From: Vape notifications
To: Vape notifications
Subject: Vape notification ID VG-2024-NTF-00221 - Mission Distribution Victoria Pty Limited - Client ID 83800 - RELX Infinity 2 Device
Date: Tuesday, 19 March 2024 11:53:04 AM

Send this email to s22 s47 [redacted]

Dear Mission Distribution Victoria Pty Limited

We have reviewed your vape notification form for:

Vaping good category: A finished good that is, or contains, a reusable vaping device, device component or reusable cartridge, not containing a vaping substance (including a pack)
Vaping good name: RELX Infinity 2 Device
Vaping good description: Therapeutic vaping device without vaping substance

Your form is considered complete by the TGA and we have issued you with the following Notification ID: VG-2024-NTF-00221.

Your notification ID is required when you submit an import permit application to the Office of Drug Control https://www.odc.gov.au/importers.

From: Vape notifications
To: Vape notifications
Subject: Vape notification ID VG-2024-NTF-00221 - Mission Distribution Victoria Pty Limited - Client ID 83800 - RELX Infinity 2 Device
Date: Tuesday, 19 March 2024 11:53:04 AM

Send this email to s22 s47 [redacted]

Dear Mission Distribution Victoria Pty Limited

We have reviewed your vape notification form for:

Vaping good category: A finished good that is, or contains, a reusable vaping device, device component or reusable cartridge, not containing a vaping substance (including a pack)
Vaping good name: RELX Infinity 2 Device
Vaping good description: Therapeutic vaping device without vaping substance

Your form is considered complete by the TGA and we have issued you with the following Notification ID: VG-2024-NTF-00221.

Your notification ID is required when you submit an import permit application to the Office of Drug Control https://www.odc.gov.au/importers.

From: Vape notifications
To: Vape notifications
Subject: Vape notification - invalid - Mission Distribution Victoria Pty Limited - Client ID 83800 - RELX Pod Pro2-Tobacco Gold-28.5mg/mL Nicotine
Date: Tuesday, 19 March 2024 9:20:30 AM

Send this email to s22 s47 [redacted]

Dear Mission Distribution Victoria Pty Limited

We have reviewed your vape notification form for:

Vaping good category: A finished good that is, or contains, a vaping substance (including a kit or pack)
Vaping good name: RELX Pod Pro2-Tobacco Gold-28.5mg/mL Nicotine
Vaping good description: Therapeutic vaping substance accessory

Your form is considered incomplete by the TGA, therefore we have not issued you with a Notification ID.

From: Vape notifications
To: Vape notifications
Subject: Vape notification - invalid - Mission Distribution Victoria Pty Limited - Client ID 83800 - RELX Infinity 2 Device
Date: Tuesday, 19 March 2024 11:45:01 AM

Send this email to s22 s47 [redacted]

Dear Mission Distribution Victoria Pty Limited

We have reviewed your vape notification form for:

Vaping good category: A finished good that is, or contains, a reusable vaping device, device component or reusable cartridge, not containing a vaping substance (including a pack)
Vaping good name: RELX Infinity 2 Device
Vaping good description: Therapeutic vaping device without vaping substance

Your form is considered incomplete by the TGA, therefore we have not issued you with a Notification ID.

From: Vape notifications
To: Vape notifications
Subject: Vape notification ID VG-2024-NTF-00218 - Mission Distribution Victoria Pty Limited - Client ID 83800 - RELX Pod Pro2-Tobacco Gold-28.5mg/mL Nicotine
Date: Tuesday, 19 March 2024 11:51:54 AM

Send this email to s22 s47 [redacted]

Dear Mission Distribution Victoria Pty Limited

We have reviewed your vape notification form for:

Vaping good category: A finished good that is, or contains, a vaping substance (including a kit or pack)
Vaping good name: RELX Pod Pro2-Tobacco Gold-28.5mg/mL Nicotine
Vaping good description: Therapeutic vaping substance accessory

Your form is considered complete by the TGA and we have issued you with the following Notification ID: VG-2024-NTF-00218.

Your notification ID is required when you submit an import permit application to the Office of Drug Control https://www.odc.gov.au/importers.

From: Vape notifications
To: Vape notifications
Subject: Vape notification ID VG-2024-NTF-00220 - Mission Distribution Victoria Pty Limited - Client ID 83800 - RELX Pod Pro2-Tobacco Red-28.5mg/mL Nicotine
Date: Tuesday, 19 March 2024 11:52:39 AM

Send this email to s22 s47 [redacted]

Dear Mission Distribution Victoria Pty Limited

We have reviewed your vape notification form for:

Vaping good category: A finished good that is, or contains, a vaping substance (including a kit or pack)
Vaping good name: RELX Pod Pro2-Tobacco Red-28.5mg/mL Nicotine
Vaping good description: Therapeutic vaping substance accessory

Your form is considered complete by the TGA and we have issued you with the following Notification ID: VG-2024-NTF-00220.

Your notification ID is required when you submit an import permit application to the Office of Drug Control https://www.odc.gov.au/importers.

From: Vape notifications
To: s2 s47
Cc: Vape notifications
Subject: Nicotine Vape Notification submission outcome - Mission Distribution Victoria Pty Limited [SEC=OFFICIAL]
Date: Tuesday, 19 March 2024 12:03:06 PM
Attachments: image001.png

Dear Mission Distribution Victoria Pty Limited

We have reviewed your nicotine vape notification forms, deemed them valid and have issued the following Notification ID numbers:

Notification ID	Nicotine Vape Device Name
VG-2024-NTF-00217	RELX Pod Pro2-Menthol-28.5mg/mL Nicotine
VG-2024-NTF-00218	RELX Pod Pro2-Tobacco Gold-28.5mg/mL Nicotine
VG-2024-NTF-00219	RELX Pod Pro2-Mint-28.5mg/mL Nicotine
VG-2024-NTF-00220	RELX Pod Pro2-Tobacco Red-28.5mg/mL Nicotine
VG-2024-NTF-00221	RELX Infinity 2 Device

Kind regards

s22
Product Import Compliance Section
Seniort Compliance Officer
Regulatory Compliance Branch
Regulatory Practice and Support Division | Health Products Regulation Group
Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care
www.tga.gov.au
PO Box 100, Woden ACT 2606, Australia

The Department of Health and Aged Care 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 all Elders both past and present.

From: Vape notifications
To: s22
Bcc: Vape notifications
Subject: Confirmation of nicotine form [SEC=OFFICIAL]
Date: Monday, 13 May 2024 11:31:33 AM
Attachments: image001.png

Good afternoon s22 ,

I have been asked to confirm the nicotine form of your products e.g. freebase or salt based for publishing. Can you please complete the table below and return to me asap.

Product Name	Nicotine Form
RELX Pod Pro2-Menthol-28.5mg/mL Nicotine	
RELX Pod Pro2-Tobacco Gold-28.5mg/mL Nicotine	
RELX Pod Pro2-Mint-28.5mg/mL Nicotine	
RELX Pod Pro2-Tobacco Red-28.5mg/mL Nicotine	

Kind regards

s22
Product Import Compliance Section
Senior Compliance Officer
Regulatory Compliance Branch
Regulatory Practice and Support Division | Health Products Regulation Group
Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care
www.tga.gov.au
PO Box 100, Woden ACT 2606, Australia

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From: Vape notifications
To: Vape notifications
Subject: Vape notification ID VG-2024-NTF-00217 - Mission Distribution Victoria Pty Limited - Client ID 83800 - RELX Pod Pro2-Menthol-28.5mg/mL Nicotine
Date: Tuesday, 19 March 2024 11:51:27 AM

Send this email to s22 s47 [redacted]

Dear Mission Distribution Victoria Pty Limited

We have reviewed your vape notification form for:

Vaping good category: A finished good that is, or contains, a vaping substance (including a kit or pack)
Vaping good name: RELX Pod Pro2-Menthol-28.5mg/mL Nicotine
Vaping good description: Therapeutic vaping substance accessory

Your form is considered complete by the TGA and we have issued you with the following Notification ID: VG-2024-NTF-00217.

Your notification ID is required when you submit an import permit application to the Office of Drug Control https://www.odc.gov.au/importers.

From: Vape notifications
To: Vape notifications
Subject: Vape notification ID VG-2024-NTF-00218 - Mission Distribution Victoria Pty Limited - Client ID 83800 - RELX Pod Pro2-Tobacco Gold-28.5mg/mL Nicotine
Date: Tuesday, 19 March 2024 11:51:57 AM

Send this email to s22 s47 [redacted]

Dear Mission Distribution Victoria Pty Limited

We have reviewed your vape notification form for:

Vaping good category: A finished good that is, or contains, a vaping substance (including a kit or pack)
Vaping good name: RELX Pod Pro2-Tobacco Gold-28.5mg/mL Nicotine
Vaping good description: Therapeutic vaping substance accessory

Your form is considered complete by the TGA and we have issued you with the following Notification ID: VG-2024-NTF-00218.

Your notification ID is required when you submit an import permit application to the Office of Drug Control https://www.odc.gov.au/importers.

From:	Vape notifications
To:	Vape notifications
Subject:	Vape notification ID VG-2024-NTF-00219 - Mission Distribution Victoria Pty Limited - Client ID 83800 - RELX Pod Pro2-Mint-28.5mg/mL Nicotine
Date:	Tuesday, 19 March 2024 11:52:17 AM

Send this email to s22 s47 [redacted]

Dear Mission Distribution Victoria Pty Limited

We have reviewed your vape notification form for:

Vaping good category: A finished good that is, or contains, a vaping substance (including a kit or pack)
Vaping good name: RELX Pod Pro2-Mint-28.5mg/mL Nicotine
Vaping good description: Therapeutic vaping substance accessory

Your form is considered complete by the TGA and we have issued you with the following Notification ID: VG-2024-NTF-00219.

Your notification ID is required when you submit an import permit application to the Office of Drug Control https://www.odc.gov.au/importers.

From: Vape notifications
To: Vape notifications
Subject: Vape notification ID VG-2024-NTF-00220 - Mission Distribution Victoria Pty Limited - Client ID 83800 - RELX Pod Pro2-Tobacco Red-28.5mg/mL Nicotine
Date: Tuesday, 19 March 2024 11:52:41 AM

Send this email to s22 s47 [redacted]

Dear Mission Distribution Victoria Pty Limited

We have reviewed your vape notification form for:

Vaping good category: A finished good that is, or contains, a vaping substance (including a kit or pack)
Vaping good name: RELX Pod Pro2-Tobacco Red-28.5mg/mL Nicotine
Vaping good description: Therapeutic vaping substance accessory

Your form is considered complete by the TGA and we have issued you with the following Notification ID: VG-2024-NTF-00220.

Your notification ID is required when you submit an import permit application to the Office of Drug Control https://www.odc.gov.au/importers.

From: Vape notifications
To: Vape notifications
Subject: Vape notification ID VG-2024-NTF-00221 - Mission Distribution Victoria Pty Limited - Client ID 83800 - RELX Infinity 2 Device
Date: Tuesday, 19 March 2024 11:53:04 AM

Send this email to s22 s47 [redacted]

Dear Mission Distribution Victoria Pty Limited

We have reviewed your vape notification form for:

Vaping good category: A finished good that is, or contains, a reusable vaping device, device component or reusable cartridge, not containing a vaping substance (including a pack)
Vaping good name: RELX Infinity 2 Device
Vaping good description: Therapeutic vaping device without vaping substance

Your form is considered complete by the TGA and we have issued you with the following Notification ID: VG-2024-NTF-00221.

Your notification ID is required when you submit an import permit application to the Office of Drug Control https://www.odc.gov.au/importers.

From: Vape notifications
To: Vape notifications
Subject: Vape notification - invalid - Mission Distribution Victoria Pty Limited - Client ID 83800 - RELX Pod Pro2-Menthol-28.5mg/mL Nicotine
Date: Tuesday, 19 March 2024 9:20:13 AM

Send this email to s22 s47 [redacted]

Dear Mission Distribution Victoria Pty Limited

We have reviewed your vape notification form for:

Vaping good category: A finished good that is, or contains, a vaping substance (including a kit or pack)
Vaping good name: RELX Pod Pro2-Menthol-28.5mg/mL Nicotine
Vaping good description: Therapeutic vaping substance accessory

Your form is considered incomplete by the TGA, therefore we have not issued you with a Notification ID.

From: Vape notifications
To: Vape notifications
Subject: Vape notification - invalid - Mission Distribution Victoria Pty Limited - Client ID 83800 - RELX Pod Pro2-Tobacco Gold-28.5mg/mL Nicotine
Date: Tuesday, 19 March 2024 9:20:33 AM

Send this email to s22 s47

Dear Mission Distribution Victoria Pty Limited

We have reviewed your vape notification form for:

Vaping good category: A finished good that is, or contains, a vaping substance (including a kit or pack)
Vaping good name: RELX Pod Pro2-Tobacco Gold-28.5mg/mL Nicotine
Vaping good description: Therapeutic vaping substance accessory

Your form is considered incomplete by the TGA, therefore we have not issued you with a Notification ID.

From: Vape notifications
To: Vape notifications
Subject: Vape notification - invalid - Mission Distribution Victoria Pty Limited - Client ID 83800 - RELX Pod Pro2-Tobacco Red-28.5mg/mL Nicotine
Date: Tuesday, 19 March 2024 9:20:54 AM

Send this email to s22 s47 [redacted]

Dear Mission Distribution Victoria Pty Limited

We have reviewed your vape notification form for:

Vaping good category: A finished good that is, or contains, a vaping substance (including a kit or pack)
Vaping good name: RELX Pod Pro2-Tobacco Red-28.5mg/mL Nicotine
Vaping good description: Therapeutic vaping substance accessory

Your form is considered incomplete by the TGA, therefore we have not issued you with a Notification ID.

From: Vape notifications
To: Vape notifications
Subject: Vape notification - invalid - Mission Distribution Victoria Pty Limited - Client ID 83800 - RELX Pod Pro2-Tobacco Red-28.5mg/mL Nicotine
Date: Tuesday, 19 March 2024 9:21:20 AM

Send this email to s22 s47 [redacted]

Dear Mission Distribution Victoria Pty Limited

We have reviewed your vape notification form for:

Vaping good category: A finished good that is, or contains, a vaping substance (including a kit or pack)
Vaping good name: RELX Pod Pro2-Tobacco Red-28.5mg/mL Nicotine
Vaping good description: Therapeutic vaping substance accessory

Your form is considered incomplete by the TGA, therefore we have not issued you with a Notification ID.

From: Vape notifications
To: Vape notifications
Subject: Vape notification - invalid - Mission Distribution Victoria Pty Limited - Client ID 83800 - RELX Infinity 2 Device
Date: Tuesday, 19 March 2024 11:45:04 AM

Send this email to s22 s47 [redacted]

Dear Mission Distribution Victoria Pty Limited

We have reviewed your vape notification form for:

Vaping good category: A finished good that is, or contains, a reusable vaping device, device component or reusable cartridge, not containing a vaping substance (including a pack)
Vaping good name: RELX Infinity 2 Device
Vaping good description: Therapeutic vaping device without vaping substance

Your form is considered incomplete by the TGA, therefore we have not issued you with a Notification ID.

From: Vape notifications
To: Vape notifications
Subject: Vape notification - invalid - Mission Distribution Victoria Pty Limited - Client ID 83800 - RELX Infinity 2 Device
Date: Tuesday, 26 March 2024 8:52:49 AM

Send this email to s22 s47 [redacted]

Dear Mission Distribution Victoria Pty Limited

We have reviewed your vape notification form for:

Vaping good category: A finished good that is, or contains, a reusable vaping device, device component or reusable cartridge, not containing a vaping substance (including a pack)
Vaping good name: RELX Infinity 2 Device
Vaping good description: Therapeutic vaping device without vaping substance

Your form is considered incomplete by the TGA, therefore we have not issued you with a Notification ID.

From: Vape notifications
To: s2 s47
Cc: Vape notifications
Subject: Nicotine Vape Notification submission outcome - Mission Distribution Victoria Pty Limited [SEC=OFFICIAL]
Date: Tuesday, 19 March 2024 12:03:09 PM
Attachments: image001.png

Dear Mission Distribution Victoria Pty Limited

We have reviewed your nicotine vape notification forms, deemed them valid and have issued the following Notification ID numbers:

Notification ID	Nicotine Vape Device Name
VG-2024-NTF-00217	RELX Pod Pro2-Menthol-28.5mg/mL Nicotine
VG-2024-NTF-00218	RELX Pod Pro2-Tobacco Gold-28.5mg/mL Nicotine
VG-2024-NTF-00219	RELX Pod Pro2-Mint-28.5mg/mL Nicotine
VG-2024-NTF-00220	RELX Pod Pro2-Tobacco Red-28.5mg/mL Nicotine
VG-2024-NTF-00221	RELX Infinity 2 Device

Kind regards

s22
Product Import Compliance Section
Seniort Compliance Officer
Regulatory Compliance Branch
Regulatory Practice and Support Division | Health Products Regulation Group
Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care
www.tga.gov.au
PO Box 100, Woden ACT 2606, Australia

The Department of Health and Aged Care 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 all Elders both past and present.

From: Vape notifications
To: s22
Subject: Confirmation of nicotine form [SEC=OFFICIAL]
Date: Monday, 13 May 2024 11:31:35 AM
Attachments: image001.png

Good afternoon s22

I have been asked to confirm the nicotine form of your products e.g. freebase or salt based for publishing. Can you please complete the table below and return to me asap.

Product Name	Nicotine Form
RELX Pod Pro2-Menthol-28.5mg/mL Nicotine	
RELX Pod Pro2-Tobacco Gold-28.5mg/mL Nicotine	
RELX Pod Pro2-Mint-28.5mg/mL Nicotine	
RELX Pod Pro2-Tobacco Red-28.5mg/mL Nicotine	

Kind regards

s22
Product Import Compliance Section
Senior Compliance Officer
Regulatory Compliance Branch
Regulatory Practice and Support Division | Health Products Regulation Group
Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care
www.tga.gov.au
PO Box 100, Woden ACT 2606, Australia

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From: s22
To: Vape notifications
Subject: Re: Confirmation of nicotine form [SEC=OFFICIAL]
Date: Monday, 13 May 2024 1:02:28 PM

Hi s22,

They are all nicotine salt base, and I have complete the table below as well.
Regards
s22

On 13 May 2024, at 13:32, Vape notifications <Vapenotifications@health.gov.au> wrote:

Good afternoon s22,
I have been asked to confirm the nicotine form of your products e.g. freebase or salt based for publishing. Can you please complete the table below and return to me asap.

Product Name	Nicotine Form
RELX Pod Pro2-Menthol-28.5mg/mL Nicotine	Nicotine Salt
RELX Pod Pro2-Tobacco Gold-28.5mg/mL Nicotine	Nicotine Salt
RELX Pod Pro2-Mint-28.5mg/mL Nicotine	Nicotine Salt
RELX Pod Pro2-Tobacco Red-28.5mg/mL Nicotine	Nicotine Salt

Kind regards

s22
Product Import Compliance Section
Senior Compliance Officer
Regulatory Compliance Branch
<image001.png>

Regulatory Practice and Support Division | Health Products Regulation Group
Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care
www.tga.gov.au
PO Box 100, Woden ACT 2606, Australia

The Department of Health and Aged Care 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 all Elders both past and present.

From: s22
To: Vape notifications
Subject: Nicotine Vape Product Notification
Date: Friday, 8 March 2024 11:18:07 AM
Attachments: image003.png
Untitled attachment 00025.htm
sponsor-notice-vaping-goods_Infinity 2 Device.docx
Untitled attachment 00028.htm
sponsor-notice-vaping-goods_Menthol.docx
Untitled attachment 00031.htm
sponsor-notice-vaping-goods_Mint.docx
Untitled attachment 00034.htm
sponsor-notice-vaping-goods_Tobacco Gold.docx
Untitled attachment 00037.htm
sponsor-notice-vaping-goods_Tobacco Red.docx
Untitled attachment 00040.htm

Hi TGA,

Please find attached nicotine product notification forms.
If you need any further information, please let me know.

Regards

Regards

s22 | Managing Partner
Mission Distribution | s22

From: Vape notifications
To: s22
Cc: Vape notifications
Subject: FW: Nicotine Vape Product Notification [SEC=OFFICIAL]
Date: Monday, 18 March 2024 3:17:10 PM
Attachments: image001.png
image002.png

Good afternoon s22,

In the notification applications for all four pods, you have missed selecting the box that indicates that the vaping substance is only indicated for 'smoking cessation' or the 'management of nicotine dependence'.

Please amend the four applications and resend them. The device application is fine. No need to resend.

s22
Product Import Compliance Section
Seniort Compliance Officer
Regulatory Compliance Branch
Regulatory Practice and Support Division | Health Products Regulation Group
Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care
www.tga.gov.au
PO Box 100, Woden ACT 2606, Australia

The Department of Health and Aged Care 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 all Elders both past and present.

From: s22 s22s47
Sent: Friday, March 8, 2024 10:46 AM
To: Vape notifications <Vapenotifications@health.gov.au>
Subject: Nicotine Vape Product Notification

Hi TGA,

Please find attached nicotine product notification forms.

If you need any further information, please let me know.

Regards

Regards

s22 | Managing Partner
Mission Distribution | s22

From: s22
To: Vape notifications
Subject: Re: Nicotine Vape Product Notification [SEC=OFFICIAL]
Date: Tuesday, 19 March 2024 7:28:07 AM

Hi s22,

Thank you for letting me know, I have updated all the pods notifications.
Let me know if you need any further information for product notification.

Regards
s22

From: s22
To: Vape notifications
Subject: Re: Nicotine Vape Product Notification [SEC=OFFICIAL]
Date: Tuesday, 19 March 2024 11:37:39 AM

Hi s22,

Please see attached revised applications, sorry for the confusion.

Regards
s22

From: s22
To: Vape notifications
Subject: Re: Nicotine Vape Product Notification [SEC=OFFICIAL]
Date: Tuesday, 19 March 2024 12:10:00 PM

Hi s22,

Please see attached revised applications, sorry for the confusion.

Regards
s22

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA USE ONLY

This form, when completed, will be classified as **'Official'**.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

Sponsor notice – Vaping goods

Notice to import or supply in Australia therapeutic vaping goods

About this form

You must submit this notice to the TGA prior to commencing importation or supply in Australia of unregistered therapeutic vaping goods that are intended for smoking cessation or the management of nicotine dependence, or ingredients or components used in the manufacture of those goods. The notice must be submitted before the therapeutic vaping goods are imported, or, for finished goods that are manufactured in Australia, before those goods are first supplied in Australia.

A separate form must be completed for each different type of therapeutic vaping good, ingredient or component intended to be imported or supplied. For example, if you have different flavours, concentrations of nicotine, or vaping device characteristics, you will need to submit a notice for each good.

If a notice is made for therapeutic vaping goods imported for further manufacture in Australia, a separate notice will need to be made for each good prior to supply.

Once complete, send this form to vapenotifications@health.gov.au

If information in the form relating to your therapeutic vaping good is incomplete, we may not be able to provide you a notification number.

You should be aware that the TGA may publish certain information relating to your notice – such as your name and details of your good.

Guidance

Guidance is available on the TGA website to help you to complete the form.

What you'll need to complete this form

- **Your TGA client ID** – see guidance on setting up a TGA client ID.
- **Details about your therapeutic vaping good, ingredient or component** – you will need to tell us key details about the good you intend to import, or supply following domestic manufacture.
- **Manufacturer information** – we need to know the TGA client ID for each manufacturer (vaping substance), or details of the manufacturers (vaping devices).
- **Evidence of compliance to applicable standards** – you will need this for each vaping good you intend to import, or supply following domestic manufacture.

Legislation

This notice is made under paragraph (a) in column 3 of item 15, and paragraph (a) in column 3 of item 16, of Schedule 5A to the *Therapeutic Goods Regulations 1990* (the TG Regulations).

This notice is also made under paragraph (a) in the column headed "Conditions" of item 2.17, and paragraph (a) in the column headed "Conditions" of item 2.18, of Part 2 of Schedule 4 to the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations)

Section 1: Sponsor information

Company name:	Mission Distribution Victoria Pty Limited
TGA client ID:	83800
Contact email:	s2 s47 [redacted]

Section 2: Vaping good category

See guidance about the definitions used in this form. Every vaping good requires a separate notice, including where those therapeutic vaping goods are contained in a therapeutic vaping kit or therapeutic vaping pack.

Select one vaping good category for this notice:

☒ A finished good that is, or contains, a vaping substance (a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a good in a ***therapeutic vaping kit*** – see item 15 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 5 and 8 below

☐ A finished good that would be a medical device except that it is for supply as part of a therapeutic vaping pack (a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** in a ***therapeutic vaping pack*** – see item 15 of Schedule 5A to the TG Regulations).[1]

Complete sections 3, 4, 5 and 8 below

☐ A finished good that does not contain a vaping substance, and is a reusable vaping device or a component of a reusable vaping device, or a reusable cartridge, capsule or pod or other vessel (a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.17 of Part 2 of Schedule 4 to the MD Regulations).

Complete sections 3, 4, 6 and 8 below.

☐ A starting material, that is not liquid nicotine, for use in the manufacture of therapeutic vaping goods that are or contain therapeutic vaping substances (see item 16 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of vaping goods in Australia (including a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a ***therapeutic vaping kit*** – see item 16 Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of other therapeutic goods in Australia (see item 16 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ A component or article intended for use in the manufacture of an unfilled vaping device (the manufacture of a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.18 of Part 2 of Schedule 4 to the MD Regulations).

Complete sections 3, 4, 7 and 8 below.

[1] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

Section 3: Vaping good details

Complete **tables 1 and 2** if your vaping good is:

- a therapeutic vaping substance;
- liquid nicotine; or
- starting material that is an ingredient for use in the manufacture of a therapeutic vaping substance or therapeutic vaping substance accessory.

Complete **table 3** if your vaping good is:

- a therapeutic vaping device, e.g. a reusable vaporiser, battery, mouthpiece, coil or other parts of a reusable therapeutic vaping device;
- a therapeutic vaping device accessory, e.g. a unfilled cartridge, capsule or pod; or
- a component or article for use in the manufacture of a therapeutic vaping device, therapeutic vaping device accessory or therapeutic vaping substance accessory.

Complete **tables 1, 2 and 3** if your vaping good is:

- a therapeutic vaping substance accessory e.g. a filled cartridge, capsule or pod.

When completing **table 2**:

- list all ingredients (except for nicotine, details of which should be included in Table 1), including flavour, using the Australian Approved Ingredient name where possible; and
- use the approved terminology in TGA Code Tables, e.g. the Australian Approved Names of ingredients, and as specified in the published guidance.

Table 1: Details of the therapeutic vaping substance, liquid nicotine or starting material

Name of good:	RELX Pod Pro2-Menthol-28.5mg/mL Nicotine
Description of good:	Therapeutic vaping substance accessory
Container type:	Prefilled Pod
Volume in mL (or weight if applicable):	1.9mL
Nicotine form (if applicable):	Nicotine ID 54852
Nicotine quantity:	28.5mg/mL

Table 2: Ingredients in the therapeutic vaping substance, liquid nicotine or starting material

Ingredient name	Quantity
s47 [redacted]	

Table 3: Details of the therapeutic vaping device, therapeutic vaping device accessory, therapeutic vaping substance accessory or articles or components for further manufacture

Vaping good name:	RELX Pod Pro2-Menthol-28.5mg/mL Nicotine		
Device model:	RELX Pod Pro2		
Vaping good description:	Therapeutic vaping substance accessory		
Liquid capacity in mL:	1.9mL		
Device product identifier GMDN or UDI:	No GMDN or UDI is available		
Rechargeable battery:	☐ Yes	☒ No	
Battery capacity:	Prefilled pod, no battery included		
Battery composition: (e.g. Nickel-Cadmium, Nickel-Metal Hydride, Lithium Ion)	Prefilled pod, no battery included		
Battery voltage:	Prefilled pod, no battery included		
Battery wattage:	Prefilled pod, no battery included		
Type of heating element:	☒ Coil	☐ Wick	☐ Other
	If Other selected, please describe:		
Charging unit:	☐ USB	☒ Other Prefilled pod, no battery included	
Is the airflow adjustable?	☐ Yes	☒ No	
Type of control unit(s): (e.g. PCB, microcontroller, software, etc)	Prefilled pod, no control unit included		

Section 4: Manufacturer details

Provide details of all prior manufacturers of the therapeutic vaping goods, ingredients or components you are importing or supplying.

