent: Friday, 9 February 2024 1:06 PM
To: s22 [redacted] <[redacted] s22 [redacted]>
Cc: JAMIESON, John <John.JAMIESON@Health.gov.au>; s22 [redacted] <[redacted]@starpharma.com>; s22 [redacted] <[redacted]@starpharma.com>; DUFFY, Tracey <Tracey.Duffy@health.gov.au>; SINGER, Simon <simon.singer@health.gov.au>; s22 [redacted] <[redacted]@Health.gov.au>
Subject: RE: Starpharma application (Submission ID: DV-2021-DA-06231-1) for SPL7013 Nasal Spray [SEC=OFFICIAL]

Dear s22 [redacted],

Following our preliminary review of your submission dated 31 Jan 2024, it has come to our attention that the submission lacks key information which is necessary to interpret the clinical study results. I understand from your response letter that you'll provide the full Clinical Investigation Report (**CIR**) as soon as possible. Can you please inform us of the expected timeline for submitting the full CIR? The full report is crucial for a thorough assessment of the submission.

In addition, you've proposed a new intended purpose. Can you please clarify if you are intending to update the IFU to be consistent with the new proposed intended purpose and if you are able to provide the updated IFU for review?

Please let me know if you have questions. I look forward to your response.

Kind Regards,

s22 [redacted]

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delete all copies of this transmission.

From: s22 <s22 s22>
Sent: Monday, February 5, 2024 4:57 PM
To: s22 @health.gov.au
Cc: JAMIESON, John <John.JAMIESON@Health.gov.au>; s22 @starpharma.com; s22 s22 @starpharma.com; DUFFY, Tracey <Tracey.Duffy@health.gov.au>; SINGER, Simon <simon.singer@health.gov.au>; s22 s22 @Health.gov.au
Subject: RE: EMAIL 1 of 2: Starpharma application (Submission ID: DV-2021-DA-06231-1) for SPL7013 Nasal Spray [SEC=OFFICIAL]

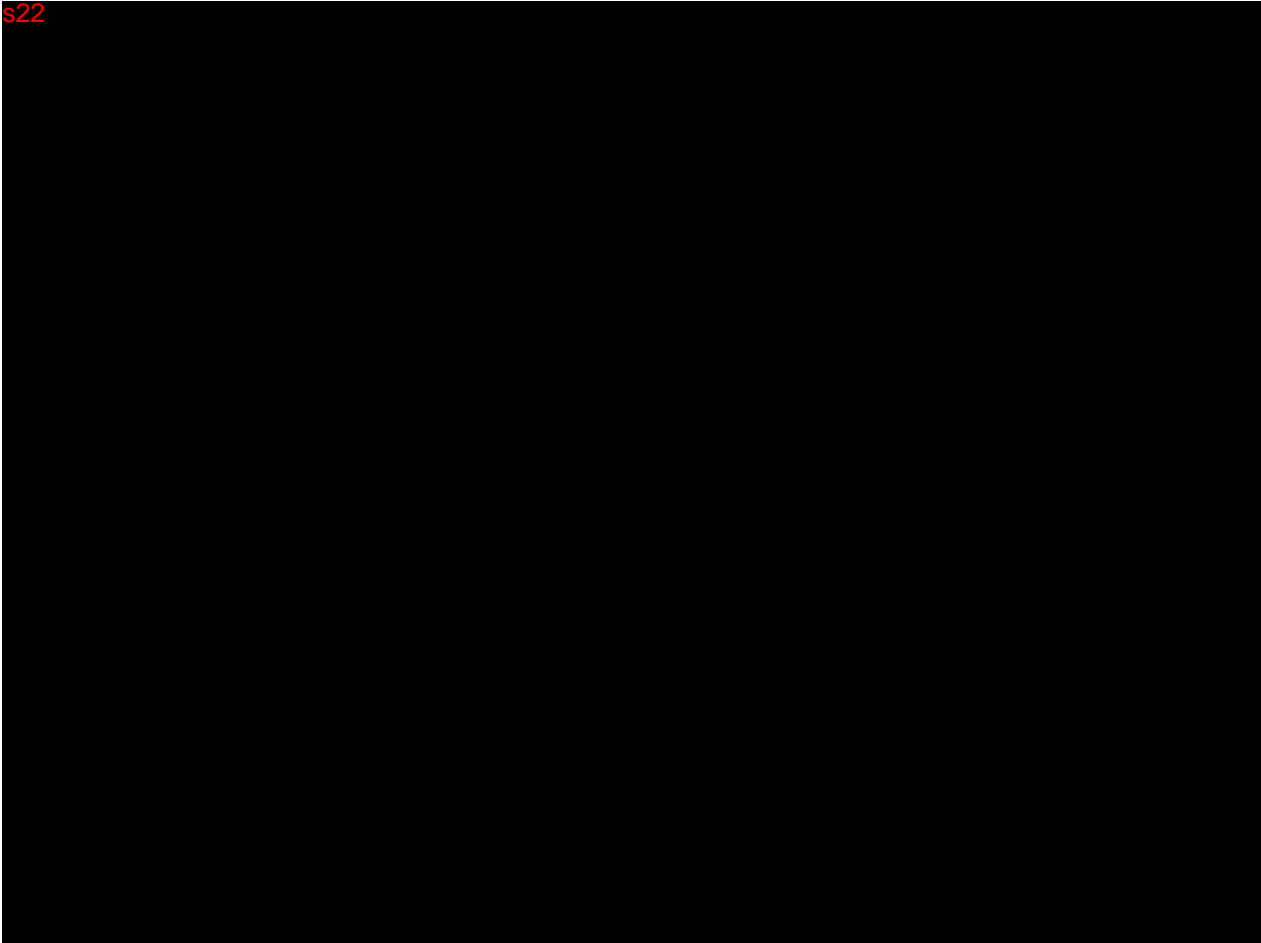
Dear s22

Many thanks for the confirmation.

Kind regards

s22

s22



From: s22 [REDACTED] <[REDACTED]@health.gov.au>
Sent: Monday, 5 February 2024 4:19 PM
To: s22 [REDACTED] <[REDACTED] s22 [REDACTED]>
Cc: JAMIESON, John <John.JAMIESON@Health.gov.au>; s22 [REDACTED] <[REDACTED]@starpharma.com>; s22 [REDACTED] <[REDACTED]@starpharma.com>; DUFFY, Tracey <Tracey.Duffy@health.gov.au>; SINGER, Simon <simon.singer@health.gov.au>; s22 [REDACTED] <[REDACTED]@Health.gov.au>
Subject: RE: EMAIL 1 of 2: Starpharma application (Submission ID: DV-2021-DA-06231-1) for SPL7013 Nasal Spray [SEC=OFFICIAL]

Dear s22 [REDACTED],

I'll be in touch to discuss the application before making a decision and after the clinical evaluation is done.

Kind Regards,
s22 [REDACTED]

From: s22 [REDACTED] <[REDACTED] s22 [REDACTED]>
Sent: Monday, February 5, 2024 9:08 AM
To: s22 [REDACTED], s22 [REDACTED] <[REDACTED] s22 [REDACTED]@health.gov.au>
Cc: JAMIESON, John <John.JAMIESON@Health.gov.au>; s22 [REDACTED] <[REDACTED]@starpharma.com>; s22 [REDACTED] <[REDACTED] s22 [REDACTED]@starpharma.com>; DUFFY, Tracey <Tracey.Duffy@health.gov.au>; SINGER, Simon <simon.singer@health.gov.au>; s22 [REDACTED], s22 [REDACTED] <[REDACTED] s22 [REDACTED]@Health.gov.au>
Subject: RE: EMAIL 1 of 2: Starpharma application (Submission ID: DV-2021-DA-06231-1) for SPL7013 Nasal Spray [SEC=OFFICIAL]

Dear s22 [REDACTED]

Thank you for confirming receipt of our emails and the documents attached therein.

For the avoidance of doubt, I would be grateful if you could also confirm that a decision will not be made regarding the Application until we have had the opportunity to obtain your (and other TGA stakeholders') feedback about the additional data our client has submitted. I apologise if I am being overly cautious, but my request for confirmation is in the context of the statement in your email of 17 November 2023, in which you stated that, following our client's response, you would decide whether or not the application ought to be refused and would "proceed with a decision promptly with no further meetings or involvements".

I just wanted to make sure that you would afford our client the opportunity to discuss the outcome of the clinical assessment with the TGA, and the TGA's proposed decision having regard to the additional clinical evidence and the (revised) proposed intended purpose.

I look forward to your confirmation.

Kind regards

s22

s22

From: s22, s22 <s22, s22@health.gov.au>
Sent: Thursday, 1 February 2024 11:24 AM
To: s22 <s22, s22>
Cc: JAMIESON, John <John.JAMIESON@Health.gov.au>; s22, s22@starpharma.com; s22
s22 <s22, s22@starpharma.com>; DUFFY, Tracey <Tracey.Duffy@health.gov.au>;
SINGER, Simon <simon.singer@health.gov.au>; s22, s22
<s22, s22@Health.gov.au>
Subject: RE: EMAIL 1 of 2: Starpharma application (Submission ID: DV-2021-DA-06231-1) for
SPL7013 Nasal Spray [SEC=OFFICIAL]

Dear s22,

Thank you for your email.

This is to confirm the receipt of your two emails containing the attachments outlined in your email below.

We'll contact you if we have any questions or require further information. Otherwise, we'll be in contact once the clinical assessor has completed the assessment.

Kind Regards,

s22

Devices Application & Triage Section | Medical Devices Authorisation Branch

Australian Government, Department of Health and Aged Care

Therapeutic Goods Administration

27 Scherger Drive, Fairbairn ACT 2609, Australia

Phone: 1800 141 144

PO Box 100, Woden ACT 2606

www.tga.gov.au

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From: JAMIESON, John <John.JAMIESON@Health.gov.au>

Sent: Wednesday, January 31, 2024 4:16 PM

To: s22 <s22 s22 s22, s22 s22 s22 @health.gov.au>

Cc: s22 s22 @starpharma.com; s22 s22 s22 @starpharma.com; DUFFY, Tracey <Tracey.Duffy@health.gov.au>; SINGER, Simon <simon.singer@health.gov.au>; s22 s22 s22 @Health.gov.au

Subject: RE: EMAIL 1 of 2: Starpharma application (Submission ID: DV-2021-DA-06231-1) for SPL7013 Nasal Spray [SEC=OFFICIAL]

Dear s22

This is to acknowledge receipt of your email and to let you know that s22 is out of the office today.

s22 is due back at work tomorrow and will then be able to send you a more detailed confirmation of receipt of all the relevant emails and attachments.

Regards

John

John Jamieson*Assistant Secretary, Medical Devices Authorisation Branch*

Medical Devices and Product Quality Division

Australian Government, Department of Health and Aged Care

s22

From: s22 <s22 s22>
Sent: Wednesday, January 31, 2024 2:23 PM
To: s22, s22 <s22, s22@health.gov.au>
Cc: s22, s22@starpharma.com; s22 <s22, s22@starpharma.com>; DUFFY, Tracey <Tracey.Duffy@health.gov.au>; JAMIESON, John <John.JAMIESON@Health.gov.au>; SINGER, Simon <simon.singer@health.gov.au>; s22, s22 <s22, s22@Health.gov.au>
Subject: EMAIL 1 of 2: Starpharma application (Submission ID: DV-2021-DA-06231-1) for SPL7013 Nasal Spray

Dear s22

Further to your email dated 17 November 2023, please find – in TWO separate emails – the following additional information, which responds to the concerns raised by the TGA following its assessment of the data submitted in support of Starpharma’s application for inclusion of its product, SPL7013 Nasal Spray, in the Australian Register of Therapeutic Goods (**ARTG**):

In this email (EMAIL 1):

1. Copy of s22 cover letter dated 31 January 2024;
2. Starpharma response document dated 29 January 2024, and the following attachments:
 - a. **Attachment 1:** Updated clinical evaluation report (CER-003A-02), including the following appendices:

CER-003A-02 – Appendix 1 – CV s22

CER-003A-02 – Appendix 2 – CV s22

In EMAIL 2:

CER-003A-02 – Appendix 3 – CV s22

CER-003A-02 – Appendix 4 – Initial Literature Search Output

CER-003A-02 – Appendix 5 – Data Appraisal

CER-003A-02 – Appendix 6 – Subsequent Literature Search Output

- b. **Attachment 2:** DRA-4_Risk Management Plan & Risk Analysis - SPL7013 Nasal Spary_v3.0 and DRA-4_v3.0_1_DRA-4 v3.0 - Risk Matrix - SPL7013 Nasal Spray
- c. **Attachment 3:** DRR-5_Risk Management Report – SPL7013 Nasal Spray_v3.0

I would be grateful if you could confirm receipt of both emails and all documents listed above.

We look forward to hearing from you in due course.

Yours sincerely

s22

s22

From: s22
Sent: Monday, 20 November 2023 10:28 AM
To: s22, s22 <s22, s22@health.gov.au>
Cc: s22 <s22, s22@starpharma.com>; s22, s22@starpharma.com; s22, s22 <s22, s22@starpharma.com>; DUFFY, Tracey <Tracey.Duffy@health.gov.au>; JAMIESON, John <John.JAMIESON@Health.gov.au>; SINGER, Simon <simon.singer@health.gov.au>; s22, s22 <s22, s22@Health.gov.au>
Subject: RE: Starpharma application (Submission ID: DV-2021-DA-06231-1) for the SPL7013 barrier nasal spray [SEC=OFFICIAL]

Dear s22

Thank you for your email below and for accommodating the additional time. It is greatly appreciated by my client.

Kind regards

s22

s22

From: s22, s22 <s22, s22@health.gov.au>
Sent: Friday, 17 November 2023 10:08 AM
To: s22 <s22, s22>
Cc: s22 <s22, s22@starpharma.com>; s22, s22@starpharma.com; s22
s22 <s22, s22@starpharma.com>; DUFFY, Tracey <Tracey.Duffy@health.gov.au>;
JAMIESON, John <John.JAMIESON@Health.gov.au>; SINGER, Simon
<simon.singer@health.gov.au>; s22, s22 <s22, s22@Health.gov.au>
Subject: RE: Starpharma application (Submission ID: DV-2021-DA-06231-1) for the SPL7013
barrier nasal spray [SEC=OFFICIAL]

Dear s22,

Thank you for your email below.

I have reviewed your request and will extend the deadline, originally specified in my email on 2
November 2023, until 31 January 2024.

I look forward to your response by then.

Kind Regards,

s22

Devices Application & Triage Section | Medical Devices Authorisation Branch
Australian Government, Department of Health and Aged Care
Therapeutic Goods Administration

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From: s22 <s22 s22>
Sent: Thursday, 16 November 2023 2:24 PM
To: s22, s22 <s22 s22@health.gov.au>
Cc: s22 <s22 s22@starpharma.com>; s22 s22@starpharma.com; s22 s22 <s22 s22@starpharma.com>; DUFFY, Tracey <Tracey.Duffy@health.gov.au>; JAMIESON, John <John.JAMIESON@Health.gov.au>; SINGER, Simon <simon.singer@health.gov.au>; s22, s22 <s22 s22@Health.gov.au>
Subject: RE: Starpharma application (Submission ID: DV-2021-DA-06231-1) for the SPL7013 barrier nasal spray [SEC=OFFICIAL]

Dear s22

Many thanks for your email. Our client anticipates that they will be in a position to submit information which addresses the TGA's perceived concerns regarding Essential Principles 1, 2, 3, 6 and 14 **by no later than 15 January 2024**. This information will include an updated risk management file and an updated clinical evaluation report (**CER**) which incorporates the results of the UK clinical study and assesses the clinical data in the context of the proposed (further modified) intended purpose. The updated CER will be based on the results of the clinical study and draft clinical study report, the final version of which Starpharma anticipates will be available for submission to the TGA **by no later than 31 January 2024**. If it would be preferable to the TGA, Starpharma could submit all the information, including the final clinical study report, at the same time, noting that this would mean that the submission date for that information would be by no later than 31 January 2024.

Please note that the above timeline takes into account the Christmas/New Year shutdown period, and the s22 offices shutting down for a full three weeks from 22 December 2023 until 12 January 2024 (reopening on 15 January 2024).

We hope that the proposed timelines are acceptable to the TGA, but would be happy to discuss

our email further with you if you see any issues.

We look forward to hearing from you.

Kind regards

s22

s22

From: s22, s22 <s22, s22@health.gov.au>
Sent: Tuesday, 14 November 2023 2:11 PM
To: s22 <s22, s22>
Cc: s22 <s22, s22@starpharma.com>; s22, s22@starpharma.com; s22, s22 <s22, s22@starpharma.com>; DUFFY, Tracey <Tracey.Duffy@health.gov.au>; JAMIESON, John <John.JAMIESON@Health.gov.au>; SINGER, Simon <simon.singer@health.gov.au>; s22, s22 <s22, s22@Health.gov.au>
Subject: RE: Starpharma application (Submission ID: DV-2021-DA-06231-1) for the SPL7013 barrier nasal spray [SEC=OFFICIAL]

Dear s22,

Thank you for your email.

Can you please specify the date by which you or your client expect to be ready to provide all the

information in support of the application?

Kind Regards,

s22

Devices Application & Triage Section | Medical Devices Authorisation Branch

Australian Government, Department of Health and Aged Care

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27 Scherger Drive, Fairbairn ACT 2609, Australia

Phone: 1800 141 144

PO Box 100, Woden ACT 2606

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From: s22 s22
Sent: Monday, 13 November 2023 5:15 PM
To: s22 @health.gov.au>
Cc: s22 @starpharma.com>; s22 @starpharma.com; s22
s22 @starpharma.com>; DUFFY, Tracey <Tracey.Duffy@health.gov.au>;
JAMIESON, John <John.JAMIESON@Health.gov.au>; SINGER, Simon
<simon.singer@health.gov.au>; s22 @Health.gov.au>
Subject: RE: Starpharma application (Submission ID: DV-2021-DA-06231-1) for the SPL7013
barrier nasal spray [SEC=OFFICIAL]
Importance: High

Dear s22

Thank you for your email below. We have now had the opportunity to have some further discussions with our client regarding your email. In the course of discussing the shorter timeframe that our client has been given in which to respond, we have been made aware that our client has just completed a clinical study involving SPL7013 Barrier Nasal Spray (**Product**). The study is a post-market, randomised, placebo-controlled, clinical follow-up study that has generated direct clinical data on the Product. While the final preparations for data analysis are ongoing, our client believes that the study will likely provide highly relevant data that they expect may address the TGA's perceived concern that safety and performance cannot be conclusively

established without direct clinical data.

As stated in our email dated 31 October 2023, our client had proposed to prepare and submit a consolidated response that takes into account the consolidated clinical assessor's report (**CCAR**) and previous evaluation reports. However, given that our client anticipates that preliminary clinical trial results regarding the above-referenced study will be available within the next few weeks, it would make absolute sense for the Application to be paused to allow our client to submit those data for the TGA's consideration. We are instructed, in this regard, to request that the Application be paused to permit our client to submit the preliminary clinical study data when they become available. Assuming the anticipated preliminary data are favourable, it would make sense for our client to then agree on a timeline with the TGA for submission of the final clinical study report, and further submissions about the Product's compliance with the Essential Principles having regard to the additional clinical study data. In this regard, we are instructed that favourable clinical study data will very likely address the TGA's perceived concerns regarding Essential Principles 1,3, 6 and 14. With respect to Essential Principle 2, which is broadly concerned with the risks from the use of a medical device, we are instructed that our client is currently revising the risk management file for the Product, and would appreciate your feedback on the most appropriate time to submit it. For example, proceeding on the basis that the TGA agrees to pause the Application so that the additional clinical study data can be submitted, we presume it would be acceptable to the TGA for our client to submit the risk management file at the same time as the clinical study data?

Separate to the above, having regard to your feedback on our client's revised intended purpose, our client intends to propose a further modified intended purpose which aligns more closely with the anticipated clinical study results and also takes into account your feedback. Our client proposes to submit this revised intended purpose at the same time as the preliminary clinical study data are submitted.

Given the long history of this Application (it now having been on foot for more than two years), we do not see that our client's request for a further short delay in the processing of the Application to allow it to submit the additional clinical study data would give rise to any prejudice to the TGA. In fact, it would be a far more efficient use of the TGA's and our client's resources to seek to resolve the issues by allowing the submission of the additional clinical study data which, if favourable, may ultimately satisfy the TGA that an approval is justified.

We look forward to your favourable consideration of our request. We would be happy to arrange a call with you to discuss the clinical study in more detail, should this be of assistance.

Kind regards

s22

s22

s22

From: s22, s22 <s22, s22@health.gov.au>
Sent: Thursday, 2 November 2023 5:14 PM
To: s22 <s22, s22>
Cc: s22 <s22, s22@starpharma.com>; s22, s22@starpharma.com; s22
s22 <s22, s22@starpharma.com>; DUFFY, Tracey <Tracey.Duffy@health.gov.au>;
JAMIESON, John <John.JAMIESON@Health.gov.au>; SINGER, Simon
<simon.singer@health.gov.au>; s22, s22 <s22, s22@Health.gov.au>; s22
s22 <s22, s22>
Subject: RE: Starpharma application (Submission ID: DV-2021-DA-06231-1) for the SPL7013
barrier nasal spray [SEC=OFFICIAL]

Dear s22,

Thank you for your email.

s47G

Regarding the potential revision of the intended purpose, it's important to highlight that any revised intended purpose must be substantiated by adequate clinical data to demonstrate compliance. As the Delegate, I am not at a position to advise whether it is appropriate for you to propose another intended purpose.

I have considered your request for additional time to provide a response, and can extend the deadline by three weeks as you've already been provided a considerable period since our last meeting. Therefore, the deadline for your response is **23 November 2023**.

I also confirm that following your client's response I will decide whether or not the application ought to be refused. Upon receiving your response, I will proceed with a decision promptly with

no further meetings or involvements.

I look forward to your response by the specified deadline.

Kind Regards,

s22
[Redacted]



Devices Application & Triage Section | Medical Devices Authorisation Branch
Australian Government, Department of Health and Aged Care
Therapeutic Goods Administration

27 Scherger Drive, Fairbairn ACT 2609, Australia

Phone: 1800 141 144

PO Box 100, Woden ACT 2606

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From: s22 <s22 s22>
Sent: Tuesday, 31 October 2023 6:07 PM
To: s22, s22 <s22 s22@health.gov.au>
Cc: s22 <s22 s22 @starpharma.com>; s22 s22 @starpharma.com; s22 s22 <s22 s22 @starpharma.com>; DUFFY, Tracey <Tracey.Duffy@health.gov.au>; JAMIESON, John <John.JAMIESON@Health.gov.au>; s22 s22, s22 <s22 s22 @health.gov.au>; SINGER, Simon <simon.singer@health.gov.au>; s22 s22, s22 <s22 s22 @Health.gov.au>; s22 s22 <s22 s22>
Subject: Starpharma application (Submission ID: DV-2021-DA-06231-1) for the SPL7013 barrier nasal spray [SEC=OFFICIAL]

Dear s22

Apologies for the delay in responding to your email below. Our client's leadership team was overseas when we received your email and we only had a chance to confer with them late last week to discuss the email and the attached combined clinical assessment report (**CCAR**).

Our client is mindful that its response to the CCAR will be the final opportunity to address the TGA's perceived concerns regarding our client's application (**Application**). We also understand that following our client's response, s47G

[Redacted]

We note that the previous concerns raised by our client regarding the TGA's evaluation of the Application have not been alleviated by your email, or by the issuing of the CCAR, which again highlights some fundamental misunderstandings which our client would like the opportunity to address. Further, given that the history of the Application spans more than 2 years (the Application having been filed in July 2021), our client would like the opportunity to prepare and submit a consolidated response which takes into account the CCAR and previous evaluation reports, and focuses on further submissions that address your reiterated contention that the Product does not comply with EPs 1, 2, 3, 6 and 14. Our client would like to also consider your feedback about the revised intended purpose for the Product (which we proposed at the TGA's suggestion) and whether it would be appropriate to propose another intended purpose, given your feedback.

Having regard to the history of this matter and the breadth of issues raised by the TGA and our client, we respectfully request another month to prepare a response, which we do not regard as a significant time period given the course of the Application and the volume of correspondence relating to it. We note, further, that there is no statutory impediment to the requested timeframe, and no apparent prejudice to the TGA by granting the additional time – other than the Application not being finalised during that period.