Manufacturers of the therapeutic vaping substance, therapeutic vaping substance accessory, liquid nicotine or starting material for further manufacture

Manufacturer name:	s47 [redacted]
TGA client ID:	s47 [redacted]
Steps in manufacture:	Vaping substance manufacturer/testing chemical manufacturer

Manufacturer name:	s47 [redacted]
TGA client ID:	s47 [redacted]
Steps in manufacture:	Finished product manufacturer/packaging manufacturer/testing physical manufacturer

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturers of the therapeutic vaping device, therapeutic vaping device accessory, therapeutic vaping substance accessory or articles or components for further manufacture

Manufacturer name:	s47 [redacted]				
Site street address:	s47 [redacted]				
Suburb/Town/City:	s47 [redacted]	**State/Territory:**	s47 [redacted]	**Post code:**	s47 [redacted]
Country:	s47 [redacted]				
Contact email:	s22 s47 [redacted]				

Manufacturer name:	s47 [redacted]				
Site street address:	s47 [redacted]				
Suburb/Town/City:	s47 [redacted]	**State/Territory:**	s47 [redacted]	**Post code:**	s47 [redacted]
Country:	s47 [redacted]				
Contact email:	s22 s47 [redacted]				

Manufacturer name:					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Manufacturer name:	
Site street address:	

Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Section 5: Compliance – vaping substances etc

Complete this section if the therapeutic vaping good is ready to be supplied in Australia and is, or contains, a therapeutic vaping substance, including a therapeutic vaping substance accessory, therapeutic vaping kit or is a good in a therapeutic vaping pack.[2].

The therapeutic vaping good:

☒ is only indicated for 'smoking cessation' or the 'management of nicotine dependence'.

The therapeutic vaping good:

☒ conforms with applicable standards, including *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021*. **Complete the TGO 110 compliance evidence below.**

OR

☐ is the subject of a consent from the Secretary under section 14 or 14A of the Therapeutic Goods Act for importation or supply. (Note: consent is only granted in exceptional circumstances).

TGO 110 compliance evidence

☒ Testing is performed on each batch of vaping goods.

- ☒ We hold an example of recent testing performed on a batch of vaping goods supplied or to be supplied in Australia:

Name of the facility:	s47 [redacted]
Address of the facility:	s47 [redacted]
Date tested: (dd/mm/yyyy)	14/12/2023

- ☒ Testing performed will confirm the nicotine concentration, which aligns with the label claim (where applicable).
- ☒ Testing will confirm the absence of prohibited ingredients.
- ☒ Batch-specific test results can be made available upon request.

☒ The good only contains mint, menthol, or tobacco flavour, if it contains a flavour.

☒ The labels comply with the requirements of TGO 110.

- ☒ The product label includes a list of all ingredients required by TGO 110.
- ☒ The product label includes quantity of nicotine as an active ingredient (if applicable).
- ☒ The product label includes applicable warning statements.
- ☒ Copies of labels can be provided upon request.

☒ The good has child-resistant packaging.

☒ For a vaping substance accessory, vaping device, vaping device accessory or vaping substance accessories in a kit, the good(s) conforms with the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023* or essential principles, as appropriate (see footnote 3 and 4).

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[2] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

Section 6: Compliance – vaping devices etc

Complete this section for a good that is a therapeutic vaping device or therapeutic vaping device accessory that does not contain a therapeutic vaping substance and is not to be imported or supplied in a therapeutic vaping pack. See footnotes 3 and 4 as to which standards apply to your vaping device.

The therapeutic vaping device or therapeutic device accessory:

☐ is only intended to administer a therapeutic vaping substance that is indicated for 'smoking cessation' or the 'management of nicotine dependence'.

The therapeutic vaping device or therapeutic device accessory:

☐ conforms with the Essential Principles[3]. **Complete the *Essential Principles* checklist available on the TGA website** (https://www.tga.gov.au/resources/resource/forms/essential-principles-checklist-medical-devices). You do not need to submit the completed checklist. **Go to section 8.**

OR

☐ is a device to which the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023*[4] (MDSO) applies and conforms with the MDSO. **Complete the vaping device compliance evidence below.**

OR

☐ is the subject of consent from the Secretary under section 41MA or 41MAA of the Act for non-compliance with the essential principles. (Note: consent is only granted in exceptional circumstances, for a limited period). **Go to section 8.**

Evidence of compliance – vaping device or vaping device accessory

If your therapeutic vaping device or therapeutic vaping device accessory does not comply with the Essential Principles and the MDSO applies, select one or more types of valid evidence held that demonstrates compliance with applicable requirements:

☐ US FDA - Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS)

☐ EU - European Tobacco Products Directive - A valid notification under Article 20 of Directive 2014/40/EU

☐ UK MHRA - notification through the Tobacco and related Products Regulations (TRPR), as listed on the notified e-cigarette products publication (database) ecig (cms.mhra.gov.uk/ecig)

☐ Certificate, licence, notification, or other approval establishing compliance for supply of therapeutic goods (TGA, US FDA, EU notified body, or designated body by UK MHRA)

☐ ISO 9001 certificate

☐ ISO13485 certificate

Based on the selection above, provide the following information as evidence (the table can be duplicated if more than one type of evidence is held or there are multiple manufacturing sites holding separate certifications):

Authorising authority / certification or notification body	
Scope of authorisation / certification / notification	
Authorisation / certificate / notification number or identifier	

[3] The essential principles apply to therapeutic vaping devices and therapeutic vaping device accessories by default under the *Therapeutic Goods Act 1989*.

[4] The MDSO applies to therapeutic vaping devices and therapeutic vaping device accessories, imported or manufactured on or after 1 March 2024, that prior to 1 January 2024 were excluded from the operation of the *Therapeutic Goods Act 1989*. Vaping devices and vaping device accessories previously excluded were those not intended to be used exclusively for the administration of a medicine.

Section 7: Ingredients or components for further manufacture in Australia

Complete this section if the good is a starting material, component or article being imported for the purpose of further manufacture in Australia.

☐ The starting material is for use in the lawful manufacture of a therapeutic vaping substance or a therapeutic vaping substance accessory or another therapeutic good by a manufacturer that holds all relevant licences or approvals. Provide details of manufacturing sites in the table below. Duplicate the table as necessary.

Manufacturer name:	
TGA licence number:	
Steps in manufacture:	

☐ The article or component is for use in the lawful manufacture of a therapeutic vaping device or a therapeutic vaping device accessory by a manufacturer that holds all relevant licences or approvals. Provide details of manufacturing sites in the table below. Duplicate the table as necessary.

Manufacturer name:					
Conformity assessment evidence					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Section 8: Declaration

Section 8.1: Privacy information

General privacy information is available on the TGA website.

The TGA is collecting personal information in this form in order to contact the sponsor to discuss the notice where necessary.

Section 8.2: Declaration

☒ I declare that the information provided in this form, is, to the best of my knowledge, current and correct.

☒ I certify that the statements made in this notice are supported by information and evidence which will be provided to the TGA upon request.

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 section 137.1 of the Commonwealth Criminal Code.

Name	s22 [redacted]		
Signature	s22 [redacted]	Date	04.03.2024

Send this completed notification form to vapenotifications@health.gov.au

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA USE ONLY

This form, when completed, will be classified as **'Official'**.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

Sponsor notice – Vaping goods

Notice to import or supply in Australia therapeutic vaping goods

About this form

You must submit this notice to the TGA prior to commencing importation or supply in Australia of unregistered therapeutic vaping goods that are intended for smoking cessation or the management of nicotine dependence, or ingredients or components used in the manufacture of those goods. The notice must be submitted before the therapeutic vaping goods are imported, or, for finished goods that are manufactured in Australia, before those goods are first supplied in Australia.

A separate form must be completed for each different type of therapeutic vaping good, ingredient or component intended to be imported or supplied. For example, if you have different flavours, concentrations of nicotine, or vaping device characteristics, you will need to submit a notice for each good.

If a notice is made for therapeutic vaping goods imported for further manufacture in Australia, a separate notice will need to be made for each good prior to supply.

Once complete, send this form to vapenotifications@health.gov.au

If information in the form relating to your therapeutic vaping good is incomplete, we may not be able to provide you a notification number.

You should be aware that the TGA may publish certain information relating to your notice – such as your name and details of your good.

Guidance

Guidance is available on the TGA website to help you to complete the form.

What you'll need to complete this form

- **Your TGA client ID** – see guidance on setting up a TGA client ID.
- **Details about your therapeutic vaping good, ingredient or component** – you will need to tell us key details about the good you intend to import, or supply following domestic manufacture.
- **Manufacturer information** – we need to know the TGA client ID for each manufacturer (vaping substance), or details of the manufacturers (vaping devices).
- **Evidence of compliance to applicable standards** – you will need this for each vaping good you intend to import, or supply following domestic manufacture.

Legislation

This notice is made under paragraph (a) in column 3 of item 15, and paragraph (a) in column 3 of item 16, of Schedule 5A to the *Therapeutic Goods Regulations 1990* (the TG Regulations).

This notice is also made under paragraph (a) in the column headed "Conditions" of item 2.17, and paragraph (a) in the column headed "Conditions" of item 2.18, of Part 2 of Schedule 4 to the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations)

Section 1: Sponsor information

Company name:	Mission Distribution Victoria Pty Limited
TGA client ID:	83800
Contact email:	s2 s47 [redacted]

Section 2: Vaping good category

See guidance about the definitions used in this form. Every vaping good requires a separate notice, including where those therapeutic vaping goods are contained in a therapeutic vaping kit or therapeutic vaping pack.

Select one vaping good category for this notice:

☒ A finished good that is, or contains, a vaping substance (a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a good in a ***therapeutic vaping kit*** – see item 15 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 5 and 8 below

☐ A finished good that would be a medical device except that it is for supply as part of a therapeutic vaping pack (a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** in a ***therapeutic vaping pack*** – see item 15 of Schedule 5A to the TG Regulations).[1]

Complete sections 3, 4, 5 and 8 below

☐ A finished good that does not contain a vaping substance, and is a reusable vaping device or a component of a reusable vaping device, or a reusable cartridge, capsule or pod or other vessel (a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.17 of Part 2 of Schedule 4 to the MD Regulations).

Complete sections 3, 4, 6 and 8 below.

☐ A starting material, that is not liquid nicotine, for use in the manufacture of therapeutic vaping goods that are or contain therapeutic vaping substances (see item 16 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of vaping goods in Australia (including a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a ***therapeutic vaping kit*** – see item 16 Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of other therapeutic goods in Australia (see item 16 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ A component or article intended for use in the manufacture of an unfilled vaping device (the manufacture of a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.18 of Part 2 of Schedule 4 to the MD Regulations).

Complete sections 3, 4, 7 and 8 below.

[1] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

Section 3: Vaping good details

Complete **tables 1 and 2** if your vaping good is:

- a therapeutic vaping substance;
- liquid nicotine; or
- starting material that is an ingredient for use in the manufacture of a therapeutic vaping substance or therapeutic vaping substance accessory.

Complete **table 3** if your vaping good is:

- a therapeutic vaping device, e.g. a reusable vaporiser, battery, mouthpiece, coil or other parts of a reusable therapeutic vaping device;
- a therapeutic vaping device accessory, e.g. a unfilled cartridge, capsule or pod; or
- a component or article for use in the manufacture of a therapeutic vaping device, therapeutic vaping device accessory or therapeutic vaping substance accessory.

Complete **tables 1, 2 and 3** if your vaping good is:

- a therapeutic vaping substance accessory e.g. a filled cartridge, capsule or pod.

When completing **table 2**:

- list all ingredients (except for nicotine, details of which should be included in Table 1), including flavour, using the Australian Approved Ingredient name where possible; and
- use the approved terminology in TGA Code Tables, e.g. the Australian Approved Names of ingredients, and as specified in the published guidance.

Table 1: Details of the therapeutic vaping substance, liquid nicotine or starting material

Name of good:	RELX Pod Pro2-Mint-28.5mg/mL Nicotine
Description of good:	Therapeutic vaping substance accessory
Container type:	Prefilled Pod
Volume in mL (or weight if applicable):	1.9mL
Nicotine form (if applicable):	Nicotine ID 54852
Nicotine quantity:	28.5mg/mL

Table 2: Ingredients in the therapeutic vaping substance, liquid nicotine or starting material

Ingredient name	Quantity
s47	

s47

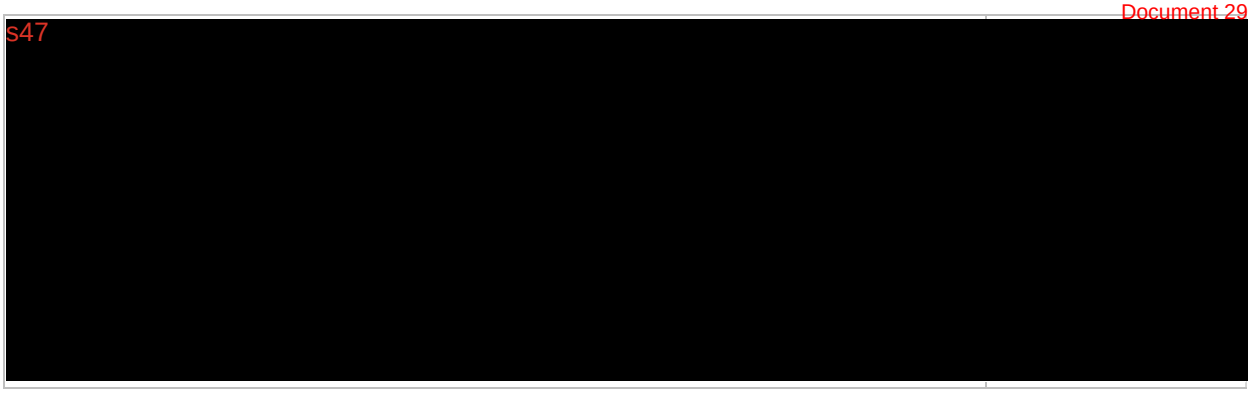

Table 3: Details of the therapeutic vaping device, therapeutic vaping device accessory, therapeutic vaping substance accessory or articles or components for further manufacture

Vaping good name:	RELX Pod Pro2-Mint-28.5mg/mL Nicotine		
Device model:	RELX Pod Pro2		
Vaping good description:	Therapeutic vaping substance accessory		
Liquid capacity in mL:	1.9mL		
Device product identifier GMDN or UDI:	No GMDN or UDI is available		
Rechargeable battery:	☐ Yes	☒ No	
Battery capacity:	Prefilled pod, no battery included		
Battery composition: (e.g. Nickel-Cadmium, Nickel-Metal Hydride, Lithium Ion)	Prefilled pod, no battery included		
Battery voltage:	Prefilled pod, no battery included		
Battery wattage:	Prefilled pod, no battery included		
Type of heating element:	☒ Coil	☐ Wick	☐ Other
	If Other selected, please describe:		
Charging unit:	☐ USB	☒ Other Prefilled pod, no battery included	
Is the airflow adjustable?	☐ Yes	☒ No	
Type of control unit(s): (e.g. PCB, microcontroller, software, etc)	Prefilled pod, no control unit included		

Section 4: Manufacturer details

Provide details of all prior manufacturers of the therapeutic vaping goods, ingredients or components you are importing or supplying.

Manufacturers of the therapeutic vaping substance, therapeutic vaping substance accessory, liquid nicotine or starting material for further manufacture

Manufacturer name:	s47 [redacted]
TGA client ID:	s47 [redacted]
Steps in manufacture:	Vaping substance manufacturer/testing chemical manufacturer

Manufacturer name:	s47 [redacted]
TGA client ID:	s47 [redacted]
Steps in manufacture:	Finished product manufacturer/packaging manufacturer/testing physical manufacturer

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturers of the therapeutic vaping device, therapeutic vaping device accessory, therapeutic vaping substance accessory or articles or components for further manufacture

Manufacturer name:	s47 [redacted]				
Site street address:	s47 [redacted]				
Suburb/Town/City:	s47 [redacted]	**State/Territory:**	s47 [redacted]	**Post code:**	s47 [redacted]
Country:	s47 [redacted]				
Contact email:	s22 s47 [redacted]				

Manufacturer name:	s47 [redacted]				
Site street address:	s47 [redacted]				
Suburb/Town/City:	s47 [redacted]	**State/Territory:**	s47 [redacted]	**Post code:**	s 4 [redacted]
Country:	s47 [redacted]				
Contact email:	s22 s47 [redacted]				

Manufacturer name:					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Manufacturer name:	
Site street address:	

Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Section 5: Compliance – vaping substances etc

Complete this section if the therapeutic vaping good is ready to be supplied in Australia and is, or contains, a therapeutic vaping substance, including a therapeutic vaping substance accessory, therapeutic vaping kit or is a good in a therapeutic vaping pack.[2].

The therapeutic vaping good:

☒ is only indicated for 'smoking cessation' or the 'management of nicotine dependence'.

The therapeutic vaping good:

☒ conforms with applicable standards, including *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021*. **Complete the TGO 110 compliance evidence below.**

OR

☐ is the subject of a consent from the Secretary under section 14 or 14A of the Therapeutic Goods Act for importation or supply. (Note: consent is only granted in exceptional circumstances).

TGO 110 compliance evidence

☒ Testing is performed on each batch of vaping goods.

- ☒ We hold an example of recent testing performed on a batch of vaping goods supplied or to be supplied in Australia:

Name of the facility:	s47 [redacted]
Address of the facility:	s47 [redacted]
Date tested: (dd/mm/yyyy)	16/12/2023

- ☒ Testing performed will confirm the nicotine concentration, which aligns with the label claim (where applicable).
- ☒ Testing will confirm the absence of prohibited ingredients.
- ☒ Batch-specific test results can be made available upon request.

☒ The good only contains mint, menthol, or tobacco flavour, if it contains a flavour.

☒ The labels comply with the requirements of TGO 110.

- ☒ The product label includes a list of all ingredients required by TGO 110.
- ☒ The product label includes quantity of nicotine as an active ingredient (if applicable).
- ☒ The product label includes applicable warning statements.
- ☒ Copies of labels can be provided upon request.

☒ The good has child-resistant packaging.

☒ For a vaping substance accessory, vaping device, vaping device accessory or vaping substance accessories in a kit, the good(s) conforms with the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023* or essential principles, as appropriate (see footnote 3 and 4).

---

[2] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

Section 6: Compliance – vaping devices etc

Complete this section for a good that is a therapeutic vaping device or therapeutic vaping device accessory that does not contain a therapeutic vaping substance and is not to be imported or supplied in a therapeutic vaping pack. See footnotes 3 and 4 as to which standards apply to your vaping device.

The therapeutic vaping device or therapeutic device accessory:

☐ is only intended to administer a therapeutic vaping substance that is indicated for 'smoking cessation' or the 'management of nicotine dependence'.

The therapeutic vaping device or therapeutic device accessory:

☐ conforms with the Essential Principles[3]. **Complete the *Essential Principles* checklist available on the TGA website** (https://www.tga.gov.au/resources/resource/forms/essential-principles-checklist-medical-devices). You do not need to submit the completed checklist. **Go to section 8.**

OR

☐ is a device to which the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023*[4] (MDSO) applies and conforms with the MDSO. **Complete the vaping device compliance evidence below.**

OR

☐ is the subject of consent from the Secretary under section 41MA or 41MAA of the Act for non-compliance with the essential principles. (Note: consent is only granted in exceptional circumstances, for a limited period). **Go to section 8.**

Evidence of compliance – vaping device or vaping device accessory

If your therapeutic vaping device or therapeutic vaping device accessory does not comply with the Essential Principles and the MDSO applies, select one or more types of valid evidence held that demonstrates compliance with applicable requirements:

☐ US FDA - Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS)

☐ EU - European Tobacco Products Directive - A valid notification under Article 20 of Directive 2014/40/EU

☐ UK MHRA - notification through the Tobacco and related Products Regulations (TRPR), as listed on the notified e-cigarette products publication (database) ecig (cms.mhra.gov.uk/ecig)

☐ Certificate, licence, notification, or other approval establishing compliance for supply of therapeutic goods (TGA, US FDA, EU notified body, or designated body by UK MHRA)

☐ ISO 9001 certificate

☐ ISO13485 certificate

Based on the selection above, provide the following information as evidence (the table can be duplicated if more than one type of evidence is held or there are multiple manufacturing sites holding separate certifications):

Authorising authority / certification or notification body	
Scope of authorisation / certification / notification	
Authorisation / certificate / notification number or identifier	

[3] The essential principles apply to therapeutic vaping devices and therapeutic vaping device accessories by default under the *Therapeutic Goods Act 1989*.

[4] The MDSO applies to therapeutic vaping devices and therapeutic vaping device accessories, imported or manufactured on or after 1 March 2024, that prior to 1 January 2024 were excluded from the operation of the *Therapeutic Goods Act 1989*. Vaping devices and vaping device accessories previously excluded were those not intended to be used exclusively for the administration of a medicine.

Section 7: Ingredients or components for further manufacture in Australia

Complete this section if the good is a starting material, component or article being imported for the purpose of further manufacture in Australia.

☐ The starting material is for use in the lawful manufacture of a therapeutic vaping substance or a therapeutic vaping substance accessory or another therapeutic good by a manufacturer that holds all relevant licences or approvals. Provide details of manufacturing sites in the table below. Duplicate the table as necessary.

Manufacturer name:	
TGA licence number:	
Steps in manufacture:	

☐ The article or component is for use in the lawful manufacture of a therapeutic vaping device or a therapeutic vaping device accessory by a manufacturer that holds all relevant licences or approvals. Provide details of manufacturing sites in the table below. Duplicate the table as necessary.

Manufacturer name:					
Conformity assessment evidence					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Section 8: Declaration

Section 8.1: Privacy information

General privacy information is available on the TGA website.

The TGA is collecting personal information in this form in order to contact the sponsor to discuss the notice where necessary.

Section 8.2: Declaration

☒ I declare that the information provided in this form, is, to the best of my knowledge, current and correct.

☒ I certify that the statements made in this notice are supported by information and evidence which will be provided to the TGA upon request.

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 section 137.1 of the Commonwealth Criminal Code.

Name	s22 [redacted]		
Signature	s22 [redacted]	Date	04.03.2024

Send this completed notification form to vapenotifications@health.gov.au

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA USE ONLY

This form, when completed, will be classified as **'Official'**.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

Sponsor notice – Vaping goods

Notice to import or supply in Australia therapeutic vaping goods

About this form

You must submit this notice to the TGA prior to commencing importation or supply in Australia of unregistered therapeutic vaping goods that are intended for smoking cessation or the management of nicotine dependence, or ingredients or components used in the manufacture of those goods. The notice must be submitted before the therapeutic vaping goods are imported, or, for finished goods that are manufactured in Australia, before those goods are first supplied in Australia.

A separate form must be completed for each different type of therapeutic vaping good, ingredient or component intended to be imported or supplied. For example, if you have different flavours, concentrations of nicotine, or vaping device characteristics, you will need to submit a notice for each good.

If a notice is made for therapeutic vaping goods imported for further manufacture in Australia, a separate notice will need to be made for each good prior to supply.

Once complete, send this form to vapenotifications@health.gov.au

If information in the form relating to your therapeutic vaping good is incomplete, we may not be able to provide you a notification number.

You should be aware that the TGA may publish certain information relating to your notice – such as your name and details of your good.

Guidance

Guidance is available on the TGA website to help you to complete the form.

What you'll need to complete this form

- **Your TGA client ID** – see guidance on setting up a TGA client ID.
- **Details about your therapeutic vaping good, ingredient or component** – you will need to tell us key details about the good you intend to import, or supply following domestic manufacture.
- **Manufacturer information** – we need to know the TGA client ID for each manufacturer (vaping substance), or details of the manufacturers (vaping devices).
- **Evidence of compliance to applicable standards** – you will need this for each vaping good you intend to import, or supply following domestic manufacture.

Legislation

This notice is made under paragraph (a) in column 3 of item 15, and paragraph (a) in column 3 of item 16, of Schedule 5A to the *Therapeutic Goods Regulations 1990* (the TG Regulations).

This notice is also made under paragraph (a) in the column headed "Conditions" of item 2.17, and paragraph (a) in the column headed "Conditions" of item 2.18, of Part 2 of Schedule 4 to the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations)

Section 1: Sponsor information

Company name:	Mission Distribution Victoria Pty Limited
TGA client ID:	83800
Contact email:	s2 s47 [redacted]

Section 2: Vaping good category

See guidance about the definitions used in this form. Every vaping good requires a separate notice, including where those therapeutic vaping goods are contained in a therapeutic vaping kit or therapeutic vaping pack.

Select one vaping good category for this notice:

☒ A finished good that is, or contains, a vaping substance (a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a good in a ***therapeutic vaping kit*** – see item 15 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 5 and 8 below

☐ A finished good that would be a medical device except that it is for supply as part of a therapeutic vaping pack (a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** in a ***therapeutic vaping pack*** – see item 15 of Schedule 5A to the TG Regulations).[1]

Complete sections 3, 4, 5 and 8 below

☐ A finished good that does not contain a vaping substance, and is a reusable vaping device or a component of a reusable vaping device, or a reusable cartridge, capsule or pod or other vessel (a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.17 of Part 2 of Schedule 4 to the MD Regulations).

Complete sections 3, 4, 6 and 8 below.

☐ A starting material, that is not liquid nicotine, for use in the manufacture of therapeutic vaping goods that are or contain therapeutic vaping substances (see item 16 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of vaping goods in Australia (including a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a ***therapeutic vaping kit*** – see item 16 Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of other therapeutic goods in Australia (see item 16 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ A component or article intended for use in the manufacture of an unfilled vaping device (the manufacture of a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.18 of Part 2 of Schedule 4 to the MD Regulations).

Complete sections 3, 4, 7 and 8 below.

[1] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

Section 3: Vaping good details

Complete **tables 1 and 2** if your vaping good is:

- a therapeutic vaping substance;
- liquid nicotine; or
- starting material that is an ingredient for use in the manufacture of a therapeutic vaping substance or therapeutic vaping substance accessory.

Complete **table 3** if your vaping good is:

- a therapeutic vaping device, e.g. a reusable vaporiser, battery, mouthpiece, coil or other parts of a reusable therapeutic vaping device;
- a therapeutic vaping device accessory, e.g. a unfilled cartridge, capsule or pod; or
- a component or article for use in the manufacture of a therapeutic vaping device, therapeutic vaping device accessory or therapeutic vaping substance accessory.

Complete **tables 1, 2 and 3** if your vaping good is:

- a therapeutic vaping substance accessory e.g. a filled cartridge, capsule or pod.

When completing **table 2**:

- list all ingredients (except for nicotine, details of which should be included in Table 1), including flavour, using the Australian Approved Ingredient name where possible; and
- use the approved terminology in TGA Code Tables, e.g. the Australian Approved Names of ingredients, and as specified in the published guidance.

Table 1: Details of the therapeutic vaping substance, liquid nicotine or starting material

Name of good:	RELX Pod Pro2-Mint-28.5mg/mL Nicotine
Description of good:	Therapeutic vaping substance accessory
Container type:	Prefilled Pod
Volume in mL (or weight if applicable):	1.9mL
Nicotine form (if applicable):	Nicotine ID 54852
Nicotine quantity:	28.5mg/mL

Table 2: Ingredients in the therapeutic vaping substance, liquid nicotine or starting material

Ingredient name	Quantity
s47	

s47

Table 3: Details of the therapeutic vaping device, therapeutic vaping device accessory, therapeutic vaping substance accessory or articles or components for further manufacture

Vaping good name:	RELX Pod Pro2-Mint-28.5mg/mL Nicotine		
Device model:	RELX Pod Pro2		
Vaping good description:	Therapeutic vaping substance accessory		
Liquid capacity in mL:	1.9mL		
Device product identifier GMDN or UDI:	No GMDN or UDI is available		
Rechargeable battery:	☐ Yes	☒ No	
Battery capacity:	Prefilled pod, no battery included		
Battery composition: (e.g. Nickel-Cadmium, Nickel-Metal Hydride, Lithium Ion)	Prefilled pod, no battery included		
Battery voltage:	Prefilled pod, no battery included		
Battery wattage:	Prefilled pod, no battery included		
Type of heating element:	☒ Coil	☐ Wick	☐ Other
	If Other selected, please describe:		
Charging unit:	☐ USB	☒ Other Prefilled pod, no battery included	
Is the airflow adjustable?	☐ Yes	☒ No	
Type of control unit(s): (e.g. PCB, microcontroller, software, etc)	Prefilled pod, no control unit included		

Section 4: Manufacturer details

Provide details of all prior manufacturers of the therapeutic vaping goods, ingredients or components you are importing or supplying.

Manufacturers of the therapeutic vaping substance, therapeutic vaping substance accessory, liquid nicotine or starting material for further manufacture

Manufacturer name:	s47 [redacted]
TGA client ID:	s47 [redacted]
Steps in manufacture:	Vaping substance manufacturer/testing chemical manufacturer

Manufacturer name:	s47 [redacted]
TGA client ID:	s47 [redacted]
Steps in manufacture:	Finished product manufacturer/packaging manufacturer/testing physical manufacturer

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturers of the therapeutic vaping device, therapeutic vaping device accessory, therapeutic vaping substance accessory or articles or components for further manufacture

Manufacturer name:	s47 [redacted]				
Site street address:	s47 [redacted]				
Suburb/Town/City:	s47 [redacted]	**State/Territory:**	s47 [redacted]	**Post code:**	s47 [redacted]
Country:	s47 [redacted]				
Contact email:	s22 s47 [redacted]				

Manufacturer name:	s47 [redacted]				
Site street address:	s47 [redacted]				
Suburb/Town/City:	s47 [redacted]	**State/Territory:**	s47 [redacted]	**Post code:**	s47 [redacted]
Country:	s47 [redacted]				
Contact email:	s22 s47 [redacted]				

Manufacturer name:					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Manufacturer name:	
Site street address:	

Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Section 5: Compliance – vaping substances etc

Complete this section if the therapeutic vaping good is ready to be supplied in Australia and is, or contains, a therapeutic vaping substance, including a therapeutic vaping substance accessory, therapeutic vaping kit or is a good in a therapeutic vaping pack.[2].

The therapeutic vaping good:

☒ is only indicated for 'smoking cessation' or the 'management of nicotine dependence'.

The therapeutic vaping good:

☒ conforms with applicable standards, including *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021*. **Complete the TGO 110 compliance evidence below.**

OR

☐ is the subject of a consent from the Secretary under section 14 or 14A of the Therapeutic Goods Act for importation or supply. (Note: consent is only granted in exceptional circumstances).

TGO 110 compliance evidence

☒ Testing is performed on each batch of vaping goods.

- ☒ We hold an example of recent testing performed on a batch of vaping goods supplied or to be supplied in Australia:

Name of the facility:	s47 [redacted]
Address of the facility:	s47 [redacted]
Date tested: (dd/mm/yyyy)	16/12/2023

- ☒ Testing performed will confirm the nicotine concentration, which aligns with the label claim (where applicable).
- ☒ Testing will confirm the absence of prohibited ingredients.
- ☒ Batch-specific test results can be made available upon request.

☒ The good only contains mint, menthol, or tobacco flavour, if it contains a flavour.

☒ The labels comply with the requirements of TGO 110.

- ☒ The product label includes a list of all ingredients required by TGO 110.
- ☒ The product label includes quantity of nicotine as an active ingredient (if applicable).
- ☒ The product label includes applicable warning statements.
- ☒ Copies of labels can be provided upon request.

☒ The good has child-resistant packaging.

☒ For a vaping substance accessory, vaping device, vaping device accessory or vaping substance accessories in a kit, the good(s) conforms with the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023* or essential principles, as appropriate (see footnote 3 and 4).

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[2] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

Section 6: Compliance – vaping devices etc

Complete this section for a good that is a therapeutic vaping device or therapeutic vaping device accessory that does not contain a therapeutic vaping substance and is not to be imported or supplied in a therapeutic vaping pack. See footnotes 3 and 4 as to which standards apply to your vaping device.

The therapeutic vaping device or therapeutic device accessory:

☐ is only intended to administer a therapeutic vaping substance that is indicated for 'smoking cessation' or the 'management of nicotine dependence'.

The therapeutic vaping device or therapeutic device accessory:

☐ conforms with the Essential Principles[3]. **Complete the *Essential Principles* checklist available on the TGA website** (https://www.tga.gov.au/resources/resource/forms/essential-principles-checklist-medical-devices). You do not need to submit the completed checklist. **Go to section 8.**

OR

☐ is a device to which the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023*[4] (MDSO) applies and conforms with the MDSO. **Complete the vaping device compliance evidence below.**

OR

☐ is the subject of consent from the Secretary under section 41MA or 41MAA of the Act for non-compliance with the essential principles. (Note: consent is only granted in exceptional circumstances, for a limited period). **Go to section 8.**

Evidence of compliance – vaping device or vaping device accessory

If your therapeutic vaping device or therapeutic vaping device accessory does not comply with the Essential Principles and the MDSO applies, select one or more types of valid evidence held that demonstrates compliance with applicable requirements:

☐ US FDA - Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS)

☐ EU - European Tobacco Products Directive - A valid notification under Article 20 of Directive 2014/40/EU

☐ UK MHRA - notification through the Tobacco and related Products Regulations (TRPR), as listed on the notified e-cigarette products publication (database) ecig (cms.mhra.gov.uk/ecig)

☐ Certificate, licence, notification, or other approval establishing compliance for supply of therapeutic goods (TGA, US FDA, EU notified body, or designated body by UK MHRA)

☐ ISO 9001 certificate

☐ ISO13485 certificate

Based on the selection above, provide the following information as evidence (the table can be duplicated if more than one type of evidence is held or there are multiple manufacturing sites holding separate certifications):

Authorising authority / certification or notification body	
Scope of authorisation / certification / notification	
Authorisation / certificate / notification number or identifier	

[3] The essential principles apply to therapeutic vaping devices and therapeutic vaping device accessories by default under the *Therapeutic Goods Act 1989*.

[4] The MDSO applies to therapeutic vaping devices and therapeutic vaping device accessories, imported or manufactured on or after 1 March 2024, that prior to 1 January 2024 were excluded from the operation of the *Therapeutic Goods Act 1989*. Vaping devices and vaping device accessories previously excluded were those not intended to be used exclusively for the administration of a medicine.

Section 7: Ingredients or components for further manufacture in Australia

Complete this section if the good is a starting material, component or article being imported for the purpose of further manufacture in Australia.

☐ The starting material is for use in the lawful manufacture of a therapeutic vaping substance or a therapeutic vaping substance accessory or another therapeutic good by a manufacturer that holds all relevant licences or approvals. Provide details of manufacturing sites in the table below. Duplicate the table as necessary.

Manufacturer name:	
TGA licence number:	
Steps in manufacture:	

☐ The article or component is for use in the lawful manufacture of a therapeutic vaping device or a therapeutic vaping device accessory by a manufacturer that holds all relevant licences or approvals. Provide details of manufacturing sites in the table below. Duplicate the table as necessary.

Manufacturer name:					
Conformity assessment evidence					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Section 8: Declaration

Section 8.1: Privacy information

General privacy information is available on the TGA website.

The TGA is collecting personal information in this form in order to contact the sponsor to discuss the notice where necessary.

Section 8.2: Declaration

☒ I declare that the information provided in this form, is, to the best of my knowledge, current and correct.

☒ I certify that the statements made in this notice are supported by information and evidence which will be provided to the TGA upon request.

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 section 137.1 of the Commonwealth Criminal Code.

Name	s22 [redacted]		
Signature	s22 [redacted]	Date	04.03.2024

Send this completed notification form to vapenotifications@health.gov.au

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA USE ONLY

This form, when completed, will be classified as **'Official'**.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

Sponsor notice – Vaping goods

Notice to import or supply in Australia therapeutic vaping goods

About this form

You must submit this notice to the TGA prior to commencing importation or supply in Australia of unregistered therapeutic vaping goods that are intended for smoking cessation or the management of nicotine dependence, or ingredients or components used in the manufacture of those goods. The notice must be submitted before the therapeutic vaping goods are imported, or, for finished goods that are manufactured in Australia, before those goods are first supplied in Australia.

A separate form must be completed for each different type of therapeutic vaping good, ingredient or component intended to be imported or supplied. For example, if you have different flavours, concentrations of nicotine, or vaping device characteristics, you will need to submit a notice for each good.

If a notice is made for therapeutic vaping goods imported for further manufacture in Australia, a separate notice will need to be made for each good prior to supply.

Once complete, send this form to vapenotifications@health.gov.au

If information in the form relating to your therapeutic vaping good is incomplete, we may not be able to provide you a notification number.

You should be aware that the TGA may publish certain information relating to your notice – such as your name and details of your good.

Guidance

Guidance is available on the TGA website to help you to complete the form.

What you'll need to complete this form

- **Your TGA client ID** – see guidance on setting up a TGA client ID.
- **Details about your therapeutic vaping good, ingredient or component** – you will need to tell us key details about the good you intend to import, or supply following domestic manufacture.
- **Manufacturer information** – we need to know the TGA client ID for each manufacturer (vaping substance), or details of the manufacturers (vaping devices).
- **Evidence of compliance to applicable standards** – you will need this for each vaping good you intend to import, or supply following domestic manufacture.

Legislation

This notice is made under paragraph (a) in column 3 of item 15, and paragraph (a) in column 3 of item 16, of Schedule 5A to the *Therapeutic Goods Regulations 1990* (the TG Regulations).

This notice is also made under paragraph (a) in the column headed "Conditions" of item 2.17, and paragraph (a) in the column headed "Conditions" of item 2.18, of Part 2 of Schedule 4 to the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations)

Section 1: Sponsor information

Company name:	Mission Distribution Victoria Pty Limited
TGA client ID:	83800
Contact email:	s2 s47 [redacted]

Section 2: Vaping good category

See guidance about the definitions used in this form. Every vaping good requires a separate notice, including where those therapeutic vaping goods are contained in a therapeutic vaping kit or therapeutic vaping pack.

Select one vaping good category for this notice:

☒ A finished good that is, or contains, a vaping substance (a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a good in a ***therapeutic vaping kit*** – see item 15 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 5 and 8 below

☐ A finished good that would be a medical device except that it is for supply as part of a therapeutic vaping pack (a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** in a ***therapeutic vaping pack*** – see item 15 of Schedule 5A to the TG Regulations).[1]

Complete sections 3, 4, 5 and 8 below

☐ A finished good that does not contain a vaping substance, and is a reusable vaping device or a component of a reusable vaping device, or a reusable cartridge, capsule or pod or other vessel (a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.17 of Part 2 of Schedule 4 to the MD Regulations).

Complete sections 3, 4, 6 and 8 below.

☐ A starting material, that is not liquid nicotine, for use in the manufacture of therapeutic vaping goods that are or contain therapeutic vaping substances (see item 16 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of vaping goods in Australia (including a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a ***therapeutic vaping kit*** – see item 16 Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of other therapeutic goods in Australia (see item 16 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ A component or article intended for use in the manufacture of an unfilled vaping device (the manufacture of a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.18 of Part 2 of Schedule 4 to the MD Regulations).

Complete sections 3, 4, 7 and 8 below.

[1] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

Section 3: Vaping good details

Complete **tables 1 and 2** if your vaping good is:

- a therapeutic vaping substance;
- liquid nicotine; or
- starting material that is an ingredient for use in the manufacture of a therapeutic vaping substance or therapeutic vaping substance accessory.

Complete **table 3** if your vaping good is:

- a therapeutic vaping device, e.g. a reusable vaporiser, battery, mouthpiece, coil or other parts of a reusable therapeutic vaping device;
- a therapeutic vaping device accessory, e.g. a unfilled cartridge, capsule or pod; or
- a component or article for use in the manufacture of a therapeutic vaping device, therapeutic vaping device accessory or therapeutic vaping substance accessory.

Complete **tables 1, 2 and 3** if your vaping good is:

- a therapeutic vaping substance accessory e.g. a filled cartridge, capsule or pod.

When completing **table 2**:

- list all ingredients (except for nicotine, details of which should be included in Table 1), including flavour, using the Australian Approved Ingredient name where possible; and
- use the approved terminology in TGA Code Tables, e.g. the Australian Approved Names of ingredients, and as specified in the published guidance.

Table 1: Details of the therapeutic vaping substance, liquid nicotine or starting material

Name of good:	RELX Pod Pro2-Menthol-28.5mg/mL Nicotine
Description of good:	Therapeutic vaping substance accessory
Container type:	Prefilled Pod
Volume in mL (or weight if applicable):	1.9mL
Nicotine form (if applicable):	Nicotine ID 54852
Nicotine quantity:	28.5mg/mL

Table 2: Ingredients in the therapeutic vaping substance, liquid nicotine or starting material

Ingredient name	Quantity
s47	

Table 3: Details of the therapeutic vaping device, therapeutic vaping device accessory, therapeutic vaping substance accessory or articles or components for further manufacture

Vaping good name:	RELX Pod Pro2-Menthol-28.5mg/mL Nicotine		
Device model:	RELX Pod Pro2		
Vaping good description:	Therapeutic vaping substance accessory		
Liquid capacity in mL:	1.9mL		
Device product identifier GMDN or UDI:	No GMDN or UDI is available		
Rechargeable battery:	☐ Yes	☒ No	
Battery capacity:	Prefilled pod, no battery included		
Battery composition: (e.g. Nickel-Cadmium, Nickel-Metal Hydride, Lithium Ion)	Prefilled pod, no battery included		
Battery voltage:	Prefilled pod, no battery included		
Battery wattage:	Prefilled pod, no battery included		
Type of heating element:	☒ Coil	☐ Wick	☐ Other
	If Other selected, please describe:		
Charging unit:	☐ USB	☒ Other Prefilled pod, no battery included	
Is the airflow adjustable?	☐ Yes	☒ No	
Type of control unit(s): (e.g. PCB, microcontroller, software, etc)	Prefilled pod, no control unit included		

Section 4: Manufacturer details

Provide details of all prior manufacturers of the therapeutic vaping goods, ingredients or components you are importing or supplying.

Manufacturers of the therapeutic vaping substance, therapeutic vaping substance accessory, liquid nicotine or starting material for further manufacture

Manufacturer name:	s47 [redacted]
TGA client ID:	s47 [redacted]
Steps in manufacture:	Vaping substance manufacturer/testing chemical manufacturer

Manufacturer name:	s47 [redacted]
TGA client ID:	s47 [redacted]
Steps in manufacture:	Finished product manufacturer/packaging manufacturer/testing physical manufacturer

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturers of the therapeutic vaping device, therapeutic vaping device accessory, therapeutic vaping substance accessory or articles or components for further manufacture

Manufacturer name:	s47 [redacted]				
Site street address:	s47 [redacted]				
Suburb/Town/City:	s47 [redacted]	**State/Territory:**	s47 [redacted]	**Post code:**	s47 [redacted]
Country:	s47 [redacted]				
Contact email:	s22 s47 [redacted]				

Manufacturer name:	s47 [redacted]				
Site street address:	s47 [redacted]				
Suburb/Town/City:	s47 [redacted]	**State/Territory:**	s47 [redacted]	**Post code:**	s47 [redacted]
Country:	s47 [redacted]				
Contact email:	s22 s47 [redacted]				

Manufacturer name:					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Manufacturer name:	
Site street address:	

Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Section 5: Compliance – vaping substances etc

Complete this section if the therapeutic vaping good is ready to be supplied in Australia and is, or contains, a therapeutic vaping substance, including a therapeutic vaping substance accessory, therapeutic vaping kit or is a good in a therapeutic vaping pack.[2].

The therapeutic vaping good:

☒ is only indicated for 'smoking cessation' or the 'management of nicotine dependence'.

The therapeutic vaping good:

☒ conforms with applicable standards, including *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021*. **Complete the TGO 110 compliance evidence below.**

OR

☐ is the subject of a consent from the Secretary under section 14 or 14A of the Therapeutic Goods Act for importation or supply. (Note: consent is only granted in exceptional circumstances).

TGO 110 compliance evidence

☒ Testing is performed on each batch of vaping goods.

- ☒ We hold an example of recent testing performed on a batch of vaping goods supplied or to be supplied in Australia:

Name of the facility:	s47 [redacted]
Address of the facility:	s47 [redacted]
Date tested: (dd/mm/yyyy)	14/12/2023

- ☒ Testing performed will confirm the nicotine concentration, which aligns with the label claim (where applicable).
- ☒ Testing will confirm the absence of prohibited ingredients.
- ☒ Batch-specific test results can be made available upon request.

☒ The good only contains mint, menthol, or tobacco flavour, if it contains a flavour.

☒ The labels comply with the requirements of TGO 110.

- ☒ The product label includes a list of all ingredients required by TGO 110.
- ☒ The product label includes quantity of nicotine as an active ingredient (if applicable).
- ☒ The product label includes applicable warning statements.
- ☒ Copies of labels can be provided upon request.

☒ The good has child-resistant packaging.

☒ For a vaping substance accessory, vaping device, vaping device accessory or vaping substance accessories in a kit, the good(s) conforms with the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023* or essential principles, as appropriate (see footnote 3 and 4).

---

[2] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

Section 6: Compliance – vaping devices etc

Complete this section for a good that is a therapeutic vaping device or therapeutic vaping device accessory that does not contain a therapeutic vaping substance and is not to be imported or supplied in a therapeutic vaping pack. See footnotes 3 and 4 as to which standards apply to your vaping device.

The therapeutic vaping device or therapeutic device accessory:

☐ is only intended to administer a therapeutic vaping substance that is indicated for 'smoking cessation' or the 'management of nicotine dependence'.

The therapeutic vaping device or therapeutic device accessory:

☐ conforms with the Essential Principles[3]. **Complete the *Essential Principles* checklist available on the TGA website** (https://www.tga.gov.au/resources/resource/forms/essential-principles-checklist-medical-devices). You do not need to submit the completed checklist. **Go to section 8.**

OR

☐ is a device to which the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023*[4] (MDSO) applies and conforms with the MDSO. **Complete the vaping device compliance evidence below.**

OR

☐ is the subject of consent from the Secretary under section 41MA or 41MAA of the Act for non-compliance with the essential principles. (Note: consent is only granted in exceptional circumstances, for a limited period). **Go to section 8.**

Evidence of compliance – vaping device or vaping device accessory

If your therapeutic vaping device or therapeutic vaping device accessory does not comply with the Essential Principles and the MDSO applies, select one or more types of valid evidence held that demonstrates compliance with applicable requirements:

☐ US FDA - Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS)

☐ EU - European Tobacco Products Directive - A valid notification under Article 20 of Directive 2014/40/EU

☐ UK MHRA - notification through the Tobacco and related Products Regulations (TRPR), as listed on the notified e-cigarette products publication (database) ecig (cms.mhra.gov.uk/ecig)

☐ Certificate, licence, notification, or other approval establishing compliance for supply of therapeutic goods (TGA, US FDA, EU notified body, or designated body by UK MHRA)

☐ ISO 9001 certificate

☐ ISO13485 certificate

Based on the selection above, provide the following information as evidence (the table can be duplicated if more than one type of evidence is held or there are multiple manufacturing sites holding separate certifications):

Authorising authority / certification or notification body	
Scope of authorisation / certification / notification	
Authorisation / certificate / notification number or identifier	

[3] The essential principles apply to therapeutic vaping devices and therapeutic vaping device accessories by default under the *Therapeutic Goods Act 1989*.

[4] The MDSO applies to therapeutic vaping devices and therapeutic vaping device accessories, imported or manufactured on or after 1 March 2024, that prior to 1 January 2024 were excluded from the operation of the *Therapeutic Goods Act 1989*. Vaping devices and vaping device accessories previously excluded were those not intended to be used exclusively for the administration of a medicine.

Section 7: Ingredients or components for further manufacture in Australia

Complete this section if the good is a starting material, component or article being imported for the purpose of further manufacture in Australia.

☐ The starting material is for use in the lawful manufacture of a therapeutic vaping substance or a therapeutic vaping substance accessory or another therapeutic good by a manufacturer that holds all relevant licences or approvals. Provide details of manufacturing sites in the table below. Duplicate the table as necessary.

Manufacturer name:	
TGA licence number:	
Steps in manufacture:	

☐ The article or component is for use in the lawful manufacture of a therapeutic vaping device or a therapeutic vaping device accessory by a manufacturer that holds all relevant licences or approvals. Provide details of manufacturing sites in the table below. Duplicate the table as necessary.

Manufacturer name:					
Conformity assessment evidence					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Section 8: Declaration

Section 8.1: Privacy information

General privacy information is available on the TGA website.

The TGA is collecting personal information in this form in order to contact the sponsor to discuss the notice where necessary.

Section 8.2: Declaration

☒ I declare that the information provided in this form, is, to the best of my knowledge, current and correct.

☒ I certify that the statements made in this notice are supported by information and evidence which will be provided to the TGA upon request.

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 section 137.1 of the Commonwealth Criminal Code.

Name	s22 [redacted]		
Signature	s22 [redacted]	Date	04.03.2024

Send this completed notification form to vapenotifications@health.gov.au

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA USE ONLY

This form, when completed, will be classified as **'Official'**.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

Sponsor notice – Vaping goods

Notice to import or supply in Australia therapeutic vaping goods

About this form

You must submit this notice to the TGA prior to commencing importation or supply in Australia of unregistered therapeutic vaping goods that are intended for smoking cessation or the management of nicotine dependence, or ingredients or components used in the manufacture of those goods. The notice must be submitted before the therapeutic vaping goods are imported, or, for finished goods that are manufactured in Australia, before those goods are first supplied in Australia.

A separate form must be completed for each different type of therapeutic vaping good, ingredient or component intended to be imported or supplied. For example, if you have different flavours, concentrations of nicotine, or vaping device characteristics, you will need to submit a notice for each good.

If a notice is made for therapeutic vaping goods imported for further manufacture in Australia, a separate notice will need to be made for each good prior to supply.

Once complete, send this form to vapenotifications@health.gov.au

If information in the form relating to your therapeutic vaping good is incomplete, we may not be able to provide you a notification number.

You should be aware that the TGA may publish certain information relating to your notice – such as your name and details of your good.

Guidance

Guidance is available on the TGA website to help you to complete the form.

What you'll need to complete this form

- **Your TGA client ID** – see guidance on setting up a TGA client ID.
- **Details about your therapeutic vaping good, ingredient or component** – you will need to tell us key details about the good you intend to import, or supply following domestic manufacture.
- **Manufacturer information** – we need to know the TGA client ID for each manufacturer (vaping substance), or details of the manufacturers (vaping devices).
- **Evidence of compliance to applicable standards** – you will need this for each vaping good you intend to import, or supply following domestic manufacture.

Legislation

This notice is made under paragraph (a) in column 3 of item 15, and paragraph (a) in column 3 of item 16, of Schedule 5A to the *Therapeutic Goods Regulations 1990* (the TG Regulations).

This notice is also made under paragraph (a) in the column headed "Conditions" of item 2.17, and paragraph (a) in the column headed "Conditions" of item 2.18, of Part 2 of Schedule 4 to the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations)

Section 1: Sponsor information

Company name:	Mission Distribution Victoria Pty Limited
TGA client ID:	83800
Contact email:	s2 s47 [redacted]

Section 2: Vaping good category

See guidance about the definitions used in this form. Every vaping good requires a separate notice, including where those therapeutic vaping goods are contained in a therapeutic vaping kit or therapeutic vaping pack.

Select one vaping good category for this notice:

☒ A finished good that is, or contains, a vaping substance (a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a good in a ***therapeutic vaping kit*** – see item 15 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 5 and 8 below

☐ A finished good that would be a medical device except that it is for supply as part of a therapeutic vaping pack (a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** in a ***therapeutic vaping pack*** – see item 15 of Schedule 5A to the TG Regulations).[1]

Complete sections 3, 4, 5 and 8 below

☐ A finished good that does not contain a vaping substance, and is a reusable vaping device or a component of a reusable vaping device, or a reusable cartridge, capsule or pod or other vessel (a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.17 of Part 2 of Schedule 4 to the MD Regulations).

Complete sections 3, 4, 6 and 8 below.

☐ A starting material, that is not liquid nicotine, for use in the manufacture of therapeutic vaping goods that are or contain therapeutic vaping substances (see item 16 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of vaping goods in Australia (including a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a ***therapeutic vaping kit*** – see item 16 Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of other therapeutic goods in Australia (see item 16 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ A component or article intended for use in the manufacture of an unfilled vaping device (the manufacture of a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.18 of Part 2 of Schedule 4 to the MD Regulations).

Complete sections 3, 4, 7 and 8 below.

[1] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

Section 3: Vaping good details

Complete **tables 1 and 2** if your vaping good is:

- a therapeutic vaping substance;
- liquid nicotine; or
- starting material that is an ingredient for use in the manufacture of a therapeutic vaping substance or therapeutic vaping substance accessory.

Complete **table 3** if your vaping good is:

- a therapeutic vaping device, e.g. a reusable vaporiser, battery, mouthpiece, coil or other parts of a reusable therapeutic vaping device;
- a therapeutic vaping device accessory, e.g. a unfilled cartridge, capsule or pod; or
- a component or article for use in the manufacture of a therapeutic vaping device, therapeutic vaping device accessory or therapeutic vaping substance accessory.

Complete **tables 1, 2 and 3** if your vaping good is:

- a therapeutic vaping substance accessory e.g. a filled cartridge, capsule or pod.

When completing **table 2**:

- list all ingredients (except for nicotine, details of which should be included in Table 1), including flavour, using the Australian Approved Ingredient name where possible; and
- use the approved terminology in TGA Code Tables, e.g. the Australian Approved Names of ingredients, and as specified in the published guidance.

Table 1: Details of the therapeutic vaping substance, liquid nicotine or starting material

Name of good:	RELX Pod Pro2-Tobacco Gold-28.5mg/mL Nicotine
Description of good:	Therapeutic vaping substance accessory
Container type:	Prefilled Pod
Volume in mL (or weight if applicable):	1.9mL
Nicotine form (if applicable):	Nicotine ID 54852
Nicotine quantity:	28.5mg/mL

Table 2: Ingredients in the therapeutic vaping substance, liquid nicotine or starting material

Ingredient name	Quantity
s47	

Table 3: Details of the therapeutic vaping device, therapeutic vaping device accessory, therapeutic vaping substance accessory or articles or components for further manufacture

Vaping good name:	RELX Pod Pro2-Tobacco Gold-28.5mg/mL Nicotine		
Device model:	RELX Pod Pro2		
Vaping good description:	Therapeutic vaping substance accessory		
Liquid capacity in mL:	1.9mL		
Device product identifier GMDN or UDI:	No GMDN or UDI is available		
Rechargeable battery:	☐ Yes	☒ No	
Battery capacity:	Prefilled pod, no battery included		
Battery composition: (e.g. Nickel-Cadmium, Nickel-Metal Hydride, Lithium Ion)	Prefilled pod, no battery included		
Battery voltage:	Prefilled pod, no battery included		
Battery wattage:	Prefilled pod, no battery included		
Type of heating element:	☒ Coil	☐ Wick	☐ Other
	If Other selected, please describe:		
Charging unit:	☐ USB	☒ Other Prefilled pod, no battery included	
Is the airflow adjustable?	☐ Yes	☒ No	
Type of control unit(s): (e.g. PCB, microcontroller, software, etc)	Prefilled pod, no control unit included		

Section 4: Manufacturer details

Provide details of all prior manufacturers of the therapeutic vaping goods, ingredients or components you are importing or supplying.

Manufacturers of the therapeutic vaping substance, therapeutic vaping substance accessory, liquid nicotine or starting material for further manufacture

Manufacturer name:	s47 [redacted]
TGA client ID:	s47 [redacted]
Steps in manufacture:	Vaping substance manufacturer/testing chemical manufacturer

Manufacturer name:	s47 [redacted]
TGA client ID:	s47 [redacted]
Steps in manufacture:	Finished product manufacturer/packaging manufacturer/testing physical manufacturer

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturers of the therapeutic vaping device, therapeutic vaping device accessory, therapeutic vaping substance accessory or articles or components for further manufacture

Manufacturer name:	s47 [redacted]				
Site street address:	s47 [redacted]				
Suburb/Town/City:	s47 [redacted]	**State/Territory:**	s47 [redacted]	**Post code:**	s47 [redacted]
Country:	s47 [redacted]				
Contact email:	s22 s47 [redacted]				

Manufacturer name:	s47 [redacted]				
Site street address:	s47 [redacted]				
Suburb/Town/City:	s47 [redacted]	**State/Territory:**	s47 [redacted]	**Post code:**	s47 [redacted]
Country:	s47 [redacted]				
Contact email:	s22 s47 [redacted]				

Manufacturer name:					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Manufacturer name:	
Site street address:	

Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Section 5: Compliance – vaping substances etc

Complete this section if the therapeutic vaping good is ready to be supplied in Australia and is, or contains, a therapeutic vaping substance, including a therapeutic vaping substance accessory, therapeutic vaping kit or is a good in a therapeutic vaping pack.[2].