We look forward to your favourable response, and to working towards a final position with respect to the Application.

Kind regards

s22

s22

From: s22, s22 <s22, s22@health.gov.au>
Sent: Wednesday, 11 October 2023 6:15 PM
To: s22 <s22, s22>
Cc: s22 <s22, s22@starpharma.com>; s22, s22@starpharma.com; s22
s22 <s22, s22@starpharma.com>; DUFFY, Tracey <Tracey.Duffy@health.gov.au>;
JAMIESON, John <John.JAMIESON@Health.gov.au>; s22, s22
<s22, s22@health.gov.au>; SINGER, Simon <simon.singer@health.gov.au>; s22
<s22, s22>; s22, s22 <s22, s22@Health.gov.au>
Subject: RE: Starpharma application (Submission ID: DV-2021-DA-06231-1) for the SPL7013
barrier nasal spray [SEC=OFFICIAL]

Dear s22,

Hope the email finds you well.

I'm writing to follow up on our meeting that took place on 6 October 2023. During the discussion, we covered i) the TGA's view on your submission dated on 4 August 2023 to support your application for the SPL7013 barrier nasal spray and ii) the TGA's position on the application. I've summarized these points below:

TGA's view on your submission dated on 4 August 2023

On 4 August 2023, you've made a submission which includes the following:

- (1) a revised proposed intended purpose for the Product;
- (2) additional justification for the application of the term "well established technology" to the Product; and
- (3) responses to the concerns raised following the clinical review and biomaterial review in the TGA's letter dated 4 May 2023, including additional stability data.

The revised intended purpose states:

s47

s47

. Although the intended purpose has been modified, there is a lack of clinical evidence to substantiate that this will be achieved when used in humans.

In your submission, you proposed to demonstrate that the Product is a well-established technology, a term you noted from the *TGA's Clinical Evidence Guidelines: Medical Devices V3.1 June 2022 (Clinical Evidence Guidelines)* for the purpose of justifying that the indirect clinical evidence of comparable devices can substantiate the compliance of the subject device with the Essential Principles. You proposed to demonstrate by referencing the ordinary meaning of the words and guidance provided by the European Medical Agency (EMA).

However, the statement in the Clinical Evidence Guidance using the referenced term "well-established technology" is not a black and white rule that dictates when indirect clinical evidence can be used. The key point is whether the indirect clinical evidence can inform the safety/performance of the subject device. Further, your justification to demonstrate the product is a well-established technology is generic and did not address the key concern that the subject device contains a chemical whose use in the nose for the claims is not well-established.

Your responses to the assessor's comments following the clinical assessment and biomaterials assessment are noted. However, it remains concerning that there is insufficient clinical evidence to substantiate the revised intended purpose.

For more details, please find the attached clinical assessment report that contains the

assessment of your submission on 4 August.

TGA's position on the application

s47G



Please let me know if you have any question. Look forward to hearing from you.

Kind Regards,

s22

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From: s22 <s22 s22>
Sent: Friday, 4 August 2023 4:21 PM
To: s22, s22 <s22 s22@health.gov.au>
Cc: s22 <s22 s22@starpharma.com>; s22 s22@starpharma.com; s22 s22 <s22 s22@starpharma.com>; DUFFY, Tracey <Tracey.Duffy@health.gov.au>; JAMIESON, John <John.JAMIESON@Health.gov.au>; s22 s22 <s22 s22@health.gov.au>; SINGER, Simon <simon.singer@health.gov.au>; s22 s22 <s22 s22@health.gov.au>; s22 <s22 s22>
Subject: FW: Starpharma application (Submission ID: DV-2021-DA-06231-1) for the SPL7013 barrier nasal spray [SEC=OFFICIAL]

Dear s22

Further to my email below, I attach Starpharma's submission (including stability data in Attachment 1) in response to the Webex meeting on 12 July 2023 (**Conference**) attended by Starpharma, s22 and the TGA, during which we discussed the status of Starpharma's application for inclusion of its product, SPL7013 barrier nasal spray (**Product**), in the Australian Register of Therapeutic Goods.

We look forward to your review of the information provided by Starpharma and to hearing from you further to arrange another Webex meeting, as was agreed during the Conference, in case there are any matters requiring further clarification and so that the TGA can verbally inform Starpharma of the decision it proposes to make with respect to the Application.

Please do not hesitate to contact us if you require any further information or you have any questions about the submission and attached stability data.

Yours sincerely

s22

s22

From: s22, s22 <s22, s22@health.gov.au>
Sent: Wednesday, 2 August 2023 4:52 PM
To: s22 <s22, s22>
Cc: s22 <s22, s22@starpharma.com>; s22, s22@starpharma.com; s22 <s22, s22@starpharma.com>; s22 <s22, s22>
Subject: RE: Starpharma application (Submission ID: DV-2021-DA-06231-1) for the SPL7013 barrier nasal spray [SEC=OFFICIAL]

Thanks, s22. Look forward to receiving the information.

Kind Regards,

s22

From: s22 <s22, s22>
Sent: Wednesday, 2 August 2023 4:42 PM
To: s22, s22 <s22, s22@health.gov.au>
Cc: s22 <s22, s22@starpharma.com>; s22, s22@starpharma.com; s22 <s22, s22@starpharma.com>; s22 <s22, s22>
Subject: RE: Starpharma application (Submission ID: DV-2021-DA-06231-1) for the SPL7013 barrier nasal spray [SEC=OFFICIAL]

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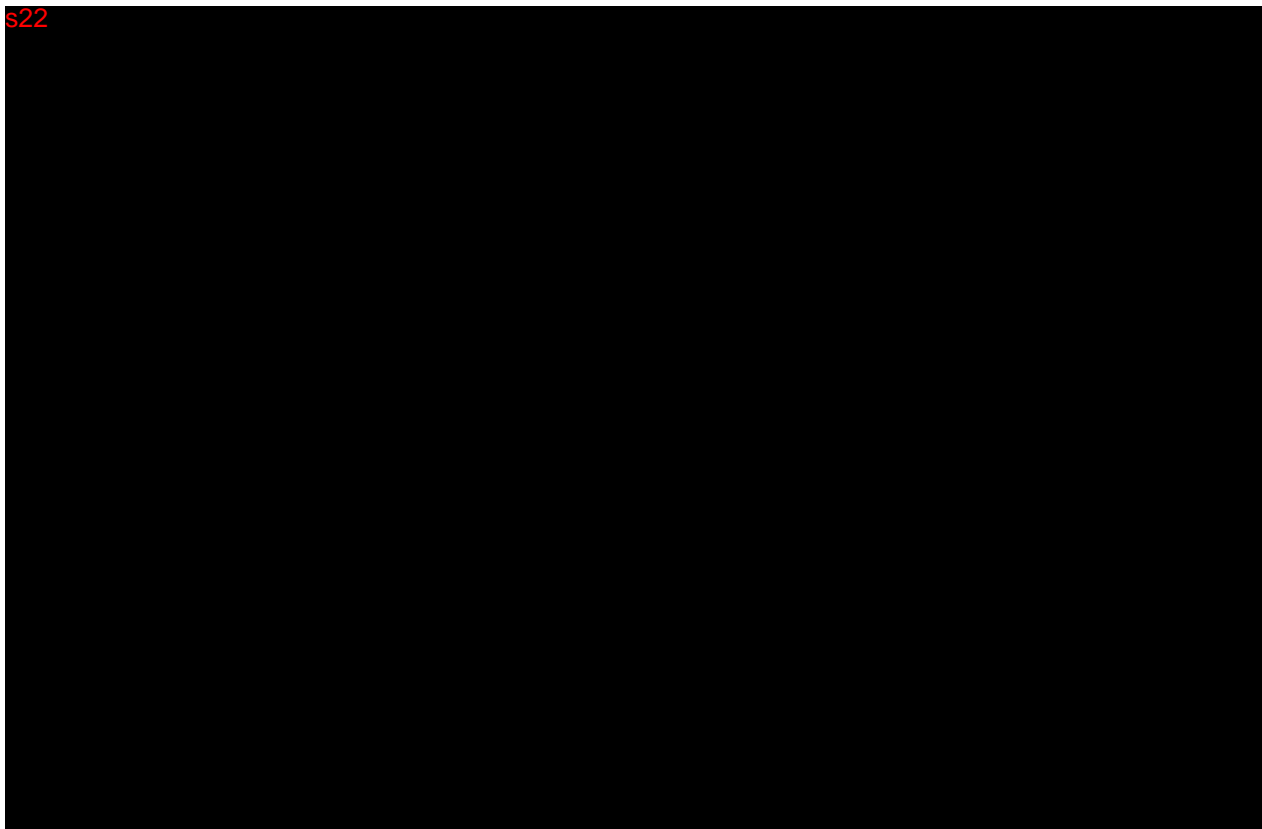
Dear s22

Thanks for your email. I am well and hope you are too.

We are just working through the draft that Starpharma sent through today and we hope to provide our input to them tomorrow. I anticipate that Starpharma will be able to send the information through to you by the end of the week.

Kind regards

s22



From: s22, s22 <s22, s22@health.gov.au>

Sent: Wednesday, 2 August 2023 3:07 PM

To: s22 <s22, s22>

Subject: RE: Starpharma application (Submission ID: DV-2021-DA-06231-1) for the SPL7013 barrier nasal spray [SEC=OFFICIAL]

Dear s22,

Hope the email finds you well. I'm writing in relation to the Starpharma application DV-2021-DA-06231-1.

As discussed at our last meeting on 12 July 2023, you indicated Starpharma would send more information about the safety, performance and intended purpose of the device in support of the application.

I'd like to enquire if you have any update or an estimated timeline for providing that information?

Please let me know if you have any question.

Thank you.

Kind Regards,

s22

Devices Applications Section | Medical Devices Authorisation Branch

Australian Government, Department of Health and Aged Care
Therapeutic Goods Administration

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Phone: 1800 141 144

PO Box 100, Woden ACT 2606

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transmission."

s22
s22
31 January 2024

s22

Devices Applications Section
Medical Devices Authorisation Branch
Therapeutic Goods Administration
PO BOX 100
Woden ACT 2000

Email: s22@health.gov.au

Copy: tracey.duffy@health.gov.au
john.jamieson@health.gov.au

Dear s22

**Application for inclusion of SPL7013 Nasal Spray in the ARTG
Submission ID: DV-2021-DA-06231-1**

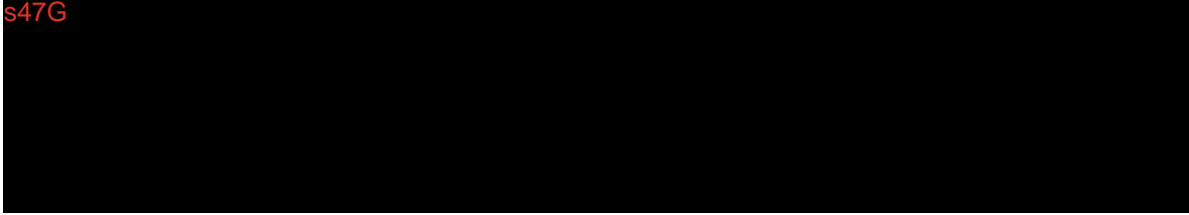
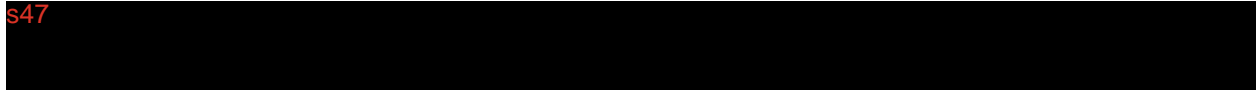
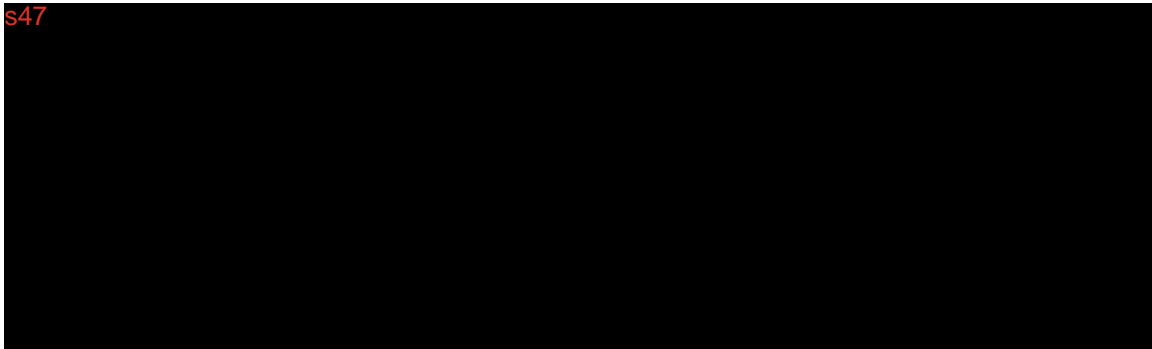
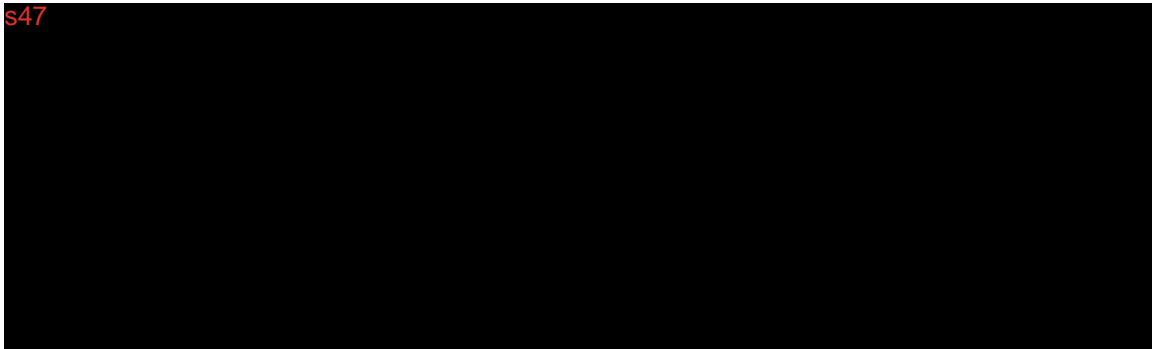
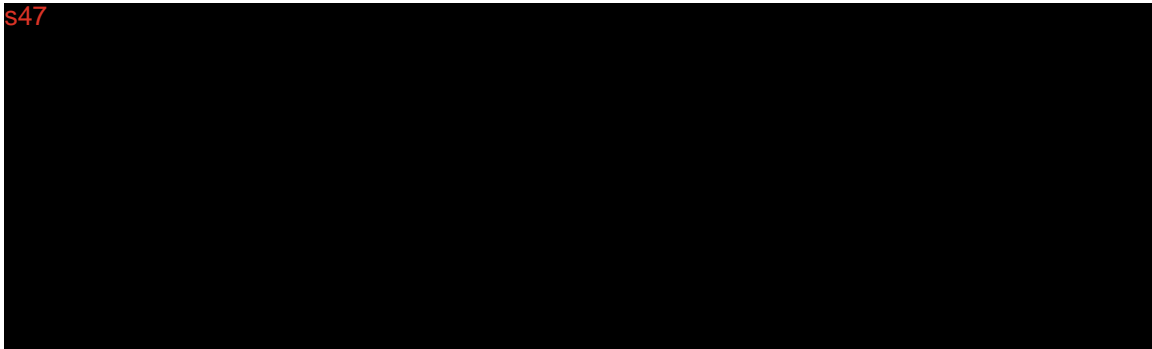
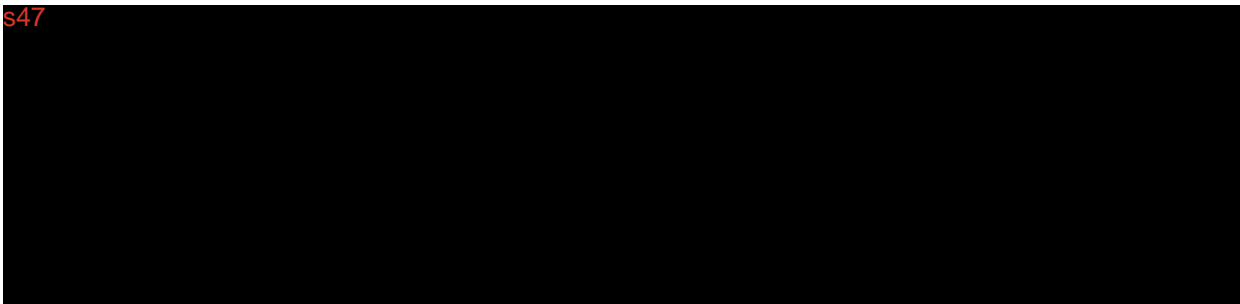
1. I refer to your email dated 17 November 2023 regarding Starpharma's application for inclusion of its product, SPL7013 Nasal Spray (**Product**) in the Australian Register of Therapeutic Goods (**ARTG**).
2. s47G
3. Starpharma would like to thank the TGA for accommodating this additional period of time to submit further data and believes that the additional direct clinical evidence and other data submitted herein will address the TGA's concerns, such that an approval of the Product is justified.
4. The information provided in Starpharma's response includes an updated risk management file and clinical evaluation report (**CER**) which incorporates results from Clinical Investigation SPL7013-022 and arrives at a (further) proposed and modified intended purpose having regard to the totality of evidence held by Starpharma.
5. As the final clinical investigation report is still being drafted, the updated CER includes the results of Clinical Investigation SPL7013-022 that have been analysed to date. We appreciate that we stated in our email dated 16 November 2023 that Starpharma anticipated that the final version of the clinical investigation report would be available for submission to the TGA by no later than 31 January 2024, but there was a delay in the release of the data relating to the investigation, which has had a knock-on effect in the

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s22

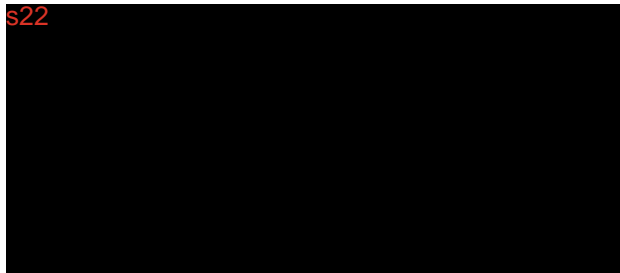
subsequent steps to complete the analysis and prepare the final clinical investigation report.

6. s47G 
7. To ensure Starpharma's adherence to the timeframe agreed with the TGA, Starpharma herein submits the following:
- (a) A response document, summarising the additional information that Starpharma presents;
 - (b) An updated Clinical Evaluation Report which includes results from Clinical Investigation SP7013-022 and addresses compliance with Essential Principles 1, 2, 3, 6 and 14;
 - (c) An updated Risk Management File; and
 - (d) A further modified intended purpose, which has regard to the latest clinical evidence afforded by study SPL7013-022.
8. In relation to paragraph 7(d)6(d) above, we note that the CER proposes an intended purpose which the experts (collectively) regarded as reasonably substantiated by the direct clinical evidence from Clinical Investigation SPL7013-022 and the clinical evidence as a whole. However, following further internal discussions and further consideration of results from Clinical Investigation SPL7013-022, in the interests of facilitating an approval of the Product, Starpharma wishes to propose the following intended purpose, which is narrower than the intended purpose proposed in the CER, and which objectively (and perhaps more precisely) reflects the clinical evidence from Clinical Investigation SPL7013-022 and other clinical evidence previously submitted by Starpharma (which is set out in the updated CER):
- s47 
9. The above intended purpose has been proposed having regard to the follow key propositions:
- (a) s47 
 - (b) 
 - (c) 
10. s47 

11. Starpharma believes that the final clinical investigation report will essentially confirm the data already presented in these submissions, and therefore respectfully requests that the TGA proceeds on the basis that the data presented herein regarding Clinical Investigation SPL7013-022 will be reflected in the final clinical investigation report, noting that Starpharma appreciates that a final decision by the TGA would rest on Starpharma providing the final clinical investigation report to the TGA for review.
12. As has been agreed previously with the TGA, we would be grateful if the clinical assessor could review the evidence submitted by Starpharma therein and then for a teleconference to be arranged between TGA stakeholders, Starpharma and s22 to discuss the TGA's preliminary assessment of the additional evidence and whether it has addressed the TGA's concerns and supports the proposed intended purpose, such that it is minded to approve the Product, or otherwise whether there are any residual concerns that remain, in which case Starpharma would appreciate the opportunity to discuss those concerns during a conference so that it can respond to them accordingly.
13. We look forward to hearing from the TGA in due course, once the clinical assessor has completed their assessment of the additional evidence.
14. In the meantime, if you have any questions or require further information, please do not hesitate to contact us on s22 or s22

Yours sincerely

s22

A large black rectangular redaction box covers the signature area, with the text 's22' visible in the top-left corner.

From: [Devices](#)
To: [s22](#), [s22](#) [@starpharma.com](#)
Cc: [s22](#), [s22](#)
Subject: RE: Starpharma application (Submission ID: DV-2021-DA-06231-1) for SPL7013 Nasal Spray [SEC=OFFICIAL]
Date: Monday, 15 April 2024 10:18:52 AM
Attachments: [image001.png](#)
[image002.png](#)
[image009.png](#)
[image010.png](#)
[image011.png](#)
[image012.png](#)
[image013.png](#)
[image014.png](#)

Good Morning [s22](#)

You will soon receive an invitation to join GovTEAMS.
Please follow the instructions below to register and access the TGA electronic submissions site within GovTEAMS.

GovTEAMS Guest Registration:

Click on the Join GovTEAMS link within the invitation email.
The link will step you through the simple registration process.

Helpful tips:

- GovTEAMS requires multi-factor authentication, we recommend that you download Microsoft Authenticator App to your phone.
- If this email address belongs to an existing Microsoft account, then you must use the password for that Microsoft account to set up and access GovTEAMS.

Should you have any issues please refer to the GovTEAMS Guest Registration help card at <https://www.govteams.gov.au/guest-registration> or contact us.

GovTEAMS Log-in:

Once you have registered please log into GovTEAMS via <https://www.govteams.gov.au/>
You should be a member of the group; TGA Medical Devices.

Please email us once you have completed these steps so that we can allocate you to your company upload folder.

Kind regards,

[s22](#)

**Device Engagement Section
Medical Device Information Unit**

Medical Devices Authorisation Branch | Medical Devices and Product Quality Division

Australian Government, Department of Health and Aged Care

T: [s22](#) | E: [s22](#), [s22](#) [@health.gov.au](#)

Location: Gulgana Building, Fairbairn, Canberra

PO Box 9848, Canberra ACT 2601, Australia



The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our

respects to them and their cultures, and to all Elders both past and present.

From: s22, s22 <s22, s22@health.gov.au>
Sent: Monday, April 15, 2024 9:52 AM
To: Devices <devices@tga.gov.au>
Subject: FW: Starpharma application (Submission ID: DV-2021-DA-06231-1) for SPL7013 Nasal Spray [SEC=OFFICIAL]
Importance: High

Hi team,

Can I get your help to arrange access for the following client for data submission through Govteams? This is in relation to their application DV-2021-DA-06231-1/ DA-2021-06851-1.

Name: s22
Email: s22, s22 @starpharma.com
Phone: s22

Thank you.

Kind Regards,
s22

From: s22 <s22, s22 @starpharma.com>
Sent: Friday, April 12, 2024 6:00 PM
To: s22, s22 <s22, s22@health.gov.au>; s22 <s22, s22>
Cc: JAMIESON, John <John.JAMIESON@Health.gov.au>; SINGER, Simon <simon.singer@health.gov.au>; s22, s22 <s22, s22 @Health.gov.au>; s22 <s22, s22 @starpharma.com>
Subject: RE: Starpharma application (Submission ID: DV-2021-DA-06231-1) for SPL7013 Nasal Spray [SEC=OFFICIAL]
Importance: High

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear s22,

The files are definitely too large to be send via email. I can submit the files via GovTEAMS.

Could you please invite me as a Guest to join the GovTEAMS community?