The therapeutic vaping good:

☒ is only indicated for 'smoking cessation' or the 'management of nicotine dependence'.

The therapeutic vaping good:

☒ conforms with applicable standards, including *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021*. **Complete the TGO 110 compliance evidence below.**

OR

☐ is the subject of a consent from the Secretary under section 14 or 14A of the Therapeutic Goods Act for importation or supply. (Note: consent is only granted in exceptional circumstances).

TGO 110 compliance evidence

☒ Testing is performed on each batch of vaping goods.

- ☒ We hold an example of recent testing performed on a batch of vaping goods supplied or to be supplied in Australia:

Name of the facility:	s47 [redacted]
Address of the facility:	s47 [redacted]
Date tested: (dd/mm/yyyy)	26/01/2024

- ☒ Testing performed will confirm the nicotine concentration, which aligns with the label claim (where applicable).
- ☒ Testing will confirm the absence of prohibited ingredients.
- ☒ Batch-specific test results can be made available upon request.

☒ The good only contains mint, menthol, or tobacco flavour, if it contains a flavour.

☒ The labels comply with the requirements of TGO 110.

- ☒ The product label includes a list of all ingredients required by TGO 110.
- ☒ The product label includes quantity of nicotine as an active ingredient (if applicable).
- ☒ The product label includes applicable warning statements.
- ☒ Copies of labels can be provided upon request.

☒ The good has child-resistant packaging.

☒ For a vaping substance accessory, vaping device, vaping device accessory or vaping substance accessories in a kit, the good(s) conforms with the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023* or essential principles, as appropriate (see footnote 3 and 4).

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[2] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

Section 6: Compliance – vaping devices etc

Complete this section for a good that is a therapeutic vaping device or therapeutic vaping device accessory that does not contain a therapeutic vaping substance and is not to be imported or supplied in a therapeutic vaping pack. See footnotes 3 and 4 as to which standards apply to your vaping device.

The therapeutic vaping device or therapeutic device accessory:

☐ is only intended to administer a therapeutic vaping substance that is indicated for 'smoking cessation' or the 'management of nicotine dependence'.

The therapeutic vaping device or therapeutic device accessory:

☐ conforms with the Essential Principles[3]. **Complete the *Essential Principles* checklist available on the TGA website** (https://www.tga.gov.au/resources/resource/forms/essential-principles-checklist-medical-devices). You do not need to submit the completed checklist. **Go to section 8.**

OR

☐ is a device to which the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023*[4] (MDSO) applies and conforms with the MDSO. **Complete the vaping device compliance evidence below.**

OR

☐ is the subject of consent from the Secretary under section 41MA or 41MAA of the Act for non-compliance with the essential principles. (Note: consent is only granted in exceptional circumstances, for a limited period). **Go to section 8.**

Evidence of compliance – vaping device or vaping device accessory

If your therapeutic vaping device or therapeutic vaping device accessory does not comply with the Essential Principles and the MDSO applies, select one or more types of valid evidence held that demonstrates compliance with applicable requirements:

☐ US FDA - Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS)

☐ EU - European Tobacco Products Directive - A valid notification under Article 20 of Directive 2014/40/EU

☐ UK MHRA - notification through the Tobacco and related Products Regulations (TRPR), as listed on the notified e-cigarette products publication (database) ecig (cms.mhra.gov.uk/ecig)

☐ Certificate, licence, notification, or other approval establishing compliance for supply of therapeutic goods (TGA, US FDA, EU notified body, or designated body by UK MHRA)

☐ ISO 9001 certificate

☐ ISO13485 certificate

Based on the selection above, provide the following information as evidence (the table can be duplicated if more than one type of evidence is held or there are multiple manufacturing sites holding separate certifications):

Authorising authority / certification or notification body	
Scope of authorisation / certification / notification	
Authorisation / certificate / notification number or identifier	

[3] The essential principles apply to therapeutic vaping devices and therapeutic vaping device accessories by default under the *Therapeutic Goods Act 1989*.

[4] The MDSO applies to therapeutic vaping devices and therapeutic vaping device accessories, imported or manufactured on or after 1 March 2024, that prior to 1 January 2024 were excluded from the operation of the *Therapeutic Goods Act 1989*. Vaping devices and vaping device accessories previously excluded were those not intended to be used exclusively for the administration of a medicine.

Section 7: Ingredients or components for further manufacture in Australia

Complete this section if the good is a starting material, component or article being imported for the purpose of further manufacture in Australia.

☐ The starting material is for use in the lawful manufacture of a therapeutic vaping substance or a therapeutic vaping substance accessory or another therapeutic good by a manufacturer that holds all relevant licences or approvals. Provide details of manufacturing sites in the table below. Duplicate the table as necessary.

Manufacturer name:	
TGA licence number:	
Steps in manufacture:	

☐ The article or component is for use in the lawful manufacture of a therapeutic vaping device or a therapeutic vaping device accessory by a manufacturer that holds all relevant licences or approvals. Provide details of manufacturing sites in the table below. Duplicate the table as necessary.

Manufacturer name:					
Conformity assessment evidence					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Section 8: Declaration

Section 8.1: Privacy information

General privacy information is available on the TGA website.

The TGA is collecting personal information in this form in order to contact the sponsor to discuss the notice where necessary.

Section 8.2: Declaration

☒ I declare that the information provided in this form, is, to the best of my knowledge, current and correct.

☒ I certify that the statements made in this notice are supported by information and evidence which will be provided to the TGA upon request.

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 section 137.1 of the Commonwealth Criminal Code.

Name	s22 [redacted]		
Signature	s22 [redacted]	Date	04.03.2024

Send this completed notification form to vapenotifications@health.gov.au

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA USE ONLY

This form, when completed, will be classified as **'Official'**.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

Sponsor notice – Vaping goods

Notice to import or supply in Australia therapeutic vaping goods

About this form

You must submit this notice to the TGA prior to commencing importation or supply in Australia of unregistered therapeutic vaping goods that are intended for smoking cessation or the management of nicotine dependence, or ingredients or components used in the manufacture of those goods. The notice must be submitted before the therapeutic vaping goods are imported, or, for finished goods that are manufactured in Australia, before those goods are first supplied in Australia.

A separate form must be completed for each different type of therapeutic vaping good, ingredient or component intended to be imported or supplied. For example, if you have different flavours, concentrations of nicotine, or vaping device characteristics, you will need to submit a notice for each good.

If a notice is made for therapeutic vaping goods imported for further manufacture in Australia, a separate notice will need to be made for each good prior to supply.

Once complete, send this form to vapenotifications@health.gov.au

If information in the form relating to your therapeutic vaping good is incomplete, we may not be able to provide you a notification number.

You should be aware that the TGA may publish certain information relating to your notice – such as your name and details of your good.

Guidance

Guidance is available on the TGA website to help you to complete the form.

What you'll need to complete this form

- **Your TGA client ID** – see guidance on setting up a TGA client ID.
- **Details about your therapeutic vaping good, ingredient or component** – you will need to tell us key details about the good you intend to import, or supply following domestic manufacture.
- **Manufacturer information** – we need to know the TGA client ID for each manufacturer (vaping substance), or details of the manufacturers (vaping devices).
- **Evidence of compliance to applicable standards** – you will need this for each vaping good you intend to import, or supply following domestic manufacture.

Legislation

This notice is made under paragraph (a) in column 3 of item 15, and paragraph (a) in column 3 of item 16, of Schedule 5A to the *Therapeutic Goods Regulations 1990* (the TG Regulations).

This notice is also made under paragraph (a) in the column headed "Conditions" of item 2.17, and paragraph (a) in the column headed "Conditions" of item 2.18, of Part 2 of Schedule 4 to the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations)

Section 1: Sponsor information

Company name:	Mission Distribution Victoria Pty Limited
TGA client ID:	83800
Contact email:	s2 s47 [redacted]

Section 2: Vaping good category

See guidance about the definitions used in this form. Every vaping good requires a separate notice, including where those therapeutic vaping goods are contained in a therapeutic vaping kit or therapeutic vaping pack.

Select one vaping good category for this notice:

☒ A finished good that is, or contains, a vaping substance (a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a good in a ***therapeutic vaping kit*** – see item 15 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 5 and 8 below

☐ A finished good that would be a medical device except that it is for supply as part of a therapeutic vaping pack (a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** in a ***therapeutic vaping pack*** – see item 15 of Schedule 5A to the TG Regulations).[1]

Complete sections 3, 4, 5 and 8 below

☐ A finished good that does not contain a vaping substance, and is a reusable vaping device or a component of a reusable vaping device, or a reusable cartridge, capsule or pod or other vessel (a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.17 of Part 2 of Schedule 4 to the MD Regulations).

Complete sections 3, 4, 6 and 8 below.

☐ A starting material, that is not liquid nicotine, for use in the manufacture of therapeutic vaping goods that are or contain therapeutic vaping substances (see item 16 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of vaping goods in Australia (including a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a ***therapeutic vaping kit*** – see item 16 Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of other therapeutic goods in Australia (see item 16 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ A component or article intended for use in the manufacture of an unfilled vaping device (the manufacture of a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.18 of Part 2 of Schedule 4 to the MD Regulations).

Complete sections 3, 4, 7 and 8 below.

[1] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

Section 3: Vaping good details

Complete **tables 1 and 2** if your vaping good is:

- a therapeutic vaping substance;
- liquid nicotine; or
- starting material that is an ingredient for use in the manufacture of a therapeutic vaping substance or therapeutic vaping substance accessory.

Complete **table 3** if your vaping good is:

- a therapeutic vaping device, e.g. a reusable vaporiser, battery, mouthpiece, coil or other parts of a reusable therapeutic vaping device;
- a therapeutic vaping device accessory, e.g. a unfilled cartridge, capsule or pod; or
- a component or article for use in the manufacture of a therapeutic vaping device, therapeutic vaping device accessory or therapeutic vaping substance accessory.

Complete **tables 1, 2 and 3** if your vaping good is:

- a therapeutic vaping substance accessory e.g. a filled cartridge, capsule or pod.

When completing **table 2**:

- list all ingredients (except for nicotine, details of which should be included in Table 1), including flavour, using the Australian Approved Ingredient name where possible; and
- use the approved terminology in TGA Code Tables, e.g. the Australian Approved Names of ingredients, and as specified in the published guidance.

Table 1: Details of the therapeutic vaping substance, liquid nicotine or starting material

Name of good:	RELX Pod Pro2-Tobacco Red-28.5mg/mL Nicotine
Description of good:	Therapeutic vaping substance accessory
Container type:	Prefilled Pod
Volume in mL (or weight if applicable):	1.9mL
Nicotine form (if applicable):	Nicotine ID 54852
Nicotine quantity:	28.5mg/mL

Table 2: Ingredients in the therapeutic vaping substance, liquid nicotine or starting material

Ingredient name	Quantity
s47	

Table 3: Details of the therapeutic vaping device, therapeutic vaping device accessory, therapeutic vaping substance accessory or articles or components for further manufacture

Vaping good name:	RELX Pod Pro2-Tobacco Red-28.5mg/mL Nicotine		
Device model:	RELX Pod Pro2		
Vaping good description:	Therapeutic vaping substance accessory		
Liquid capacity in mL:	1.9mL		
Device product identifier GMDN or UDI:	No GMDN or UDI is available		
Rechargeable battery:	☐ Yes	☒ No	
Battery capacity:	Prefilled pod, no battery included		
Battery composition: (e.g. Nickel-Cadmium, Nickel-Metal Hydride, Lithium Ion)	Prefilled pod, no battery included		
Battery voltage:	Prefilled pod, no battery included		
Battery wattage:	Prefilled pod, no battery included		
Type of heating element:	☒ Coil	☐ Wick	☐ Other
	If Other selected, please describe:		
Charging unit:	☐ USB	☒ Other Prefilled pod, no battery included	
Is the airflow adjustable?	☐ Yes	☒ No	
Type of control unit(s): (e.g. PCB, microcontroller, software, etc)	Prefilled pod, no control unit included		

Section 4: Manufacturer details

Provide details of all prior manufacturers of the therapeutic vaping goods, ingredients or components you are importing or supplying.

Manufacturers of the therapeutic vaping substance, therapeutic vaping substance accessory, liquid nicotine or starting material for further manufacture

Manufacturer name:	s47 [redacted]
TGA client ID:	s47 [redacted]
Steps in manufacture:	Vaping substance manufacturer/testing chemical manufacturer

Manufacturer name:	s47 [redacted]
TGA client ID:	s47 [redacted]
Steps in manufacture:	Finished product manufacturer/packaging manufacturer/testing physical manufacturer

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturers of the therapeutic vaping device, therapeutic vaping device accessory, therapeutic vaping substance accessory or articles or components for further manufacture

Manufacturer name:	s47 [redacted]				
Site street address:	s47 [redacted]				
Suburb/Town/City:	s47 [redacted]	**State/Territory:**	s47 [redacted]	**Post code:**	s47 [redacted]
Country:	s47 [redacted]				
Contact email:	s22 s47 [redacted]				

Manufacturer name:	s47 [redacted]				
Site street address:	s47 [redacted]				
Suburb/Town/City:	s47 [redacted]	**State/Territory:**	s47 [redacted]	**Post code:**	s47 [redacted]
Country:	s47 [redacted]				
Contact email:	s22 s47 [redacted]				

Manufacturer name:					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Manufacturer name:	
Site street address:	

Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Section 5: Compliance – vaping substances etc

Complete this section if the therapeutic vaping good is ready to be supplied in Australia and is, or contains, a therapeutic vaping substance, including a therapeutic vaping substance accessory, therapeutic vaping kit or is a good in a therapeutic vaping pack.[2].

The therapeutic vaping good:

☒ is only indicated for 'smoking cessation' or the 'management of nicotine dependence'.

The therapeutic vaping good:

☒ conforms with applicable standards, including *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021*. **Complete the TGO 110 compliance evidence below.**

OR

☐ is the subject of a consent from the Secretary under section 14 or 14A of the Therapeutic Goods Act for importation or supply. (Note: consent is only granted in exceptional circumstances).

TGO 110 compliance evidence

☒ Testing is performed on each batch of vaping goods.

- ☒ We hold an example of recent testing performed on a batch of vaping goods supplied or to be supplied in Australia:

Name of the facility:	s47 [redacted]
Address of the facility:	s47 [redacted]
Date tested: (dd/mm/yyyy)	14/12/2023

- ☒ Testing performed will confirm the nicotine concentration, which aligns with the label claim (where applicable).
- ☒ Testing will confirm the absence of prohibited ingredients.
- ☒ Batch-specific test results can be made available upon request.

☒ The good only contains mint, menthol, or tobacco flavour, if it contains a flavour.

☒ The labels comply with the requirements of TGO 110.

- ☒ The product label includes a list of all ingredients required by TGO 110.
- ☒ The product label includes quantity of nicotine as an active ingredient (if applicable).
- ☒ The product label includes applicable warning statements.
- ☒ Copies of labels can be provided upon request.

☒ The good has child-resistant packaging.

☒ For a vaping substance accessory, vaping device, vaping device accessory or vaping substance accessories in a kit, the good(s) conforms with the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023* or essential principles, as appropriate (see footnote 3 and 4).

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[2] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

Section 6: Compliance – vaping devices etc

Complete this section for a good that is a therapeutic vaping device or therapeutic vaping device accessory that does not contain a therapeutic vaping substance and is not to be imported or supplied in a therapeutic vaping pack. See footnotes 3 and 4 as to which standards apply to your vaping device.

The therapeutic vaping device or therapeutic device accessory:

☐ is only intended to administer a therapeutic vaping substance that is indicated for 'smoking cessation' or the 'management of nicotine dependence'.

The therapeutic vaping device or therapeutic device accessory:

☐ conforms with the Essential Principles[3]. **Complete the *Essential Principles* checklist available on the TGA website** (https://www.tga.gov.au/resources/resource/forms/essential-principles-checklist-medical-devices). You do not need to submit the completed checklist. **Go to section 8.**

OR

☐ is a device to which the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023*[4] (MDSO) applies and conforms with the MDSO. **Complete the vaping device compliance evidence below.**

OR

☐ is the subject of consent from the Secretary under section 41MA or 41MAA of the Act for non-compliance with the essential principles. (Note: consent is only granted in exceptional circumstances, for a limited period). **Go to section 8.**

Evidence of compliance – vaping device or vaping device accessory

If your therapeutic vaping device or therapeutic vaping device accessory does not comply with the Essential Principles and the MDSO applies, select one or more types of valid evidence held that demonstrates compliance with applicable requirements:

☐ US FDA - Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS)

☐ EU - European Tobacco Products Directive - A valid notification under Article 20 of Directive 2014/40/EU

☐ UK MHRA - notification through the Tobacco and related Products Regulations (TRPR), as listed on the notified e-cigarette products publication (database) ecig (cms.mhra.gov.uk/ecig)

☐ Certificate, licence, notification, or other approval establishing compliance for supply of therapeutic goods (TGA, US FDA, EU notified body, or designated body by UK MHRA)

☐ ISO 9001 certificate

☐ ISO13485 certificate

Based on the selection above, provide the following information as evidence (the table can be duplicated if more than one type of evidence is held or there are multiple manufacturing sites holding separate certifications):

Authorising authority / certification or notification body	
Scope of authorisation / certification / notification	
Authorisation / certificate / notification number or identifier	

[3] The essential principles apply to therapeutic vaping devices and therapeutic vaping device accessories by default under the *Therapeutic Goods Act 1989*.

[4] The MDSO applies to therapeutic vaping devices and therapeutic vaping device accessories, imported or manufactured on or after 1 March 2024, that prior to 1 January 2024 were excluded from the operation of the *Therapeutic Goods Act 1989*. Vaping devices and vaping device accessories previously excluded were those not intended to be used exclusively for the administration of a medicine.

Section 7: Ingredients or components for further manufacture in Australia

Complete this section if the good is a starting material, component or article being imported for the purpose of further manufacture in Australia.

☐ The starting material is for use in the lawful manufacture of a therapeutic vaping substance or a therapeutic vaping substance accessory or another therapeutic good by a manufacturer that holds all relevant licences or approvals. Provide details of manufacturing sites in the table below. Duplicate the table as necessary.

Manufacturer name:	
TGA licence number:	
Steps in manufacture:	

☐ The article or component is for use in the lawful manufacture of a therapeutic vaping device or a therapeutic vaping device accessory by a manufacturer that holds all relevant licences or approvals. Provide details of manufacturing sites in the table below. Duplicate the table as necessary.

Manufacturer name:					
Conformity assessment evidence					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Section 8: Declaration

Section 8.1: Privacy information

General privacy information is available on the TGA website.

The TGA is collecting personal information in this form in order to contact the sponsor to discuss the notice where necessary.

Section 8.2: Declaration

☒ I declare that the information provided in this form, is, to the best of my knowledge, current and correct.

☒ I certify that the statements made in this notice are supported by information and evidence which will be provided to the TGA upon request.

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 section 137.1 of the Commonwealth Criminal Code.

Name	s22 [redacted]		
Signature	s22 [redacted]	Date	04.03.2024

Send this completed notification form to vapenotifications@health.gov.au

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA USE ONLY

This form, when completed, will be classified as **'Official'**.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

Sponsor notice – Vaping goods

Notice to import or supply in Australia therapeutic vaping goods

About this form

You must submit this notice to the TGA prior to commencing importation or supply in Australia of unregistered therapeutic vaping goods that are intended for smoking cessation or the management of nicotine dependence, or ingredients or components used in the manufacture of those goods. The notice must be submitted before the therapeutic vaping goods are imported, or, for finished goods that are manufactured in Australia, before those goods are first supplied in Australia.

A separate form must be completed for each different type of therapeutic vaping good, ingredient or component intended to be imported or supplied. For example, if you have different flavours, concentrations of nicotine, or vaping device characteristics, you will need to submit a notice for each good.

If a notice is made for therapeutic vaping goods imported for further manufacture in Australia, a separate notice will need to be made for each good prior to supply.

Once complete, send this form to vapenotifications@health.gov.au

If information in the form relating to your therapeutic vaping good is incomplete, we may not be able to provide you a notification number.

You should be aware that the TGA may publish certain information relating to your notice – such as your name and details of your good.

Guidance

Guidance is available on the TGA website to help you to complete the form.

What you'll need to complete this form

- **Your TGA client ID** – see guidance on setting up a TGA client ID.
- **Details about your therapeutic vaping good, ingredient or component** – you will need to tell us key details about the good you intend to import, or supply following domestic manufacture.
- **Manufacturer information** – we need to know the TGA client ID for each manufacturer (vaping substance), or details of the manufacturers (vaping devices).
- **Evidence of compliance to applicable standards** – you will need this for each vaping good you intend to import, or supply following domestic manufacture.

Legislation

This notice is made under paragraph (a) in column 3 of item 15, and paragraph (a) in column 3 of item 16, of Schedule 5A to the *Therapeutic Goods Regulations 1990* (the TG Regulations).

This notice is also made under paragraph (a) in the column headed "Conditions" of item 2.17, and paragraph (a) in the column headed "Conditions" of item 2.18, of Part 2 of Schedule 4 to the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations)

Section 1: Sponsor information

Company name:	Mission Distribution Victoria Pty Limited
TGA client ID:	83800
Contact email:	s2 s47 [redacted]

Section 2: Vaping good category

See guidance about the definitions used in this form. Every vaping good requires a separate notice, including where those therapeutic vaping goods are contained in a therapeutic vaping kit or therapeutic vaping pack.

Select one vaping good category for this notice:

☒ A finished good that is, or contains, a vaping substance (a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a good in a ***therapeutic vaping kit*** – see item 15 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 5 and 8 below

☐ A finished good that would be a medical device except that it is for supply as part of a therapeutic vaping pack (a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** in a ***therapeutic vaping pack*** – see item 15 of Schedule 5A to the TG Regulations).[1]

Complete sections 3, 4, 5 and 8 below

☐ A finished good that does not contain a vaping substance, and is a reusable vaping device or a component of a reusable vaping device, or a reusable cartridge, capsule or pod or other vessel (a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.17 of Part 2 of Schedule 4 to the MD Regulations).

Complete sections 3, 4, 6 and 8 below.

☐ A starting material, that is not liquid nicotine, for use in the manufacture of therapeutic vaping goods that are or contain therapeutic vaping substances (see item 16 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of vaping goods in Australia (including a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a ***therapeutic vaping kit*** – see item 16 Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of other therapeutic goods in Australia (see item 16 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ A component or article intended for use in the manufacture of an unfilled vaping device (the manufacture of a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.18 of Part 2 of Schedule 4 to the MD Regulations).

Complete sections 3, 4, 7 and 8 below.

[1] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

Section 3: Vaping good details

Complete **tables 1 and 2** if your vaping good is:

- a therapeutic vaping substance;
- liquid nicotine; or
- starting material that is an ingredient for use in the manufacture of a therapeutic vaping substance or therapeutic vaping substance accessory.

Complete **table 3** if your vaping good is:

- a therapeutic vaping device, e.g. a reusable vaporiser, battery, mouthpiece, coil or other parts of a reusable therapeutic vaping device;
- a therapeutic vaping device accessory, e.g. a unfilled cartridge, capsule or pod; or
- a component or article for use in the manufacture of a therapeutic vaping device, therapeutic vaping device accessory or therapeutic vaping substance accessory.

Complete **tables 1, 2 and 3** if your vaping good is:

- a therapeutic vaping substance accessory e.g. a filled cartridge, capsule or pod.

When completing **table 2**:

- list all ingredients (except for nicotine, details of which should be included in Table 1), including flavour, using the Australian Approved Ingredient name where possible; and
- use the approved terminology in TGA Code Tables, e.g. the Australian Approved Names of ingredients, and as specified in the published guidance.

Table 1: Details of the therapeutic vaping substance, liquid nicotine or starting material

Name of good:	RELX Pod Pro2-Menthol-28.5mg/mL Nicotine
Description of good:	Therapeutic vaping substance accessory
Container type:	Prefilled Pod
Volume in mL (or weight if applicable):	1.9mL
Nicotine form (if applicable):	Nicotine ID 54852
Nicotine quantity:	28.5mg/mL

Table 2: Ingredients in the therapeutic vaping substance, liquid nicotine or starting material

Ingredient name	Quantity
s47	

Table 3: Details of the therapeutic vaping device, therapeutic vaping device accessory, therapeutic vaping substance accessory or articles or components for further manufacture

Vaping good name:	RELX Pod Pro2-Menthol-28.5mg/mL Nicotine		
Device model:	RELX Pod Pro2		
Vaping good description:	Therapeutic vaping substance accessory		
Liquid capacity in mL:	1.9mL		
Device product identifier GMDN or UDI:	No GMDN or UDI is available		
Rechargeable battery:	☐ Yes	☒ No	
Battery capacity:	Prefilled pod, no battery included		
Battery composition: (e.g. Nickel-Cadmium, Nickel-Metal Hydride, Lithium Ion)	Prefilled pod, no battery included		
Battery voltage:	Prefilled pod, no battery included		
Battery wattage:	Prefilled pod, no battery included		
Type of heating element:	☒ Coil	☐ Wick	☐ Other
	If Other selected, please describe:		
Charging unit:	☐ USB	☒ Other Prefilled pod, no battery included	
Is the airflow adjustable?	☐ Yes	☒ No	
Type of control unit(s): (e.g. PCB, microcontroller, software, etc)	Prefilled pod, no control unit included		

Section 4: Manufacturer details

Provide details of all prior manufacturers of the therapeutic vaping goods, ingredients or components you are importing or supplying.

Manufacturers of the therapeutic vaping substance, therapeutic vaping substance accessory, liquid nicotine or starting material for further manufacture

Manufacturer name:	s47 [redacted]
TGA client ID:	s47 [redacted]
Steps in manufacture:	Vaping substance manufacturer/testing chemical manufacturer

Manufacturer name:	s47 [redacted]
TGA client ID:	s47 [redacted]
Steps in manufacture:	Finished product manufacturer/packaging manufacturer/testing physical manufacturer

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturers of the therapeutic vaping device, therapeutic vaping device accessory, therapeutic vaping substance accessory or articles or components for further manufacture

Manufacturer name:	s47 [redacted]				
Site street address:	s47 [redacted]				
Suburb/Town/City:	s47 [redacted]	**State/Territory:**	s47 [redacted]	**Post code:**	s47 [redacted]
Country:	s47 [redacted]				
Contact email:	s22 s47 [redacted]				

Manufacturer name:	s47 [redacted]				
Site street address:	s47 [redacted]				
Suburb/Town/City:	s47 [redacted]	**State/Territory:**	s47 [redacted]	**Post code:**	s47 [redacted]
Country:	s47 [redacted]				
Contact email:	s22 s47 [redacted]				

Manufacturer name:					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Manufacturer name:	
Site street address:	

Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Section 5: Compliance – vaping substances etc

Complete this section if the therapeutic vaping good is ready to be supplied in Australia and is, or contains, a therapeutic vaping substance, including a therapeutic vaping substance accessory, therapeutic vaping kit or is a good in a therapeutic vaping pack.[2].

The therapeutic vaping good:

☒ is only indicated for 'smoking cessation' or the 'management of nicotine dependence'.

The therapeutic vaping good:

☒ conforms with applicable standards, including *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021*. **Complete the TGO 110 compliance evidence below.**

OR

☐ is the subject of a consent from the Secretary under section 14 or 14A of the Therapeutic Goods Act for importation or supply. (Note: consent is only granted in exceptional circumstances).

TGO 110 compliance evidence

☒ Testing is performed on each batch of vaping goods.

- ☒ We hold an example of recent testing performed on a batch of vaping goods supplied or to be supplied in Australia:

Name of the facility:	s47 [redacted]
Address of the facility:	s47 [redacted]
Date tested: (dd/mm/yyyy)	16/12/2023

- ☒ Testing performed will confirm the nicotine concentration, which aligns with the label claim (where applicable).
- ☒ Testing will confirm the absence of prohibited ingredients.
- ☒ Batch-specific test results can be made available upon request.