Name: s22
Email: s22, s22 @starpharma.com
Phone: s22

Many thanks,

s22

s22

s22, Quality & Regulatory
 Starpharma Pty Ltd
 4-6 Southampton Crescent, Abbotsford VIC 3067 Australia
 Tel: s22 | Mob: s22
 s22@s22@starpharma.com | www.starpharma.com



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From: s22, s22 <s22, s22@health.gov.au>

Sent: Friday, April 12, 2024 5:40 PM

To: s22 <s22, s22>

Cc: JAMIESON, John <John.JAMIESON@Health.gov.au>; SINGER, Simon

<simon.singer@health.gov.au>; s22, s22 <s22, s22@Health.gov.au>; s22

<s22, s22@starpharma.com>; s22, s22 <s22, s22@starpharma.com>

Subject: RE: Starpharma application (Submission ID: DV-2021-DA-06231-1) for SPL7013 Nasal Spray [SEC=OFFICIAL]

Hi s22,

Thank you for your email.

Thank you for sharing the sharepoint link and providing me the access. However, due to security reasons, our network policy has blocked access to any external sharepoint.

I suppose the file is too big to be submitted via email. Therefore, may I request you to submit the response via [GovTEAMS](#) (please refer to the attachment for instructions).

Alternatively, please provide the response as an electronic copy in the form of a CD, DVD or USB and send it to the following address. Please reference the application and submission ID in the electronic submission.

Postal Address

Devices Applications Section
 Medical Devices Authorisation Branch
 Therapeutic Goods Administration
 PO Box 100
 Woden ACT 2606

or

Courier Address

Devices Applications Section
 Medical Devices Authorisation Branch
 Therapeutic Goods Administration
 1 Tindal Lane
 Canberra Airport ACT 2609

Appreciate if you could submit the response via one of the above options as soon as possible. Apologies for the inconvenience.

Kind Regards,

s22

Devices Application & Triage Section | Medical Devices Authorisation Branch
Australian Government, Department of Health and Aged Care
Therapeutic Goods Administration

27 Scherger Drive, Fairbairn ACT 2609, Australia
Phone: 1800 141 144

PO Box 100, Woden ACT 2606

www.tga.gov.au

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From: s22 <s22 s22>
Sent: Friday, April 12, 2024 4:54 PM
To: s22, s22 <s22 s22@health.gov.au>
Cc: JAMIESON, John <John.JAMIESON@Health.gov.au>; SINGER, Simon <simon.singer@health.gov.au>; s22, s22 <s22 s22@Health.gov.au>; s22 s22@starpharma.com; s22 <s22 s22@starpharma.com>
Subject: RE: Starpharma application (Submission ID: DV-2021-DA-06231-1) for SPL7013 Nasal Spray [SEC=OFFICIAL]
Importance: High

Dear s22

I hope this email finds you well

Further to our Webex call on 8 March 2024 and your email of the same date regarding our client's application for inclusion of SPL7013 Nasal Spray in the ARTG (Submission ID: DV-2021-DA-06231-1), we provide herein our client's additional response to the issues raised in your email, along with a copy of the full clinical investigation report and annexures. You will find the referenced documents at the following link: [SPL7013 Nasal Spray](#)

Please note that our client has only given access to you, but please let us know if you require other TGA officers to be given direct access.

I would be grateful if you could confirm receipt of this email and that you are able to access the documents at the link.

Kind regards

s22

s22



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From: s22, s22
To: s22; s22
Cc: JAMIESON, John; SINGER, Simon; s22; s22; s22
Subject: RE: Starpharma application (Submission ID: DV-2021-DA-06231-1) for SPL7013 Nasal Spray [SEC=OFFICIAL]
Date: Monday, 15 April 2024 3:20:24 PM
Attachments: [image001.png](#)
[image002.png](#)
[image003.png](#)
[image004.png](#)
[image005.png](#)

Dear s22 and s22,

Thank you for your prompt action to submit the data via GovTEAMS.

I confirm the data is now received, including your response along with a copy of the full clinical investigation report and annexures.

Thank you.

Kind Regards,

s22
[Redacted]

Devices Application & Triage Section | Medical Devices Authorisation Branch

Australian Government, Department of Health and Aged Care
Therapeutic Goods Administration

27 Scherger Drive, Fairbairn ACT 2609, Australia
Phone: 1800 141 144

PO Box 100, Woden ACT 2606

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From: s22 <s22, s22@starpharma.com>

Sent: Friday, April 12, 2024 6:00 PM

To: s22, s22 <s22, s22@health.gov.au>; s22 <s22, s22@health.gov.au>

Cc: JAMIESON, John <John.JAMIESON@Health.gov.au>; SINGER, Simon

<simon.singer@health.gov.au>; s22, s22 <s22, s22@Health.gov.au>; s22

<s22, s22@starpharma.com>

Subject: RE: Starpharma application (Submission ID: DV-2021-DA-06231-1) for SPL7013 Nasal Spray [SEC=OFFICIAL]

Importance: High

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Name: s22
 Email: s22 s22@starpharma.com
 Phone: s22

Many thanks,

s22

s22
 s22, Quality & Regulatory
 Starpharma Pty Ltd
 4-6 Southampton Crescent, Abbotsford VIC 3067 Australia
 Tel: s22 | Mob: s22
 s22 s22@starpharma.com | www.starpharma.com



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Subject: RE: Starpharma application (Submission ID: DV-2021-DA-06231-1) for SPL7013 Nasal Spray [SEC=OFFICIAL]

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Kind Regards,

s22



Devices Application & Triage Section | Medical Devices Authorisation Branch

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From: s22 <s22 s22>
Sent: Friday, April 12, 2024 4:54 PM
To: s22, s22 <s22 s22@health.gov.au>
Cc: JAMIESON, John <John.JAMIESON@Health.gov.au>; SINGER, Simon <simon.singer@health.gov.au>; s22, s22 <s22 s22@Health.gov.au>; s22 s22@starpharma.com; s22 <s22 s22@starpharma.com>
Subject: RE: Starpharma application (Submission ID: DV-2021-DA-06231-1) for SPL7013 Nasal Spray [SEC=OFFICIAL]
Importance: High

Dear s22

I hope this email finds you well

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I would be grateful if you could confirm receipt of this email and that you are able to access the documents at the link.

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s22

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From: s22, s22
To: s22
Cc: JAMIESON, John; SINGER, Simon; s22; s22; s22; s22@starpharma.com; s22
Subject: RE: Starpharma application (Submission ID: DV-2021-DA-06231-1) for SPL7013 Nasal Spray [SEC=OFFICIAL]
Date: Wednesday, 15 May 2024 1:13:13 PM
Attachments: [image002.png](#)
[image003.png](#)

Hi s22,

I hope the email finds you well.

I'm writing to confirm that the review of Starpharma application is in progress and we can provide feedback on the application via a meeting before making our final decision.

In about a week, I will follow up with a few available timeslots for you to confirm your preference.

Thank you for your patience and understanding.

Kind Regards,

s22

From: s22, s22 <s22, s22@health.gov.au>
Sent: Wednesday, April 24, 2024 9:45 AM
To: s22 's22 s22'
Cc: JAMIESON, John <John.JAMIESON@Health.gov.au>; SINGER, Simon <simon.singer@health.gov.au>; s22, s22 <s22, s22@Health.gov.au>; s22, s22 @starpharma.com; s22 <s22, s22@starpharma.com>
Subject: RE: Starpharma application (Submission ID: DV-2021-DA-06231-1) for SPL7013 Nasal Spray [SEC=OFFICIAL]

Hi s22,

Thank you for your email.

Your client's submission of the final CIR and additional responses is currently under review. At this stage, we anticipate that we need at least another couple of weeks to thoroughly assess the submission. I expect I'll have a clearer timeline on when we can provide feedback in about two weeks. I'll be in contact then with an update.

Thank you for your understanding.

Kind Regards,

s22



Devices Application & Triage Section | Medical Devices Authorisation Branch

Australian Government, Department of Health and Aged Care
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Phone: 1800 141 144

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From: s22 <s22 s22>
Sent: Tuesday, April 23, 2024 12:34 PM
To: s22, s22 <s22 s22@health.gov.au>
Cc: JAMIESON, John <John.JAMIESON@Health.gov.au>; SINGER, Simon <simon.singer@health.gov.au>; s22, s22 <s22 s22@Health.gov.au>; s22 s22@starpharma.com; s22 <s22 s22@starpharma.com>
Subject: Starpharma application (Submission ID: DV-2021-DA-06231-1) for SPL7013 Nasal Spray

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Dear s22

I refer to the application (**Application**) by Starpharma Pty Ltd to include SPL7013 Nasal Spray in the Australian Register of Therapeutic Goods (Submission ID: DV-2021-DA-06231-1).

In follow-up to our client's submission of the final clinical investigation report (**CIR**) for SPL7013-022 and additional response to the issues raised during the Webex meeting on 8 March 2024, I would be grateful if you could confirm that our client will be given the opportunity to obtain your (and other TGA stakeholders') feedback about the CIR and additional response (including our client's proposed intended purpose) before any decision is made with respect to the Application. Our client would be grateful for the opportunity to discuss the TGA's review of the final CIR and the TGA's proposed decision having regard to the data in the final CIR and our client's (revised) proposed intended purpose.

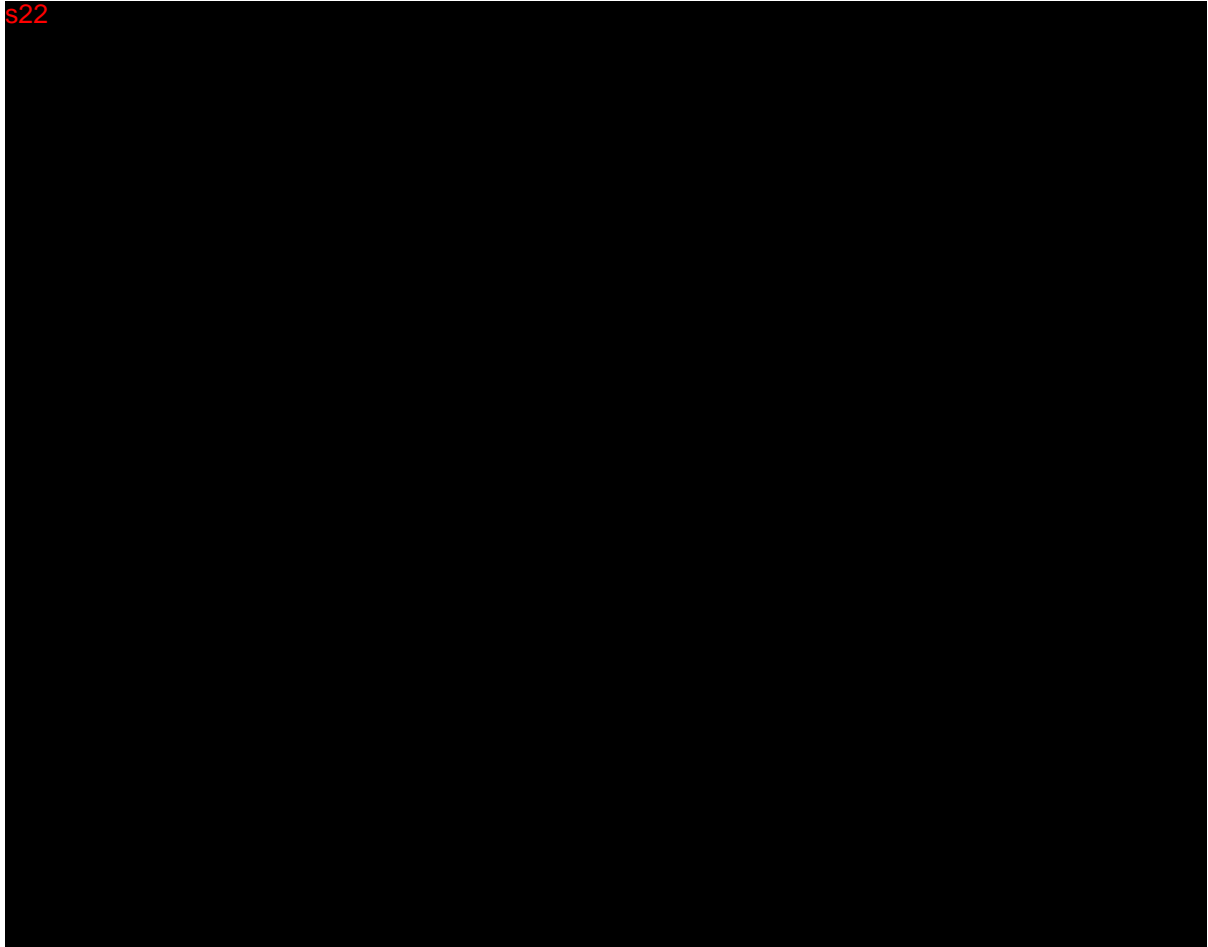
Assuming you are amenable to providing our client with the requested feedback, in order to assist with our client's planning, it would be greatly appreciated if you could provide an estimate as to when you think that feedback might be provided.

I look forward to your response.

Kind regards

s22

s22



Schedule Cycle Summary

NOVEMBER 2023 Meeting Cycle



Contents



Substance	Applicant	Description	Secretariat suggestion	Delegate recommendation
-----------	-----------	-------------	------------------------	-------------------------

ACMS #43

s22

Astodrimer sodium	Private	Amend S3 entry to allow proposed nasal spray be available unscheduled.	ACMS	ACMS
-------------------	---------	--	------	------

s22

ACMS

s22

s22

Astodrimer
sodium

s22

Astodrimmer sodium - E23-195500

<p>Who made the application? Starpharma Pty Ltd</p>	<p>What is the substance used for?</p> <ul style="list-style-type: none"> • To provide moisture barrier in the nasal cavity that physically traps common cold viruses • Treatment and prevention of recurrent bacterial vaginosis • Blocks viruses associated with STIs in condom 	<p>How is it used or applied?</p> <ul style="list-style-type: none"> • Lubricant (for male condoms) 0.5% • Vaginal gel 1% • Nasal spray 1%
<p>What is the proposal? Amendment of S3 entry of astodrimmer sodium to allow the proposed nasal spray product be available unscheduled.</p> <p>Proposed Entry: Schedule 3 ASTODRIMER SODIUM except when used in: a) a condom lubricant; or b) a barrier nasal spray.</p>	<p>What are the relevant scheduling factors</p> <ul style="list-style-type: none"> • Non-pharmacological, non-metabolic and non-immunological mechanism of action • Not systemically absorbed following topical application • No concerns about dependency or misuse • Risk profile is well defined 	<p>Who else do we need to consult? OTC?</p>
<p>Why are they making the application? Proposed new product – 1% astodrimmer sodium nasal spray to be unscheduled for the management of colds or cold symptoms</p>	<p>Details of previous applications/proposals (if applicable) Nov 2008 – listed in S3, Appendix F & H Nov 2021 – amendment of Appendix F and H entry Not considered since</p>	<p>Additional comments or notes. Application contains confidential materials</p>
<p>Suggested approach: Delegate only / Proceed to NOVEMBER 2023 ACMS, ACCS, Joint Meeting / Other: Need to seek clarification from applicants</p>		

November 2023 delegate meeting outcomes and actions Document 31

Substance	Outcome	Action	Staff Allocation
s22			
Astodrimmer sodium	• ACMS	<ul style="list-style-type: none">• Attain more information from medical devices approval board and OTC• Consider removing barrier from entry as it implies device• Ensure regulatory history (device vs medicine) is captured for committee consideration	s22

s22			
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Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Seeking advice on proposed scheduling amendments

According to subsection 52E(4) of the Act, in exercising a power under subsection 52D(2), the Secretary may seek advice from any person or any committee that the Secretary considers appropriate (whether or not the committee is established under the Act or the *Therapeutic Goods Regulations 1990* (the Regulations)). This includes an evaluator, the Advisory Committee on Medicines Scheduling (ACMS) and/or the Advisory Committee on Chemicals Scheduling (ACCS). Subsection 52E(3) of the Act also sets out that, where the Secretary decides to seek the advice of the ACMS and/or the ACCS, the Secretary must have regard to that advice.

Delegations

As a Medical Officer Class 5 in the Medicines Regulation Division you have [powers delegated by the Secretary of the Department of Health](#) under subsections 52D(2) and 52E(4) of the *Therapeutic Goods Act 1989* (the Act) to amend or replace the Poisons Standard [52D(2)] and in doing so, seek advice from any person or committee that the Secretary considers appropriate [52E(4)].

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Timeframes

ACMS or Joint ACMS-ACCS

If you decide these matters require ACMS or Joint ACCS-ACMS advice, then the public notice of proposed amendments must be published on the TGA website on 31 August 2023. Your decision regarding referral to ACMS or Joint ACMS-ACCS for advice and your confirmation of the details to be included in the public notices is required by **11 August 2023**.

Delegate-only decision

1. If you decide that an application *does not require ACMS or Joint ACMS-ACCS advice* and that a delegate-only decision is appropriate and that it is *the same as the applicant's proposal*, then the final decision and reasons for the decision will be published on the TGA website with the June 2023 cycle final decisions, in November 2023. Your final decision is therefore required by **1 September 2023**; or
2. If you decide that an application *does not require ACMS or Joint ACCS-ACMS advice* and that a delegate-only decision is appropriate but that it is *different from the applicant's proposal*, then the decision will be an interim decision and will be published on the TGA website with the November 2023 cycle interim decisions in February 2024. The secretariat will also notify the applicant in writing of your interim decision and provide the applicant at least 20 working days to make a written submission in response to your decision. Delegate-only decisions that are different from the applicant's proposal are therefore required by **1 November 2023**.

Astodrimmer sodium

R1. Having considered the attachments listed below, that you decide to consider this matter as a delegate-only decision.²

AGREE
DISAGREE

Reasons: N/A

R2. That you decide to refer this matter to the ACMS.

AGREE
DISAGREE

Reasons: The exclusion of a specific dosage forms of the substance from the Schedule 3 entry requires referral to the appropriate Committee for discussion.

R3. That you decide that the application requires an external evaluation.

AGREE
DISAGREE

Reasons: Sufficient information on this substance is already available.

Signed in TRIM

s22

Director, Advanced and Biological Therapies Section

11 August 2023

Attachments for Astodrimmer sodium

Attachment A: Application for astodrimmer sodium [E23-195500](#)

² Please note that by accepting this recommendation the delegate is not making an interim decision or final decision

ACMS MEETING #43

17 November 2023

AGENDA PAPER

Astodrimmer sodium

Referred scheduling proposal

The delegate¹ of the Secretary of the Department of Health and Aged Care that is responsible for medicines scheduling (the **Delegate**) is seeking advice from the Advisory Committee on Medicines Scheduling (the **Committee**) on a scheduling proposal with respect to astodrimmer sodium. The proposal, received in July 2023, is to amend the Schedule 3 entry to exempt astodrimmer sodium from scheduling when used in a barrier nasal spray preparation.

Proposed scheduling

The applicant's proposed amendments to the Poisons Standard are:²

Schedule 3 – Amend Entry

ASTODRIMER SODIUM **except** when used in:

- a) a condom lubricant; or
- b) a barrier nasal spray.

Index

ASTODRIMER SODIUM

Schedule 3

Appendix F, clause 4

Appendix H, clause 1

Appendix F, clause 4 – Poisons that must be labelled with warning statements and safety directions.

Item	Poison	Warning statement
30	ASTODRIMER SODIUM – for the treatment and relief of bacterial vaginosis	63 – See a doctor (or) (dentist) if no better after (Insert number of days as approved Product Information) days.
		64 – If getting better, keep using for (Insert number of days as per approved Product Information) days.
		69 – If symptoms recur within two weeks of completing the course, consult a doctor.

¹ For the purposes of s 52D of the *Therapeutic Goods Act 1989* (Cth).

² Proposed additions are shown in green underlined font, proposed deletions are shown in red strikethrough font, and text without this formatting represents the current text in the Poisons Standard.

		<p>75 – Do not use under waterproof bandages unless a doctor has told you to.</p> <p>109 – See your healthcare provider if you consider that you may be at risk of a Sexually Transmitted Infection (STI).</p> <p>110 – See a doctor if you plan to become pregnant or are breastfeeding or plan to breastfeed.</p>
31	ASTODRIMER SODIUM – for the prevention of recurrent bacterial vaginosis	<p>63 – See a doctor (or) (dentist) if no better after (Insert number of days as approved Product Information) days.</p> <p>75 – Do not use under waterproof bandages unless a doctor has told you to.</p> <p>109 – See your healthcare provider if you consider that you may be at risk of a Sexually Transmitted Infection (STI).</p> <p>110 – See a doctor if you plan to become pregnant or are breastfeeding or plan to breastfeed.</p>

Appendix H, clause 1 – Schedule 3 medicines permitted to be advertised.

Item	Poison
3	ASTODRIMER SODIUM – for the treatment and relief of bacterial vaginosis and for the prevention of recurrent bacterial vaginosis

Background

Astodrimersodium is a non-antibiotic microbicidal that is used in the treatment of bacterial vaginosis as a topical gel, and the prevention of sexually transmitted diseases (STD) as a condom lubricant.

Astodrimersodium is currently a Schedule 3 medication (except when used in condom lubricants) with labelled warning statements of ‘for the treatment and relief of bacterial vaginosis’ and ‘for the prevention of recurrent bacterial vaginosis.’ The Appendix H entry permits advertising of Schedule 3 preparations containing astodrimersodium for these indications.

Summary of applicant’s reasons for the proposal

- The non-serious and self-limiting nature of the condition (the common cold) is consistent with the risk profile of over the counter (OTC) medicines. Similar products used in the treatment of the condition are OTC medicines and readily available in Australia.
- The purpose of astodrimersodium’s inclusion in a nasal spray product is to act as a physical barrier to trap and block cold viruses such as the common cold, allowing the body’s natural defences to remove them with the nasal mucus.
- Astodrimersodium poses low risk of harm, as noted in the delegate’s previous decision in November 2021. The risks associated with misuse, abuse and overuse are very low. Astodrimersodium is not systemically absorbed when used as a barrier nasal spray.

- Adverse effects are rare and well-characterised, with no known interactions with commonly used food and consumables, or contra-indications. The risk profile of the substance is well defined, and risks can be appropriately managed through labelling and packaging.
- The use of astodrimmer sodium in a nasal spray is not likely to mask the symptoms or delay diagnosis of a serious condition. Appropriate labelling and packaging can manage any perceived risk.

Scheduling history

Astodrimmer was first entered into the Poisons Standard on 1 February 2019. This followed the delegate's decision in November 2018³ to include astodrimmer into Schedule 3, Appendix F and Appendix H except when present in a condom lubricant.

The substance was then discussed at the November 2021 ACMS #36 meeting. The proposed amendments to the Poisons Standard were to include new warning statements for preventative use in the existing Appendix F entry for astodrimmer, and to remove existing restrictions on advertising for preparations that contained this substance by inclusion in Appendix H. The Delegate's final decision was to amend the Poisons Standard as per the proposed changes.

Australian regulations

- According to the [TGA Ingredient Database](#), astodrimmer sodium is:
 - Available for use as an Active ingredient in Devices
 - Available for use as an Excipient in Devices
 - Not available as an Equivalent Ingredient in any application.
- As of July 2023, there were no medicines containing astodrimmer sodium on the [Australian Register of Therapeutic Goods \(ARTG\)](#).
- Astodrimmer sodium is not permitted to be included in listed medicines as it is not included in the [Therapeutic Goods \(Permissible Ingredients\) Determination](#) No.3 of 2023.
- Astodrimmer sodium is not listed in the [TGA prescribing medicines in pregnancy database](#).
- There are no warning statements pertaining to astodrimmer sodium in the [Therapeutic Goods \(Medicines Advisory Statements\) Specification 2021](#).
- As of July 2023, there were no reports of adverse events for products containing astodrimmer sodium as an active ingredient on the [Database of Adverse Event Notifications \(DAEN\)](#).
- As of July 2023, there were no products containing astodrimmer sodium as an active ingredient/constituent or scheduled substance listed on the [Public Chemical Registration Information System Search \(PubCRIS\)](#).

International regulations

- Astodrimmer sodium is not included in the [Health Canada drug product database](#), the [United States Food and Drug Administration's](#) approved drug products database, the [New Zealand Inventory of Chemicals](#), the [New Zealand Medicines and Medical Devices Safety Authority](#)

³ [Final decisions amending, or not amending, the current Poisons Standard, November 2018: 2.4. Astodrimmer sodium | Therapeutic Goods Administration \(TGA\)](#)

(MedSafe), the [European Commission database](#) for information on cosmetic substances and ingredients, or [Ireland's Health Products Regulatory Authority](#) medicines database.