☒ The good only contains mint, menthol, or tobacco flavour, if it contains a flavour.

☒ The labels comply with the requirements of TGO 110.

- ☒ The product label includes a list of all ingredients required by TGO 110.
- ☒ The product label includes quantity of nicotine as an active ingredient (if applicable).
- ☒ The product label includes applicable warning statements.
- ☒ Copies of labels can be provided upon request.

☒ The good has child-resistant packaging.

☒ For a vaping substance accessory, vaping device, vaping device accessory or vaping substance accessories in a kit, the good(s) conforms with the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023* or essential principles, as appropriate (see footnote 3 and 4).

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[2] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

Section 6: Compliance – vaping devices etc

Complete this section for a good that is a therapeutic vaping device or therapeutic vaping device accessory that does not contain a therapeutic vaping substance and is not to be imported or supplied in a therapeutic vaping pack. See footnotes 3 and 4 as to which standards apply to your vaping device.

The therapeutic vaping device or therapeutic device accessory:

☐ is only intended to administer a therapeutic vaping substance that is indicated for 'smoking cessation' or the 'management of nicotine dependence'.

The therapeutic vaping device or therapeutic device accessory:

☐ conforms with the Essential Principles[3]. **Complete the *Essential Principles* checklist available on the TGA website** (https://www.tga.gov.au/resources/resource/forms/essential-principles-checklist-medical-devices). You do not need to submit the completed checklist. **Go to section 8.**

OR

☐ is a device to which the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023*[4] (MDSO) applies and conforms with the MDSO. **Complete the vaping device compliance evidence below.**

OR

☐ is the subject of consent from the Secretary under section 41MA or 41MAA of the Act for non-compliance with the essential principles. (Note: consent is only granted in exceptional circumstances, for a limited period). **Go to section 8.**

Evidence of compliance – vaping device or vaping device accessory

If your therapeutic vaping device or therapeutic vaping device accessory does not comply with the Essential Principles and the MDSO applies, select one or more types of valid evidence held that demonstrates compliance with applicable requirements:

☐ US FDA - Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS)

☐ EU - European Tobacco Products Directive - A valid notification under Article 20 of Directive 2014/40/EU

☐ UK MHRA - notification through the Tobacco and related Products Regulations (TRPR), as listed on the notified e-cigarette products publication (database) ecig (cms.mhra.gov.uk/ecig)

☐ Certificate, licence, notification, or other approval establishing compliance for supply of therapeutic goods (TGA, US FDA, EU notified body, or designated body by UK MHRA)

☐ ISO 9001 certificate

☐ ISO13485 certificate

Based on the selection above, provide the following information as evidence (the table can be duplicated if more than one type of evidence is held or there are multiple manufacturing sites holding separate certifications):

Authorising authority / certification or notification body	
Scope of authorisation / certification / notification	
Authorisation / certificate / notification number or identifier	

[3] The essential principles apply to therapeutic vaping devices and therapeutic vaping device accessories by default under the *Therapeutic Goods Act 1989*.

[4] The MDSO applies to therapeutic vaping devices and therapeutic vaping device accessories, imported or manufactured on or after 1 March 2024, that prior to 1 January 2024 were excluded from the operation of the *Therapeutic Goods Act 1989*. Vaping devices and vaping device accessories previously excluded were those not intended to be used exclusively for the administration of a medicine.

Section 7: Ingredients or components for further manufacture in Australia

Complete this section if the good is a starting material, component or article being imported for the purpose of further manufacture in Australia.

☐ The starting material is for use in the lawful manufacture of a therapeutic vaping substance or a therapeutic vaping substance accessory or another therapeutic good by a manufacturer that holds all relevant licences or approvals. Provide details of manufacturing sites in the table below. Duplicate the table as necessary.

Manufacturer name:	
TGA licence number:	
Steps in manufacture:	

☐ The article or component is for use in the lawful manufacture of a therapeutic vaping device or a therapeutic vaping device accessory by a manufacturer that holds all relevant licences or approvals. Provide details of manufacturing sites in the table below. Duplicate the table as necessary.

Manufacturer name:					
Conformity assessment evidence					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Section 8: Declaration

Section 8.1: Privacy information

General privacy information is available on the TGA website.

The TGA is collecting personal information in this form in order to contact the sponsor to discuss the notice where necessary.

Section 8.2: Declaration

☒ I declare that the information provided in this form, is, to the best of my knowledge, current and correct.

☒ I certify that the statements made in this notice are supported by information and evidence which will be provided to the TGA upon request.

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 section 137.1 of the Commonwealth Criminal Code.

Name	s22 [redacted]		
Signature	s22 [redacted]	Date	04.03.2024

Send this completed notification form to vapenotifications@health.gov.au

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA USE ONLY

This form, when completed, will be classified as **'Official'**.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

Sponsor notice – Vaping goods

Notice to import or supply in Australia therapeutic vaping goods

About this form

You must submit this notice to the TGA prior to commencing importation or supply in Australia of unregistered therapeutic vaping goods that are intended for smoking cessation or the management of nicotine dependence, or ingredients or components used in the manufacture of those goods. The notice must be submitted before the therapeutic vaping goods are imported, or, for finished goods that are manufactured in Australia, before those goods are first supplied in Australia.

A separate form must be completed for each different type of therapeutic vaping good, ingredient or component intended to be imported or supplied. For example, if you have different flavours, concentrations of nicotine, or vaping device characteristics, you will need to submit a notice for each good.

If a notice is made for therapeutic vaping goods imported for further manufacture in Australia, a separate notice will need to be made for each good prior to supply.

Once complete, send this form to vapenotifications@health.gov.au

If information in the form relating to your therapeutic vaping good is incomplete, we may not be able to provide you a notification number.

You should be aware that the TGA may publish certain information relating to your notice – such as your name and details of your good.

Guidance

Guidance is available on the TGA website to help you to complete the form.

What you'll need to complete this form

- **Your TGA client ID** – see guidance on setting up a TGA client ID.
- **Details about your therapeutic vaping good, ingredient or component** – you will need to tell us key details about the good you intend to import, or supply following domestic manufacture.
- **Manufacturer information** – we need to know the TGA client ID for each manufacturer (vaping substance), or details of the manufacturers (vaping devices).
- **Evidence of compliance to applicable standards** – you will need this for each vaping good you intend to import, or supply following domestic manufacture.

Legislation

This notice is made under paragraph (a) in column 3 of item 15, and paragraph (a) in column 3 of item 16, of Schedule 5A to the *Therapeutic Goods Regulations 1990* (the TG Regulations).

This notice is also made under paragraph (a) in the column headed "Conditions" of item 2.17, and paragraph (a) in the column headed "Conditions" of item 2.18, of Part 2 of Schedule 4 to the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations)

Section 1: Sponsor information

Company name:	Mission Distribution Victoria Pty Limited
TGA client ID:	83800
Contact email:	s2 s47 [redacted]

Section 2: Vaping good category

See guidance about the definitions used in this form. Every vaping good requires a separate notice, including where those therapeutic vaping goods are contained in a therapeutic vaping kit or therapeutic vaping pack.

Select one vaping good category for this notice:

☒ A finished good that is, or contains, a vaping substance (a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a good in a ***therapeutic vaping kit*** – see item 15 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 5 and 8 below

☐ A finished good that would be a medical device except that it is for supply as part of a therapeutic vaping pack (a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** in a ***therapeutic vaping pack*** – see item 15 of Schedule 5A to the TG Regulations).[1]

Complete sections 3, 4, 5 and 8 below

☐ A finished good that does not contain a vaping substance, and is a reusable vaping device or a component of a reusable vaping device, or a reusable cartridge, capsule or pod or other vessel (a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.17 of Part 2 of Schedule 4 to the MD Regulations).

Complete sections 3, 4, 6 and 8 below.

☐ A starting material, that is not liquid nicotine, for use in the manufacture of therapeutic vaping goods that are or contain therapeutic vaping substances (see item 16 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of vaping goods in Australia (including a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a ***therapeutic vaping kit*** – see item 16 Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of other therapeutic goods in Australia (see item 16 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ A component or article intended for use in the manufacture of an unfilled vaping device (the manufacture of a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.18 of Part 2 of Schedule 4 to the MD Regulations).

Complete sections 3, 4, 7 and 8 below.

[1] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

Section 3: Vaping good details

Complete **tables 1 and 2** if your vaping good is:

- a therapeutic vaping substance;
- liquid nicotine; or
- starting material that is an ingredient for use in the manufacture of a therapeutic vaping substance or therapeutic vaping substance accessory.

Complete **table 3** if your vaping good is:

- a therapeutic vaping device, e.g. a reusable vaporiser, battery, mouthpiece, coil or other parts of a reusable therapeutic vaping device;
- a therapeutic vaping device accessory, e.g. a unfilled cartridge, capsule or pod; or
- a component or article for use in the manufacture of a therapeutic vaping device, therapeutic vaping device accessory or therapeutic vaping substance accessory.

Complete **tables 1, 2 and 3** if your vaping good is:

- a therapeutic vaping substance accessory e.g. a filled cartridge, capsule or pod.

When completing **table 2**:

- list all ingredients (except for nicotine, details of which should be included in Table 1), including flavour, using the Australian Approved Ingredient name where possible; and
- use the approved terminology in TGA Code Tables, e.g. the Australian Approved Names of ingredients, and as specified in the published guidance.

Table 1: Details of the therapeutic vaping substance, liquid nicotine or starting material

Name of good:	RELX Pod Pro2-Tobacco Red-28.5mg/mL Nicotine
Description of good:	Therapeutic vaping substance accessory
Container type:	Prefilled Pod
Volume in mL (or weight if applicable):	1.9mL
Nicotine form (if applicable):	Nicotine ID 54852
Nicotine quantity:	28.5mg/mL

Table 2: Ingredients in the therapeutic vaping substance, liquid nicotine or starting material

Ingredient name	Quantity
s47 [redacted]	

Table 3: Details of the therapeutic vaping device, therapeutic vaping device accessory, therapeutic vaping substance accessory or articles or components for further manufacture

Vaping good name:	RELX Pod Pro2-Tobacco Red-28.5mg/mL Nicotine		
Device model:	RELX Pod Pro2		
Vaping good description:	Therapeutic vaping substance accessory		
Liquid capacity in mL:	1.9mL		
Device product identifier GMDN or UDI:	No GMDN or UDI is available		
Rechargeable battery:	☐ Yes	☒ No	
Battery capacity:	Prefilled pod, no battery included		
Battery composition: (e.g. Nickel-Cadmium, Nickel-Metal Hydride, Lithium Ion)	Prefilled pod, no battery included		
Battery voltage:	Prefilled pod, no battery included		
Battery wattage:	Prefilled pod, no battery included		
Type of heating element:	☒ Coil	☐ Wick	☐ Other
	If Other selected, please describe:		
Charging unit:	☐ USB	☒ Other Prefilled pod, no battery included	
Is the airflow adjustable?	☐ Yes	☒ No	
Type of control unit(s): (e.g. PCB, microcontroller, software, etc)	Prefilled pod, no control unit included		

Section 4: Manufacturer details

Provide details of all prior manufacturers of the therapeutic vaping goods, ingredients or components you are importing or supplying.

Manufacturers of the therapeutic vaping substance, therapeutic vaping substance accessory, liquid nicotine or starting material for further manufacture

Manufacturer name:	s47 [redacted]
TGA client ID:	s47 [redacted]
Steps in manufacture:	Vaping substance manufacturer/testing chemical manufacturer

Manufacturer name:	s47 [redacted]
TGA client ID:	s47 [redacted]
Steps in manufacture:	Finished product manufacturer/packaging manufacturer/testing physical manufacturer

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturers of the therapeutic vaping device, therapeutic vaping device accessory, therapeutic vaping substance accessory or articles or components for further manufacture

Manufacturer name:	s47 [redacted]				
Site street address:	s47 [redacted]				
Suburb/Town/City:	s47 [redacted]	**State/Territory:**	s47 [redacted]	**Post code:**	s47 [redacted]
Country:	s47 [redacted]				
Contact email:	s22 s47 [redacted]				

Manufacturer name:	s47 [redacted]				
Site street address:	s47 [redacted]				
Suburb/Town/City:	s47 [redacted]	**State/Territory:**	s47 [redacted]	**Post code:**	s47 [redacted]
Country:	s47 [redacted]				
Contact email:	s22 s47 [redacted]				

Manufacturer name:					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Manufacturer name:	
Site street address:	

Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Section 5: Compliance – vaping substances etc

Complete this section if the therapeutic vaping good is ready to be supplied in Australia and is, or contains, a therapeutic vaping substance, including a therapeutic vaping substance accessory, therapeutic vaping kit or is a good in a therapeutic vaping pack.[2].

The therapeutic vaping good:

☐ is only indicated for 'smoking cessation' or the 'management of nicotine dependence'.

The therapeutic vaping good:

☒ conforms with applicable standards, including *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021*. **Complete the TGO 110 compliance evidence below.**

OR

☐ is the subject of a consent from the Secretary under section 14 or 14A of the Therapeutic Goods Act for importation or supply. (Note: consent is only granted in exceptional circumstances).

TGO 110 compliance evidence

☒ Testing is performed on each batch of vaping goods.

- ☒ We hold an example of recent testing performed on a batch of vaping goods supplied or to be supplied in Australia:

Name of the facility:	s47 [redacted]
Address of the facility:	s47 [redacted]
Date tested: (dd/mm/yyyy)	14/12/2023

- ☒ Testing performed will confirm the nicotine concentration, which aligns with the label claim (where applicable).
- ☒ Testing will confirm the absence of prohibited ingredients.
- ☒ Batch-specific test results can be made available upon request.

☒ The good only contains mint, menthol, or tobacco flavour, if it contains a flavour.

☒ The labels comply with the requirements of TGO 110.

- ☒ The product label includes a list of all ingredients required by TGO 110.
- ☒ The product label includes quantity of nicotine as an active ingredient (if applicable).
- ☒ The product label includes applicable warning statements.
- ☒ Copies of labels can be provided upon request.

☒ The good has child-resistant packaging.

☒ For a vaping substance accessory, vaping device, vaping device accessory or vaping substance accessories in a kit, the good(s) conforms with the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023* or essential principles, as appropriate (see footnote 3 and 4).

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[2] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

Section 6: Compliance – vaping devices etc

Complete this section for a good that is a therapeutic vaping device or therapeutic vaping device accessory that does not contain a therapeutic vaping substance and is not to be imported or supplied in a therapeutic vaping pack. See footnotes 3 and 4 as to which standards apply to your vaping device.

The therapeutic vaping device or therapeutic device accessory:

☐ is only intended to administer a therapeutic vaping substance that is indicated for 'smoking cessation' or the 'management of nicotine dependence'.

The therapeutic vaping device or therapeutic device accessory:

☐ conforms with the Essential Principles[3]. **Complete the *Essential Principles* checklist available on the TGA website** (https://www.tga.gov.au/resources/resource/forms/essential-principles-checklist-medical-devices). You do not need to submit the completed checklist. **Go to section 8.**

OR

☐ is a device to which the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023*[4] (MDSO) applies and conforms with the MDSO. **Complete the vaping device compliance evidence below.**

OR

☐ is the subject of consent from the Secretary under section 41MA or 41MAA of the Act for non-compliance with the essential principles. (Note: consent is only granted in exceptional circumstances, for a limited period). **Go to section 8.**

Evidence of compliance – vaping device or vaping device accessory

If your therapeutic vaping device or therapeutic vaping device accessory does not comply with the Essential Principles and the MDSO applies, select one or more types of valid evidence held that demonstrates compliance with applicable requirements:

☐ US FDA - Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS)

☐ EU - European Tobacco Products Directive - A valid notification under Article 20 of Directive 2014/40/EU

☐ UK MHRA - notification through the Tobacco and related Products Regulations (TRPR), as listed on the notified e-cigarette products publication (database) ecig (cms.mhra.gov.uk/ecig)

☐ Certificate, licence, notification, or other approval establishing compliance for supply of therapeutic goods (TGA, US FDA, EU notified body, or designated body by UK MHRA)

☐ ISO 9001 certificate

☐ ISO13485 certificate

Based on the selection above, provide the following information as evidence (the table can be duplicated if more than one type of evidence is held or there are multiple manufacturing sites holding separate certifications):

Authorising authority / certification or notification body	
Scope of authorisation / certification / notification	
Authorisation / certificate / notification number or identifier	

[3] The essential principles apply to therapeutic vaping devices and therapeutic vaping device accessories by default under the *Therapeutic Goods Act 1989*.

[4] The MDSO applies to therapeutic vaping devices and therapeutic vaping device accessories, imported or manufactured on or after 1 March 2024, that prior to 1 January 2024 were excluded from the operation of the *Therapeutic Goods Act 1989*. Vaping devices and vaping device accessories previously excluded were those not intended to be used exclusively for the administration of a medicine.

Section 7: Ingredients or components for further manufacture in Australia

Complete this section if the good is a starting material, component or article being imported for the purpose of further manufacture in Australia.

☐ The starting material is for use in the lawful manufacture of a therapeutic vaping substance or a therapeutic vaping substance accessory or another therapeutic good by a manufacturer that holds all relevant licences or approvals. Provide details of manufacturing sites in the table below. Duplicate the table as necessary.

Manufacturer name:	
TGA licence number:	
Steps in manufacture:	

☐ The article or component is for use in the lawful manufacture of a therapeutic vaping device or a therapeutic vaping device accessory by a manufacturer that holds all relevant licences or approvals. Provide details of manufacturing sites in the table below. Duplicate the table as necessary.

Manufacturer name:					
Conformity assessment evidence					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Section 8: Declaration

Section 8.1: Privacy information

General privacy information is available on the TGA website.

The TGA is collecting personal information in this form in order to contact the sponsor to discuss the notice where necessary.

Section 8.2: Declaration

☒ I declare that the information provided in this form, is, to the best of my knowledge, current and correct.

☒ I certify that the statements made in this notice are supported by information and evidence which will be provided to the TGA upon request.

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 section 137.1 of the Commonwealth Criminal Code.

Name	s22 [redacted]		
Signature	s22 [redacted]	Date	04.03.2024

Send this completed notification form to vapenotifications@health.gov.au

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA USE ONLY

This form, when completed, will be classified as **'Official'**.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

Sponsor notice – Vaping goods

Notice to import or supply in Australia therapeutic vaping goods

About this form

You must submit this notice to the TGA prior to commencing importation or supply in Australia of unregistered therapeutic vaping goods that are intended for smoking cessation or the management of nicotine dependence, or ingredients or components used in the manufacture of those goods. The notice must be submitted before the therapeutic vaping goods are imported, or, for finished goods that are manufactured in Australia, before those goods are first supplied in Australia.

A separate form must be completed for each different type of therapeutic vaping good, ingredient or component intended to be imported or supplied. For example, if you have different flavours, concentrations of nicotine, or vaping device characteristics, you will need to submit a notice for each good.

If a notice is made for therapeutic vaping goods imported for further manufacture in Australia, a separate notice will need to be made for each good prior to supply.

Once complete, send this form to vapenotifications@health.gov.au

If information in the form relating to your therapeutic vaping good is incomplete, we may not be able to provide you a notification number.

You should be aware that the TGA may publish certain information relating to your notice – such as your name and details of your good.

Guidance

Guidance is available on the TGA website to help you to complete the form.

What you'll need to complete this form

- **Your TGA client ID** – see guidance on setting up a TGA client ID.
- **Details about your therapeutic vaping good, ingredient or component** – you will need to tell us key details about the good you intend to import, or supply following domestic manufacture.
- **Manufacturer information** – we need to know the TGA client ID for each manufacturer (vaping substance), or details of the manufacturers (vaping devices).
- **Evidence of compliance to applicable standards** – you will need this for each vaping good you intend to import, or supply following domestic manufacture.

Legislation

This notice is made under paragraph (a) in column 3 of item 15, and paragraph (a) in column 3 of item 16, of Schedule 5A to the *Therapeutic Goods Regulations 1990* (the TG Regulations).

This notice is also made under paragraph (a) in the column headed "Conditions" of item 2.17, and paragraph (a) in the column headed "Conditions" of item 2.18, of Part 2 of Schedule 4 to the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations)

Section 1: Sponsor information

Company name:	Mission Distribution Victoria Pty Limited
TGA client ID:	83800
Contact email:	s2 s47 [redacted]

Section 2: Vaping good category

See guidance about the definitions used in this form. Every vaping good requires a separate notice, including where those therapeutic vaping goods are contained in a therapeutic vaping kit or therapeutic vaping pack.

Select one vaping good category for this notice:

☒ A finished good that is, or contains, a vaping substance (a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a good in a ***therapeutic vaping kit*** – see item 15 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 5 and 8 below

☐ A finished good that would be a medical device except that it is for supply as part of a therapeutic vaping pack (a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** in a ***therapeutic vaping pack*** – see item 15 of Schedule 5A to the TG Regulations).[1]

Complete sections 3, 4, 5 and 8 below

☐ A finished good that does not contain a vaping substance, and is a reusable vaping device or a component of a reusable vaping device, or a reusable cartridge, capsule or pod or other vessel (a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.17 of Part 2 of Schedule 4 to the MD Regulations).

Complete sections 3, 4, 6 and 8 below.

☐ A starting material, that is not liquid nicotine, for use in the manufacture of therapeutic vaping goods that are or contain therapeutic vaping substances (see item 16 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of vaping goods in Australia (including a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a ***therapeutic vaping kit*** – see item 16 Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of other therapeutic goods in Australia (see item 16 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ A component or article intended for use in the manufacture of an unfilled vaping device (the manufacture of a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.18 of Part 2 of Schedule 4 to the MD Regulations).

Complete sections 3, 4, 7 and 8 below.

[1] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

Section 3: Vaping good details

Complete **tables 1 and 2** if your vaping good is:

- a therapeutic vaping substance;
- liquid nicotine; or
- starting material that is an ingredient for use in the manufacture of a therapeutic vaping substance or therapeutic vaping substance accessory.

Complete **table 3** if your vaping good is:

- a therapeutic vaping device, e.g. a reusable vaporiser, battery, mouthpiece, coil or other parts of a reusable therapeutic vaping device;
- a therapeutic vaping device accessory, e.g. a unfilled cartridge, capsule or pod; or
- a component or article for use in the manufacture of a therapeutic vaping device, therapeutic vaping device accessory or therapeutic vaping substance accessory.

Complete **tables 1, 2 and 3** if your vaping good is:

- a therapeutic vaping substance accessory e.g. a filled cartridge, capsule or pod.

When completing **table 2**:

- list all ingredients (except for nicotine, details of which should be included in Table 1), including flavour, using the Australian Approved Ingredient name where possible; and
- use the approved terminology in TGA Code Tables, e.g. the Australian Approved Names of ingredients, and as specified in the published guidance.

Table 1: Details of the therapeutic vaping substance, liquid nicotine or starting material

Name of good:	RELX Pod Pro2-Tobacco Gold-28.5mg/mL Nicotine
Description of good:	Therapeutic vaping substance accessory
Container type:	Prefilled Pod
Volume in mL (or weight if applicable):	1.9mL
Nicotine form (if applicable):	Nicotine ID 54852
Nicotine quantity:	28.5mg/mL

Table 2: Ingredients in the therapeutic vaping substance, liquid nicotine or starting material

Ingredient name	Quantity
s47 [redacted]	

Table 3: Details of the therapeutic vaping device, therapeutic vaping device accessory, therapeutic vaping substance accessory or articles or components for further manufacture

Vaping good name:	RELX Pod Pro2-Tobacco Gold-28.5mg/mL Nicotine		
Device model:	RELX Pod Pro2		
Vaping good description:	Therapeutic vaping substance accessory		
Liquid capacity in mL:	1.9mL		
Device product identifier GMDN or UDI:	No GMDN or UDI is available		
Rechargeable battery:	☐ Yes	☒ No	
Battery capacity:	Prefilled pod, no battery included		
Battery composition: (e.g. Nickel-Cadmium, Nickel-Metal Hydride, Lithium Ion)	Prefilled pod, no battery included		
Battery voltage:	Prefilled pod, no battery included		
Battery wattage:	Prefilled pod, no battery included		
Type of heating element:	☒ Coil	☐ Wick	☐ Other
	If Other selected, please describe:		
Charging unit:	☐ USB	☒ Other Prefilled pod, no battery included	
Is the airflow adjustable?	☐ Yes	☒ No	
Type of control unit(s): (e.g. PCB, microcontroller, software, etc)	Prefilled pod, no control unit included		

Section 4: Manufacturer details

Provide details of all prior manufacturers of the therapeutic vaping goods, ingredients or components you are importing or supplying.

Manufacturers of the therapeutic vaping substance, therapeutic vaping substance accessory, liquid nicotine or starting material for further manufacture

Manufacturer name:	s47 [redacted]
TGA client ID:	s47 [redacted]
Steps in manufacture:	Vaping substance manufacturer/testing chemical manufacturer

Manufacturer name:	s47 [redacted]
TGA client ID:	s47 [redacted]
Steps in manufacture:	Finished product manufacturer/packaging manufacturer/testing physical manufacturer

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturers of the therapeutic vaping device, therapeutic vaping device accessory, therapeutic vaping substance accessory or articles or components for further manufacture

Manufacturer name:	s47 [redacted]				
Site street address:	s47 [redacted]				
Suburb/Town/City:	s47 [redacted]	**State/Territory:**	s47 [redacted]	**Post code:**	s47 [redacted]
Country:	s47 [redacted]				
Contact email:	s22 s47 [redacted]				

Manufacturer name:	s47 [redacted]				
Site street address:	s47 [redacted]				
Suburb/Town/City:	s47 [redacted]	**State/Territory:**	s47 [redacted]	**Post code:**	s47 [redacted]
Country:	s47 [redacted]				
Contact email:	s22 s47 [redacted]				

Manufacturer name:					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Manufacturer name:	
Site street address:	

Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Section 5: Compliance – vaping substances etc

Complete this section if the therapeutic vaping good is ready to be supplied in Australia and is, or contains, a therapeutic vaping substance, including a therapeutic vaping substance accessory, therapeutic vaping kit or is a good in a therapeutic vaping pack.[2].

The therapeutic vaping good:

☐ is only indicated for 'smoking cessation' or the 'management of nicotine dependence'.

The therapeutic vaping good:

☒ conforms with applicable standards, including *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021*. **Complete the TGO 110 compliance evidence below.**

OR

☐ is the subject of a consent from the Secretary under section 14 or 14A of the Therapeutic Goods Act for importation or supply. (Note: consent is only granted in exceptional circumstances).

TGO 110 compliance evidence

☒ Testing is performed on each batch of vaping goods.

- ☒ We hold an example of recent testing performed on a batch of vaping goods supplied or to be supplied in Australia:

Name of the facility:	s47 [redacted]
Address of the facility:	s47 [redacted]
Date tested: (dd/mm/yyyy)	26/01/2024

- ☒ Testing performed will confirm the nicotine concentration, which aligns with the label claim (where applicable).
- ☒ Testing will confirm the absence of prohibited ingredients.
- ☒ Batch-specific test results can be made available upon request.

☒ The good only contains mint, menthol, or tobacco flavour, if it contains a flavour.

☒ The labels comply with the requirements of TGO 110.

- ☒ The product label includes a list of all ingredients required by TGO 110.
- ☒ The product label includes quantity of nicotine as an active ingredient (if applicable).
- ☒ The product label includes applicable warning statements.
- ☒ Copies of labels can be provided upon request.

☒ The good has child-resistant packaging.

☒ For a vaping substance accessory, vaping device, vaping device accessory or vaping substance accessories in a kit, the good(s) conforms with the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023* or essential principles, as appropriate (see footnote 3 and 4).

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[2] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

Section 6: Compliance – vaping devices etc

Complete this section for a good that is a therapeutic vaping device or therapeutic vaping device accessory that does not contain a therapeutic vaping substance and is not to be imported or supplied in a therapeutic vaping pack. See footnotes 3 and 4 as to which standards apply to your vaping device.

The therapeutic vaping device or therapeutic device accessory:

☐ is only intended to administer a therapeutic vaping substance that is indicated for 'smoking cessation' or the 'management of nicotine dependence'.