- Nasal sprays containing astodrimmer sodium are registered in the EU and UK as a Class 1 medical device; relying on manufacturer's self-declaration for compliance. An [ASX announcement by the manufacturer in November 2022](#) claimed the product is registered as a medical device in more than 30 countries and in certain markets online.

Substance summary

Table 1: Chemical information for astodrimmer sodium

Property	Astodrimmer sodium
Chemical structure	
Molecular formula	
CAS numbers	676271-69-5
IUPAC and/or common and/or other names	
	SPL7013

Pre-meeting public submissions

A total of 167 public submissions were received: 166 in support and one in partial support. Of the submissions received, 137 contained a written component, with 136 of these in support and one in partial support of the proposal (see **Attachment B**).

Main points in support:

- The proposal would provide an additional means of protection (in addition to vaccines, hand hygiene, and masks) against the common cold and viruses, including SAR-CoV-2, particularly for individuals unable to receive COVID-19 vaccinations or wear protective masks.
- Reduced severity and transmission of such diseases would provide economic benefits through reducing their impact on worker productivity, particularly among workers in environments with high risk of transmissibility.
- Astodimer sodium barrier nasal spray products are already available over the counter in other countries, namely the UK and EU member states. Current consumers are importing astodimer sodium barrier nasal spray products from these countries via family and friends or locally from illicit online retailers.
- A barrier nasal spray may help to prevent upper respiratory tract infections, which may in turn reduce exacerbations of lung diseases like COPD, especially amongst the elderly and immunocompromised.

Main points in support with caveats:

- Support of the proposal provided there is sufficient safety data in human trials, and no adverse active ingredients are absorbed into the bloodstream.
- Products that provide extra protection against COVID-19 should be made available over the counter to the public given the on-going emergence of new variants, and claims of reduced public uptake of self-protective measures (such as mask wearing) and poor availability of PCR testing.

Internal consultation

A request was made to the following sections at the TGA for feedback on the regulatory history of astodimer sodium:

- Medical Devices Engagement Section (see **Attachment C**)
- Complementary Medicines Evaluation Section (CMES) (see **Attachment D**)
- Over-the-Counter Medicines Evaluation Section (OTCMES) (see **Attachment E**)

The Medical Devices Engagement Section noted they have received one application for an astodimer sodium-based nasal spray that is currently under review, though has not been discussed by the Advisory Committee for Medical Devices. Notably, the application (received 23 July 2021) was rejected by the delegate of the Secretary in a notice published 24 November 2021 on the basis that the product did not satisfy the definition of a medical device.

s47G

s47G

CMES indicated that they had not received any complementary medicine applications for a nasal spray dosage form that contains astodrimmer sodium, nor any new ingredients applications for astodrimmer sodium to be used in listed medicines. Similarly, OTCMES has not received any OTC medicine applications for a nasal spray or other OTC medicine containing astodrimmer sodium. OTCMES advised that astodrimmer sodium-containing nasal spray should be considered a medicine not a device.

In July 2021 a media release was published regarding the applicant, Starpharma Holdings Limited, receiving seven infringement notices, totalling \$93,240 in fines, for [alleged unlawful advertising of Viraleze \(astodrimmer sodium nasal spray\) in relation to COVID-19](#). The alleged advertising, on two of Starpharma's websites, included a restricted representation claiming that Viraleze is an antiviral nasal spray that stops SARS-CoV-2. Any claims or references to preventing or treating a serious form of a disease, condition, ailment or defect are [restricted representations](#).

Delegate's specific issues and questions to be considered by the Committee

The Medicines Scheduling Delegate seeks advice from the Committee on the following questions:

1. Does the substance, astodrimmer sodium, require control through scheduling when in barrier nasal spray preparations?
2. If so, are Schedules 2 or 3 appropriate, so that consumers may have access to health professional guidance prior to purchase?

OPTIONS

OPTION 1

The Committee recommends that the current scheduling of astodrimmer sodium remains appropriate.

OPTION 2

The Committee recommends that the current Schedule 3 entry for astodrimmer sodium be amended as follows:

Schedule 3 – Amend Entry

ASTODRIMER SODIUM **except** [when used](#) in:

- [a\) a condom lubricant; or](#)
- [b\) a barrier nasal spray](#)

Index

<p>ASTODRIMER SODIUM Schedule 3 Appendix F, clause 4 Appendix H, clause 1</p>
<p>OPTION 3</p>
<p>The Committee recommends Appendix E/F entries be created /amended as follows: <i>[specific phrases/statements to be decided pending discussion, if applicable]</i></p> <p>Appendix E, Part 1 – Standard Statement/s: Appendix F, Part 1 – Warning Statement/s: Appendix F, Part 2 – Safety Direction/s:</p>
<p>IMPLEMENTATION DATE</p>
<p>The Committee is asked to discuss and consider the resolutions with an implementation date of 1 June 2024/1 October 2024/1 February 2025.</p>
<p>..... RECOMMENDATION FOR OTHER ACTION BY THE DELEGATE</p>

ATTACHMENTS

Attachment A: Application to amend the Poisons Standard with respect to astodrimmer sodium

Attachment B: Public submissions relating to astodrimmer sodium

Attachment C: Email response regarding scheduling history of astodrimmer sodium from TGA Medical Devices Section

Attachment D: Email response regarding scheduling history of astodrimmer sodium from Complementary Medicines Evaluation Section

Attachment E: Email response regarding scheduling history of astodrimmer sodium from Over-The-Counter Medicines Evaluation Section

Application to amend the Poisons Standard

Astodrimmer sodium (INN, USAN)

s22

Starpharma Pty Ltd

Applicant's details

1. What is your name?

s22

2. What is your email address?

s22 s22 @starpharma.com

3. What is your phone number?

s22

4. What is the name of the organisation you are representing for this application?

Starpharma Pty Ltd

5. Are you the contact person for this application?

Yes. I will skip the 'Contact person's details' page and proceed to the 'Substance details' page.

Contact Person's details

If you are the contact person for this application and you have given your details in the 'Applicant's details' page, disregard the questions below and proceed to the 'Substance details' page.

If we have any questions regarding the application, we will contact the nominated contact person.

1. What is your name of the contact person?

s22

2. What is your email address of the contact person?

s22 s22 @starpharma.com

3. What is the phone number of the contact person?

s22

Substance details

4. What is the name of the substance?

Astodrimer sodium (INN, USAN)

5. What are the alternative names of the substance?

s47

or
SPL7013

6. Is the substance a derivative of any currently scheduled poisons?

No

If yes, please specify each derivative on a separate line below:

7. What are the CAS numbers of the substance?

676271-69-5

8. Upload an image of the chemical structure of the substance.

To ensure we can view the chemical structure of the substance, upload an image file in one of these formats: .jpg, .jpeg, .img, .png.

s47

9. What are the known uses of the substance?

Enter each known use on a separate line (only if applicable).

Astodrimer sodium is a component of the following medical devices:

Vaginal Gel: for the treatment and relief of bacterial vaginosis and for the prevention of recurrent bacterial vaginosis in women.

Male condom: blocking of common sexually transmitted infections (STIs), including HIV, HSV and HPV.

Nasal Spray: trapping and blocking of cold/respiratory viruses (outside of Australia)

10. What are the proposed uses of the substance?

Enter each proposed use on a separate line (only if applicable).

s47

11. What are the pack sizes of products marketed or supplied in Australia that contain the substance?

Enter each pack size on a separate line (only if applicable).

Astodrimer has been/is supplied in Australia in the following pack sizes:

Vaginal Gel: 45 g tube

Male condom: male lubricated condom. each

12. What are the proposed pack sizes for products that contain the substance?

Enter each pack size on a separate line (only if applicable).

The proposed nasal spray pack size is: 10 mL bottle

13. In what forms do products containing the substance currently appear in Australia?

Enter each form on a separate line (only if applicable).

Astodrimer has been/is supplied in Australia in the following forms:

Vaginal Gel: 1% w/w astodrimer sodium vaginal gel

Male condom : Male condom lubricated with 0.5% astodrimer sodium lubricant

14. What are the proposed forms for products containing the substance?

Enter each form on a separate line (only if applicable).

Proposed form for astodrimer to be supplied in Australia:

Nasal Spray: 1% astodrimer sodium nasal spray

Purpose of application

15. What title would you like to give to this application?

Amendment of Entry in Schedule 3 for Astodimer Sodium

16. What type of change to the Poisons Standard are you requesting in this application?

Amend or add entries for a substance already included in the Poisons Standard

17. Provide an overview of your application in plain English (500 words or less).

Astodimer sodium is an ingredient in a number of medical devices, including:

- a vaginal gel for the treatment of bacterial vaginosis (BV) and prevention of recurrent BV;
- a condom lubricant to block viruses associated with sexually transmitted infections (STIs); and
- a nasal spray as a barrier that traps and blocks viruses in the nose.

This application is a request for an amendment to the entry in Schedule 3 to include nasal spray formulations of astodimer sodium in the list of exceptions.

Current Entry:

ASTODRIMER SODIUM except in a condom lubricant.

Proposed Entry:

ASTODRIMER SODIUM except when used in:

- a) a condom lubricant; or
- b) a barrier nasal spray.

The nasal spray containing astodimer sodium is regulated as a low-risk (Class I) medical device in the European Union, Malaysia, Vietnam, Hong Kong, Macao and Australia based on its non-pharmacological, non-metabolic and non-immunological mechanism of action.

Due to its physical size and negative charge, astodimer sodium is not absorbed into the bloodstream following topical application to mucosal epithelial surfaces.

The safety and tolerability profile of astodimer sodium alone and in various formulations has been demonstrated in an extensive suite of nonclinical studies in a range of species, including biocompatibility studies, single and repeat-dose/chronic dosing studies, genotoxicity and mutagenicity studies, carcinogenicity studies, and development and reproductive toxicology studies.

The clinical safety and efficacy of astodimer sodium in condom lubricant, vaginal gel and nasal spray preparations has been demonstrated in 13 completed clinical studies involving more than 2000 patients.

A consistent benign toxicological profile has emerged for astodimer sodium. In all species studied, there was no systemic exposure or systemic toxicity following repeated nasal application. In addition, astodimer sodium does not represent a genetic, carcinogenic, or reproductive risk.

Nasal spray with astodimer sodium is aligned to other nasal sprays in its class. That is, nasal sprays that are classified as medical devices and have the same mechanism of action to trap and block (inactivate) virus in the nose. These nasal sprays are freely available in Australian

supermarket chains and pharmacies based on safety profile of the products and the non-serious nature of the condition (i.e., common colds) they are used for.

As noted by the delegate in the “Delegate’s final decisions and reasons for decisions (ACCS#32, ACMS#36, Joint ACMS-ACCS#29, November 2021)” document, the delegate acknowledged that astodrimmer is a topical treatment with a low risk of harm itself, however advice from a medical practitioner should be sought before using the substance for the treatment and prevention of BV. To this end, astodrimmer sodium was originally included in the Poisons Standard as a Schedule 3 poison, with an exclusion when included in a condom lubricant, and in Appendix H for the treatment of BV, which was subsequently updated to include prevention of recurrent BV.

The request to exclude scheduling of astodrimmer sodium in both condom lubricants and nasal sprays in the entry in Schedule 3 is valid given: the low risk of harm (noted by the delegate above), the non-seriousness of the condition (the common cold), and the availability of many nasal spray products supplied to the Australian market for the management of colds or cold symptoms.

Amendments to the Schedules of the Poisons Standard

18. In what Schedules of the current Poisons Standard is the substance included?

Schedule 3

19. What is the current text for the substance as it appears in the Schedules of the Poisons Standard?

ASTODRIMER SODIUM except in a condom lubricant.

In what Schedules of the Poisons Standard do you propose the substance to be included?

Schedule 3

20. What text are you proposing for the substance in the Schedules and Index of the Poisons Standard?

ASTODRIMER SODIUM except when used in:

- a) a condom lubricant; or
- b) a barrier nasal spray.

Amendments to the Appendices of the Poisons Standard

21. In which Appendices of the current Poisons Standard is the substance included?

22. What is the current text for the substance as it appears in the Appendices of the Poisons Standard?

23. In what Appendices of the Poisons Standard do you propose the substance to be included?

24. What text are you proposing for the substance in the Appendices and Index of the Poisons Standard?

(Only if applicable)

Detailed claims against the requirements of the scheduling criteria

a. What are the risks and benefits associated with the use of the substance?

Astodimer sodium itself poses a low risk of harm.*

Furthermore, a nasal spray containing astodimer sodium (referred to herein as SPL7013 Nasal Spray) is deemed to be low risk as it meets the criteria for classification as a Class I medical device.

The risks and benefits described below are with respect to the nasal spray product.

Risks:

The risk analysis for SPL7013 Nasal Spray has identified the expected and unexpected clinical safety concerns of the product, including those arising from improper use. Such safety concerns were identified to include potential injury, irritation or sensitisation effects, and more serious systemic toxicity. The more common clinical safety concerns, such as exacerbation of symptoms or infection, are considered acceptable residual risks given the benefits of using the device.

The safety of astodimer sodium (SPL7013), SPL7013 Nasal Spray and SPL7013 Vaginal Gel has been demonstrated in; non-clinical toxicology studies, including studies of chronic dosing, carcinogenicity and reproductive/developmental effects, and clinical studies involving nasal administration of SPL7013 Nasal Spray and vaginal administration of SPL7013 gel doses that far exceed the amount of SPL7013 in SPL7013 Nasal Spray.

Astodimer sodium is not systemically absorbed following topical application, meaning that any adverse effects that have been observed with astodimer sodium products are limited to mostly mild, local, self-limiting effects that are often observed with control products.

Therefore, the risk of adverse clinical effects with SPL7013 Nasal Spray is deemed to be low and of minimal consequence.

It is considered that, through application of design and manufacturing controls in particular, the identified risks have been reduced as far as possible.

Benefits:

Astodimer sodium has a favourable toxicity and safety profile and is not systemically absorbed.

Astodimer sodium has been shown to have potent broad-spectrum effect against respiratory viruses and it is intended to trap common cold viruses and reduce exposure to viral load. The moisture barrier properties of the nasal spray formulation mitigate drying of the nasal cavity, thereby conserving the integrity of the nasal mucosa, a major physiological defence mechanism against infection.

The virus trapping and blocking properties of astodimer sodium warrant the use of SPL7013 Nasal Spray to physically trap and block extracellular cold viruses and reduce exposure to viral load. Reducing viral load may reduce exposure to infectious virus and help prevent acquisition or transmission of infection and reduce severity of disease and symptoms.

Summary:

Inherent safety by design was considered and applied as a priority measure wherever possible to eliminate or reduce risk of harm as far as possible. Protective measures and information for safety were also applied wherever possible.

It was concluded in the Risk Management Plan and Risk Analysis for SPL7013 Nasal Spray that, through application of design and manufacturing controls, as well as other controls including provision of information on safety, the identified risks have been reduced as far as possible. No economic factors were considered in applying controls and mitigation factors.

Based on these findings, any residual risks regarding SPL7013 Nasal Spray was deemed to be outweighed by the benefits afforded by the device. The mitigation actions identified during the

risk management process were considered appropriate and the resulting and overall residual risks identified for SPL7013 Nasal Spray were considered acceptable.

The residual risks are considered acceptable, and do not outweigh the benefits of placing this device on the market, when considering the risks individually or combined. This review found that the overall residual risk for SPL7013 Nasal Spray is acceptable for placement on the market.

Overall, the risk analysis and evaluation has shown that the controls implemented and applied to SPL7013 Nasal Spray reduce the risk of possible harms associated with the device.

Given the acceptable safety profile and benefits for use in physically trapping respiratory viruses and thereby reducing viral load, the residual risks of the potential harms are outweighed by the clinical performance as shown through the nonclinical investigations evaluated and the data on similar devices. The product risks are considered acceptable and do not outweigh the potentially significant benefits of the product, when considering the risks individually or combined.

*"Delegate's final decisions and reasons for decisions (ACCS#32, ACMS#36, Joint ACMS-ACCS#29, November 2021)"

b. What are the purposes for which the substance is to be used and the extent of use of the substance?

Starpharma has developed a nasal spray product that contains astodimer sodium.

s47



c. What is the toxicity of the substance?

s47



A cold is a non-serious, self-limiting condition that does not require oversight from a medical practitioner. Treatment can be managed without the need for medical intervention. This is evidenced by the plethora of nasal spray products and non-nasal spray products available for purchase at supermarket chains and pharmacies for management of colds and cold symptoms.

Based on the toxicity profile described below for astodimer sodium, its use in a nasal spray is substantially safe for short-term treatment, and the potential for harm from inappropriate use is low.

Toxicity summary of astodimer sodium (also referred to as SPL7013) and formulations containing astodimer sodium such as nasal spray and vaginal gel.

The results of the in vitro cytotoxicity study demonstrated that at 5000 µg/mL, SPL7013 Nasal Spray is not cytotoxic.

In a nasal irritation study, rats were administered 100 µL of 1% SPL7013 Nasal Spray in each nostril, four times a day for 14 consecutive days. The results of the study from the in-life phase and the histopathological examinations indicate that SPL7013 Nasal Spray is not an irritant.

The skin sensitisation study consisted of a Guinea Pig Maximization Test (GMPT) according to Magnusson and Kligman (1969). The test demonstrated that 1% SPL7013 Nasal Spray is not a sensitiser.

SPL7013 Nasal Spray containing 1% or 3% astodrimmer sodium (SPL7013) was also administered nasally 4 times a day (50 µL per nostril) for 7 days to rats to test local toxicity as well as the potential for systemic absorption of astodrimmer sodium. The study showed that repeated nasal administration of SPL7013 Nasal Spray was well-tolerated and did not cause any clinical signs of local or systemic toxicity. Astodrimmer sodium was also not detected in plasma samples of animals administered 3% or 1% SPL7013 Nasal Spray, indicating that the compound is not systemically absorbed following nasal application.

An extensive body of toxicological data has been generated on SPL7013 Nasal Spray or SPL7013 Gel of varying strengths through a comprehensive testing program of toxicology studies covering nasal, vaginal, penile, rectal, oral and intravenous administrations. Studies have assessed single-dose toxicity and repeat-dose toxicity (up to 6 months in rats and 9 months in dogs), as well as developmental and reproductive (Segments I, II and III) toxicity, carcinogenicity and genetic toxicity. The toxicology was conducted in accordance with ICH guidelines and in compliance with US FDA GLP regulations. The performance and results of the toxicological testing have been examined against the requirements of the relevant parts of ISO 10993 and found to be sufficient.

No toxicity was observed following single oral doses of up to 1600 mg/kg of astodrimmer sodium in rats. In acute intravenous toxicity studies in rats and rabbits with astodrimmer sodium, no effects occurred at 25 mg/kg, but toxicity, including mortality, was noted at 50 and 75 mg/kg.

Rats, rabbits and dogs treated vaginally with 1, 3 or 5% w/w astodrimmer sodium (SPL7013) Gels for 14 days exhibited no evidence of systemic toxicity and no detectable levels of astodrimmer sodium in the plasma.

No severe findings (i.e., mortality or gross toxicology) have been seen in mice, rats and dogs dosed for up to 90, 180 and 270 days, respectively.

The oncogenic potential of 1, 3 and 5% w/w SPL7013 vaginal gel has been evaluated following daily vaginal administration in both mice and rats for 104 consecutive weeks (2 years). In both species, no evidence of a carcinogenic effect was observed.

In two in vitro mutagenicity assays, astodrimmer sodium produced negative results, suggesting a lack of damaging effects on genes and chromosomes. Astodrimmer sodium administered intravenously was also negative in the rat micronucleus genotoxicity assay.

A complete assessment of the potential reproductive and developmental effects of astodrimmer sodium was conducted. All studies involved vaginal dosing with SPL7013 Gels containing 0, 1, 3, and 5% astodrimmer sodium. In the fertility and early embryonic development study in female rats, there were no adverse test article-related effects at any dose level on clinical observations, body weights, food consumption or the reproductive process, including length of oestrous cycle, reproductive performance and early development of the embryo. The NOAEL was 5% w/w SPL7013 Gel.

Studies to investigate the effects on embryofetal development with astodrimmer sodium in rats and rabbits have been conducted. No evidence of teratogenicity was observed in rats or rabbits at any dose and the no-observed-effect-level (NOEL) was determined to be 5% w/w SPL7013 Gel.

A study of pre- and postnatal development, including maternal function, with the vaginal gels in rats concluded that no toxicity was observed in any generation when F0 maternal animals were administered SPL7013 Gel vaginally from GD 6 through lactation day 20. The NOEL was 5% w/w SPL7013 Gel.

No evidence of dermal sensitization was noted in guinea pigs treated with 2% w/w SPL7013 Gel.

No safety concerns were identified during this non-clinical phase, including no signs of teratogenic or carcinogenic potential, and no genotoxic risks. The toxic potential of astodrimmer sodium as a topical, non-systemically absorbed product is, therefore, considered to be well-characterized in a comprehensive nonclinical development program.

The clinical safety of astodrimmer sodium in condom lubricant, vaginal gel and nasal spray preparations has been demonstrated in 13 completed clinical studies involving more than 2000 patients.

SPL7013 Nasal Spray was shown to be safe and well tolerated when administered to nasal epithelium 4 times daily per nostril, for up to 14 consecutive days. Throughout the course of the study, there were no deaths nor SAEs, nor any Grade 2, 3 or 4 AEs. All AEs were mild and were primarily self-limiting. No clinically significant findings were noted on examination of the nasal cavity (nasal septum, inferior nasal turbinates and nasal vestibule). Based on the results of this investigation, the safety profiles of SPL7013 Nasal Spray and placebo were equivalent and the product was well-tolerated.

A total of 11 clinical investigations have been completed on SPL7013 Gel, which has a very similar formulation to SPL7013 Nasal Spray, and are strongly supportive of the clinical safety of SPL7013 Nasal Spray medical device.

SPL7013 Gel up to 3% w/w astodrimmer sodium has been shown to be safe and well tolerated when administered to the vaginal epithelium once daily or twice daily for up to 14 consecutive days, and once every second day for up to 16 weeks. Throughout the course of the Phase 1/2 studies, there were no deaths nor serious adverse events (SAEs), nor any Grade 3 or 4 adverse events (AEs). All other AEs were mild or, in a few cases, moderate, and were generally self-limiting and resolved. The frequency of treatment-emergent AEs was low in large Phase 3 studies, with no related SAEs reported. There was a lack of systemic side effects attributable to the product, consistent with the lack of systemic absorption of astodrimmer sodium.

The extent of systemic absorption of astodrimmer sodium was evaluated in studies SPL7013-001, -002, -004 and -006 in healthy volunteers following vaginal or penile administration in females and males respectively. Systemic absorption was also evaluated in female subjects as part of the Phase 3 clinical study in women with BV, study SPL7013-015. Blood samples were analysed using a validated bioanalytical method (LLOQ 0.5 µg/mL [30nM]). Astodrimmer sodium was not detected in any of the samples.

These findings indicate that astodrimmer sodium is not systemically absorbed following nasal administration and vaginal administration.

d. What is the dosage, formulation, labelling, packaging and presentation of the substance?

The product is an aqueous-based, isotonic nasal spray containing 1% w/w astodrimmer sodium. It is supplied in a 10mL plastic bottle fitted with a nasal pump applicator and an IFU leaflet, which are contained in an outer carton. The application of the nasal spray is aligned with that of other nasal spray products currently supplied to Australia for the management of colds and cold symptoms.

The requested amendments to Schedule 3 will allow for the nasal spray product to be made available in the same way as other nasal spray products in its class are available in the market.

e. What is the potential for the substance to be misused or abused?

Astodrimmer sodium is not systemically absorbed; therefore dependence, misuse or overdose of astodrimmer sodium in a nasal spray is of no concern.

f. Are there any other matters that may be necessary to protect public health?

g. Would you like to provide any other information to support your application to amend the Poisons Standard?

Astodrimer sodium is included in multiple products, all regulated as medical devices, and include a condom lubricated with astodrimer sodium lubricant, a vaginal gel, and now a nasal spray. When the condom product was supplied in Australia, it was available in pharmacies and supermarket chains. Astodrimer sodium was not included in the Poison Standard for this product. The purpose of astodrimer sodium in the condom lubricant was as an agent proven, in laboratory studies, to inactivate HIV, HSV, and HPV, which are viruses that cause STIs.

As currently written, astodrimer sodium is a Schedule 3 substance, except in a condom lubricant.

As acknowledged by the delegate in the “Delegate's final decisions and reasons for decisions (ACCS#32, ACMS#36, Joint ACMS-ACCS#29, November 2021)” astodrimer is a topical treatment with a low risk of harm itself, however advice from a medical practitioner should be sought before using the substance for the treatment and prevention of BV.

It is for this reason, and only this reason, that astodrimer sodium was included in the Poison Standard, noting that at that time, a condom with a lubricant that contained astodrimer sodium was being supplied to the Australian market, and hence the entry in Schedule 3 excluded a condom lubricant containing astodrimer sodium from Schedule 3.

A cold is not a serious condition and does not require oversight from a medical practitioner. This is evidenced by the plethora of nasal spray and other products available direct to consumers for purchase at supermarkets and pharmacies for management of colds and cold symptoms.

Toxicity information

- 25. If you have prepared a document with toxicity information, please upload your document as an attachment in an email when you send in your application.**

See attachment A

- 26. Where data is available, we encourage you to provide the acute toxicity information in the Toxicity Table above and other toxicities under the relevant sub-headings below. If there is no data available, please indicate this with words to the effect of “no information” along with your justification as to why this should not hinder the scheduling consideration.**

a. Additional information on acute toxicity

The results of the astodrimmer sodium acute toxicity tests in rats and rabbits are presented in Annex A of the Toxicity Summary document.

In the rat, following a single vaginal dose using the 5% w/w SPL7013 Gel, there was no observed systemic toxicity or localised vaginal irritation. Similarly, following single oral doses up to 1600 mg/kg astodrimmer sodium, there were no adverse clinical signs observed. With intravenous dosing, there were no observed effects noted at 25 mg/kg astodrimmer sodium, but at higher doses (50 and 75 mg/kg), significant toxicity was evident.

In the rabbit, a single vaginal dose produced no systemic effects and very slight to well-defined erythema and very slight oedema 12 to 15 days post-dosing with 0% or 5% w/w SPL7013 Gel. No evidence of vaginal irritation was observed in any animal at necropsy. Following a single intravenous dose, there were no significant effects noted at doses of 25 mg/kg, but at higher doses (50 and 75 mg/kg), significant toxicity was evident.

b. Repeat dose toxicity

The results of the astodrimmer sodium (SPL7013), including SPL7013 Nasal Spray, subacute/subchronic toxicity tests in rats and rabbits are discussed below.

SPL7013 Nasal Spray containing 1% or 3% astodrimmer sodium was administered nasally 4 times a day (50 µL per nostril) for 7 days to male rats to test local toxicity as well as potential for systemic absorption of astodrimmer sodium. The study showed that repeated nasal administration of SPL7013 Nasal Spray was well-tolerated and did not cause any clinical signs of local or systemic toxicity. Astodrimmer sodium was also not detected in plasma samples of animals administered 3% or 1% SPL7013 Nasal Spray, indicating that the compound is not systemically absorbed following nasal application.

Repeated administration of astodrimmer sodium by once-daily oral gavage for 14 days was well tolerated in rats at up to 2000 mg/kg/day. Based on the bioanalytical results, there was very limited systemic exposure to astodrimmer sodium after administration of 500, 1000 or 2000 mg/kg/day. There was some evidence that systemic exposure was greater for 2000 mg/kg/day than for the two lower doses, but there was no clear difference between the two lower doses.

In a study of repeated daily intravenous (bolus) injection of astodrimmer sodium for 7 days in rats, astodrimmer sodium was well tolerated at levels of 0.4 and 1.7 mg/kg/day, with only minor, transient clinical signs (decreased activity and reddened ears) noted at 9 mg/kg/day.

In male dogs, penile administration of 3% w/w SPL7013 Gel for 7 consecutive days was well tolerated. There were no test article-related clinical signs, penile irritation, or impact to body weight or food consumption.

In two-week vaginal toxicity studies, rats and rabbits were treated with 1, 3, or 5% w/w SPL7013 Gels, vehicle gel, or K-Y Plus (a reference compound, containing N-9). There was no evidence of systemic toxicity and no detectable levels of astodrimmer sodium in the plasma. The only

finding was minimal irritation in the vagina. A similar lack of systemic toxicity was reported in a 14-day dog vaginal toxicity study (0, 1, 3, 5% w/w SPL7013 Gels). Microscopic examination revealed a dose-related increase in the severity of subacute inflammation in the cervix and vagina (proximal, mid and distal sections). This occurred in all animals from all groups, including the vehicle control. A minimal to mild response was produced in the dogs receiving the vehicle gel and 1% w/w SPL7013 Gel whereas a moderate response was produced in the dogs receiving the 3% w/w SPL7013 Gel, and a moderate to severe response was produced in the dogs receiving the 5% w/w SPL7013 Gel.

The daily rectal administration of SPL7013 gels for 4 weeks to experimentally naïve rats at concentrations of 1%, 3%, and 5% w/w astodimer sodium did not produce any adverse test article-related effects. There were no astodimer sodium-related microscopic changes indicative of localised anal or large intestinal irritation or systemic toxicity. Possible vehicle-related microscopic findings were present in males and were limited to the large intestine adjacent to the anus and 1 cm from the anus. These findings consisted of a very slight increase in leukocyte infiltration of the lamina propria in animals that received the vehicle compared to the sham group animals; there was no substantial exacerbation of this finding with increasing astodimer sodium dosage. The leukocyte infiltration was comprised primarily of macrophages, as well as lesser numbers of lymphocytes, eosinophils, neutrophils and plasma cells. Due to the low magnitude of the change and lack of similar findings in females, the role of the vehicle in this finding remains uncertain and the changes may merely represent normal biologic variation. All other microscopic observations were considered to be incidental.

c. Genotoxicity

Astodimer sodium was not mutagenic or clastogenic in in vitro and in vivo genetic toxicity studies and was not carcinogenic in mice or rats.

In two in vitro mutagenicity assays, astodimer sodium produced negative results, suggesting a lack of damaging effects on genes and chromosomes. Astodimer sodium administered intravenously was also negative in the rat micronucleus genotoxicity assay.

The oncogenic potential of 1, 3 and 5% w/w SPL7013 Gel has been evaluated following daily vaginal administration in both mice and rats for 104 consecutive weeks (2 years). In both species, no evidence of a carcinogenic effect was observed.

d. Carcinogenicity

Daily vaginal administration of SPL7013 Gel for 2 years to mice at concentrations of 1%, 3%, and 5% w/w astodimer sodium did not produce any evidence of a carcinogenic effect.

Daily vaginal administration of SPL7013 Gel for 2 years to rats at concentrations of 1%, 3%, and 5% w/w astodimer sodium did not produce any evidence of a carcinogenic effect.

e. Reproduction and developmental toxicity

There were no adverse effects on fertility and early embryonic development in rats, embryofetal development in rats and rabbits and pre- and post-natal development in rats when SPL7013 Gel was administered intravaginally at concentrations up to 5% astodimer sodium, the highest dose tested. Unexpected mortality was noted in rabbits with repeated administrations, but this was determined to be a species-specific response associated with the presence of a unique anatomical feature in rabbits, being the vaginal plexus. Because this plexus is not present in mice, rats, dogs or humans, the findings in rabbits were considered to not be representative of a safety concern for humans.

f. Observation in humans

The clinical safety and efficacy of astodimer sodium in condom lubricant, vaginal gel and nasal spray preparations has been demonstrated in 13 completed clinical studies involving more than 2000 patients.

SPL7013 Nasal Spray containing 1% astodimer sodium was shown to be safe and well tolerated when administered to the nasal epithelium 4 times daily per nostril, for up to 14 consecutive days. Throughout the course of the study, there were no deaths nor SAEs, nor any Grade 2, 3 or 4 AEs. All AEs were mild and were primarily self-limiting. No clinically significant findings were noted on examination of the nasal cavity (nasal septum, inferior nasal turbinates and nasal vestibule).

SPL7013 Gel up to 3% w/w astodimer sodium has been shown to be safe and well tolerated when administered to the vaginal epithelium once daily or twice daily for up to 14 consecutive days, and once every second day for up to 16 weeks. Throughout the course of the Phase 1/2 studies, there were no deaths nor serious adverse events (SAEs), nor any Grade 3 or 4 adverse events (AEs). All other AEs were mild or, in a few cases, moderate, and were generally self-limiting and resolved. The frequency of treatment-emergent AEs was low in large Phase 3 studies, with no related SAEs reported.

Taken together, there was a lack of systemic side effects attributable to the product, consistent with the lack of systemic absorption of astodimer sodium.

g. International regulations

Study designs, group sizes and parameters evaluated were consistent with currently accepted toxicology principles and practices (21 CFR Part 58). In addition, the following ICH safety guidelines were followed when conducting the toxicology studies: S1A, S1B, and S1C(R2) for carcinogenicity testing, S2A and S2B (later replaced by S2(R1)) for genotoxicity studies, S3A and S3B for toxicokinetics and pharmacokinetics, S4 for duration of chronic toxicity studies and S5(R2) for reproductive toxicity. Any deviations that occurred during the performance of the non-clinical studies were minor and did not affect the integrity of the study or the interpretation of the data.

h. Other toxicity information

The pharmacokinetic (PK) profile of astodimer sodium was evaluated in healthy volunteers following nasal, vaginal or penile administration. Astodimer sodium was not detected in any of the samples, indicating that astodimer sodium is a non-systemically absorbed product having a very low to non-existent risk of systemic toxicity.

Claims against the Scheduling Policy Framework (SPF) - scheduling factors

27. How does your proposed amendment of the Poisons Standard align with the scheduling factors?

The proposed amendment to the Poison Standard is to amend the Schedule 3 entry to read:

ASTODRIMER SODIUM except when used in:

- a) a condom lubricant; or
- b) a barrier nasal spray.

Therefore, the scheduling factors do not apply to SPL7013 Nasal Spray as evident by the information provided in the application.

To further justify:

1. the quality use of the medical device containing astodrimmer sodium can be achieved by labelling, packaging and/or provision of other information. The medical device is for minor ailments or symptoms that can easily be recognised and are unlikely to be confused with other more serious diseases or conditions. Treatment can be managed without the need for medical intervention or a pharmacist at the point of sale.
2. the use of the medical device containing astodrimmer sodium is substantially safe for short-term treatment and the potential for harm from inappropriate use is low, as evidenced by the clinical safety and post market data, and the lack of toxicity.
3. the use of the medical device is extremely unlikely to produce dependency is very unlikely to be misused, abused or illicitly used as astodrimmer sodium is not systemically absorbed.
4. the risk profile of astodrimmer sodium is well defined and the risks can be identified and managed through appropriate packaging and labelling. There is a low and well-characterised incidence of adverse effects and there are no known interactions with commonly used substances or food, or contra-indications as astodrimmer sodium is not systemically absorbed.
5. the use of astodrimmer sodium in a nasal spray is not likely to mask the symptoms or delay diagnosis of a serious condition, and appropriate labelling and packaging can manage any perceived risk.

28. Have you read and understood the scheduling factors and Scheduling Policy Framework?

Yes

Related documents

29. References

Please enter a list of your references in the text box below:

For all references listed, please attach the reference documents in a compressed .zip or .rar file to your application.

Not Answered

30. Bibliography and supporting data

Please enter a list of the bibliography or supporting data in the text box below:

For all bibliographies or support data listed, please attach all the documents in a compressed .zip or .rar file to your application.

Not Answered

Confidentiality including personal information and declaration

Confidentiality including personal information

Please select all checkboxes below that are relevant to your application:

My application contains material that is confidential and restricted to use for scheduling purposes only.

Declaration

I declare that all information provided in this form is true and correct at the time of submission.

Important note: Providing information that is false or misleading to a Commonwealth entity or in connection with a Commonwealth law is a serious offence subject to criminal penalties under the Criminal Code Act 1995.

Yes

ACMS #43

Public submissions for

Astodrimer Sodium



PROPOSED AMENDMENTS TO POISONS STANDARD

ACMS and Joint ACMS/ACCS Meetings November 2023

Comments by The Pharmacy Guild of Australia to the proposed amendments referred by the delegate for scheduling advice for consideration by the Advisory Committee on Medicines Scheduling

1. Astodrimmer Sodium

2. §22 [REDACTED]

3. §22 [REDACTED]

4. §22 [REDACTED]

5. §22 [REDACTED]

6. §22 [REDACTED]

7. §22 [REDACTED]

8. §22 [REDACTED]

Date 18/09/2023

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ASTODRIMER SODIUM

Proposal

It has been proposed to amend the Poisons Standard as follows:

Schedule 3 – Amend Entry

ASTODRIMER SODIUM except [when used](#) in:

[\(a\) a condom lubricant; or](#)

[\(b\) a barrier nasal spray.](#)

Overview

Astodimer sodium is a dendrimer molecule which has antiviral and virucidal properties due to its polyanionic surface charge.¹ Astodimer sodium is currently approved for use as an active ingredient in medical devices only.

Scheduling Considerations

The risks and benefits of the use of a substance

Astodimer sodium is used as a topical microbicide that is used in a class 2A medical device for the treatment of bacterial vaginosis (BV) and for the prevention of sexually transmitted diseases as a condom lubricant.² Studies done to understand its effectiveness against COVID have found astodimer sodium to be well tolerated with no systemic absorption being detected.³

The purposes for which a substance is to be used and the extent of use of a substance

Astodimer sodium demonstrated potent antiviral activity in various studies across the globe.¹ However, further studies are required to measure the extent of the virucidal activity that it promises. Nasal sprays containing Carrageenan help with relieving some symptoms of cold and flu and is generally used for nasal dryness and crusting.⁴ Astodimer sodium potentially could be used for the same indications.

Any other matters necessary to protect public health

There have been advertising compliance issues in the past with similar nasal sprays where the alleged company advertised a product with certain therapeutic claims (restricted representations).⁵ Manufacturers should be reminded that if they wish to advertise a restricted representation, they must submit a formal application to the TGA for approval.⁶

Summary

The Guild supports the proposed amendments for Astodimer sodium.

¹ [Virucidal and antiviral activity of astodimer sodium against SARS-CoV-2 in vitro - ScienceDirect](#)

² [2.4 Astodimer sodium | Therapeutic Goods Administration \(TGA\)](#)

³ [Astodimer sodium antiviral nasal spray for reducing respiratory infections is safe and well tolerated in a randomized controlled trial - PMC \(nih.gov\)](#)

⁴ [FLO Travel Nasal Spray - NPS MedicineWise](#)

⁵ [Starpharma Holdings Limited fined \\$93,240 for alleged unlawful advertising of 'Viraleze' in relation to COVID-19 | Therapeutic Goods Administration \(TGA\)](#)

⁶ [Restricted representations | Therapeutic Goods Administration \(TGA\)](#)


Short-text responses for Astodrimmer sodium

Type of responder	Vote	Short-text response
Organisation (Pharmaceutical Society of Australia)	Support proposal for ASTODRIMER SODIUM	Astodrimmer sodium - No objections to proposed amendment to S3 entry with regards to barrier nasal spray preparations.

Type of responder	Vote	Short-text response
Individual	Support proposal for ASTODRIMER SODIUM	I STRONGLY SUPPORT the amendment to Schedule 3 for astodrimmer sodium barrier nasal sprays" as added support against cold viruses.
Individual	Support proposal for ASTODRIMER SODIUM	"Contracting the cold virus affects my ability to work effectively. I STRONGLY SUPPORT the amendment to Schedule 3 for sodium barrier nasal sprays
Individual	Support proposal for ASTODRIMER SODIUM	"Contracting the cold virus affects my ability to astodrimmer work effectively. I STRONGLY SUPPORT the amendment to Schedule 3 for astodrimmer sodium barrier nasal sprays"
Individual	Support proposal for ASTODRIMER SODIUM	Any medication which can help with reducing the severity of common viruses should be available to the public in this country, especially when it is made her and readily available elsewhere in the world.
Individual	Support proposal for ASTODRIMER SODIUM	As a patient with primary immunodeficiency, I am often suffer lengthy illness, and can be severely impacted by viruses, including those associated with colds and respiratory illnesses. Having early, 'over-the-counter access to a treatment, without the delays associated with seeking a medical appointment to obtain a prescription, would potentially reduce the duration and severity if my symptoms, thus improving my quality of life. Astronomer Sodium has been shown to be a safe and effective physical barrier to trap the viruses associated with colds within the nasal passages, and would this be an ideal option.
Individual	Support proposal for ASTODRIMER SODIUM	As a Respiratory Physician I would like myself and my patients to have access to Astodrimmer Sodium as a barrier nasal spray. A barrier nasal spray may help to prevent upper respiratory tract infections which may in turn reduce exacerbations of lung diseases like COPD which have a devastating impact on my patients. I would like to strongly advocate that this is made available as soon as possible.
Individual	Support proposal for ASTODRIMER SODIUM	As a young person who suffers from lingering heart issues after one omicron covid infection I am very interested in avoiding any further infections. In addition to the benefits to my own health I also believe that supporting the proposal for Astodrimmer sodium will help the economy. I had to take 6 months off work to somewhat recover from the heart issues which covid caused me. The long covid inquiry conducted by the government demonstrated the economic impacts of long covid on various industries. Nasal sprays such as Viraleze containing Astodrimmer solution can help reduce the burden of covid and long covid on the economy if it helps halt infections. Finally, it is in the interest of Australians to be able to support Australian businesses such as Viraleze, especially when other countries with similarly stringent regulations (such as those in the European Economic Area (EEA) have already approved it. With respect to s 52E of the THERAPEUTIC GOODS ACT 1989 the benefits far outweigh the risks of such a product, there is an extremely low potential for abuse of the substance, and it is of low toxicity.
Individual	Support proposal for ASTODRIMER SODIUM	As I suffer from a chronic health condition where colds can wipe me out, having a nasal barrier spray that would help to protect from colds would be very beneficial.
Individual	Support proposal for ASTODRIMER SODIUM	As someone who works in close quarters as a FIFO worker, contracting a the cold virus on either the plane flights to and from site or whilst living at work drastically affects my ability to work effectively (and spreads rapidly amongst the workers, leading to even lower productivity). Therefore I STRONGLY SUPPORT the amendment to Schedule 3 for astodrimmer sodium barrier nasal sprays.
Individual	Support proposal for ASTODRIMER SODIUM	As someone who works in healthcare, I am exposed to respiratory viruses a lot more than the average person and as such, often am on sick leave. I strongly support the proposed changes to approve nasal spray containing astodrimmer sodium so that I and many others in healthcare settings can avoid getting sick with colds and flus as often, especially considering the current shortages happening at the moment. Being able to use a low cost low risk OTC nasal spray such as those containing this active ingredient to avoid the common cold would be a welcome change.
Individual	Support proposal for ASTODRIMER SODIUM	ASTODRIMER SODIUM (in products such as Viraleze) has been shown as safe and effective in reducing the viral load of SARS-CoV-2, influenza, and respiratory syncytial virus (RSV). Given it is already approved in Europe, it should be allowed in Australia so the public can better protect themselves against outbreaks.
Individual	Support proposal for ASTODRIMER SODIUM	Astodrimmer sodium barrier nasal sprays will be of very HIGH BENEFIT in protecting healthcare and allied healthcare workers such as myself (Registered PSYCHOLOGIST) who are at significant risk of contracting the cold virus through the close personal physical interaction with clients and patients required in the delivery of healthcare services. With the high level of cold and respiratory viruses circulating I am currently avoiding face-to-face interaction with clients, but remote interaction via video-conferencing limits my ability to build a professional relationship and trusting rapport with clients. This is ADVERSELY IMPACTING my ability to deliver effective psychological assessments and interventions. Astodrimmer sodium barrier nasal sprays will lower the risk of infection and enable me to more fully interact face-to-face with clients and provide a full range of psychological services.

		I STRONGLY SUPPORT the amendment to Schedule 3 for astodimer sodium barrier nasal sprays. §22
Individual	Support proposal for ASTODRIMER SODIUM	Being infected with common cold viruses has a significant impact on my ability to work, and leads me to take increased sick leave. I am in strong support for the amendment to Schedule 3 for astodimer sodium barrier nasal sprays.
Individual	Support proposal for ASTODRIMER SODIUM	Catching a cold virus impacts work. I STRONGLY SUPPORT the amendment to Schedule 3 for astodimer sodium barrier nasal sprays.
Individual	Support proposal for ASTODRIMER SODIUM	Catching colds affects my ability to work effectively. Hence I support the amendment to Schedule 3 for astodimer sodium barrier nasal sprays
Individual	Support proposal for ASTODRIMER SODIUM	Catching colds and illnesses hinders my ability to care for my children. I strongly support astodimer sodium sprays like viraleze being made available to the Australian public.
Individual	Support proposal for ASTODRIMER SODIUM	Contracting the cold and covid viruses affects my ability to work effectively. I STRONGLY SUPPORT the amendment to Schedule 3 for astodimer sodium barrier nasal sprays
Individual	Support proposal for ASTODRIMER SODIUM	Contracting the cold impacts my ability to earn and support myself. This would help against that. I STRONGLY SUPPORT the amendment to Schedule 3 for astodimer sodium barrier nasal sprays"
Individual	Support proposal for ASTODRIMER SODIUM	Contracting the cold virus affects my ability to function and work effectively. I strongly support the amendment to Schedule 3 for astodimer sodium barrier nasal sprays.
Individual	Support proposal for ASTODRIMER SODIUM	Contracting the cold virus affects my ability to work effectively as well as my husband's. We also have two children at school who are regularly exposed to respiratory viruses that interfere with their school attendance & academic progression. I STRONGLY SUPPORT the amendment to Schedule 3 for astodimer sodium barrier nasal sprays.
Individual	Support proposal for ASTODRIMER SODIUM	Contracting the cold virus affects my ability to work effectively, and care for my family. I STRONGLY SUPPORT the amendment to Schedule 3 for astodimer sodium barrier nasal sprays
Individual	Support proposal for ASTODRIMER SODIUM	Contracting the cold virus affects my ability to work effectively, and my children's ability to attend school. Consequently, I STRONGLY SUPPORT the amendment to Schedule 3 for astodimer sodium barrier nasal sprays.
Individual	Support proposal for ASTODRIMER SODIUM	Contracting the cold virus affects my ability to work effectively. I STRONGLY SUPPORT the amendment to Schedule 3 for astodimer sodium barrier nasal sprays"
Individual	Support proposal for ASTODRIMER SODIUM	Contracting the cold virus affects my ability to work effectively. I STRONGLY SUPPORT the amendment to Schedule 3 for astodimer sodium barrier nasal spray.
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Individual	Support proposal for ASTODRIMER SODIUM	Contracting the cold virus affects my ability to work effectively. I STRONGLY SUPPORT the amendment to Schedule 3 for astodimer sodium barrier nasal sprays
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Individual	Support proposal for ASTODRIMER SODIUM	Contracting the cold virus affects my ability to work effectively. I STRONGLY SUPPORT the amendment to Schedule 3 for astodimer sodium barrier nasal sprays.
Individual	Support proposal for ASTODRIMER SODIUM	Contracting the cold virus affects my ability to work effectively. I STRONGLY SUPPORT the amendment to Schedule 3 for astodimer sodium barrier nasal sprays.
Individual	Support proposal for ASTODRIMER SODIUM	Contracting the cold virus affects my ability to work effectively. I STRONGLY SUPPORT the amendment to Schedule 3 for astodimer sodium barrier nasal sprays. At the moment, I buy Enovid from overseas, and it is very expensive.
Individual	Support proposal for	Contracting the cold virus affects my ability to work effectively. I STRONGLY SUPPORT the amendment to Schedule 3 for astodimer sodium barrier nasal sprays. I already import it at large expense!