The therapeutic vaping device or therapeutic device accessory:

☐ conforms with the Essential Principles[3]. **Complete the *Essential Principles* checklist available on the TGA website** (https://www.tga.gov.au/resources/resource/forms/essential-principles-checklist-medical-devices). You do not need to submit the completed checklist. **Go to section 8.**

OR

☐ is a device to which the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023*[4] (MDSO) applies and conforms with the MDSO. **Complete the vaping device compliance evidence below.**

OR

☐ is the subject of consent from the Secretary under section 41MA or 41MAA of the Act for non-compliance with the essential principles. (Note: consent is only granted in exceptional circumstances, for a limited period). **Go to section 8.**

Evidence of compliance – vaping device or vaping device accessory

If your therapeutic vaping device or therapeutic vaping device accessory does not comply with the Essential Principles and the MDSO applies, select one or more types of valid evidence held that demonstrates compliance with applicable requirements:

☐ US FDA - Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS)

☐ EU - European Tobacco Products Directive - A valid notification under Article 20 of Directive 2014/40/EU

☐ UK MHRA - notification through the Tobacco and related Products Regulations (TRPR), as listed on the notified e-cigarette products publication (database) ecig (cms.mhra.gov.uk/ecig)

☐ Certificate, licence, notification, or other approval establishing compliance for supply of therapeutic goods (TGA, US FDA, EU notified body, or designated body by UK MHRA)

☐ ISO 9001 certificate

☐ ISO13485 certificate

Based on the selection above, provide the following information as evidence (the table can be duplicated if more than one type of evidence is held or there are multiple manufacturing sites holding separate certifications):

Authorising authority / certification or notification body	
Scope of authorisation / certification / notification	
Authorisation / certificate / notification number or identifier	

[3] The essential principles apply to therapeutic vaping devices and therapeutic vaping device accessories by default under the *Therapeutic Goods Act 1989*.

[4] The MDSO applies to therapeutic vaping devices and therapeutic vaping device accessories, imported or manufactured on or after 1 March 2024, that prior to 1 January 2024 were excluded from the operation of the *Therapeutic Goods Act 1989*. Vaping devices and vaping device accessories previously excluded were those not intended to be used exclusively for the administration of a medicine.

Section 7: Ingredients or components for further manufacture in Australia

Complete this section if the good is a starting material, component or article being imported for the purpose of further manufacture in Australia.

☐ The starting material is for use in the lawful manufacture of a therapeutic vaping substance or a therapeutic vaping substance accessory or another therapeutic good by a manufacturer that holds all relevant licences or approvals. Provide details of manufacturing sites in the table below. Duplicate the table as necessary.

Manufacturer name:	
TGA licence number:	
Steps in manufacture:	

☐ The article or component is for use in the lawful manufacture of a therapeutic vaping device or a therapeutic vaping device accessory by a manufacturer that holds all relevant licences or approvals. Provide details of manufacturing sites in the table below. Duplicate the table as necessary.

Manufacturer name:					
Conformity assessment evidence					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Section 8: Declaration

Section 8.1: Privacy information

General privacy information is available on the TGA website.

The TGA is collecting personal information in this form in order to contact the sponsor to discuss the notice where necessary.

Section 8.2: Declaration

☒ I declare that the information provided in this form, is, to the best of my knowledge, current and correct.

☒ I certify that the statements made in this notice are supported by information and evidence which will be provided to the TGA upon request.

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 section 137.1 of the Commonwealth Criminal Code.

Name	s22 [redacted]		
Signature	s22 [redacted]	Date	04.03.2024

Send this completed notification form to vapenotifications@health.gov.au

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA USE ONLY

This form, when completed, will be classified as **'Official'**.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

Sponsor notice – Vaping goods

Notice to import or supply in Australia therapeutic vaping goods

About this form

You must submit this notice to the TGA prior to commencing importation or supply in Australia of unregistered therapeutic vaping goods that are intended for smoking cessation or the management of nicotine dependence, or ingredients or components used in the manufacture of those goods. The notice must be submitted before the therapeutic vaping goods are imported, or, for finished goods that are manufactured in Australia, before those goods are first supplied in Australia.

A separate form must be completed for each different type of therapeutic vaping good, ingredient or component intended to be imported or supplied. For example, if you have different flavours, concentrations of nicotine, or vaping device characteristics, you will need to submit a notice for each good.

If a notice is made for therapeutic vaping goods imported for further manufacture in Australia, a separate notice will need to be made for each good prior to supply.

Once complete, send this form to vapenotifications@health.gov.au

If information in the form relating to your therapeutic vaping good is incomplete, we may not be able to provide you a notification number.

You should be aware that the TGA may publish certain information relating to your notice – such as your name and details of your good.

Guidance

Guidance is available on the TGA website to help you to complete the form.

What you'll need to complete this form

- **Your TGA client ID** – see guidance on setting up a TGA client ID.
- **Details about your therapeutic vaping good, ingredient or component** – you will need to tell us key details about the good you intend to import, or supply following domestic manufacture.
- **Manufacturer information** – we need to know the TGA client ID for each manufacturer (vaping substance), or details of the manufacturers (vaping devices).
- **Evidence of compliance to applicable standards** – you will need this for each vaping good you intend to import, or supply following domestic manufacture.

Legislation

This notice is made under paragraph (a) in column 3 of item 15, and paragraph (a) in column 3 of item 16, of Schedule 5A to the *Therapeutic Goods Regulations 1990* (the TG Regulations).

This notice is also made under paragraph (a) in the column headed "Conditions" of item 2.17, and paragraph (a) in the column headed "Conditions" of item 2.18, of Part 2 of Schedule 4 to the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations)

Section 1: Sponsor information

Company name:	Mission Distribution Victoria Pty Limited
TGA client ID:	83800
Contact email:	s2 s47 [redacted]

Section 2: Vaping good category

See guidance about the definitions used in this form. Every vaping good requires a separate notice, including where those therapeutic vaping goods are contained in a therapeutic vaping kit or therapeutic vaping pack.

Select one vaping good category for this notice:

☒ A finished good that is, or contains, a vaping substance (a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a good in a ***therapeutic vaping kit*** – see item 15 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 5 and 8 below

☐ A finished good that would be a medical device except that it is for supply as part of a therapeutic vaping pack (a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** in a ***therapeutic vaping pack*** – see item 15 of Schedule 5A to the TG Regulations).[1]

Complete sections 3, 4, 5 and 8 below

☐ A finished good that does not contain a vaping substance, and is a reusable vaping device or a component of a reusable vaping device, or a reusable cartridge, capsule or pod or other vessel (a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.17 of Part 2 of Schedule 4 to the MD Regulations).

Complete sections 3, 4, 6 and 8 below.

☐ A starting material, that is not liquid nicotine, for use in the manufacture of therapeutic vaping goods that are or contain therapeutic vaping substances (see item 16 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of vaping goods in Australia (including a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a ***therapeutic vaping kit*** – see item 16 Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of other therapeutic goods in Australia (see item 16 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ A component or article intended for use in the manufacture of an unfilled vaping device (the manufacture of a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.18 of Part 2 of Schedule 4 to the MD Regulations).

Complete sections 3, 4, 7 and 8 below.

[1] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

Section 3: Vaping good details

Complete **tables 1 and 2** if your vaping good is:

- a therapeutic vaping substance;
- liquid nicotine; or
- starting material that is an ingredient for use in the manufacture of a therapeutic vaping substance or therapeutic vaping substance accessory.

Complete **table 3** if your vaping good is:

- a therapeutic vaping device, e.g. a reusable vaporiser, battery, mouthpiece, coil or other parts of a reusable therapeutic vaping device;
- a therapeutic vaping device accessory, e.g. a unfilled cartridge, capsule or pod; or
- a component or article for use in the manufacture of a therapeutic vaping device, therapeutic vaping device accessory or therapeutic vaping substance accessory.

Complete **tables 1, 2 and 3** if your vaping good is:

- a therapeutic vaping substance accessory e.g. a filled cartridge, capsule or pod.

When completing **table 2**:

- list all ingredients (except for nicotine, details of which should be included in Table 1), including flavour, using the Australian Approved Ingredient name where possible; and
- use the approved terminology in TGA Code Tables, e.g. the Australian Approved Names of ingredients, and as specified in the published guidance.

Table 1: Details of the therapeutic vaping substance, liquid nicotine or starting material

Name of good:	RELX Pod Pro2-Menthol-28.5mg/mL Nicotine
Description of good:	Therapeutic vaping substance accessory
Container type:	Prefilled Pod
Volume in mL (or weight if applicable):	1.9mL
Nicotine form (if applicable):	Nicotine ID 54852
Nicotine quantity:	28.5mg/mL

Table 2: Ingredients in the therapeutic vaping substance, liquid nicotine or starting material

Ingredient name	Quantity
s47 [redacted]	

Table 3: Details of the therapeutic vaping device, therapeutic vaping device accessory, therapeutic vaping substance accessory or articles or components for further manufacture

Vaping good name:	RELX Pod Pro2-Menthol-28.5mg/mL Nicotine		
Device model:	RELX Pod Pro2		
Vaping good description:	Therapeutic vaping substance accessory		
Liquid capacity in mL:	1.9mL		
Device product identifier GMDN or UDI:	No GMDN or UDI is available		
Rechargeable battery:	☐ Yes	☒ No	
Battery capacity:	Prefilled pod, no battery included		
Battery composition: (e.g. Nickel-Cadmium, Nickel-Metal Hydride, Lithium Ion)	Prefilled pod, no battery included		
Battery voltage:	Prefilled pod, no battery included		
Battery wattage:	Prefilled pod, no battery included		
Type of heating element:	☒ Coil	☐ Wick	☐ Other
	If Other selected, please describe:		
Charging unit:	☐ USB	☒ Other Prefilled pod, no battery included	
Is the airflow adjustable?	☐ Yes	☒ No	
Type of control unit(s): (e.g. PCB, microcontroller, software, etc)	Prefilled pod, no control unit included		

Section 4: Manufacturer details

Provide details of all prior manufacturers of the therapeutic vaping goods, ingredients or components you are importing or supplying.

Manufacturers of the therapeutic vaping substance, therapeutic vaping substance accessory, liquid nicotine or starting material for further manufacture

Manufacturer name:	s47 [redacted]
TGA client ID:	s47 [redacted]
Steps in manufacture:	Vaping substance manufacturer/testing chemical manufacturer

Manufacturer name:	s47 [redacted]
TGA client ID:	s47 [redacted]
Steps in manufacture:	Finished product manufacturer/packaging manufacturer/testing physical manufacturer

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturers of the therapeutic vaping device, therapeutic vaping device accessory, therapeutic vaping substance accessory or articles or components for further manufacture

Manufacturer name:	s47 [redacted]				
Site street address:	s47 [redacted]				
Suburb/Town/City:	s47 [redacted]	**State/Territory:**	s47 [redacted]	**Post code:**	s47 [redacted]
Country:	s47 [redacted]				
Contact email:	s22 s47 [redacted]				

Manufacturer name:	s47 [redacted]				
Site street address:	s47 [redacted]				
Suburb/Town/City:	s47 [redacted]	**State/Territory:**	s47 [redacted]	**Post code:**	s47 [redacted]
Country:	s47 [redacted]				
Contact email:	s22 s47 [redacted]				

Manufacturer name:					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Manufacturer name:	
Site street address:	

Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Section 5: Compliance – vaping substances etc

Complete this section if the therapeutic vaping good is ready to be supplied in Australia and is, or contains, a therapeutic vaping substance, including a therapeutic vaping substance accessory, therapeutic vaping kit or is a good in a therapeutic vaping pack.[2].

The therapeutic vaping good:

☐ is only indicated for 'smoking cessation' or the 'management of nicotine dependence'.

The therapeutic vaping good:

☒ conforms with applicable standards, including *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021*. **Complete the TGO 110 compliance evidence below.**

OR

☐ is the subject of a consent from the Secretary under section 14 or 14A of the Therapeutic Goods Act for importation or supply. (Note: consent is only granted in exceptional circumstances).

TGO 110 compliance evidence

☒ Testing is performed on each batch of vaping goods.

- ☒ We hold an example of recent testing performed on a batch of vaping goods supplied or to be supplied in Australia:

Name of the facility:	s47 [redacted]
Address of the facility:	s47 [redacted]
Date tested: (dd/mm/yyyy)	16/12/2023

- ☒ Testing performed will confirm the nicotine concentration, which aligns with the label claim (where applicable).
- ☒ Testing will confirm the absence of prohibited ingredients.
- ☒ Batch-specific test results can be made available upon request.

☒ The good only contains mint, menthol, or tobacco flavour, if it contains a flavour.

☒ The labels comply with the requirements of TGO 110.

- ☒ The product label includes a list of all ingredients required by TGO 110.
- ☒ The product label includes quantity of nicotine as an active ingredient (if applicable).
- ☒ The product label includes applicable warning statements.
- ☒ Copies of labels can be provided upon request.

☒ The good has child-resistant packaging.

☒ For a vaping substance accessory, vaping device, vaping device accessory or vaping substance accessories in a kit, the good(s) conforms with the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023* or essential principles, as appropriate (see footnote 3 and 4).

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[2] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

Section 6: Compliance – vaping devices etc

Complete this section for a good that is a therapeutic vaping device or therapeutic vaping device accessory that does not contain a therapeutic vaping substance and is not to be imported or supplied in a therapeutic vaping pack. See footnotes 3 and 4 as to which standards apply to your vaping device.

The therapeutic vaping device or therapeutic device accessory:

☐ is only intended to administer a therapeutic vaping substance that is indicated for 'smoking cessation' or the 'management of nicotine dependence'.

The therapeutic vaping device or therapeutic device accessory:

☐ conforms with the Essential Principles[3]. **Complete the *Essential Principles* checklist available on the TGA website** (https://www.tga.gov.au/resources/resource/forms/essential-principles-checklist-medical-devices). You do not need to submit the completed checklist. **Go to section 8.**

OR

☐ is a device to which the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023*[4] (MDSO) applies and conforms with the MDSO. **Complete the vaping device compliance evidence below.**

OR

☐ is the subject of consent from the Secretary under section 41MA or 41MAA of the Act for non-compliance with the essential principles. (Note: consent is only granted in exceptional circumstances, for a limited period). **Go to section 8.**

Evidence of compliance – vaping device or vaping device accessory

If your therapeutic vaping device or therapeutic vaping device accessory does not comply with the Essential Principles and the MDSO applies, select one or more types of valid evidence held that demonstrates compliance with applicable requirements:

☐ US FDA - Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS)

☐ EU - European Tobacco Products Directive - A valid notification under Article 20 of Directive 2014/40/EU

☐ UK MHRA - notification through the Tobacco and related Products Regulations (TRPR), as listed on the notified e-cigarette products publication (database) ecig (cms.mhra.gov.uk/ecig)

☐ Certificate, licence, notification, or other approval establishing compliance for supply of therapeutic goods (TGA, US FDA, EU notified body, or designated body by UK MHRA)

☐ ISO 9001 certificate

☐ ISO13485 certificate

Based on the selection above, provide the following information as evidence (the table can be duplicated if more than one type of evidence is held or there are multiple manufacturing sites holding separate certifications):

Authorising authority / certification or notification body	
Scope of authorisation / certification / notification	
Authorisation / certificate / notification number or identifier	

[3] The essential principles apply to therapeutic vaping devices and therapeutic vaping device accessories by default under the *Therapeutic Goods Act 1989*.
[4] The MDSO applies to therapeutic vaping devices and therapeutic vaping device accessories, imported or manufactured on or after 1 March 2024, that prior to 1 January 2024 were excluded from the operation of the *Therapeutic Goods Act 1989*. Vaping devices and vaping device accessories previously excluded were those not intended to be used exclusively for the administration of a medicine.

Section 7: Ingredients or components for further manufacture in Australia

Complete this section if the good is a starting material, component or article being imported for the purpose of further manufacture in Australia.

☐ The starting material is for use in the lawful manufacture of a therapeutic vaping substance or a therapeutic vaping substance accessory or another therapeutic good by a manufacturer that holds all relevant licences or approvals. Provide details of manufacturing sites in the table below. Duplicate the table as necessary.

Manufacturer name:	
TGA licence number:	
Steps in manufacture:	

☐ The article or component is for use in the lawful manufacture of a therapeutic vaping device or a therapeutic vaping device accessory by a manufacturer that holds all relevant licences or approvals. Provide details of manufacturing sites in the table below. Duplicate the table as necessary.

Manufacturer name:					
Conformity assessment evidence					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Section 8: Declaration

Section 8.1: Privacy information

General privacy information is available on the TGA website.

The TGA is collecting personal information in this form in order to contact the sponsor to discuss the notice where necessary.

Section 8.2: Declaration

☒ I declare that the information provided in this form, is, to the best of my knowledge, current and correct.

☒ I certify that the statements made in this notice are supported by information and evidence which will be provided to the TGA upon request.

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 section 137.1 of the Commonwealth Criminal Code.

Name	s22 [redacted]		
Signature	s22 [redacted]	Date	04.03.2024

Send this completed notification form to vapenotifications@health.gov.au

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA USE ONLY

This form, when completed, will be classified as **'Official'**.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

Sponsor notice – Vaping goods

Notice to import or supply in Australia therapeutic vaping goods

About this form

You must submit this notice to the TGA prior to commencing importation or supply in Australia of unregistered therapeutic vaping goods that are intended for smoking cessation or the management of nicotine dependence, or ingredients or components used in the manufacture of those goods. The notice must be submitted before the therapeutic vaping goods are imported, or, for finished goods that are manufactured in Australia, before those goods are first supplied in Australia.

A separate form must be completed for each different type of therapeutic vaping good, ingredient or component intended to be imported or supplied. For example, if you have different flavours, concentrations of nicotine, or vaping device characteristics, you will need to submit a notice for each good.

If a notice is made for therapeutic vaping goods imported for further manufacture in Australia, a separate notice will need to be made for each good prior to supply.

Once complete, send this form to vapenotifications@health.gov.au

If information in the form relating to your therapeutic vaping good is incomplete, we may not be able to provide you a notification number.

You should be aware that the TGA may publish certain information relating to your notice – such as your name and details of your good.

Guidance

Guidance is available on the TGA website to help you to complete the form.

What you'll need to complete this form

- **Your TGA client ID** – see guidance on setting up a TGA client ID.
- **Details about your therapeutic vaping good, ingredient or component** – you will need to tell us key details about the good you intend to import, or supply following domestic manufacture.
- **Manufacturer information** – we need to know the TGA client ID for each manufacturer (vaping substance), or details of the manufacturers (vaping devices).
- **Evidence of compliance to applicable standards** – you will need this for each vaping good you intend to import, or supply following domestic manufacture.

Legislation

This notice is made under paragraph (a) in column 3 of item 15, and paragraph (a) in column 3 of item 16, of Schedule 5A to the *Therapeutic Goods Regulations 1990* (the TG Regulations).

This notice is also made under paragraph (a) in the column headed "Conditions" of item 2.17, and paragraph (a) in the column headed "Conditions" of item 2.18, of Part 2 of Schedule 4 to the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations)

Section 1: Sponsor information

Company name:	Mission Distribution Victoria Pty Limited
TGA client ID:	83800
Contact email:	s2 s47 [redacted]

Section 2: Vaping good category

See guidance about the definitions used in this form. Every vaping good requires a separate notice, including where those therapeutic vaping goods are contained in a therapeutic vaping kit or therapeutic vaping pack.

Select one vaping good category for this notice:

☒ A finished good that is, or contains, a vaping substance (a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a good in a ***therapeutic vaping kit*** – see item 15 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 5 and 8 below

☐ A finished good that would be a medical device except that it is for supply as part of a therapeutic vaping pack (a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** in a ***therapeutic vaping pack*** – see item 15 of Schedule 5A to the TG Regulations).[1]

Complete sections 3, 4, 5 and 8 below

☐ A finished good that does not contain a vaping substance, and is a reusable vaping device or a component of a reusable vaping device, or a reusable cartridge, capsule or pod or other vessel (a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.17 of Part 2 of Schedule 4 to the MD Regulations).

Complete sections 3, 4, 6 and 8 below.

☐ A starting material, that is not liquid nicotine, for use in the manufacture of therapeutic vaping goods that are or contain therapeutic vaping substances (see item 16 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of vaping goods in Australia (including a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a ***therapeutic vaping kit*** – see item 16 Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of other therapeutic goods in Australia (see item 16 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ A component or article intended for use in the manufacture of an unfilled vaping device (the manufacture of a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.18 of Part 2 of Schedule 4 to the MD Regulations).

Complete sections 3, 4, 7 and 8 below.

[1] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

Section 3: Vaping good details

Complete **tables 1 and 2** if your vaping good is:

- a therapeutic vaping substance;
- liquid nicotine; or
- starting material that is an ingredient for use in the manufacture of a therapeutic vaping substance or therapeutic vaping substance accessory.

Complete **table 3** if your vaping good is:

- a therapeutic vaping device, e.g. a reusable vaporiser, battery, mouthpiece, coil or other parts of a reusable therapeutic vaping device;
- a therapeutic vaping device accessory, e.g. a unfilled cartridge, capsule or pod; or
- a component or article for use in the manufacture of a therapeutic vaping device, therapeutic vaping device accessory or therapeutic vaping substance accessory.

Complete **tables 1, 2 and 3** if your vaping good is:

- a therapeutic vaping substance accessory e.g. a filled cartridge, capsule or pod.

When completing **table 2**:

- list all ingredients (except for nicotine, details of which should be included in Table 1), including flavour, using the Australian Approved Ingredient name where possible; and
- use the approved terminology in TGA Code Tables, e.g. the Australian Approved Names of ingredients, and as specified in the published guidance.

Table 1: Details of the therapeutic vaping substance, liquid nicotine or starting material

Name of good:	RELX Pod Pro2-Tobacco Red-28.5mg/mL Nicotine
Description of good:	Therapeutic vaping substance accessory
Container type:	Prefilled Pod
Volume in mL (or weight if applicable):	1.9mL
Nicotine form (if applicable):	Nicotine ID 54852
Nicotine quantity:	28.5mg/mL

Table 2: Ingredients in the therapeutic vaping substance, liquid nicotine or starting material

Ingredient name	Quantity
s47	

Table 3: Details of the therapeutic vaping device, therapeutic vaping device accessory, therapeutic vaping substance accessory or articles or components for further manufacture

Vaping good name:	RELX Pod Pro2-Tobacco Red-28.5mg/mL Nicotine		
Device model:	RELX Pod Pro2		
Vaping good description:	Therapeutic vaping substance accessory		
Liquid capacity in mL:	1.9mL		
Device product identifier GMDN or UDI:	No GMDN or UDI is available		
Rechargeable battery:	☐ Yes	☒ No	
Battery capacity:	Prefilled pod, no battery included		
Battery composition: (e.g. Nickel-Cadmium, Nickel-Metal Hydride, Lithium Ion)	Prefilled pod, no battery included		
Battery voltage:	Prefilled pod, no battery included		
Battery wattage:	Prefilled pod, no battery included		
Type of heating element:	☒ Coil	☐ Wick	☐ Other
	If Other selected, please describe:		
Charging unit:	☐ USB	☒ Other Prefilled pod, no battery included	
Is the airflow adjustable?	☐ Yes	☒ No	
Type of control unit(s): (e.g. PCB, microcontroller, software, etc)	Prefilled pod, no control unit included		

Section 4: Manufacturer details

Provide details of all prior manufacturers of the therapeutic vaping goods, ingredients or components you are importing or supplying.

Manufacturers of the therapeutic vaping substance, therapeutic vaping substance accessory, liquid nicotine or starting material for further manufacture

Manufacturer name:	s47 [redacted]
TGA client ID:	s47 [redacted]
Steps in manufacture:	Vaping substance manufacturer/testing chemical manufacturer

Manufacturer name:	s47 [redacted]
TGA client ID:	s47 [redacted]
Steps in manufacture:	Finished product manufacturer/packaging manufacturer/testing physical manufacturer

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturers of the therapeutic vaping device, therapeutic vaping device accessory, therapeutic vaping substance accessory or articles or components for further manufacture

Manufacturer name:	s47 [redacted]				
Site street address:	s47 [redacted]				
Suburb/Town/City:	s47 [redacted]	**State/Territory:**	s47 [redacted]	**Post code:**	s47 [redacted]
Country:	s47 [redacted]				
Contact email:	s22 s47 [redacted]				

Manufacturer name:	s47 [redacted]				
Site street address:	s47 [redacted]				
Suburb/Town/City:	s47 [redacted]	**State/Territory:**	s47 [redacted]	**Post code:**	s47 [redacted]
Country:	s47 [redacted]				
Contact email:	s22 s47 [redacted]				

Manufacturer name:					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Manufacturer name:	
Site street address:	

Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Section 5: Compliance – vaping substances etc

Complete this section if the therapeutic vaping good is ready to be supplied in Australia and is, or contains, a therapeutic vaping substance, including a therapeutic vaping substance accessory, therapeutic vaping kit or is a good in a therapeutic vaping pack.[2].

The therapeutic vaping good:

☐ is only indicated for 'smoking cessation' or the 'management of nicotine dependence'.

The therapeutic vaping good:

☒ conforms with applicable standards, including *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021*. **Complete the TGO 110 compliance evidence below.**

OR

☐ is the subject of a consent from the Secretary under section 14 or 14A of the Therapeutic Goods Act for importation or supply. (Note: consent is only granted in exceptional circumstances).

TGO 110 compliance evidence

☒ Testing is performed on each batch of vaping goods.

- ☒ We hold an example of recent testing performed on a batch of vaping goods supplied or to be supplied in Australia:

Name of the facility:	s47 [redacted]
Address of the facility:	s47 [redacted]
Date tested: (dd/mm/yyyy)	14/12/2023

- ☒ Testing performed will confirm the nicotine concentration, which aligns with the label claim (where applicable).
- ☒ Testing will confirm the absence of prohibited ingredients.
- ☒ Batch-specific test results can be made available upon request.

☒ The good only contains mint, menthol, or tobacco flavour, if it contains a flavour.

☒ The labels comply with the requirements of TGO 110.

- ☒ The product label includes a list of all ingredients required by TGO 110.
- ☒ The product label includes quantity of nicotine as an active ingredient (if applicable).
- ☒ The product label includes applicable warning statements.
- ☒ Copies of labels can be provided upon request.

☒ The good has child-resistant packaging.

☒ For a vaping substance accessory, vaping device, vaping device accessory or vaping substance accessories in a kit, the good(s) conforms with the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023* or essential principles, as appropriate (see footnote 3 and 4).

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[2] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

Section 6: Compliance – vaping devices etc

Complete this section for a good that is a therapeutic vaping device or therapeutic vaping device accessory that does not contain a therapeutic vaping substance and is not to be imported or supplied in a therapeutic vaping pack. See footnotes 3 and 4 as to which standards apply to your vaping device.

The therapeutic vaping device or therapeutic device accessory:

☐ is only intended to administer a therapeutic vaping substance that is indicated for 'smoking cessation' or the 'management of nicotine dependence'.

The therapeutic vaping device or therapeutic device accessory:

☐ conforms with the Essential Principles[3]. **Complete the *Essential Principles* checklist available on the TGA website** (https://www.tga.gov.au/resources/resource/forms/essential-principles-checklist-medical-devices). You do not need to submit the completed checklist. **Go to section 8.**

OR

☐ is a device to which the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023*[4] (MDSO) applies and conforms with the MDSO. **Complete the vaping device compliance evidence below.**

OR

☐ is the subject of consent from the Secretary under section 41MA or 41MAA of the Act for non-compliance with the essential principles. (Note: consent is only granted in exceptional circumstances, for a limited period). **Go to section 8.**

Evidence of compliance – vaping device or vaping device accessory

If your therapeutic vaping device or therapeutic vaping device accessory does not comply with the Essential Principles and the MDSO applies, select one or more types of valid evidence held that demonstrates compliance with applicable requirements:

☐ US FDA - Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS)

☐ EU - European Tobacco Products Directive - A valid notification under Article 20 of Directive 2014/40/EU

☐ UK MHRA - notification through the Tobacco and related Products Regulations (TRPR), as listed on the notified e-cigarette products publication (database) ecig (cms.mhra.gov.uk/ecig)

☐ Certificate, licence, notification, or other approval establishing compliance for supply of therapeutic goods (TGA, US FDA, EU notified body, or designated body by UK MHRA)

☐ ISO 9001 certificate

☐ ISO13485 certificate

Based on the selection above, provide the following information as evidence (the table can be duplicated if more than one type of evidence is held or there are multiple manufacturing sites holding separate certifications):

Authorising authority / certification or notification body	
Scope of authorisation / certification / notification	
Authorisation / certificate / notification number or identifier	

[3] The essential principles apply to therapeutic vaping devices and therapeutic vaping device accessories by default under the *Therapeutic Goods Act 1989*.