	ASTODRIMER SODIUM	
Individual	Support proposal for ASTODRIMER SODIUM	Contracting the cold virus affects my ability to work effectively. I STRONGLY SUPPORT the amendment to Schedule 3 for astodimer sodium barrier nasal sprays. I have been having this sent over from UK by relatives to use here in Australia. We should be able to access these types of products here in Australia.
Individual	Support proposal for ASTODRIMER SODIUM	Contracting the cold virus affects my ability to work effectively. I STRONGLY SUPPORT the amendment to Schedule 3 for astodimer sodium barrier nasal sprays"
Individual	Support proposal for ASTODRIMER SODIUM	Contracting the cold virus affects my ability to work effectively. I work in a mental health clinic and I STRONGLY SUPPORT the amendment to Schedule 3 for astodimer sodium barrier nasal sprays.
Individual	Support proposal for ASTODRIMER SODIUM	Contracting the cold virus inhibits my ability to work and care for my grandchildren, requiring their parents to take time off work. This spray will help to reduce the number of times I catch cold and also the severity of symptoms. I strongly support the amendments to Schedule 3 for ASTRODRIMER SODIUM nasal spray which will bring Australian in line with many other countries that currently sell this product.
Individual	Support proposal for ASTODRIMER SODIUM	Contracting viruses affects my ability to work effectively and impedes my capacities as a carer for a disabled person. I STRONGLY SUPPORT the amendment to Schedule 3 for astodimer sodium barrier nasal sprays on this basis.
Individual	Support proposal for ASTODRIMER SODIUM	Fully Support proposal for Astrodrimer Sodium
Individual	Support proposal for ASTODRIMER SODIUM	Getting colds affects my ability to work effectively. I strongly support the proposal to make this product available
Individual	Support proposal for ASTODRIMER SODIUM	Given places previously deemed 'essential' are no longer safely accessible for the medically vulnerable and disabled community, Astodimer Sodium should be made available to the general public as another tool in the fight against COVID19 and other AIRBORNE pathogens.
Individual	Support proposal for ASTODRIMER SODIUM	Have contacts all over the world who swear by this product Fr colds sinus and other Ridiculous we still dont have it approved Please do tge right thing here Thanks 
Individual	Support proposal for ASTODRIMER SODIUM	Having a nasal spray containing Astodimer sodium readily available to control throat infections would be extremely helpful for the general population as it would avoid the need for medical appointments and the socio-economic constraints this imposes. It would also allow a more rapid and effective response to nasal and throat viral infections such as a cold or flu
Individual	Support proposal for ASTODRIMER SODIUM	Having a number of underlying medical conditions contracting any virus negatively impacts my health. As public health are not promoting collective risk mitigation having an approved nasal spray that can contribute to my personal risk mitigation strategies is very important. I STRONGLY SUPPORT the amendment to Schedule 3 for astodimer sodium barrier nasal sprays"
Individual	Support proposal for ASTODRIMER SODIUM	Having a number of underlying medical conditions contracting any virus negatively impacts my health. I STRONGLY SUPPORT the amendment to Schedule 3 for astodimer sodium barrier nasal sprays.
Individual	Support proposal for ASTODRIMER SODIUM	High level of support. Australian's who are vulnerable to COVID have been abandoned by Public Health and if Astodimer Sodium could provide even a small barrier to infection then I'm all for it. The product appears safe and effective and I would value the opportunity to add it to my array of covid protections.
Individual	Support proposal for ASTODRIMER SODIUM	I am a General Practitioner. I strongly support the proposal for Astodimer sodium being available OTC as a nasal spray. I agree with all of the applicant's reasons for the proposal (as summarised in the Pre-meeting Public Notice document). Many of my patients are looking for something else (in addition to vaccines and other preventive measures such as hand hygiene and masks) that may reduce their risk of contracting respiratory viruses.

		<p>Also, many people seek something that may reduce their viral load and possibly, therefore, reduce transmission of respiratory viruses to others.</p> <p>None of my patients who have expressed interest in this product (which currently is very difficult to obtain in Australia) have said they would use this instead of vaccination or other protective measures, but have said they would use it as an additional protective measure.</p> <p>The pre-clinical testing of Astodrimmer Sodium against respiratory viruses is impressive and its claimed mechanism of action - to block the virus in the nasal mucosa and reduce the chance of contracting respiratory viruses and reduce viral load and, therefore, transmission - is very plausible. Its broad antiviral action is also very attractive, especially as many respiratory viruses have no available vaccine against them available and viruses mutate which can affect the efficacy of available vaccines.</p> <p>I agree with the applicants statements that allowing over the counter availability of astrodrimer sodium in a nasal spray formulation is of very low risk to consumers and to the public. In addition to the statements made by the applicant regarding safety, this antiviral nasal spray appeals to me, as a general practitioner, as it is not an antiseptic / bactericidal agent, nor an antibiotic and so is very unlikely to adversely impact the nasal and upper respiratory tract flora (unlike some other antiviral nasal sprays under development or already in use) which could be an unintended harmful consequence of using some antiviral nasal sprays.</p>
Individual	Support proposal for ASTODRIMER SODIUM	I am a healthy retiree. I would like to limit the number of colds I catch each year to stay active for my grandchildren. I strongly support this Astodrimmer Sodium application. Thank you.
Individual	Support proposal for ASTODRIMER SODIUM	I am a primary school teacher who is often contracting colds and needing to stay away from work, I STRONGLY SUPPORT the amendment to Schedule 3 for astodrimmer sodium barrier nasal sprays. I would find it highly beneficial.
Individual	Support proposal for ASTODRIMER SODIUM	I am a self employed carer. Contracting any type of cold virus affects my ability to work effectively and safely. If I don't work I have NO income. I therefore STRONGLY SUPPORT the amendment to Schedule 3 for astodrimmer sodium barrier nasal sprays!
Individual	Support proposal for ASTODRIMER SODIUM	I am a teacher so having access to this product will reduce the number of sick days I have.
Individual	Support proposal for ASTODRIMER SODIUM	I am immunocompromised and at increased risk of severe Covid, long Covid and other post Covid sequelae. My understanding is that Astodrimmer Sodium is safe and another layer in the Swiss cheese model to reduce transmission of Covid. We need every measure we can get to take personal responsibility to minimise risk of infection the context of minimal mitigations being taken in the community at large.
Individual	Support proposal for ASTODRIMER SODIUM	I am writing in support of the approval for Viraleze to be sold in Australia. Many nasal sprays, including viraleze, have been shown to provide a protective barrier to prevent infection with cold and respiratory viruses. Viraleze is readily available in many other countries, including the UK, and people living in Australia would benefit from having another nasal spray option, particularly in light of the ongoing pandemic.
Individual	Support proposal for ASTODRIMER SODIUM	<p>I find that as I get older (I'll be 60 in December), that getting even a common cold virus affects my ability to work effectively, and it takes me longer to recover.</p> <p>That's why I STRONGLY SUPPORT the amendment to Schedule 3 for astodrimmer sodium barrier nasal sprays.</p> <p>I also think it's very important to support Australian-led medical research discoveries, and encourage commercialisation.</p>
Individual	Support proposal for ASTODRIMER SODIUM	I fully support the changes for astodrimmer sodium because if I get a cold I cannot work
Individual	Support proposal for ASTODRIMER SODIUM	I have an autoimmune disease and contracting viruses like the common cold triggers my immune system to attack my own body. This impacts my health, quality of life and productivity. I STRONGLY SUPPORT the amendment to Schedule 3 for astodrimmer sodium barrier nasal sprays. It would hugely benefit me and others like me. Thanks for your consideration
Individual	Support proposal for ASTODRIMER SODIUM	<p>I have been using viraleze myself here in Australia for the past 5 months after my cousin purchased it in Ireland from viraleze.co website which had it sent to them and then forwarded onto my for personal use as allowed by the Australian regulations for personal use. Since it is not available here in Australia, it's the only way we can get it. I also wear a N95 mask as I have to visit hospitals for monthly venesection for haemochromatosis and am high risk with asthma and had a radical hysterectomy 2 years ago for uterine cancer ... margins not clear...genetic cancer..lynch syndrome..which means I have been in and out of medical care with cat scans, and other treatments. And after all that, my doctors are astonished I gave not gotten covid. I smile and show them what I call, my savour...viraleze. They are shocked that they never heard of it and shocked it has not been approved yet here in Australia and say...what ever your doing keep doing it as it's rare to find someone as vulnerable as myself... in high risk environments not picked up covid. I also would like to add my twin brother uses it too and was at the dentist recently, so had to be unmasked, and the nurse was sick and coughing, he did not get the flu off her afterwards... as she was very unwell. He believes viraleze helped him not get sick. The fact is we have been using this wonderful potential life saving product, for months, we have no side effects, .. it is comforting to know that you are protected, I still keep all my boosters up to date, but viraleze is that one extra element to help stop viruses entering the nasal passage. I have a nursing background...I read the science, I watch the stats ... I look overseas at what us coming down the pipeline with new variants and would live the rest of the Australian population to have the opportunity to purchase viraleze here in Australia and have a very high chance of not getting covid or long covid with wave after wave of infections rolling through the communities... they also would be protected from flu, Bird flu, swine flu and other debilitating respiratory viruses. And the cost benefit to the community would be so beneficial with less workers going off sick.. saving potentially millions. Australia would be one of the powerhouse countries with booming industries....full workforce's all for the want of a little bottle of nasal spray to keep viruses at bay, hospitals would not have the critical burdens ... surgeries would not be cancelled, sick patients in hospitals would not pick up covid in hospital and die at 10% death rate ... it's time all Australians learned about viraleze. Millions are using it overseas... we should too. The cost of asking family and friends to buy it, wears thin after the 3rd order...it's a lot to ask and we shouldn't have to do it. And lastly, and this is extremely hard for me to admit, but I was given a recommendation to purchase viraleze from a online store, I was desperate to get it, and knew better.. but it seemed like a good idea at the time, we'll long story short it was a Australian con artist Andrew Pike.. and he took my money and 5</p>

		<p>months later, still no delivery. I am ashamed and devastated as other family and friends also were conned too.. once again, I should not have to try and buy viraleze outside Australia and end up in the arms of con artists...costing thousands we all will never get back. The trauma and guilt I feel from the whole ordeal has been taxing on my fragile health. I rather give my limited funds to a licensed chemist here in Australia... keep the money here and not send it overseas.</p> <p>Sorry for rambling on, I have read all the studies on all nasal antiviral sprays and viraleze came out in top... it not only protects you from getting covid but if you do get it, the antiviral properties will help, you fight it off. I have heard plenty of stories from people who returned from Europe and picked up viraleze overseas ... and then either them or son or daughter picked up covid on the plane... treated with viraleze and by day 3 RAT was negative. It definitely fought off the worst of covid.</p> <p>So I am submitting by story and my covid free status with the extra protection and use of viraleze with no side effects, no issues at all... and am far more confident visiting medical establishments...the local shops without trembling at the knees at the thought of catching covid and making me very very sick or at worse, Killing me as I am in the targeted group not to get covidfemale...57.. with serous underlying medical conditions.</p> <p>I really feel it has saved my life...</p> <p>It needs to save other lives too...</p> <p>please approve viraleze...for sale in Australia as it has been approved and sold oversea with no issues or concerns by many other well established medical and government agencies.</p>
Individual	Support proposal for ASTODRIMER SODIUM	I have Cystic Fibrosis any help reducing the chances of a severe cold is much appreciated. I STRONGLY SUPPORT the amendment to Schedule 3 for astodimer sodium barrier nasal sprays
Individual	Support proposal for ASTODRIMER SODIUM	I have post-infective bronchial hyperresponsiveness. Contacting any cold or respiratory virus affects my ability to parent and earn a living. I strongly support the amendment to Schedule 3 for astodimer sodium barrier nasal sprays.
Individual	Support proposal for ASTODRIMER SODIUM	I have several conditions that make me immunocompromised. The last rhinovirus I caught has left me bedbound and with a serious heart arrhythmia. I STRONGLY SUPPORT the amendment to Schedule 3 for astodimer sodium barrier nasal sprays so I can better protect myself from further damage
Individual	Support proposal for ASTODRIMER SODIUM	<p>I have used the Astodimer sodium (ASNS) nasal spray, Viraleze, which a Spanish friend brought back from Europe for me, under the TGA allowed 3mth Personal Importation scheme of unapproved medications.</p> <p>For decades, although never a smoker, I have suffered chronic cough, post nasal drip and blocked sinus. This worsens if I catch viral respiratory infections such as common colds or flu. Invariably common colds turn to bronchitis and need one or two courses of antibiotics to clear the secondary infection so avoiding them it very important to me. I've been taking Viraleze for almost a year and hoping also to clear sinus problems which ultra sound revealed included a bacterial patch and my ENT specialist said it needed a hospital operation to remove. Viraleze was remarkably effective with absolutely no adverse effects. Using only once a day until my hospital appointment my nose has NEVER felt better - although I still have the tickle of a cough, the post nasal drip improved and when examined by the registrar pre op we decided that the sinus had recovered and no operation was needed. I really hope that TGA approve this for over the counter pharmacy sale like many other nasal sprays which are less effective. There is no irritation with AS Nasal Spray unlike many others OTC sprays where sneezing, tickling and even bleeding occurs. Preventing and treating respiratory infections is so important to the community - this is far better than anything else I have used.</p> <p>Before using medications, I read the studies and information on the internet. ^[1]International references In UK the ASNS is approved as a Barrier Nasal Spray approved by UK MHRA March 2022 and EU Medical Device approval November 2020. Marketed in Netherlands/ Manu in Belgium and described as ANTIVIRAL NASAL SPRAY for multiple viruses (common cold is of course a VIRUS). EU EMA is recognised in Australian legislation as the expert in Nano Particles and TGA is recommended to refer to them. AS SP7013 is part of the dendrimer range of nanoparticle chemicals already TGA approved unscheduled in condoms and as BV treatment and preventative for BV. ^[2] find it strange that in "Proposed amendments to the Poisons Standard – ACMS, ACCS and Joint ACMS-ACCS meetings, November 2023" 1.1 INTERNATIONAL REGULATIONS which the delegate is currently reviewing and to which I am responding, there is no mention of European Medical Device approval Nov 2020 or UK MHRA MD revised 2022/03 P712362 PM05002 and ask that the delegate refer to those INCLUSIONS and not just the EXCLUSIONS listed.</p> <p>In the UK the post marketing study of ASNS brand name VIRALEZE, has recently completed participant data collection, with results to be published in Q4/2023 so hopefully that human placebo controlled study of over 200 covid positive participants will complete before the FINAL report of the delegate and inform whether COMMON COLD is the relevant condition for packaging information or SAR-COV2.</p> <p>https://cdn-api.markitdigital.com/apiman-gateway/ASX/asx-research/1.0/file/2924-02715741-3A626784?access_token=83ff96335c2d45a094df02a206a39ff4</p> <p>This international information should inform the TGA delegate prior to decision at the November committee meeting but if study results are later it will be available at any appeal stage of the delegates decision if application is unsuccessful or needs amendments.</p> <p>AS has undergone a safety placebo controlled trial in WA which showed that it is exceptionally safe in the nasal mucosa https://www.researchgate.net/journal/Scientific-Reports-2045-2322/publication/361382162_Astodimer_sodium_antiviral_nasal_spray_for_reducing_respiratory_infections_is_safe_and_well_tolerated_in_a_randomised_controlled_trial/links/62ad43cb40d84c1401b3290a/Astodimer-sodium-antiviral-nasal-spray-for-reducing-respiratory-infections-is-safe-and-well-tolerated-in-a-randomized-controlled-trial.pdf</p> <p>AND significantly there is no absorption into the bloodstream as it is a surface barrier by fine nano particle nasal spray. "The finding that astodimer sodium was not detected in the bloodstream following repeated nasal application is consistent with previous extensive nonclinical and clinical data showing lack of absorption into the blood- stream following topical application to mucosal membranes^{21,22}. Therefore, systemic adverse events would not be expected to occur from nasal administration of astodimer sodium, and there was no evidence of such events occurring in the current investigation"</p> <p>Scripps Research Institute has tested AS from August 2020 to 2023, on humanised mouse genome which was nominated early in the pandemic by WHO as an appropriate in-vivo test where population vaccine and exposure status lacks stability for accurate human trials. ie As noted in the Prof Jane Halton report to the new Health Minister Mark Butler re Vaccines and Treatments, PF-07321332 Paxlovid trials from March 2021 were conducted on unvaccinated persons and approved by FDA in late 2021 under EUA with an efficacy of 86%, in seeking full authorisation Pfizer conducted further trials reported mid 2022 which selected vaccinated participants and saw the efficacy drop to 51% no better statistically than the placebo group. Variant changes and number of boosters also have effected results for most vaccines in the pandemic making the WHO recommendation to use controlled humanised genome mice a rational choice which I think the TGA should also support. ^[3]ASNS SP7013 aka VIRALEZE had stunning results of 99.9% inactivation of all variants up to</p>

		<p>Kappa were achieved within 30 secs - see table in that report and reference reports. https://www.scripps.edu/gallay/sars-cov-2.html.</p> <p>The advantage of Scripps trials is that dissection of the mice afterwards can show if the virus is present in organs - lungs, trachea, nasal mucosa, brain , heart and liver and that detection was almost nil in all tests. As SARS COV2 is a Coronavirus and a particularly dangerous one in the pandemic, the common cold is also a coronavirus in most of its forms. Needless to say I have not had covid in the three years of the pandemic and after staying home during the first years of the pandemic, feel I can confidently go out now protected by the antiviral nasal spray which prevents multi viruses.</p> <p>It is also interesting that Lloyds Pharmacy in the UK had Viraleze discounted to £2 a bottle in April this year and was selling over 2000 bottles a day with 5 star rating and excellent customer reviews. It is very good. When family members or social contacts have a cold or flu I just spray my nose and I haven't caught a cold or flu or covid during the time I've used this spray. Not only do I support Astodimer sodium nasal spray for common cold being approved as an over the counter pharmacy product but I would support further applications to include Covid treatment and preventative when the UK NHS results on VIRALEZE are published. Over 16 million Australians, mostly working age, have no access to antivirals as Covid19 preventatives or treatments with the restrictions applied to Paxlovid (nirmatrelvir and ritonavir), Veklury (remdesivir) & failed Lagevrio (molnupiravir). All Australians, unless they legally import Viraleze or Enovid under the 3mth personal importation scheme, have no access to antivirals as preventatives. Please approve this application - it is probably one of the most important decisions TGA could rectify.</p>
Individual	Support proposal for ASTODRIMER SODIUM	I presently use a nasal spray in certain situations in order to reduce my risk of contracting viral infections (such as colds etc.), and I would like to have the opportunity to try and perhaps choose one containing astodimer sodium in case it works better or has less side effects than the one I am presently using.
Individual	Support proposal for ASTODRIMER SODIUM	<p>I respectfully urge the TGA to approve the sale and distribution of Astodimer sodium in Australia for the following reasons:</p> <ol style="list-style-type: none"> 1/ Proven safety profile - this substance has been approved for use in many countries around the world with few side effects being reported. 2/ Proven efficacy - the use of this substance has been shown to reduce the risk of infection for many airborne diseases. 3/ Australia is falling behind the rest of the world in not having effective anti-viral nasal sprays available. 4/ Airborne diseases of many kinds bring significant suffering to thousands of people every day and having prophylactics available would reduce this impost. 5/ Economic benefits would ensue by having fewer people succumb to contagious airborne viruses and thus needing time off work. Absenteeism is a major problem for industry and staff shortages are very common. If this issue is not addressed, Australian productivity will suffer. Anything that can reduce the chance of sickness could help this problem. 6/ In the case of COVID-19, not everyone is suitable for vaccinations and wearing of masks is not popular. Anti-virals are only available to a select few and the majority of patients do not qualify. Therefore, a nasal spray that reduces the chance of catching COVID-19 or any other airborne disease represents another layer of protection available to the young, the elderly or those who are disabled with a cognitive impairment which makes the wearing of masks unsuitable. <p>I write this as someone employed in the field of education. My job is high-risk and my health has suffered severely since contracting COVID. An early retirement from a job that I love remains a distinct possibility. Teacher shortages are at an all-time high and fill-in staff to cover for sick colleagues are often unavailable. The cost to the students of having a disrupted education bodes ill for the future of our youth.</p> <p>I have no affiliation with any company associated with this product. I merely want the best outcome for the Australian people.</p> <p>I therefore implore the TGA to consider this proposal on its merits and to approve the sale and distribution of Astodimer sodium in Australia.</p> <p>Thank you for your consideration of this matter.</p> <p>\$22</p>
Individual	Support proposal for ASTODRIMER SODIUM	I strongly support the amendment to Schedule 3 for Astodimer sodium barrier nasal spray, as contracting a cold interferes with my ability to work.
Individual	Support proposal for ASTODRIMER SODIUM	I strongly support the amendment to Schedule 3 for astodimer sodium barrier nasal sprays as I need to be in good health to do my job efficiently and I can't afford to be off work sick.
Individual	Support proposal for ASTODRIMER SODIUM	I strongly support the amendment to Schedule 3 for astodimer sodium barrier nasal sprays which have been shown to be very safe and effective against coronaviruses such as the common cold. As I have an autoimmune condition which is made worse by viruses, any additional layer of protection that prevents or lessens infection is very welcome.
Individual	Support proposal for ASTODRIMER SODIUM	I STRONGLY SUPPORT the amendment to Schedule 3 for astodimer sodium barrier nasal sprays, because it greatly improves recovery time and is found to reduce viral loads for colds.
Individual	Support proposal for ASTODRIMER SODIUM	I strongly support the amendment to Schedule 3 for astodimer sodium barrier nasal sprays. Getting sick from colds affects my ability to earn a living and care for my family as I often end up with secondary middle ear and sinus infections from mild colds. Availability of a preventive nasal spray would help me to stay healthy.
Individual	Support proposal for ASTODRIMER SODIUM	I STRONGLY SUPPORT the amendment to Schedule 3 for astodimer sodium barrier nasal sprays. I use other nasal sprays for protection against the cold virus when out in public, particularly when travelling. I believe they are effective and would like to see an Australian-developed version made available in Australia.
Individual	Support proposal	I STRONGLY SUPPORT the amendment to Schedule 3 for astodimer sodium barrier nasal sprays. My husband is immunocompromised and it would hugely benefit him and others like him. Thanks for your consideration.

	for ASTODRI MER SODIUM	
Individual	Support proposal for ASTODRI MER SODIUM	<p>I strongly support the amendment to Schedule 3 for astodrimmer sodium barrier nasal sprays. The product is designed as a barrier prophylaxis to reduce symptoms of respiratory virus and should be approved for such use.</p> <p>Already registered across the 27 countries of the European Union and the UK and Asia, it is another addition to already approved products to reduce symptoms of a cold such as Vicks First Defence nasal spray.</p> <p>The National Institute of Health study found no adverse effects and it was well tolerated in a randomised control trial.</p> <p>It is a Melbourne designed product licensed overseas and it would be sensible to launch here as well, given its success overseas.</p> <p>Personal benefits for this product being available are for personal relief from colds, meaning less time off work. It is a convenient, cheap and easy to use solution that has no ill effects on me. The public already has access to nasal sprays to treat colds and allergies so are used to using the product.</p>
Individual	Support proposal for ASTODRI MER SODIUM	I STRONGLY SUPPORT the amendment to Schedule 3 for the above nasal spray, as catching the cold virus impedes my ability to participate in employment.
Individual	Support proposal for ASTODRI MER SODIUM	I strongly support the amendments to allow wider access to the barrier nasal spray. This would enable me to participate more fully in my place of employment among children.
Individual	Support proposal for ASTODRI MER SODIUM	I strongly support the approval of this product. It will help my family avoid colds, and will therefore allow us to continue to work, study and play.
Individual	Support proposal for ASTODRI MER SODIUM	I STRONGLY SUPPORT the proposal for astodrimmer sodium barrier nasal sprays.
Individual	Support proposal for ASTODRI MER SODIUM	I strongly support the proposed changes for Astodrimmer Sodium. Contracting the cold virus affects my ability to work effectively. The availability of products containing the above ingredient would be of great use in order to be able to work.
Individual	Support proposal for ASTODRI MER SODIUM	<p>I strongly support this. We really need this safe and relatively cheap antiviral nasal spray because the common cold lowers productivity and creates workplace absences and labour shortages. I certainly can't work when I have a bad cold, and don't want to go in and give it to others anyway. This spray helps to stop catching it, or at least shortens symptom if unlucky enough to get sick anyway.</p> <p>I believe it is being safely used in quite a few other countries already, and has been for a fairly long time now. Similar products are already sold over the counter here but they often run out and a greater range of options should be available to consumers when this happens.</p>
Individual	Support proposal for ASTODRI MER SODIUM	I support the amendment to Schedule 3 for astodrimmer sodium barrier nasal sprays" I suffer from RA, SLE and have reoccurring nasal infections. I need this astodrimmer sodium barrier nasal spray. Thank you. \$22
Individual	Support proposal for ASTODRI MER SODIUM	I support Astodrimmer as it will help me feel safe in crowded situations. My sister lives overseas and she uses it all the time to stay safe from circulating viruses and I would like to be able to access it here please.
Individual	Support proposal for ASTODRI MER SODIUM	<p>I support the proposal for astrodrimer sodium, manufactured in Australia as the product Viraleze, to be able for sale to the Australian public as it has been shown overseas (where it is freely able for public purchase) to be a safe and efficacious nasal spray medication to be used during the covid pandemic we are currently dealing with.</p> <p>Thank you for considering my proposal for support of this product.</p>
Individual	Support proposal for ASTODRI MER SODIUM	I support the proposal to allow the use of Astodrimmer Sodium nasal spray. It will help prevent/ameliorate the effects of some inhaled viruses eg common cold which can cause misery for days.
Individual	Support proposal for ASTODRI MER SODIUM	<p>I teach at least 5 classes of primary aged children over a day. Schools are the major site of transmission of airborne viruses, sickness with which is a major cause of increased absenteeism among teachers and students (who then suffer negative impacts on their academic achievement).</p> <p>Contracting the cold virus or worse not only affects my ability to work effectively, but has implications for my long term health and continued participation in the teaching workforce. I need to continue working and there is already a dire teacher shortage here.</p> <p>Moreover, repeated exposure of children to Covid-19 at school increases the likelihood of them developing associated chronic health conditions. It is in society's interest to reduce the spread of these viruses as these children are our future.</p> <p>These days there are few mitigations I can take to prevent contracting airborne viruses and passing them on to my students (or vice versa). This nasal spray has proven efficacy and I need it to continue to protect my health.</p> <p>I STRONGLY SUPPORT the amendment to Schedule 3 for astodrimmer sodium barrier nasal sprays.</p>

Individual	Support proposal for ASTODRIMER SODIUM	I travel by public transport and this will protect me from catching the cold virus, especially in winter when fellow travellers are coughing and sneezing. I work for myself so I need to stay healthy. I strongly support the amendment to Schedule 3 for astodrimmer sodium barrier nasal sprays.
Individual	Support proposal for ASTODRIMER SODIUM	I very strongly support the proposal for astodrimmer sodium barrier nasal sprays. This product is widely available across the world except for Australia. I strongly value anything to help reduce incidence of the cold virus as I am badly effected when I get colds and this severely impacts my capacity to maintain my employment.
Individual	Support proposal for ASTODRIMER SODIUM	I want to protect myself and family and friends from flu and other respiratory illnesses. This seems like an awesome step in the right direction.
Individual	Support proposal for ASTODRIMER SODIUM	I welcome and wish for the ability to avoid the common cold virus by being able to use the Astodrimmer Sodium - this would allow me to be more productive throughout the year and be less prone to getting run down and the prolonging of symptoms and time off with illness due to the common cold virus- I fully support the proposal.
Individual	Support proposal for ASTODRIMER SODIUM	I wish to have enhanced defence against colds etc as a teacher.
Individual	Support proposal for ASTODRIMER SODIUM	I work in a hospitality environment where I am exposed to seasonal viruses, and for many people in positions like mine there is a need for a safe and effective antiviral nasal spray which can help prevent catching common cold and other respiratory viruses and also I understand this product aids in reducing symptoms quickly in the event of catching a cold.
Individual	Support proposal for ASTODRIMER SODIUM	I work in an environment where I come into contact with a large number of people. This puts me and others at risk of contracting or spreading a common cold virus, which in turn will affect my ability to work effectively. Therefore, I STRONGLY SUPPORT the amendment to Schedule 3 for astodrimmer sodium barrier nasal sprays.
Individual	Support proposal for ASTODRIMER SODIUM	I would like the chance to use this due to immune dysfunction and an excessive vulnerability to viral infections, including suffering from a post-viral syndrome for more than 25 years.
Individual	Support proposal for ASTODRIMER SODIUM	I would like to have access to this product to use and purchase locally because it offers excellent protection from respiratory viruses which has significant impact to my ability to work and care for my family. I STRONGLY SUPPORT the amendment to schedule 3 for astrodrimer sodium barrier nasal sprays.
Individual	Support proposal for ASTODRIMER SODIUM	I would love for Viralese would become available in Australia. I would be keen to use it to reduce the risk of getting COVID-19.
Individual	Support proposal for ASTODRIMER SODIUM	I write to strongly support an update of Schedule 3 so my family and I can use astodrimmer sodium barrier nasal sprays that medical advice shows would be beneficial for our health.
Individual	Support proposal for ASTODRIMER SODIUM	I write to support an update of Schedule 3 so me and my family can use astodrimmer sodium barrier nasal sprays that research has shown would be beneficial for our health. https://www.nature.com/articles/s41598-022-14601-3#:~:text=Mechanism%20of%20action%20studies%20indicate,2%20(ACE2)%20receptor13.
Individual	Support proposal for ASTODRIMER SODIUM	I'm 59 and have CFS due to PCOS. Contracting the cold virus affects my ability to clean and feed myself effectively. I STRONGLY SUPPORT the amendment to Schedule 3 for astodrimmer sodium barrier nasal sprays.
Individual	Support proposal for ASTODRIMER SODIUM	It's not reasonable that Australian citizens are unable to obtain Viralese nasal spray from within Australia when it is widely available in other comparable countries: comparable in the sense of high quality regulatory and scientific systems. Since the federal government (& national cabinet) have told us we are responsible for our own health (ie. there is only private/personal health strategies and no longer any support for long established pandemic public health infection control standards) it is imperative that products such as Viralese are made available. It should have been available long ago.
Individual	Support proposal for ASTODRIMER SODIUM	I've just lost 100s of \$\$ trying to buy this from a fraudulent supplier in Cambodia. And I was forced into this situation because a product developed in Australia with my tax \$\$ isn't approved for sale here. It's been available in dozens of other countries for 2 years. It's got few side effects & works extremely well. I'm in a high risk category for catching covid & will do whatever I can to reduce the risk. Why do I have to deal with foreign fraudsters to buy an Australian product? At exorbitant prices, if at all?

	MER SODIUM	This is ridiculous! It's safe. Effective. And SHPULD be accessible to Australians. Please approve ASAP.
Individual	Support proposal for ASTODRIMER SODIUM	Low risk
Individual	Support proposal for ASTODRIMER SODIUM	My elderly parents have found that an astodimer sodium barrier nasal spray (Viraleze) is the most effective at preventing colds, but they cannot purchase it in Australia. I strongly support the proposal for astodimer sodium because if the proposed changes are made it will help protect their health.
Individual	Support proposal for ASTODRIMER SODIUM	Please approve this as it will help prevent me from taking more sick leave due to catching colds.
Individual	Support proposal for ASTODRIMER SODIUM	Please make this available in Australia as it will make it much safer for those of us with various health issues to avoid covid and continue to live and work. It's essential for us to have this to assist.
Individual	Support proposal for ASTODRIMER SODIUM	Please please allow Viraleze with the ingredient Astodimer Sodium to be sold in Australia. The company making is Australian and we should all be supporting them. Being immune compromised I want to use this along with my boosters and masks Please please think of vulnerable Australian that can benefit from this product
Individual	Support proposal for ASTODRIMER SODIUM	Reducing the impact of colds is important to me so that I can come to us to work and provide care giving duties.
Individual	Support proposal for ASTODRIMER SODIUM	Shown to be safe and effective Gives individuals a tool to provide some personal protection where other mitigations are absent7
Individual	Support proposal for ASTODRIMER SODIUM	Strongly support being able to use nasal spray to decrease downtime from illness.
Individual	Support proposal for ASTODRIMER SODIUM	Strongly support the amendment to Schedule 3 for astodimer sodium barrier nasal spray.
Individual	Support proposal for ASTODRIMER SODIUM	Strongly support this as a means to help office workers protect themselves .
Individual	Support proposal for ASTODRIMER SODIUM	Strongly support this to reduce work absence due to illness.
Individual	Support proposal for ASTODRIMER SODIUM	Support for use of nasal spray
Individual	Support proposal for ASTODRIMER SODIUM	The current spread of respiratory viruses is making society and healthcare inaccessible for medically vulnerable people - to counter this, we need as many options as possible to allow people to protect themselves from respiratory viruses. ASTODRIMER SODIUM could be an important tool to keep people safer and remove barriers which medically vulnerable people face in accessing healthcare, employment, and society generally. Fully support its approval.
Individual	Support proposal for ASTODRIMER SODIUM	The non-serious and self-limiting nature of the condition (the common cold) is consistent with the risk profile of over-the-counter (OTC) medicines. Similar products used in the treatment of the condition are OTC medicines and readily available in Australia. The purpose of astodimer sodium inclusion in a nasal spray product is to act as a physical barrier to trap and block cold viruses such as the common cold, allowing the body's natural defences to remove them with the nasal mucus. Astodimer sodium poses low risk of harm, as noted in the delegate's previous decision in November 2021. The risks associated with misuse, abuse and overuse are very low. Astodimer sodium is not systemically absorbed when used as a barrier nasal spray.

		<p>Adverse effects are rare and well-characterised; with no known interactions with commonly used food and consumables, or contra-indications. The risk profile of the substance is well defined, and risks can be appropriately managed through labelling and packaging.</p> <p>The use of astodrimmer sodium in a nasal spray is not likely to mask the symptoms or delay diagnosis of a serious condition. Appropriate labelling and packaging can manage any perceived risk. Key uses / expected use Used in medical devices</p>
Individual	Support proposal for ASTODRIMER SODIUM	There have been a lot of cold viruses lately. Contracting cold viruses affects my ability to work effectively. I STRONGLY SUPPORT the amendment to Schedule 3 for astodrimmer sodium barrier nasal sprays.
Individual	Support proposal for ASTODRIMER SODIUM	This has been a crucial part of my health process but I can't get it in the country I live in ,Australia please leave me a health option of this product
Individual	Support proposal for ASTODRIMER SODIUM	This product has shown substantial efficacy in reducing the effects of COVID-19 infection and is a simple, easy tool to mitigate the further spread of something that's killed nearly 10,000 Australians in the last year (and disabled thousands of others)
Individual	Support proposal for ASTODRIMER SODIUM	This substance has been in use in other preparations with an excellent safety record. It is a surface barrier product with no evidence of absorption into tissues or bloodstream, further reinforcing it's safety profile for use by consumers with complex co-morbidities. It's proven track record in blocking numerous viruses makes it a highly valuable, low cost, low risk accessible tool in reducing the transmission of multiple airborne pathogens. It is already in use in multiple international jurisdictions with no evidence of significant adverse reactions. This product has the potential to have a significant public health benefit, not just in mitigating the ongoing SARS-CoV-2 pandemic, but in reduction of all type airborne illness and their associated human & economic costs.
Individual	Support proposal for ASTODRIMER SODIUM	This will help me to carry on safely and well in my role as an educational tutor.
Individual	Support proposal for ASTODRIMER SODIUM	Useful for the cold
Individual	Support proposal for ASTODRIMER SODIUM	VIRALEZE PREVENTS COVID INFECTION SARS COV 2 IS BAD AND SHOULD BE AVOIDED WE NEED ALL THE TOOLS BE REAL
Individual	Support proposal for ASTODRIMER SODIUM	We need better protections against respiratory viruses. I have seen too many people become so unwell this year and they deserve to be able to protect themselves.
Individual	Support proposal for ASTODRIMER SODIUM	We really need this safe, reasonably priced antiviral nasal sprays which prevents catching common cold and other respiratory viruses and gets rid of symptoms quickly if you do catch a cold.
Individual	Support proposal for ASTODRIMER SODIUM	<p>We were able to purchase Viraleze Nasal Spray, which contains Astodrimmer Sodium while holidaying in Europe last Christmas.</p> <p>We had tentatively taken the trip to visit elderly, unwell family members, but were acutely aware of the ongoing Covid pandemic & anxious to avoid infection as we both have health issues which make us a high risk of a poor outcome.</p> <p>Being winter, most of our activities were indoors with poor ventilation & crowds - all high risk for transmission of airborne infections. Many people We met were unwell - some confirmed with covid.</p> <p>We remained 100% well the entire trip. And credit that to using viraleze regularly (in conjunction with N95 masks where possible).</p> <p>We suffered no ill effects from this medicine.</p> <p>We brought home the currently allowed 3 months supply each & have continued to remain "Novids" despite enjoying an active life & having many friends who have caught covid at events we both attended.</p> <p>Viraleze is clearly very effective. And safe.</p> <p>It's ridiculous that we are forced to go to considerable effort & expense to import 3 month supplies from overseas to continue to have access to this life saving substance. Especially considering it is developed & marketed by an Australian pharmaceutical company.</p> <p>It's also difficult to understand why it's approval has already been delayed when the exact same substance has been sold over the counter for many years in other products.</p> <p>It's known to be safe & not absorbed into the blood. So it has few side effects & can be used by people on other medications without any problems.</p> <p>It's also been used widely in dozens of other countries for 3 years. It's clearly safe.</p> <p>Many of our friends would like to ches this product too. Many have conditions which make them high risk if they catch covid.</p> <p>Without the benefit of this product, they are forced to live highly restrictive lives. That needs to change.</p> <p>Thank you.</p>
Individual	Support proposal for ASTODRIMER SODIUM	<p>Why do I have to get friends overseas to buy this for me & then pay to import it?</p> <p>I've been able to stay covid free using this spray in the workplace all year.</p> <p>It's very effective.</p> <p>Many colleagues have become unwell with all kinds of infections.</p> <p>I haven't even had a runny nose.</p> <p>This is an Australian product.</p> <p>It's absurd I can buy it here.</p> <p>It's been safely used for 2 years all over the world. Why not here?</p> <p>Please approve ASAP.</p>

Individual	Support proposal for ASTODRIMER SODIUM	With continued emergence of new variant C19 people need affordable nasal sprays to inhibit intranasal uptake of virus. In desperation I just purchased Enovid again at \$78 per unit. It is disgusting that Australians must wait for an effective and safe product that's been available in other countries for at least two years. Especially as it's an Australian product!
Individual	Support proposal for ASTODRIMER SODIUM	With continued evidence that there is increasing severity and recurrence of illness in the community, things like the cold virus is constantly circulating and can impact the ability of many to work effectively as well as impact quality of life. We need as many of the tools as possible to assist with prevention. I therefore STRONGLY SUPPORT the amendment to Schedule 3 for astodimer sodium barrier nasal sprays.
Individual	Support proposal for ASTODRIMER SODIUM	Would be good to have a nasal spray available to minimise risk of contracting viruses
Individual	Support proposal for ASTODRIMER SODIUM	Would be wonderful to have a nasal spray option that is made in Australia.

Individual	Partially support proposal for ASTODRIMER SODIUM	<p>I support this proposal provided there is sufficient safety data in human trials. The TGA should satisfy itself that no adverse active ingredients are absorbed into the bloodstream, children will undoubtedly use this product whether the packaging advises this is safe or not.</p> <p>The use case for a product that blocks transmission or reduces viral load and PCR positivity is absolutely compelling. As a user of layered mitigation, I have incorporated the use of Flotravel (Carrageenan) spray into my daily life, before and after potential exposure in conjunction with N95 masking. This is based on quite a small study, more robust trials head to head of Viraleze, Flotravel and Enovid would be welcome.</p> <p>As things stand, public health in Australia is failing. We have XBB variants and highly immune evasive BA.2.86 in our wastewater, but no announcement about imminent XBB vaccine procurement for Australia. This, despite many citizens' boosters waning in efficacy and the virus causing multiple waves per year, including in summer.</p> <p>Even the National Cabinet statement Dec 9 2022 said it will not be endemic for "some years". So, it's epidemic. We are still in a pandemic, regardless of Urgency of Normal politicking.</p> <p>PCR testing is restricted. Rapid antigen tests require serial use to lift sensitivity. Mandatory isolation was lifted without AHPPC backing and sick children attend school unmasked. Masking is almost nonexistent, even in essential services like health care.</p> <p>Any extra layer of protection, however minor, like a nasal spray, that can be made available to the public over the counter, should be, urgently, provided it is safe.</p>
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From: [TGA Medical Devices](#)
To: s22, s22; [Medicines Scheduling](#)
Subject: Fw: Regulatory history of astodimer sodium [SEC=OFFICIAL]
Date: Tuesday, 8 August 2023 12:15:00 PM
Attachments: [image001.jpg](#)
[image002.png](#)
[image003.gif](#)
[image004.png](#)

Please see below, that may assist.

s22

– Devices Engagement Section
Medical Devices Authorisation and Surveillance Branch

Medical Devices and Product Quality Division | Health Products Regulation Group
 Therapeutic Goods Administration
 Australian Government, Department of Health and Aged Care
 T: s22 | E: s22, s22 @health.gov.au
 Location: Scherger Drive, Fairbairn, Canberra, 2609

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

s22

From: s22, s22 <s22, s22@health.gov.au>
Sent: Tuesday, August 8, 2023 10:27
To: TGA Medical Devices <TGAMedicalDevices@health.gov.au>
Cc: s22, s22 <s22, s22@health.gov.au>
Subject: RE: Regulatory history of astodimer sodium [SEC=OFFICIAL]

Hi,

We have one application for astodimer sodium based nasal spray under review. As far as I know, the application did not go to ACMD. I've summarized the application history below:

Application for inclusion received by the TGA	23 July 2021
Prescribed application fee was received by the TGA	28 July 2021
s47G	24 November 2021
	22 February 2022
	20 April 2022

s47G	
The application was reactivated for assessment	16 May 2022
The application is currently under review	

Other than the nasal spray under review, there are:

- One ARTG inclusion for Astodrimer sodium based vaginal flora gel, ARTG No. 295465. I cannot find any record indicating it went to ACMD.
- One ARTG inclusion for Condoms containing astodrimer sodium based lubricant, ARTG No. 228796. During the Conformity assessment prior to the ARTG inclusion, the application was referred to ACMD R14/722374, however, the ACMD advice does not open for me R14/862130.

Kind Regards,

s22

From: s22, s22 <s22, s22@health.gov.au>
Sent: Monday, 7 August 2023 5:46 PM
To: TGA Medical Devices <TGAMedicalDevices@health.gov.au>
Cc: s22, s22 <s22, s22@health.gov.au>
Subject: RE: Regulatory history of astodrimer sodium [SEC=OFFICIAL]

Hi,

We will need to action the request below.

I suspect we have few applications that include this ingredient? And probably none that went to ACMD? If you can let me know what applications (we know of) that include this ingredient (the application history) and anything else you think relevant, that would be great.

Thanks

s22

From: TGA Medical Devices <TGAMedicalDevices@health.gov.au>
Sent: Monday, 7 August 2023 5:41 PM
To: s22, s22 <s22, s22@health.gov.au>
Subject: Fw: Regulatory history of astodrimer sodium [SEC=OFFICIAL]

Hi,

I presume that the start of this road is you and your team? Are you able to assist?

s22

– Devices Engagement Section
Medical Devices Authorisation and Surveillance Branch
 Medical Devices and Product Quality Division | Health Products Regulation Group
 Therapeutic Goods Administration
 Australian Government, Department of Health and Aged Care
 T: s22 | E: s22, s22@health.gov.au
 Location: Scherger Drive, Fairbairn, Canberra, 2609

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

s22

From: ACMD Secretariat <ACMD.Secretariat@health.gov.au>
Sent: Monday, August 7, 2023 15:20
To: TGA Medical Devices <TGAMedicalDevices@health.gov.au>
Subject: FW: Regulatory history of astodrimer sodium [SEC=OFFICIAL]

From: s22, s22 <s22, s22@Health.gov.au>
Sent: Monday, August 7, 2023 3:20:56 PM (UTC+10:00) Canberra, Melbourne, Sydney
To: ACMD Secretariat <ACMD.Secretariat@health.gov.au>
Cc: Medicines Scheduling <Medicines.Scheduling@health.gov.au>

Subject: Regulatory history of astodrimmer sodium [SEC=OFFICIAL]

Dear ACMD team,

The Medicines and Chemicals Scheduling Secretariat has received an application to amend the Poisons Standard in relation to astodrimmer sodium, which will be considered at the Advisory Committee on Medicines Scheduling (ACMS) in November 2023. The application proposes an exemption to the Schedule 3 (Pharmacist only) entry for Astodrimmer sodium when in preparations as a nasal barrier spray. The delegate for Medicines Scheduling has requested a comprehensive overview of the regulatory history of the substance, including previous applications made to advisory committees. In preparation for this meeting, we would like to seek your input regarding similar applications made to ACMD and ACCM for preparations as a nasal spray device. We would greatly appreciate a brief history of applications received regarding astodrimmer sodium and the outcomes from the advisory committees. This input would also be provided to the ACMS for their consideration during their provision of advice to the Delegate. Any assistance you can provide would be greatly appreciated.

Kind Regards,

s22
[REDACTED] – Scheduling and Chemicals Policy Section
Regulatory Engagement Branch

Health Product Regulation Group | Therapeutic Goods Administration
Australian Government Department of Health and Aged Care

E: s22 s22 @health.gov.au

Location: Gulgana building, Fairbairn office

PO Box 100, Woden ACT 2606, Australia



From: [Complementary Medicines](#)
To: s22 -s22
Subject: FW: Regulatory history of astodrimmer sodium with ACCM [SEC=OFFICIAL]
Date: Tuesday, 15 August 2023 10:03:01 AM
Attachments: [image001.jpg](#)
[image002.png](#)
[image003.gif](#)
[image004.png](#)

Dear s22 ,

Please see below response from CMES. I have also sent your email to the OTC team and am awaiting their response.

Thank you, s22

From: s22 <s22@health.gov.au>
Sent: Thursday, 10 August 2023 8:01 AM
To: OTC Medicines <otc.medicines@health.gov.au>
Cc: Complementary Medicines <complementary.medicines@health.gov.au>
Subject: RE: Regulatory history of astodrimmer sodium with ACCM [SEC=OFFICIAL]

Dear s22 ,

Based on our search, we have not received any complementary medicine application for a nasal spray dosage form that contains astodrimmer sodium. Also, we have not received any new ingredients application for astodrimmer sodium to be used in listed medicine. As such, to the best of our knowledge, astodrimmer sodium, or a medicine contains astodrimmer sodium, were not presented to ACCM for advice. Please feel free to reach to us if you need further assistance.

Kind regards,

From: MARTIN, s22 <s22 s22 @Health.gov.au>
Sent: Monday, 7 August 2023 3:23 PM
To: Complementary Medicines <complementary.medicines@health.gov.au>
Cc: Medicines Scheduling <Medicines.Scheduling@health.gov.au>
Subject: Regulatory history of astodrimmer sodium with ACCM [SEC=OFFICIAL]

Dear ACCM team,

The Medicines and Chemicals Scheduling Secretariat has received an application to amend the Poisons Standard in relation to astodrimmer sodium, which will be considered at the Advisory Committee on Medicines Scheduling (ACMS) in November 2023. The application proposes an exemption to the Schedule 3 (Pharmacist only) entry for Astodrimmer sodium when in preparations as a nasal barrier spray. The delegate for Medicines Scheduling has requested a comprehensive overview of the regulatory history of the substance, including previous applications made to advisory committees. In preparation for this meeting, we would like to seek your input regarding similar applications made to ACMD and ACCM for preparations as a nasal spray device. We

would greatly appreciate a brief history of applications received regarding astodrimer sodium and the outcomes from the advisory committees. This input would also be provided to the ACMS for their consideration during their provision of advice to the Delegate. Any assistance you can provide would be greatly appreciated.

Kind Regards,

s22
[REDACTED] – Scheduling and Chemicals Policy Section
Regulatory Engagement Branch

Health Product Regulation Group | Therapeutic Goods Administration
Australian Government Department of Health and Aged Care

E: s22 s22 @health.gov.au

Location: Gulgana building, Fairbairn office

PO Box 100, Woden ACT 2606, Australia



From: s22
To: s22, s22
Subject: FW: Regulatory history of astodimer sodium with ACCM [SEC=OFFICIAL]
Date: Tuesday, 26 September 2023 4:46:49 PM
Attachments: [image001.jpg](#)
[image002.png](#)
[image003.gif](#)
[image004.png](#)
[image005.gif](#)

Dear s22

Apologies for the delay in responding to your email below. OTCMES has not received any OTC medicine applications for a nasal spray containing astodimer sodium. As such, astodimer sodium, or an OTC medicine containing astodimer sodium, have not been referred to MEC or ACNM (non-prescription medicine expert advisory committees that have been disbanded) for advice.