[4] The MDSO applies to therapeutic vaping devices and therapeutic vaping device accessories, imported or manufactured on or after 1 March 2024, that prior to 1 January 2024 were excluded from the operation of the *Therapeutic Goods Act 1989*. Vaping devices and vaping device accessories previously excluded were those not intended to be used exclusively for the administration of a medicine.

Section 7: Ingredients or components for further manufacture in Australia

Complete this section if the good is a starting material, component or article being imported for the purpose of further manufacture in Australia.

☐ The starting material is for use in the lawful manufacture of a therapeutic vaping substance or a therapeutic vaping substance accessory or another therapeutic good by a manufacturer that holds all relevant licences or approvals. Provide details of manufacturing sites in the table below. Duplicate the table as necessary.

Manufacturer name:	
TGA licence number:	
Steps in manufacture:	

☐ The article or component is for use in the lawful manufacture of a therapeutic vaping device or a therapeutic vaping device accessory by a manufacturer that holds all relevant licences or approvals. Provide details of manufacturing sites in the table below. Duplicate the table as necessary.

Manufacturer name:					
Conformity assessment evidence					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Section 8: Declaration

Section 8.1: Privacy information

General privacy information is available on the TGA website.

The TGA is collecting personal information in this form in order to contact the sponsor to discuss the notice where necessary.

Section 8.2: Declaration

☒ I declare that the information provided in this form, is, to the best of my knowledge, current and correct.

☒ I certify that the statements made in this notice are supported by information and evidence which will be provided to the TGA upon request.

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 section 137.1 of the Commonwealth Criminal Code.

Name	s22 [redacted]		
Signature	s22 [redacted]	Date	04.03.2024

Send this completed notification form to vapenotifications@health.gov.au

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA USE ONLY

This form, when completed, will be classified as **'Official'**.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

Sponsor notice – Vaping goods

Notice to import or supply in Australia therapeutic vaping goods

About this form

You must submit this notice to the TGA prior to commencing importation or supply in Australia of unregistered therapeutic vaping goods that are intended for smoking cessation or the management of nicotine dependence, or ingredients or components used in the manufacture of those goods. The notice must be submitted before the therapeutic vaping goods are imported, or, for finished goods that are manufactured in Australia, before those goods are first supplied in Australia.

A separate form must be completed for each different type of therapeutic vaping good, ingredient or component intended to be imported or supplied. For example, if you have different flavours, concentrations of nicotine, or vaping device characteristics, you will need to submit a notice for each good.

If a notice is made for therapeutic vaping goods imported for further manufacture in Australia, a separate notice will need to be made for each good prior to supply.

Once complete, send this form to vapenotifications@health.gov.au

If information in the form relating to your therapeutic vaping good is incomplete, we may not be able to provide you a notification number.

You should be aware that the TGA may publish certain information relating to your notice – such as your name and details of your good.

Guidance

Guidance is available on the TGA website to help you to complete the form.

What you'll need to complete this form

- **Your TGA client ID** – see guidance on setting up a TGA client ID.
- **Details about your therapeutic vaping good, ingredient or component** – you will need to tell us key details about the good you intend to import, or supply following domestic manufacture.
- **Manufacturer information** – we need to know the TGA client ID for each manufacturer (vaping substance), or details of the manufacturers (vaping devices).
- **Evidence of compliance to applicable standards** – you will need this for each vaping good you intend to import, or supply following domestic manufacture.

Legislation

This notice is made under paragraph (a) in column 3 of item 15, and paragraph (a) in column 3 of item 16, of Schedule 5A to the *Therapeutic Goods Regulations 1990* (the TG Regulations).

This notice is also made under paragraph (a) in the column headed "Conditions" of item 2.17, and paragraph (a) in the column headed "Conditions" of item 2.18, of Part 2 of Schedule 4 to the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations)

Section 1: Sponsor information

Company name:	Mission Distribution Victoria Pty Limited
TGA client ID:	83800
Contact email:	s2 s47 [redacted]

Section 2: Vaping good category

See guidance about the definitions used in this form. Every vaping good requires a separate notice, including where those therapeutic vaping goods are contained in a therapeutic vaping kit or therapeutic vaping pack.

Select one vaping good category for this notice:

☐ A finished good that is, or contains, a vaping substance (a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a good in a ***therapeutic vaping kit*** – see item 15 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 5 and 8 below

☐ A finished good that would be a medical device except that it is for supply as part of a therapeutic vaping pack (a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** in a ***therapeutic vaping pack*** – see item 15 of Schedule 5A to the TG Regulations).[1]

Complete sections 3, 4, 5 and 8 below

☒ A finished good that does not contain a vaping substance, and is a reusable vaping device or a component of a reusable vaping device, or a reusable cartridge, capsule or pod or other vessel (a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.17 of Part 2 of Schedule 4 to the MD Regulations).

Complete sections 3, 4, 6 and 8 below.

☐ A starting material, that is not liquid nicotine, for use in the manufacture of therapeutic vaping goods that are or contain therapeutic vaping substances (see item 16 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of vaping goods in Australia (including a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a ***therapeutic vaping kit*** – see item 16 Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of other therapeutic goods in Australia (see item 16 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ A component or article intended for use in the manufacture of an unfilled vaping device (the manufacture of a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.18 of Part 2 of Schedule 4 to the MD Regulations).

Complete sections 3, 4, 7 and 8 below.

[1] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

Section 3: Vaping good details

Complete **tables 1 and 2** if your vaping good is:

- a therapeutic vaping substance;
- liquid nicotine; or
- starting material that is an ingredient for use in the manufacture of a therapeutic vaping substance or therapeutic vaping substance accessory.

Complete **table 3** if your vaping good is:

- a therapeutic vaping device, e.g. a reusable vaporiser, battery, mouthpiece, coil or other parts of a reusable therapeutic vaping device;
- a therapeutic vaping device accessory, e.g. a unfilled cartridge, capsule or pod; or
- a component or article for use in the manufacture of a therapeutic vaping device, therapeutic vaping device accessory or therapeutic vaping substance accessory.

Complete **tables 1, 2 and 3** if your vaping good is:

- a therapeutic vaping substance accessory e.g. a filled cartridge, capsule or pod.

When completing **table 2**:

- list all ingredients (except for nicotine, details of which should be included in Table 1), including flavour, using the Australian Approved Ingredient name where possible; and
- use the approved terminology in TGA Code Tables, e.g. the Australian Approved Names of ingredients, and as specified in the published guidance.

Table 1: Details of the therapeutic vaping substance, liquid nicotine or starting material

Name of good:	
Description of good:	
Container type:	
Volume in mL (or weight if applicable):	
Nicotine form (if applicable):	
Nicotine quantity:	

Table 2: Ingredients in the therapeutic vaping substance, liquid nicotine or starting material

Ingredient name	Quantity

Table 3: Details of the therapeutic vaping device, therapeutic vaping device accessory, therapeutic vaping substance accessory or articles or components for further manufacture

Vaping good name:	RELX Infinity 2 Device		
Device model:	P54a		
Vaping good description:	Therapeutic vaping device without vaping substance		
Liquid capacity in mL:	No applicable, it's a therapeutic vaping device without tank		
Device product identifier GMDN or UDI:	No GMDN or UDI is available		
Rechargeable battery:	☒ Yes	☐ No	
Battery capacity:	440mAh		
Battery composition: (e.g. Nickel-Cadmium, Nickel-Metal Hydride, Lithium Ion)	Lithium Ion		
Battery voltage:	3.7V~4.2V		
Battery wattage:	8W		
Type of heating element:	☐ Coil	☐ Wick	☒ Other
	If Other selected, please describe: No applicable, it's a therapeutic vaping device without tank		
Charging unit:	☒ USB	☐ Other	
Is the airflow adjustable?	☐ Yes	☒ No	
Type of control unit(s): (e.g. PCB, microcontroller, software, etc)	PCB, microcontroller, software		

Section 4: Manufacturer details

Provide details of all prior manufacturers of the therapeutic vaping goods, ingredients or components you are importing or supplying.

Manufacturers of the therapeutic vaping substance, therapeutic vaping substance accessory, liquid nicotine or starting material for further manufacture

Manufacturer name:	s47 [redacted]
TGA client ID:	s47 [redacted]
Steps in manufacture:	Finished product manufacturer/packaging manufacturer/testing physical manufacturer

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturers of the therapeutic vaping device, therapeutic vaping device accessory, therapeutic vaping substance accessory or articles or components for further manufacture

Manufacturer name:	s47 [redacted]				
Site street address:	s47 [redacted]				
Suburb/Town/City:	s47 [redacted]	**State/Territory:**	s47 [redacted]	**Post code:**	s47 [redacted]
Country:	s47 [redacted]				
Contact email:	s22 s47 [redacted]				

Manufacturer name:					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Manufacturer name:					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Manufacturer name:					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	

Country:	
Contact email:	

Section 5: Compliance – vaping substances etc

Complete this section if the therapeutic vaping good is ready to be supplied in Australia and is, or contains, a therapeutic vaping substance, including a therapeutic vaping substance accessory, therapeutic vaping kit or is a good in a therapeutic vaping pack.[2].

The therapeutic vaping good:

☐ is only indicated for 'smoking cessation' or the 'management of nicotine dependence'.

The therapeutic vaping good:

☐ conforms with applicable standards, including *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021*. **Complete the TGO 110 compliance evidence below.**

OR

☐ is the subject of a consent from the Secretary under section 14 or 14A of the Therapeutic Goods Act for importation or supply. (Note: consent is only granted in exceptional circumstances).

TGO 110 compliance evidence

☐ Testing is performed on each batch of vaping goods.

- ☐ We hold an example of recent testing performed on a batch of vaping goods supplied or to be supplied in Australia:

Name of the facility:	s47 [redacted]
Address of the facility:	s47 [redacted]
Date tested: (dd/mm/yyyy)	16/12/2023

- ☐ Testing performed will confirm the nicotine concentration, which aligns with the label claim (where applicable).
- ☐ Testing will confirm the absence of prohibited ingredients.
- ☐ Batch-specific test results can be made available upon request.

☐ The good only contains mint, menthol, or tobacco flavour, if it contains a flavour.

☐ The labels comply with the requirements of TGO 110.

- ☐ The product label includes a list of all ingredients required by TGO 110.
- ☐ The product label includes quantity of nicotine as an active ingredient (if applicable).
- ☐ The product label includes applicable warning statements.
- ☐ Copies of labels can be provided upon request.

☐ The good has child-resistant packaging.

☐ For a vaping substance accessory, vaping device, vaping device accessory or vaping substance accessories in a kit, the good(s) conforms with the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023* or essential principles, as appropriate (see footnote 3 and 4).

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[2] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

Section 6: Compliance – vaping devices etc

Complete this section for a good that is a therapeutic vaping device or therapeutic vaping device accessory that does not contain a therapeutic vaping substance and is not to be imported or supplied in a therapeutic vaping pack. See footnotes 3 and 4 as to which standards apply to your vaping device.

The therapeutic vaping device or therapeutic device accessory:

☒ is only intended to administer a therapeutic vaping substance that is indicated for 'smoking cessation' or the 'management of nicotine dependence'.

The therapeutic vaping device or therapeutic device accessory:

☒ conforms with the Essential Principles[3]. **Complete the *Essential Principles* checklist available on the TGA website** (https://www.tga.gov.au/resources/resource/forms/essential-principles-checklist-medical-devices). You do not need to submit the completed checklist. **Go to section 8.**

OR

☐ is a device to which the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023*[4] (MDSO) applies and conforms with the MDSO. **Complete the vaping device compliance evidence below.**

OR

☐ is the subject of consent from the Secretary under section 41MA or 41MAA of the Act for non-compliance with the essential principles. (Note: consent is only granted in exceptional circumstances, for a limited period). **Go to section 8.**

Evidence of compliance – vaping device or vaping device accessory

If your therapeutic vaping device or therapeutic vaping device accessory does not comply with the Essential Principles and the MDSO applies, select one or more types of valid evidence held that demonstrates compliance with applicable requirements:

☐ US FDA - Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS)

☐ EU - European Tobacco Products Directive - A valid notification under Article 20 of Directive 2014/40/EU

☐ UK MHRA - notification through the Tobacco and related Products Regulations (TRPR), as listed on the notified e-cigarette products publication (database) ecig (cms.mhra.gov.uk/ecig)

☐ Certificate, licence, notification, or other approval establishing compliance for supply of therapeutic goods (TGA, US FDA, EU notified body, or designated body by UK MHRA)

☒ ISO 9001 certificate

☐ ISO13485 certificate

Based on the selection above, provide the following information as evidence (the table can be duplicated if more than one type of evidence is held or there are multiple manufacturing sites holding separate certifications):

Authorising authority / certification or notification body	s47 [redacted]
Scope of authorisation / certification / notification	Manufacturing of Electronic Cigarette and Atomizers
Authorisation / certificate / notification number or identifier	s47 [redacted]

[3] The essential principles apply to therapeutic vaping devices and therapeutic vaping device accessories by default under the *Therapeutic Goods Act 1989*.

[4] The MDSO applies to therapeutic vaping devices and therapeutic vaping device accessories, imported or manufactured on or after 1 March 2024, that prior to 1 January 2024 were excluded from the operation of the *Therapeutic Goods Act 1989*. Vaping devices and vaping device accessories previously excluded were those not intended to be used exclusively for the administration of a medicine.

Section 7: Ingredients or components for further manufacture in Australia

Complete this section if the good is a starting material, component or article being imported for the purpose of further manufacture in Australia.

☐ The starting material is for use in the lawful manufacture of a therapeutic vaping substance or a therapeutic vaping substance accessory or another therapeutic good by a manufacturer that holds all relevant licences or approvals. Provide details of manufacturing sites in the table below. Duplicate the table as necessary.

Manufacturer name:	
TGA licence number:	
Steps in manufacture:	

☐ The article or component is for use in the lawful manufacture of a therapeutic vaping device or a therapeutic vaping device accessory by a manufacturer that holds all relevant licences or approvals. Provide details of manufacturing sites in the table below. Duplicate the table as necessary.

Manufacturer name:					
Conformity assessment evidence					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Section 8: Declaration

Section 8.1: Privacy information

General privacy information is available on the TGA website.

The TGA is collecting personal information in this form in order to contact the sponsor to discuss the notice where necessary.

Section 8.2: Declaration

☒ I declare that the information provided in this form, is, to the best of my knowledge, current and correct.

☒ I certify that the statements made in this notice are supported by information and evidence which will be provided to the TGA upon request.

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 section 137.1 of the Commonwealth Criminal Code.

Name	s22 [redacted]		
Signature	s22 [redacted]	Date	04.03.2024

Send this completed notification form to vapenotifications@health.gov.au

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA USE ONLY

This form, when completed, will be classified as **'Official'**.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

Sponsor notice – Vaping goods

Notice to import or supply in Australia therapeutic vaping goods

About this form

You must submit this notice to the TGA prior to commencing importation or supply in Australia of unregistered therapeutic vaping goods that are intended for smoking cessation or the management of nicotine dependence, or ingredients or components used in the manufacture of those goods. The notice must be submitted before the therapeutic vaping goods are imported, or, for finished goods that are manufactured in Australia, before those goods are first supplied in Australia.

A separate form must be completed for each different type of therapeutic vaping good, ingredient or component intended to be imported or supplied. For example, if you have different flavours, concentrations of nicotine, or vaping device characteristics, you will need to submit a notice for each good.

If a notice is made for therapeutic vaping goods imported for further manufacture in Australia, a separate notice will need to be made for each good prior to supply.

Once complete, send this form to vapenotifications@health.gov.au

If information in the form relating to your therapeutic vaping good is incomplete, we may not be able to provide you a notification number.

You should be aware that the TGA may publish certain information relating to your notice – such as your name and details of your good.

Guidance

Guidance is available on the TGA website to help you to complete the form.

What you'll need to complete this form

- **Your TGA client ID** – see guidance on setting up a TGA client ID.
- **Details about your therapeutic vaping good, ingredient or component** – you will need to tell us key details about the good you intend to import, or supply following domestic manufacture.
- **Manufacturer information** – we need to know the TGA client ID for each manufacturer (vaping substance), or details of the manufacturers (vaping devices).
- **Evidence of compliance to applicable standards** – you will need this for each vaping good you intend to import, or supply following domestic manufacture.

Legislation

This notice is made under paragraph (a) in column 3 of item 15, and paragraph (a) in column 3 of item 16, of Schedule 5A to the *Therapeutic Goods Regulations 1990* (the TG Regulations).

This notice is also made under paragraph (a) in the column headed "Conditions" of item 2.17, and paragraph (a) in the column headed "Conditions" of item 2.18, of Part 2 of Schedule 4 to the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations)

Section 1: Sponsor information

Company name:	Mission Distribution Victoria Pty Limited
TGA client ID:	83800
Contact email:	s2 s47 [redacted]

Section 2: Vaping good category

See guidance about the definitions used in this form. Every vaping good requires a separate notice, including where those therapeutic vaping goods are contained in a therapeutic vaping kit or therapeutic vaping pack.

Select one vaping good category for this notice:

☒ A finished good that is, or contains, a vaping substance (a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a good in a ***therapeutic vaping kit*** – see item 15 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 5 and 8 below

☐ A finished good that would be a medical device except that it is for supply as part of a therapeutic vaping pack (a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** in a ***therapeutic vaping pack*** – see item 15 of Schedule 5A to the TG Regulations).[1]

Complete sections 3, 4, 5 and 8 below

☐ A finished good that does not contain a vaping substance, and is a reusable vaping device or a component of a reusable vaping device, or a reusable cartridge, capsule or pod or other vessel (a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.17 of Part 2 of Schedule 4 to the MD Regulations).

Complete sections 3, 4, 6 and 8 below.

☐ A starting material, that is not liquid nicotine, for use in the manufacture of therapeutic vaping goods that are or contain therapeutic vaping substances (see item 16 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of vaping goods in Australia (including a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a ***therapeutic vaping kit*** – see item 16 Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of other therapeutic goods in Australia (see item 16 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ A component or article intended for use in the manufacture of an unfilled vaping device (the manufacture of a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.18 of Part 2 of Schedule 4 to the MD Regulations).

Complete sections 3, 4, 7 and 8 below.

[1] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

Section 3: Vaping good details

Complete **tables 1 and 2** if your vaping good is:

- a therapeutic vaping substance;
- liquid nicotine; or
- starting material that is an ingredient for use in the manufacture of a therapeutic vaping substance or therapeutic vaping substance accessory.

Complete **table 3** if your vaping good is:

- a therapeutic vaping device, e.g. a reusable vaporiser, battery, mouthpiece, coil or other parts of a reusable therapeutic vaping device;
- a therapeutic vaping device accessory, e.g. a unfilled cartridge, capsule or pod; or
- a component or article for use in the manufacture of a therapeutic vaping device, therapeutic vaping device accessory or therapeutic vaping substance accessory.

Complete **tables 1, 2 and 3** if your vaping good is:

- a therapeutic vaping substance accessory e.g. a filled cartridge, capsule or pod.

When completing **table 2**:

- list all ingredients (except for nicotine, details of which should be included in Table 1), including flavour, using the Australian Approved Ingredient name where possible; and
- use the approved terminology in TGA Code Tables, e.g. the Australian Approved Names of ingredients, and as specified in the published guidance.

Table 1: Details of the therapeutic vaping substance, liquid nicotine or starting material

Name of good:	RELX Pod Pro2-Tobacco Red-28.5mg/mL Nicotine
Description of good:	Therapeutic vaping substance accessory
Container type:	Prefilled Pod
Volume in mL (or weight if applicable):	1.9mL
Nicotine form (if applicable):	Nicotine ID 54852
Nicotine quantity:	28.5mg/mL

Table 2: Ingredients in the therapeutic vaping substance, liquid nicotine or starting material

Ingredient name	Quantity
s47	

Table 3: Details of the therapeutic vaping device, therapeutic vaping device accessory, therapeutic vaping substance accessory or articles or components for further manufacture

Vaping good name:	RELX Pod Pro2-Tobacco Red-28.5mg/mL Nicotine		
Device model:	RELX Pod Pro2		
Vaping good description:	Therapeutic vaping substance accessory		
Liquid capacity in mL:	1.9mL		
Device product identifier GMDN or UDI:	No GMDN or UDI is available		
Rechargeable battery:	☐ Yes	☒ No	
Battery capacity:	Prefilled pod, no battery included		
Battery composition: (e.g. Nickel-Cadmium, Nickel-Metal Hydride, Lithium Ion)	Prefilled pod, no battery included		
Battery voltage:	Prefilled pod, no battery included		
Battery wattage:	Prefilled pod, no battery included		
Type of heating element:	☒ Coil	☐ Wick	☐ Other
	If Other selected, please describe:		
Charging unit:	☐ USB	☒ Other Prefilled pod, no battery included	
Is the airflow adjustable?	☐ Yes	☒ No	
Type of control unit(s): (e.g. PCB, microcontroller, software, etc)	Prefilled pod, no control unit included		

Section 4: Manufacturer details

Provide details of all prior manufacturers of the therapeutic vaping goods, ingredients or components you are importing or supplying.

Manufacturers of the therapeutic vaping substance, therapeutic vaping substance accessory, liquid nicotine or starting material for further manufacture

Manufacturer name:	s47 [redacted]
TGA client ID:	s47 [redacted]
Steps in manufacture:	Vaping substance manufacturer/testing chemical manufacturer

Manufacturer name:	s47 [redacted]
TGA client ID:	s47 [redacted]
Steps in manufacture:	Finished product manufacturer/packaging manufacturer/testing physical manufacturer

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturers of the therapeutic vaping device, therapeutic vaping device accessory, therapeutic vaping substance accessory or articles or components for further manufacture

Manufacturer name:	s47 [redacted]				
Site street address:	s47 [redacted]				
Suburb/Town/City:	s47 [redacted]	**State/Territory:**	s47 [redacted]	**Post code:**	s47 [redacted]
Country:	s47 [redacted]				
Contact email:	s22 s47 [redacted]				

Manufacturer name:	s47 [redacted]				
Site street address:	s47 [redacted]				
Suburb/Town/City:	s47 [redacted]	**State/Territory:**	s47 [redacted]	**Post code:**	s47 [redacted]
Country:	s47 [redacted]				
Contact email:	s22 s47 [redacted]				

Manufacturer name:					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Manufacturer name:	
Site street address:	

Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Section 5: Compliance – vaping substances etc

Complete this section if the therapeutic vaping good is ready to be supplied in Australia and is, or contains, a therapeutic vaping substance, including a therapeutic vaping substance accessory, therapeutic vaping kit or is a good in a therapeutic vaping pack.[2].

The therapeutic vaping good:

☐ is only indicated for 'smoking cessation' or the 'management of nicotine dependence'.

The therapeutic vaping good:

☒ conforms with applicable standards, including *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021*. **Complete the TGO 110 compliance evidence below.**

OR

☐ is the subject of a consent from the Secretary under section 14 or 14A of the Therapeutic Goods Act for importation or supply. (Note: consent is only granted in exceptional circumstances).

TGO 110 compliance evidence

☒ Testing is performed on each batch of vaping goods.

- ☒ We hold an example of recent testing performed on a batch of vaping goods supplied or to be supplied in Australia:

Name of the facility:	s47 [redacted]
Address of the facility:	s47 [redacted]
Date tested: (dd/mm/yyyy)	14/12/2023

- ☒ Testing performed will confirm the nicotine concentration, which aligns with the label claim (where applicable).
- ☒ Testing will confirm the absence of prohibited ingredients.
- ☒ Batch-specific test results can be made available upon request.

☒ The good only contains mint, menthol, or tobacco flavour, if it contains a flavour.

☒ The labels comply with the requirements of TGO 110.

- ☒ The product label includes a list of all ingredients required by TGO 110.
- ☒ The product label includes quantity of nicotine as an active ingredient (if applicable).
- ☒ The product label includes applicable warning statements.
- ☒ Copies of labels can be provided upon request.

☒ The good has child-resistant packaging.

☒ For a vaping substance accessory, vaping device, vaping device accessory or vaping substance accessories in a kit, the good(s) conforms with the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023* or essential principles, as appropriate (see footnote 3 and 4).

---

[2] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

Section 6: Compliance – vaping devices etc

Complete this section for a good that is a therapeutic vaping device or therapeutic vaping device accessory that does not contain a therapeutic vaping substance and is not to be imported or supplied in a therapeutic vaping pack. See footnotes 3 and 4 as to which standards apply to your vaping device.

The therapeutic vaping device or therapeutic device accessory:

☐ is only intended to administer a therapeutic vaping substance that is indicated for 'smoking cessation' or the 'management of nicotine dependence'.

The therapeutic vaping device or therapeutic device accessory:

☐ conforms with the Essential Principles[3]. **Complete the *Essential Principles* checklist available on the TGA website** (https://www.tga.gov.au/resources/resource/forms/essential-principles-checklist-medical-devices). You do not need to submit the completed checklist. **Go to section 8.**

OR

☐ is a device to which the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023*[4] (MDSO) applies and conforms with the MDSO. **Complete the vaping device compliance evidence below.**

OR

☐ is the subject of consent from the Secretary under section 41MA or 41MAA of the Act for non-compliance with the essential principles. (Note: consent is only granted in exceptional circumstances, for a limited period). **Go to section 8.**

Evidence of compliance – vaping device or vaping device accessory

If your therapeutic vaping device or therapeutic vaping device accessory does not comply with the Essential Principles and the MDSO applies, select one or more types of valid evidence held that demonstrates compliance with applicable requirements:

☐ US FDA - Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS)

☐ EU - European Tobacco Products Directive - A valid notification under Article 20 of Directive 2014/40/EU

☐ UK MHRA - notification through the Tobacco and related Products Regulations (TRPR), as listed on the notified e-cigarette products publication (database) ecig (cms.mhra.gov.uk/ecig)

☐ Certificate, licence, notification, or other approval establishing compliance for supply of therapeutic goods (TGA, US FDA, EU notified body, or designated body by UK MHRA)

☐ ISO 9001 certificate

☐ ISO13485 certificate

Based on the selection above, provide the following information as evidence (the table can be duplicated if more than one type of evidence is held or there are multiple manufacturing sites holding separate certifications):

Authorising authority / certification or notification body	
Scope of authorisation / certification / notification	
Authorisation / certificate / notification number or identifier	

[3] The essential principles apply to therapeutic vaping devices and therapeutic vaping device accessories by default under the *Therapeutic Goods Act 1989*.

[4] The MDSO applies to therapeutic vaping devices and therapeutic vaping device accessories, imported or manufactured on or after 1 March 2024, that prior to 1 January 2024 were excluded from the operation of the *Therapeutic Goods Act 1989*. Vaping devices and vaping device accessories previously excluded were those not intended to be used exclusively for the administration of a medicine.

Section 7: Ingredients or components for further manufacture in Australia

Complete this section if the good is a starting material, component or article being imported for the purpose of further manufacture in Australia.

☐ The starting material is for use in the lawful manufacture of a therapeutic vaping substance or a therapeutic vaping substance accessory or another therapeutic good by a manufacturer that holds all relevant licences or approvals. Provide details of manufacturing sites in the table below. Duplicate the table as necessary.

Manufacturer name:	
TGA licence number:	
Steps in manufacture:	

☐ The article or component is for use in the lawful manufacture of a therapeutic vaping device or a therapeutic vaping device accessory by a manufacturer that holds all relevant licences or approvals. Provide details of manufacturing sites in the table below. Duplicate the table as necessary.

Manufacturer name:					
Conformity assessment evidence					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Section 8: Declaration

Section 8.1: Privacy information

General privacy information is available on the TGA website.

The TGA is collecting personal information in this form in order to contact the sponsor to discuss the notice where necessary.

Section 8.2: Declaration

☒ I declare that the information provided in this form, is, to the best of my knowledge, current and correct.

☒ I certify that the statements made in this notice are supported by information and evidence which will be provided to the TGA upon request.

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 section 137.1 of the Commonwealth Criminal Code.

Name	s22 [redacted]		
Signature	s22 [redacted]	Date	04.03.2024

Send this completed notification form to vapenotifications@health.gov.au

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA USE ONLY

This form, when completed, will be classified as **'Official'**.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

Sponsor notice – Vaping goods

Notice to import or supply in Australia therapeutic vaping goods

About this form

You must submit this notice to the TGA prior to commencing importation or supply in Australia of unregistered therapeutic vaping goods that are intended for smoking cessation or the management of nicotine dependence, or ingredients or components used in the manufacture of those goods. The notice must be submitted before the therapeutic vaping goods are imported, or, for finished goods that are manufactured in Australia, before those goods are first supplied in Australia.