OTCMES did provide advice in about 2021-22 regarding the regulatory status of an astodimer sodium-containing nasal spray as a device or as a medicine. The OTCMES advice at the time was the proposed product is a medicine and not a device. Devices may have provided info and background in relation to this matter. However, this consideration was in relation to its regulatory status and not scheduling.

Regards

s22

OTC Medicines Evaluation Section
 Complementary and OTC Medicines Branch
 Phone: s22
 Email: s22, s22@health.gov.au

Therapeutic Goods Administration
 Australian Government, Department of Health and Aged Care
 PO Box 100
 Woden ACT 2606
www.tga.gov.au



This information is given to you without prejudice and is not binding on the TGA. It is the responsibility of the sponsor to ensure that all of the legislative requirements are met.

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From: s22, s22 <s22, s22@Health.gov.au>
Sent: Monday, 25 September 2023 12:45 PM
To: OTC Medicines <otc.medicines@health.gov.au>
Cc: Medicines Scheduling <Medicines.Scheduling@health.gov.au>
Subject: RE: Regulatory history of astodimer sodium with ACCM [SEC=OFFICIAL]

Dear OTC Medicines Section,

I am just wanting to touch base regarding the request for information for the regulatory history of astodimer sodium as a barrier nasal spray. We are looking to get all internal correspondence for the ACMS meeting in November 2023 complete by 5 October so we can finalise meeting agenda documents. We would greatly appreciate a brief history of regulation of astodimer sodium within the OTC Medicines section by this date.

Kind Regards,

s22
s22 – Scheduling and Chemicals Policy Section
 Regulatory Engagement Branch

Health Product Regulation Group | Therapeutic Goods Administration
 Australian Government Department of Health and Aged Care

E: **s22** **s22** [@health.gov.au](mailto:s22@health.gov.au); M: **s22**

Location: Gulgana building, Fairbairn office

PO Box 100, Woden ACT 2606, Australia



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From: **s22**, **s22**

Sent: Tuesday, 15 August 2023 10:19 AM

To: Complementary Medicines <complementary.medicines@health.gov.au>

Cc: Medicines Scheduling <Medicines.Scheduling@health.gov.au>

Subject: RE: Regulatory history of astodimer sodium with ACCM [SEC=OFFICIAL]

Dear **s22**,

Thank you for sending through CMES' response, and forwarding on to OTC medicines.

Kind Regards,

s22
s22 – Scheduling and Chemicals Policy Section
 Regulatory Engagement Branch

Health Product Regulation Group | Therapeutic Goods Administration
 Australian Government Department of Health and Aged Care

E: **s22** **s22** [@health.gov.au](mailto:s22@health.gov.au)

Location: Gulgana building, Fairbairn office

PO Box 100, Woden ACT 2606, Australia



From: Complementary Medicines <complementary.medicines@health.gov.au>

Sent: Tuesday, 15 August 2023 10:03 AM

To: **s22**, **s22** <**s22**, **s22** [@Health.gov.au](mailto:s22@Health.gov.au)>

Subject: FW: Regulatory history of astodimer sodium with ACCM [SEC=OFFICIAL]

Dear **s22**,

Please see below response from CMES. I have also sent your email to the OTC team and am awaiting their response.

Thank you, **s22**

From: **s22** <**s22** [@health.gov.au](mailto:s22@health.gov.au)>

Sent: Thursday, 10 August 2023 8:01 AM

To: OTC Medicines <otc.medicines@health.gov.au>

Cc: Complementary Medicines <complementary.medicines@health.gov.au>

Subject: RE: Regulatory history of astodimer sodium with ACCM [SEC=OFFICIAL]

Dear **s22**,

Based on our search, we have not received any complementary medicine application for a nasal spray dosage form that contains astodimer sodium. Also, we have not received any new ingredients application for astodimer sodium to be used in listed medicine. As such, to the best of our knowledge, astodimer sodium, or a medicine contains astodimer sodium, were not presented to ACCM for advice. Please feel free to reach to us if you need further assistance.

Kind regards,

From: **s22**, **s22** <**s22**, **s22** [@Health.gov.au](mailto:s22@Health.gov.au)>

Sent: Monday, 7 August 2023 3:23 PM

To: Complementary Medicines <complementary.medicines@health.gov.au>

Cc: Medicines Scheduling <Medicines.Scheduling@health.gov.au>

Subject: Regulatory history of astodrimer sodium with ACCM [SEC=OFFICIAL]

Dear ACCM team,

The Medicines and Chemicals Scheduling Secretariat has received an application to amend the Poisons Standard in relation to astodrimer sodium, which will be considered at the Advisory Committee on Medicines Scheduling (ACMS) in November 2023. The application proposes an exemption to the Schedule 3 (Pharmacist only) entry for Astodrimer sodium when in preparations as a nasal barrier spray. The delegate for Medicines Scheduling has requested a comprehensive overview of the regulatory history of the substance, including previous applications made to advisory committees. In preparation for this meeting, we would like to seek your input regarding similar applications made to ACMD and ACCM for preparations as a nasal spray device. We would greatly appreciate a brief history of applications received regarding astodrimer sodium and the outcomes from the advisory committees. This input would also be provided to the ACMS for their consideration during their provision of advice to the Delegate. Any assistance you can provide would be greatly appreciated.

Kind Regards,

s22

Regulatory Engagement Branch

Health Product Regulation Group | Therapeutic Goods Administration
Australian Government Department of Health and Aged Care

E: s22_s22@health.gov.au

Location: Gulgana building, Fairbairn office

PO Box 100, Woden ACT 2606, Australia



ACMS MEETING #43
17 NOVEMBER 2023
ASTODRIMER SODIUM

First Speaker: s22

Main Discussion Points:

- Asodrimmer sodium is an ingredient in medical devices including a vaginal gel for the treatment of bacterial vaginosis (BV) and prevention of recurrent BV; as a condom lubricant to block viruses associated with STIs and as a nasal spray as a barrier to trap and block viruses in the nose.
- The current S3 entry is asodrimmer sodium except in a condom lubricant (primarily due to the need for medical advice related to the commencement of BV treatment).
- The applicant (Starpharma Pty Ltd) is seeking an amendment to the S3 entry for asodrimmer sodium to include nasal spray formulations in the list of exceptions.
- Asodrimmer sodium has a consistent benign toxicological profile and does not appear to represent a genetic, carcinogenic or reproductive risk. It has a non-pharmacological, non-metabolic and non-immunological mechanism of action.
- Asodrimmer Sodium has a favourable toxicity and safety profile.
- It is not systemically absorbed following topical application limiting observed adverse effects to low risk, mild, local, self-limiting conditions that are observed in the control products.
- This device is highly unlikely to produce dependency, be misused, abused or illicitly used given it cannot be systemically absorbed.
- Asodrimmer sodium has been demonstrated to provide a potent broad-spectrum effect against respiratory viruses by trapping common cold viruses and reducing exposure to viral load in non-clinical investigations as well as data on similar devices.
- Presents benefits outweigh risks for short term use at doses below 50mg/kg.
- Is currently available as a regulated low risk (Class 1) medical device in the EU, Malaysia, Vietnam, Hong Kong, Macao and Australia. There have been no reportable incidents with use outside of Australia.
- The proposed amendment to S3 entry would make asodrimmer sodium available in the same way as other nasal spray products in its class.

Delegates Questions:

Q1. Does the substance, astodrimmer sodium, require control through scheduling when in barrier nasal spray preparations?

Advice: The current S3 entry restricts asodrimmer sodium except in a condom lubricant and the applicant proposes to add its use as a barrier nasal spray to the exception.

This copy is to be edited and completed on GovTEAMS by COB 13 November 2023.

The only reason asodrimer sodium is included in the Poison Standard despite being a low-risk product is due to the decision by the delegate in a previous application (Nov 21) that advice be sought from a medical practitioner before using the substance for the treatment and prevention of BV.

Q2. If so, are Schedules 2 or 3 appropriate, so that consumers may have access to health professional guidance prior to purchase?

Advice: The Schedule 3 exception is appropriate given the low risk profile of the substance enabling treatment to be managed without medical intervention or a pharmacist's advice a point of sale. There is a plethora of nasal spray products already on the market that demonstrate use without medical oversight or intervention is appropriate.

Recommendation:

Asodrimer sodium has been demonstrated in data and evaluation in similar devices to be an effective and low risk product that, like other barrier nasal similar sprays, can effectively block and trap viruses in the nose.

The poisons standard entry in S3 should be amended to make asodrimer sodium available **except** when used in a barrier nasal spray.

This copy is to be edited and completed on GovTEAMS by COB 13 November 2023.

52E Table

Please ensure that you provide clear and concise reasons in the 52E Table below in **dot point** form. These reasons will be presented as a starting point to the committee for discussion; we therefore ask that only salient points are provided.

52E(1) Considerations	Reasons
a – the risks and benefits of the use of a substance	Asodrimmer sodium has shown limited, mil, local and self-limiting adverse events similar to control products. The risk profile is deemed to be low. Provides a potent broad-spectrum effect against respiratory viruses and is effective in trapping common cold viruses and reducing viral load. The benefits outweigh the risks.
b – the purposes for which a substance is to be used and the extent of use of a substance	As a virus trapping/blocking agent. Use would be similar to other barrier nasal spray products.
c – the toxicity of a substance	Asodrimmer sodium is substantially safe for short term treatment with risk of harm from inappropriate use extremely low. It is well tolerated and studies have shown consistent no clinical signs of local or systemic toxicity. Equivalent findings to placebo.
d – the dosage, formulation, labelling, packaging and presentation of a substance	1% asodrimmer sodium in an aqueous based, isotonic nasal spray. It is supplied in a 10mL plastic bottle with a nasal pump applicator within a carton.
e – the potential for abuse of a substance	There is no potential for abuse given that the substance is not systemically absorbed.
f – any other matters that the Secretary considers necessary to protect public health	Nil

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ACMS MEETING #43
17 NOVEMBER 2023
ASTODRIMER SODIUM

First Speaker: s22

Main Discussion Points:

- Application to exempt astodrimmer sodium from scheduling when it is used in a barrier nasal spray preparation. Its purpose in the nasal spray is to act as a physical barrier to trap and block cold viruses from entering the body and facilitate its removal with the nasal mucous.
- Currently, astodrimmer sodium is in Schedule 3, except when used in condom lubricants. Astodrimmer sodium is registered for use in the treatment and relief of bacterial vaginosis and for the prevention of recurrent bacterial vaginosis, as a class IIa medical device. Its trade name is Vivagel®. It is not registered as a medicine in Australia. The sponsor of Vivagel® is StarPharma Pty Ltd, the same applicant for this submission.
- Astodrimmer sodium is a dendrimer - a class of compounds characterised by a highly branched 3D structure. It is a very large molecule with a negative surface charge. Its mode of action is via preventing the entry of the bacteria into the host cells by blocking their attachment to the host cells and can inhibit the formation of, and disrupt existing biofilms.
- The key arguments from the applicant are
 - Has low risk of harm, favourable safety and toxicity profile, not systemically absorbed
 - Manages non-serious conditions
 - Wide availability of many nasal spray products for the management of colds or cold symptoms in Australia
- Applicant states that this proposal is in line with other nasal sprays which are medical devices that trap and block viruses in the nose which are readily available in supermarkets. The only other nasal spray currently available as a medical device that traps and block viruses which is unclassified is Vicks First Defence nasal spray. Vicks First Defence nasal spray contains 1% Hydroxypropyl Methylcellulose. Hydroxypropyl cellulose is listed in appendix B clause 3 – substances exempt from scheduling. Hydroxypropyl cellulose is exempt from scheduling due to its low toxicity. Other nasal sprays which are used to manage symptoms of cold other than nasal saline sprays are in Schedule 2.
- s47G
- Further, there is a [current clinical trial in the UK](#) where the astodrimmer sodium nasal spray is being assessed for its safety and performance in patients with COVID-19. The trial just has completed but the results are not yet available or published. It is clear that the applicant

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s47

- It is currently registered as a Class 1 medical device in the UK and EU. Astodrimmer sodium is not registered in Canada, USA, New Zealand or Ireland.
- Public submissions were substantial – 166 supportive and 1 partial support. Reasons for support mainly centred around additional means of protection against cold and viruses, reduce severity of colds and reduce transitions and that Australians are importing it for personal use from the UK and EU.

Delegates Questions:

Q1. Does the substance, astodrimmer sodium, require control through scheduling when in barrier nasal spray preparations?

Advice: Yes

Q2. If so, are Schedules 2 or 3 appropriate, so that consumers may have access to health professional guidance prior to purchase?

Advice: Schedule 2

Recommendation:

Like other nasal sprays with scheduled substances, astodrimmer sodium nasal spray should be in Schedule 2. Its listing in Schedule 2 means that it is readily available for self-selection at a pharmacy however people can also seek pharmacist advice regarding managing of their viral respiratory disease.

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52E Table

Please ensure that you provide clear and concise reasons in the 52E Table below in **dot point** form. These reasons will be presented as a starting point to the committee for discussion; we therefore ask that only salient points are provided.

52E(1) Considerations	Reasons
a – the risks and benefits of the use of a substance	<p>Risks</p> <p>Astodrimmer sodium itself is low risk, well-tolerated</p> <p>The nasal spray may deter people from getting vaccinated, wearing masks or taking other standard precautionary measures around prevention and transmission of viral respiratory diseases. May also delay seeking medical attention.</p> <p>Benefits</p> <p>May reduce severity of viral respiratory disease</p>
b – the purposes for which a substance is to be used and the extent of use of a substance	Prevent and reduce transmission of cold and flu viruses via trapping the virus in the nasal mucosal pathway
c – the toxicity of a substance	Low – nil/very low systematic absorption
d – the dosage, formulation, labelling, packaging and presentation of a substance	1% Astodrimmer sodium in nasal spray in 10ml bottle Dosage – unknown, not provided
e – the potential for abuse of a substance	Nil
f – any other matters that the Secretary considers necessary to protect public health	

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Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Record of the 43rd meeting of the Advisory Committee on Medicines Scheduling

17 November 2023

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Preliminary matters

Opening of the meeting

The 43rd meeting of the Advisory Committee on Medicines Scheduling (the **Committee**)¹ was held at the Department of Health and Aged Care's Fairbairn (ACT) office and via video conference on 17 November 2023.

The meeting was chaired by s22, who opened the meeting at 9:32 am (AEDT) and welcomed attending members and observers.

Members were informed that the discussions and recommendations of the Committee are confidential until the interim decisions are published.

A quorum was present for all decisions. Those present at the meeting were:

Committee members

Name	Representation
s22	
s22	

¹ Established under sections 52B and 52C of the *Therapeutic Goods Act 1989* (Cth)

Committee Secretariat (Commonwealth Department of Health and Aged Care)

Name
s22 [redacted]
[redacted]
[redacted]
[redacted]
[redacted]
[redacted]
[redacted]
[redacted]
[redacted]

Observers

Name	Items
<i>Commonwealth Department of Health and Aged Care (Therapeutic Goods Administration)</i>	
s22 [redacted]	s22 [redacted]
s22 [redacted]	
s22 [redacted]	
s22 [redacted]	

Conflicts of interest

s22 [redacted]

s22



Procedural matters

Members were informed of various housekeeping rules to ensure the smooth running of the meeting by videoconference.

All present were reminded of confidentiality in relation to all matters discussed by the Committee and that all decisions are to remain confidential until they are published along with the interim decision of the delegate² of the Secretary of the Department of Health and Aged Care responsible for medicines scheduling (the **Delegate**).

Proposed changes to the Poisons Standard

Astodrimmer sodium

Advice for the Delegate's consideration

The Committee recommended that the scheduling of ASTODRIMER SODIUM in the Poisons Standard be amended as follows:

Schedule 3 – Amend Entry

ASTODRIMER SODIUM except when used in:

- (a) a condom lubricant; or
- (b) when included in Schedule 2.

Schedule 2 – New Entry

ASTODRIMER SODIUM in a barrier nasal spray.

Index – Amend Entry

ASTODRIMER SODIUM

Schedule 3

Schedule 2

Appendix F, clause 4

Appendix H, clause 1

The Committee recommended an implementation date of **1 June 2024**. Due to the absence of registered products that would be affected by the change in scheduling, the Committee saw no reason to delay the implementation of the amendment in the Poisons Standard.

Committee discussion

- The Committee considered the proposal to exempt astodrimmer sodium when present in nasal spray preparations from the current Schedule 3 entry for astodrimmer sodium.
- The Committee noted that astodrimmer sodium is an ingredient in medical devices, including vaginal gel preparations for the treatment of bacterial vaginosis (BV) and prevention of recurrent BV. Astodrimmer sodium is also currently available as a condom lubricant to block viruses associated with sexually transmitted infections (STIs).
- The current Schedule 3 entry for astodrimmer sodium in the Poisons Standard exempts preparations as a condom lubricant. Astodrimmer sodium was included in Schedule 3 primarily due to the need for medical advice prior to commencement of BV treatment. The Committee also noted that astodrimmer sodium has been demonstrated to provide a potent broad-spectrum effect against respiratory viruses through physically trapping common cold viral particles and reducing exposure to viral load in non-clinical investigations, as well as data on similar devices.

² For the purposes of s 52D of the Therapeutic Goods Act 1989 (Cth).

- A committee member noted that astodimer sodium is not currently registered as a medicine in Australia, though Fleurstat vaginal flora gel is registered as a Class IIa medical device for the topical treatment and rapid relief of BV.
- The Committee agreed that while the potential benefits of exempting astodimer sodium in nasal barrier spray preparations outweigh the risks for short term use, and at doses below 50 mg/kg, inappropriate use may mask more serious health conditions. Additionally, astodimer sodium usage may delay patients seeking more effective treatments, though the Committee also noted the general cold and flu do not have an abundance of commercially available effective treatments.
- Regarding the substances' toxicity, the Committee agreed that astodimer sodium would not warrant higher scheduling on the basis of its safety profile. Astodimer sodium has a consistent low toxicity profile and does not appear to present a genetic, carcinogenic or reproductive risk. Its mechanism of action in nasal spray applications is non-pharmacological, non-metabolic and non-immunological.
- The Committee noted that astodimer sodium is part of a dendrimer class of compounds, characterised by their large, highly branched 3D structures. Given its large molecular size and negative surface charge, the substance is not systemically absorbed. Rather its mode of action is through preventing the entry of the bacteria and viral particles into the host cells by blocking their attachment to the host cells, inhibiting the formation of biofilms and causing disruption to existing biofilms.
- The Committee considered that astodimer sodium has limited observed adverse effects to low risk, mild, local, self-limiting conditions that are observed in the control products. Furthermore, the substance poses a very low risk of dependency, misuse, abuse or illicitly use given it cannot be systemically absorbed.
- The Committee acknowledged that internationally, barrier nasal sprays containing astodimer sodium are currently available as a regulated low risk (Class 1) medical device in the EU, Malaysia, Vietnam, Hong Kong, and Macao. There have been no reportable incidents with use of astodimer sodium outside of Australia.
- The Committee noted that the proposed amendment to the Schedule 3 entry would make astodimer sodium available in the same way as other nasal spray products in its class. Most notably Vicks First Defence nasal spray that is available as a similar medical device that barriers against viral particles. Vicks First Defence nasal spray contains 1% hydroxypropyl methylcellulose, which is currently unscheduled and is listed in Appendix B clause 3 – substances exempt from scheduling, given its low toxicity. Other nasal sprays which are used to manage symptoms of cold other than nasal saline sprays are in Schedule 2. A committee member acknowledged that the similar iota-Carrageenan product is unscheduled, though it was agreed that this substance does not make as substantive therapeutic claims as astodimer sodium products.
- The Committee noted that clinical trials are ongoing in the UK where astodimer sodium nasal spray is being assessed for its safety and performance in patients with COVID-19. The trial has recently completed but the results are not yet available or published. It was noted that Clinical trials are targeted at COVID-19 effectiveness, and pending the results, the applicant would likely wish to market the product as a treatment to reduce COVID symptoms.
- The Committee acknowledged claims by the applicant that astodimer sodium in barrier nasal sprays are for the management of non-serious respiratory conditions, though the Committee disagreed, noting there is a risk of its use in place of more effective treatments for serious respiratory complications, given the applicants previous alleged advertising that claims this nasal spray stops COVID-19.

- The Delegate raised concerns regarding how the proposed scheduling exception could be used for more substantial diseases in time, such as COVID-19. A committee member noted in response that astodimer sodium had never been marketed in Australia before, and the company has previously been sanctioned for advertising restricted representations.³ A blanket exception for astodimer sodium as a barrier nasal spray would open the potential for use in other applications without regulatory oversight.
- Having considered the available evidence, the Committee were satisfied that long term or overuse of the substance poses no health risk, as it is widely used in other countries and has a well-established, safe risk profile.
- A committee member queried how much regulatory oversight the Medical Devices section must have to assess the efficacy of the products claims as a COVID treatment, and how that would differ to medicines in terms of long-term safety. An observer from the Medical Devices section of the TGA noted that evidence would need to be provided regarding safety, including long term product safety prior to registration.
- The Committee acknowledged the 166 public submissions received in support of the proposal, and the 1 submission in partial support. Reasons for supporting the proposal were mainly centred around additional means of protection against the common cold and viruses, reduced severity of colds and reduced transmission. However, the Committee noted submissions in support of the proposal were worded consistently, suggesting use of a template as part of a coordinated campaign.
- The Committee also noted that Australians are currently importing barrier nasal sprays containing astodimer sodium for personal use from the UK and EU.
- The Committee recommended that the scheduling of astodimer sodium in the Poisons Standard be amended to include creation of a new Schedule 2 for astodimer sodium when in barrier nasal spray preparations.

The reasons for the advice

Members agreed that the relevant matters under Section 52E (1) of the *Therapeutic Goods Act 1989* and the Committee's reasons were:

a) the risks and benefits of the use of a substance

Benefits:

- Provides a physical barrier in which to trap respiratory viruses and reduces viral load. May reduce severity of viral respiratory disease.

Risks:

- Astodimer sodium has shown limited, local and self-limiting adverse events similar to control products. The risk profile of the substance is deemed to be low risk and well tolerated.

b) the purposes for which a substance is to be used and the extent of use of a substance

- Prevents and reduces transmission of cold and flu viruses by trapping or blocking the virus in the nasal mucosal pathway.
- Usage would be similar to other barrier nasal spray products.

c) the toxicity of a substance

³ <https://www.tga.gov.au/news/media-releases/starpharma-holdings-limited-fined-93240-alleged-unlawful-advertising-viraleze-relation-covid-19>

- Astodrimer sodium is well established as a safe short-term treatment, with a low risk of harm from inappropriate use. It is well-tolerated, and clinical studies have shown no signs of local or systemic toxicity.

d) *the dosage, formulation, labelling, packaging and presentation of a substance*

- The proposed product presents as a 1% aqueous solution of astodrimer sodium in the form of an isotonic nasal spray. It is supplied in a 10 mL plastic bottle with a nasal pump applicator within a carton. Dosage was not provided in the application.
- There are no currently marketed astodrimer sodium nasal spray products in Australia.

e) *the potential for abuse of a substance*

- There is no potential for abuse given that the substance is not systemically absorbed.

f) *any other matters that the Secretary considers necessary to protect public health*

- Safeguards may be required to address the risk as there is potential for the substance to be advertised or promoted for use as a treatment for serious respiratory conditions, such as COVID-19.
- The nasal spray may deter the public from getting vaccinated, wearing masks or taking other standard precautionary measures around prevention and transmission of viral respiratory diseases. May also delay seeking medical attention.

s22



s22



Next meeting

The members noted that the next meeting of the Committee is scheduled for 19-21 March 2024.

Closure

The Chair closed the meeting at 3:13 pm ADST, 17 November 2023.

s22



s22



Chair

43rd Meeting of the Advisory Committee on Medicines Scheduling

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Section/Office	XX/XX/XXXX or Month Year

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