A separate form must be completed for each different type of therapeutic vaping good, ingredient or component intended to be imported or supplied. For example, if you have different flavours, concentrations of nicotine, or vaping device characteristics, you will need to submit a notice for each good.

If a notice is made for therapeutic vaping goods imported for further manufacture in Australia, a separate notice will need to be made for each good prior to supply.

Once complete, send this form to vapenotifications@health.gov.au

If information in the form relating to your therapeutic vaping good is incomplete, we may not be able to provide you a notification number.

You should be aware that the TGA may publish certain information relating to your notice – such as your name and details of your good.

Guidance

Guidance is available on the TGA website to help you to complete the form.

What you'll need to complete this form

- **Your TGA client ID** – see guidance on setting up a TGA client ID.
- **Details about your therapeutic vaping good, ingredient or component** – you will need to tell us key details about the good you intend to import, or supply following domestic manufacture.
- **Manufacturer information** – we need to know the TGA client ID for each manufacturer (vaping substance), or details of the manufacturers (vaping devices).
- **Evidence of compliance to applicable standards** – you will need this for each vaping good you intend to import, or supply following domestic manufacture.

Legislation

This notice is made under paragraph (a) in column 3 of item 15, and paragraph (a) in column 3 of item 16, of Schedule 5A to the *Therapeutic Goods Regulations 1990* (the TG Regulations).

This notice is also made under paragraph (a) in the column headed "Conditions" of item 2.17, and paragraph (a) in the column headed "Conditions" of item 2.18, of Part 2 of Schedule 4 to the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations)

Section 1: Sponsor information

Company name:	Mission Distribution Victoria Pty Limited
TGA client ID:	83800
Contact email:	s2 s47 [redacted]

Section 2: Vaping good category

See guidance about the definitions used in this form. Every vaping good requires a separate notice, including where those therapeutic vaping goods are contained in a therapeutic vaping kit or therapeutic vaping pack.

Select one vaping good category for this notice:

☒ A finished good that is, or contains, a vaping substance (a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a good in a ***therapeutic vaping kit*** – see item 15 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 5 and 8 below

☐ A finished good that would be a medical device except that it is for supply as part of a therapeutic vaping pack (a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** in a ***therapeutic vaping pack*** – see item 15 of Schedule 5A to the TG Regulations).[1]

Complete sections 3, 4, 5 and 8 below

☐ A finished good that does not contain a vaping substance, and is a reusable vaping device or a component of a reusable vaping device, or a reusable cartridge, capsule or pod or other vessel (a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.17 of Part 2 of Schedule 4 to the MD Regulations).

Complete sections 3, 4, 6 and 8 below.

☐ A starting material, that is not liquid nicotine, for use in the manufacture of therapeutic vaping goods that are or contain therapeutic vaping substances (see item 16 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of vaping goods in Australia (including a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a ***therapeutic vaping kit*** – see item 16 Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of other therapeutic goods in Australia (see item 16 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ A component or article intended for use in the manufacture of an unfilled vaping device (the manufacture of a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.18 of Part 2 of Schedule 4 to the MD Regulations).

Complete sections 3, 4, 7 and 8 below.

[1] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

Section 3: Vaping good details

Complete **tables 1 and 2** if your vaping good is:

- a therapeutic vaping substance;
- liquid nicotine; or
- starting material that is an ingredient for use in the manufacture of a therapeutic vaping substance or therapeutic vaping substance accessory.

Complete **table 3** if your vaping good is:

- a therapeutic vaping device, e.g. a reusable vaporiser, battery, mouthpiece, coil or other parts of a reusable therapeutic vaping device;
- a therapeutic vaping device accessory, e.g. a unfilled cartridge, capsule or pod; or
- a component or article for use in the manufacture of a therapeutic vaping device, therapeutic vaping device accessory or therapeutic vaping substance accessory.

Complete **tables 1, 2 and 3** if your vaping good is:

- a therapeutic vaping substance accessory e.g. a filled cartridge, capsule or pod.

When completing **table 2**:

- list all ingredients (except for nicotine, details of which should be included in Table 1), including flavour, using the Australian Approved Ingredient name where possible; and
- use the approved terminology in TGA Code Tables, e.g. the Australian Approved Names of ingredients, and as specified in the published guidance.

Table 1: Details of the therapeutic vaping substance, liquid nicotine or starting material

Name of good:	RELX Pod Pro2-Menthol-28.5mg/mL Nicotine
Description of good:	Therapeutic vaping substance accessory
Container type:	Prefilled Pod
Volume in mL (or weight if applicable):	1.9mL
Nicotine form (if applicable):	Nicotine ID 54852
Nicotine quantity:	28.5mg/mL

Table 2: Ingredients in the therapeutic vaping substance, liquid nicotine or starting material

Ingredient name	Quantity
s47	

Table 3: Details of the therapeutic vaping device, therapeutic vaping device accessory, therapeutic vaping substance accessory or articles or components for further manufacture

Vaping good name:	RELX Pod Pro2-Menthol-28.5mg/mL Nicotine		
Device model:	RELX Pod Pro2		
Vaping good description:	Therapeutic vaping substance accessory		
Liquid capacity in mL:	1.9mL		
Device product identifier GMDN or UDI:	No GMDN or UDI is available		
Rechargeable battery:	☐ Yes	☒ No	
Battery capacity:	Prefilled pod, no battery included		
Battery composition: (e.g. Nickel-Cadmium, Nickel-Metal Hydride, Lithium Ion)	Prefilled pod, no battery included		
Battery voltage:	Prefilled pod, no battery included		
Battery wattage:	Prefilled pod, no battery included		
Type of heating element:	☒ Coil	☐ Wick	☐ Other
	If Other selected, please describe:		
Charging unit:	☐ USB	☒ Other Prefilled pod, no battery included	
Is the airflow adjustable?	☐ Yes	☒ No	
Type of control unit(s): (e.g. PCB, microcontroller, software, etc)	Prefilled pod, no control unit included		

Section 4: Manufacturer details

Provide details of all prior manufacturers of the therapeutic vaping goods, ingredients or components you are importing or supplying.

Manufacturers of the therapeutic vaping substance, therapeutic vaping substance accessory, liquid nicotine or starting material for further manufacture

Manufacturer name:	s47 [redacted]
TGA client ID:	s47 [redacted]
Steps in manufacture:	Vaping substance manufacturer/testing chemical manufacturer

Manufacturer name:	s47 [redacted]
TGA client ID:	s47 [redacted]
Steps in manufacture:	Finished product manufacturer/packaging manufacturer/testing physical manufacturer

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturers of the therapeutic vaping device, therapeutic vaping device accessory, therapeutic vaping substance accessory or articles or components for further manufacture

Manufacturer name:	s47 [redacted]				
Site street address:	s47 [redacted]				
Suburb/Town/City:	s47 [redacted]	**State/Territory:**	s47 [redacted]	**Post code:**	s47 [redacted]
Country:	s47 [redacted]				
Contact email:	s22 s47 [redacted]				

Manufacturer name:	s47 [redacted]				
Site street address:	s47 [redacted]				
Suburb/Town/City:	s47 [redacted]	**State/Territory:**	s47 [redacted]	**Post code:**	s47 [redacted]
Country:	s47 [redacted]				
Contact email:	s22 s47 [redacted]				

Manufacturer name:					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Manufacturer name:	
Site street address:	

Suburb/Town/City:		State/Territory:		Post code:	
Country:					
Contact email:					

Section 5: Compliance – vaping substances etc

Complete this section if the therapeutic vaping good is ready to be supplied in Australia and is, or contains, a therapeutic vaping substance, including a therapeutic vaping substance accessory, therapeutic vaping kit or is a good in a therapeutic vaping pack.[2].

The therapeutic vaping good:

☐ is only indicated for 'smoking cessation' or the 'management of nicotine dependence'.

The therapeutic vaping good:

☒ conforms with applicable standards, including *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021*. **Complete the TGO 110 compliance evidence below.**

OR

☐ is the subject of a consent from the Secretary under section 14 or 14A of the Therapeutic Goods Act for importation or supply. (Note: consent is only granted in exceptional circumstances).

TGO 110 compliance evidence

☒ Testing is performed on each batch of vaping goods.

- ☒ We hold an example of recent testing performed on a batch of vaping goods supplied or to be supplied in Australia:

Name of the facility:	s47 [redacted]
Address of the facility:	s47 [redacted]
Date tested: (dd/mm/yyyy)	16/12/2023

- ☒ Testing performed will confirm the nicotine concentration, which aligns with the label claim (where applicable).
- ☒ Testing will confirm the absence of prohibited ingredients.
- ☒ Batch-specific test results can be made available upon request.

☒ The good only contains mint, menthol, or tobacco flavour, if it contains a flavour.

☒ The labels comply with the requirements of TGO 110.

- ☒ The product label includes a list of all ingredients required by TGO 110.
- ☒ The product label includes quantity of nicotine as an active ingredient (if applicable).
- ☒ The product label includes applicable warning statements.
- ☒ Copies of labels can be provided upon request.

☒ The good has child-resistant packaging.

☒ For a vaping substance accessory, vaping device, vaping device accessory or vaping substance accessories in a kit, the good(s) conforms with the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023* or essential principles, as appropriate (see footnote 3 and 4).

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[2] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

Section 6: Compliance – vaping devices etc

Complete this section for a good that is a therapeutic vaping device or therapeutic vaping device accessory that does not contain a therapeutic vaping substance and is not to be imported or supplied in a therapeutic vaping pack. See footnotes 3 and 4 as to which standards apply to your vaping device.

The therapeutic vaping device or therapeutic device accessory:

☐ is only intended to administer a therapeutic vaping substance that is indicated for 'smoking cessation' or the 'management of nicotine dependence'.

The therapeutic vaping device or therapeutic device accessory:

☐ conforms with the Essential Principles[3]. **Complete the *Essential Principles* checklist available on the TGA website** (https://www.tga.gov.au/resources/resource/forms/essential-principles-checklist-medical-devices). You do not need to submit the completed checklist. **Go to section 8.**

OR

☐ is a device to which the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023*[4] (MDSO) applies and conforms with the MDSO. **Complete the vaping device compliance evidence below.**

OR

☐ is the subject of consent from the Secretary under section 41MA or 41MAA of the Act for non-compliance with the essential principles. (Note: consent is only granted in exceptional circumstances, for a limited period). **Go to section 8.**

Evidence of compliance – vaping device or vaping device accessory

If your therapeutic vaping device or therapeutic vaping device accessory does not comply with the Essential Principles and the MDSO applies, select one or more types of valid evidence held that demonstrates compliance with applicable requirements:

☐ US FDA - Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS)

☐ EU - European Tobacco Products Directive - A valid notification under Article 20 of Directive 2014/40/EU

☐ UK MHRA - notification through the Tobacco and related Products Regulations (TRPR), as listed on the notified e-cigarette products publication (database) ecig (cms.mhra.gov.uk/ecig)

☐ Certificate, licence, notification, or other approval establishing compliance for supply of therapeutic goods (TGA, US FDA, EU notified body, or designated body by UK MHRA)

☐ ISO 9001 certificate

☐ ISO13485 certificate

Based on the selection above, provide the following information as evidence (the table can be duplicated if more than one type of evidence is held or there are multiple manufacturing sites holding separate certifications):

Authorising authority / certification or notification body	
Scope of authorisation / certification / notification	
Authorisation / certificate / notification number or identifier	

[3] The essential principles apply to therapeutic vaping devices and therapeutic vaping device accessories by default under the *Therapeutic Goods Act 1989*.

[4] The MDSO applies to therapeutic vaping devices and therapeutic vaping device accessories, imported or manufactured on or after 1 March 2024, that prior to 1 January 2024 were excluded from the operation of the *Therapeutic Goods Act 1989*. Vaping devices and vaping device accessories previously excluded were those not intended to be used exclusively for the administration of a medicine.

Section 7: Ingredients or components for further manufacture in Australia

Complete this section if the good is a starting material, component or article being imported for the purpose of further manufacture in Australia.

☐ The starting material is for use in the lawful manufacture of a therapeutic vaping substance or a therapeutic vaping substance accessory or another therapeutic good by a manufacturer that holds all relevant licences or approvals. Provide details of manufacturing sites in the table below. Duplicate the table as necessary.

Manufacturer name:	
TGA licence number:	
Steps in manufacture:	

☐ The article or component is for use in the lawful manufacture of a therapeutic vaping device or a therapeutic vaping device accessory by a manufacturer that holds all relevant licences or approvals. Provide details of manufacturing sites in the table below. Duplicate the table as necessary.

Manufacturer name:					
Conformity assessment evidence					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Section 8: Declaration

Section 8.1: Privacy information

General privacy information is available on the TGA website.

The TGA is collecting personal information in this form in order to contact the sponsor to discuss the notice where necessary.

Section 8.2: Declaration

☒ I declare that the information provided in this form, is, to the best of my knowledge, current and correct.

☒ I certify that the statements made in this notice are supported by information and evidence which will be provided to the TGA upon request.

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 section 137.1 of the Commonwealth Criminal Code.

Name	s22 [redacted]		
Signature	s22 [redacted]	Date	04.03.2024

Send this completed notification form to vapenotifications@health.gov.au

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA USE ONLY

This form, when completed, will be classified as **'Official'**.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

Sponsor notice – Vaping goods

Notice to import or supply in Australia therapeutic vaping goods

About this form

You must submit this notice to the TGA prior to commencing importation or supply in Australia of unregistered therapeutic vaping goods that are intended for smoking cessation or the management of nicotine dependence, or ingredients or components used in the manufacture of those goods. The notice must be submitted before the therapeutic vaping goods are imported, or, for finished goods that are manufactured in Australia, before those goods are first supplied in Australia.

A separate form must be completed for each different type of therapeutic vaping good, ingredient or component intended to be imported or supplied. For example, if you have different flavours, concentrations of nicotine, or vaping device characteristics, you will need to submit a notice for each good.

If a notice is made for therapeutic vaping goods imported for further manufacture in Australia, a separate notice will need to be made for each good prior to supply.

Once complete, send this form to vapenotifications@health.gov.au

If information in the form relating to your therapeutic vaping good is incomplete, we may not be able to provide you a notification number.

You should be aware that the TGA may publish certain information relating to your notice – such as your name and details of your good.

Guidance

Guidance is available on the TGA website to help you to complete the form.

What you'll need to complete this form

- **Your TGA client ID** – see guidance on setting up a TGA client ID.
- **Details about your therapeutic vaping good, ingredient or component** – you will need to tell us key details about the good you intend to import, or supply following domestic manufacture.
- **Manufacturer information** – we need to know the TGA client ID for each manufacturer (vaping substance), or details of the manufacturers (vaping devices).
- **Evidence of compliance to applicable standards** – you will need this for each vaping good you intend to import, or supply following domestic manufacture.

Legislation

This notice is made under paragraph (a) in column 3 of item 15, and paragraph (a) in column 3 of item 16, of Schedule 5A to the *Therapeutic Goods Regulations 1990* (the TG Regulations).

This notice is also made under paragraph (a) in the column headed "Conditions" of item 2.17, and paragraph (a) in the column headed "Conditions" of item 2.18, of Part 2 of Schedule 4 to the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations)

Section 1: Sponsor information

Company name:	Mission Distribution Victoria Pty Limited
TGA client ID:	83800
Contact email:	s2 s47 [redacted]

Section 2: Vaping good category

See guidance about the definitions used in this form. Every vaping good requires a separate notice, including where those therapeutic vaping goods are contained in a therapeutic vaping kit or therapeutic vaping pack.

Select one vaping good category for this notice:

☒ A finished good that is, or contains, a vaping substance (a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a good in a ***therapeutic vaping kit*** – see item 15 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 5 and 8 below

☐ A finished good that would be a medical device except that it is for supply as part of a therapeutic vaping pack (a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** in a ***therapeutic vaping pack*** – see item 15 of Schedule 5A to the TG Regulations).[1]

Complete sections 3, 4, 5 and 8 below

☐ A finished good that does not contain a vaping substance, and is a reusable vaping device or a component of a reusable vaping device, or a reusable cartridge, capsule or pod or other vessel (a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.17 of Part 2 of Schedule 4 to the MD Regulations).

Complete sections 3, 4, 6 and 8 below.

☐ A starting material, that is not liquid nicotine, for use in the manufacture of therapeutic vaping goods that are or contain therapeutic vaping substances (see item 16 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of vaping goods in Australia (including a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a ***therapeutic vaping kit*** – see item 16 Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of other therapeutic goods in Australia (see item 16 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ A component or article intended for use in the manufacture of an unfilled vaping device (the manufacture of a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.18 of Part 2 of Schedule 4 to the MD Regulations).

Complete sections 3, 4, 7 and 8 below.

[1] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

Section 3: Vaping good details

Complete **tables 1 and 2** if your vaping good is:

- a therapeutic vaping substance;
- liquid nicotine; or
- starting material that is an ingredient for use in the manufacture of a therapeutic vaping substance or therapeutic vaping substance accessory.

Complete **table 3** if your vaping good is:

- a therapeutic vaping device, e.g. a reusable vaporiser, battery, mouthpiece, coil or other parts of a reusable therapeutic vaping device;
- a therapeutic vaping device accessory, e.g. a unfilled cartridge, capsule or pod; or
- a component or article for use in the manufacture of a therapeutic vaping device, therapeutic vaping device accessory or therapeutic vaping substance accessory.

Complete **tables 1, 2 and 3** if your vaping good is:

- a therapeutic vaping substance accessory e.g. a filled cartridge, capsule or pod.

When completing **table 2**:

- list all ingredients (except for nicotine, details of which should be included in Table 1), including flavour, using the Australian Approved Ingredient name where possible; and
- use the approved terminology in TGA Code Tables, e.g. the Australian Approved Names of ingredients, and as specified in the published guidance.

Table 1: Details of the therapeutic vaping substance, liquid nicotine or starting material

Name of good:	RELX Pod Pro2-Tobacco Gold-28.5mg/mL Nicotine
Description of good:	Therapeutic vaping substance accessory
Container type:	Prefilled Pod
Volume in mL (or weight if applicable):	1.9mL
Nicotine form (if applicable):	Nicotine ID 54852
Nicotine quantity:	28.5mg/mL

Table 2: Ingredients in the therapeutic vaping substance, liquid nicotine or starting material

Ingredient name	Quantity
s47	

Table 3: Details of the therapeutic vaping device, therapeutic vaping device accessory, therapeutic vaping substance accessory or articles or components for further manufacture

Vaping good name:	RELX Pod Pro2-Tobacco Gold-28.5mg/mL Nicotine		
Device model:	RELX Pod Pro2		
Vaping good description:	Therapeutic vaping substance accessory		
Liquid capacity in mL:	1.9mL		
Device product identifier GMDN or UDI:	No GMDN or UDI is available		
Rechargeable battery:	☐ Yes	☒ No	
Battery capacity:	Prefilled pod, no battery included		
Battery composition: (e.g. Nickel-Cadmium, Nickel-Metal Hydride, Lithium Ion)	Prefilled pod, no battery included		
Battery voltage:	Prefilled pod, no battery included		
Battery wattage:	Prefilled pod, no battery included		
Type of heating element:	☒ Coil	☐ Wick	☐ Other
	If Other selected, please describe:		
Charging unit:	☐ USB	☒ Other Prefilled pod, no battery included	
Is the airflow adjustable?	☐ Yes	☒ No	
Type of control unit(s): (e.g. PCB, microcontroller, software, etc)	Prefilled pod, no control unit included		

Section 4: Manufacturer details

Provide details of all prior manufacturers of the therapeutic vaping goods, ingredients or components you are importing or supplying.

Manufacturers of the therapeutic vaping substance, therapeutic vaping substance accessory, liquid nicotine or starting material for further manufacture

Manufacturer name:	s47 [redacted]
TGA client ID:	s47 [redacted]
Steps in manufacture:	Vaping substance manufacturer/testing chemical manufacturer

Manufacturer name:	s47 [redacted]
TGA client ID:	s47 [redacted]
Steps in manufacture:	Finished product manufacturer/packaging manufacturer/testing physical manufacturer

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturers of the therapeutic vaping device, therapeutic vaping device accessory, therapeutic vaping substance accessory or articles or components for further manufacture

Manufacturer name:	s47 [redacted]				
Site street address:	s47 [redacted]				
Suburb/Town/City:	s47 [redacted]	**State/Territory:**	s47 [redacted]	**Post code:**	s47 [redacted]
Country:	s47 [redacted]				
Contact email:	s22 s47 [redacted]				

Manufacturer name:	s47 [redacted]				
Site street address:	s47 [redacted]				
Suburb/Town/City:	s47 [redacted]	**State/Territory:**	s47 [redacted]	**Post code:**	s47 [redacted]
Country:	s47 [redacted]				
Contact email:	s22 s47 [redacted]				

Manufacturer name:					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Manufacturer name:	
Site street address:	

Suburb/Town/City:		State/Territory:		Post code:	
Country:					
Contact email:					

Section 5: Compliance – vaping substances etc

Complete this section if the therapeutic vaping good is ready to be supplied in Australia and is, or contains, a therapeutic vaping substance, including a therapeutic vaping substance accessory, therapeutic vaping kit or is a good in a therapeutic vaping pack.[2].

The therapeutic vaping good:

☐ is only indicated for 'smoking cessation' or the 'management of nicotine dependence'.

The therapeutic vaping good:

☒ conforms with applicable standards, including *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021*. **Complete the TGO 110 compliance evidence below.**

OR

☐ is the subject of a consent from the Secretary under section 14 or 14A of the Therapeutic Goods Act for importation or supply. (Note: consent is only granted in exceptional circumstances).

TGO 110 compliance evidence

☒ Testing is performed on each batch of vaping goods.

- ☒ We hold an example of recent testing performed on a batch of vaping goods supplied or to be supplied in Australia:

Name of the facility:	s47 [redacted]
Address of the facility:	s47 [redacted]
Date tested: (dd/mm/yyyy)	26/01/2024

- ☒ Testing performed will confirm the nicotine concentration, which aligns with the label claim (where applicable).
- ☒ Testing will confirm the absence of prohibited ingredients.
- ☒ Batch-specific test results can be made available upon request.

☒ The good only contains mint, menthol, or tobacco flavour, if it contains a flavour.

☒ The labels comply with the requirements of TGO 110.

- ☒ The product label includes a list of all ingredients required by TGO 110.
- ☒ The product label includes quantity of nicotine as an active ingredient (if applicable).
- ☒ The product label includes applicable warning statements.
- ☒ Copies of labels can be provided upon request.

☒ The good has child-resistant packaging.

☒ For a vaping substance accessory, vaping device, vaping device accessory or vaping substance accessories in a kit, the good(s) conforms with the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023* or essential principles, as appropriate (see footnote 3 and 4).

---

[2] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

Section 6: Compliance – vaping devices etc

Complete this section for a good that is a therapeutic vaping device or therapeutic vaping device accessory that does not contain a therapeutic vaping substance and is not to be imported or supplied in a therapeutic vaping pack. See footnotes 3 and 4 as to which standards apply to your vaping device.

The therapeutic vaping device or therapeutic device accessory:

☐ is only intended to administer a therapeutic vaping substance that is indicated for 'smoking cessation' or the 'management of nicotine dependence'.

The therapeutic vaping device or therapeutic device accessory:

☐ conforms with the Essential Principles[3]. **Complete the *Essential Principles* checklist available on the TGA website** (https://www.tga.gov.au/resources/resource/forms/essential-principles-checklist-medical-devices). You do not need to submit the completed checklist. **Go to section 8.**

OR

☐ is a device to which the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023*[4] (MDSO) applies and conforms with the MDSO. **Complete the vaping device compliance evidence below.**

OR

☐ is the subject of consent from the Secretary under section 41MA or 41MAA of the Act for non-compliance with the essential principles. (Note: consent is only granted in exceptional circumstances, for a limited period). **Go to section 8.**

Evidence of compliance – vaping device or vaping device accessory

If your therapeutic vaping device or therapeutic vaping device accessory does not comply with the Essential Principles and the MDSO applies, select one or more types of valid evidence held that demonstrates compliance with applicable requirements:

☐ US FDA - Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS)

☐ EU - European Tobacco Products Directive - A valid notification under Article 20 of Directive 2014/40/EU

☐ UK MHRA - notification through the Tobacco and related Products Regulations (TRPR), as listed on the notified e-cigarette products publication (database) ecig (cms.mhra.gov.uk/ecig)

☐ Certificate, licence, notification, or other approval establishing compliance for supply of therapeutic goods (TGA, US FDA, EU notified body, or designated body by UK MHRA)

☐ ISO 9001 certificate

☐ ISO13485 certificate

Based on the selection above, provide the following information as evidence (the table can be duplicated if more than one type of evidence is held or there are multiple manufacturing sites holding separate certifications):

Authorising authority / certification or notification body	
Scope of authorisation / certification / notification	
Authorisation / certificate / notification number or identifier	

[3] The essential principles apply to therapeutic vaping devices and therapeutic vaping device accessories by default under the *Therapeutic Goods Act 1989*.

[4] The MDSO applies to therapeutic vaping devices and therapeutic vaping device accessories, imported or manufactured on or after 1 March 2024, that prior to 1 January 2024 were excluded from the operation of the *Therapeutic Goods Act 1989*. Vaping devices and vaping device accessories previously excluded were those not intended to be used exclusively for the administration of a medicine.

Section 7: Ingredients or components for further manufacture in Australia

Complete this section if the good is a starting material, component or article being imported for the purpose of further manufacture in Australia.

☐ The starting material is for use in the lawful manufacture of a therapeutic vaping substance or a therapeutic vaping substance accessory or another therapeutic good by a manufacturer that holds all relevant licences or approvals. Provide details of manufacturing sites in the table below. Duplicate the table as necessary.

Manufacturer name:	
TGA licence number:	
Steps in manufacture:	

☐ The article or component is for use in the lawful manufacture of a therapeutic vaping device or a therapeutic vaping device accessory by a manufacturer that holds all relevant licences or approvals. Provide details of manufacturing sites in the table below. Duplicate the table as necessary.

Manufacturer name:					
Conformity assessment evidence					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Section 8: Declaration

Section 8.1: Privacy information

General privacy information is available on the TGA website.

The TGA is collecting personal information in this form in order to contact the sponsor to discuss the notice where necessary.

Section 8.2: Declaration

☒ I declare that the information provided in this form, is, to the best of my knowledge, current and correct.

☒ I certify that the statements made in this notice are supported by information and evidence which will be provided to the TGA upon request.

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 section 137.1 of the Commonwealth Criminal Code.

Name	s22 [redacted]		
Signature	s22 [redacted]	Date	04.03.2024

Send this completed notification form to vapenotifications@health.gov.au

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA USE ONLY

This form, when completed, will be classified as **'Official'**.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

Sponsor notice – Vaping goods

Notice to import or supply in Australia therapeutic vaping goods

About this form

You must submit this notice to the TGA prior to commencing importation or supply in Australia of unregistered therapeutic vaping goods that are intended for smoking cessation or the management of nicotine dependence, or ingredients or components used in the manufacture of those goods. The notice must be submitted before the therapeutic vaping goods are imported, or, for finished goods that are manufactured in Australia, before those goods are first supplied in Australia.

A separate form must be completed for each different type of therapeutic vaping good, ingredient or component intended to be imported or supplied. For example, if you have different flavours, concentrations of nicotine, or vaping device characteristics, you will need to submit a notice for each good.

If a notice is made for therapeutic vaping goods imported for further manufacture in Australia, a separate notice will need to be made for each good prior to supply.

Once complete, send this form to vapenotifications@health.gov.au

If information in the form relating to your therapeutic vaping good is incomplete, we may not be able to provide you a notification number.

You should be aware that the TGA may publish certain information relating to your notice – such as your name and details of your good.

Guidance

Guidance is available on the TGA website to help you to complete the form.

What you'll need to complete this form

- **Your TGA client ID** – see guidance on setting up a TGA client ID.
- **Details about your therapeutic vaping good, ingredient or component** – you will need to tell us key details about the good you intend to import, or supply following domestic manufacture.
- **Manufacturer information** – we need to know the TGA client ID for each manufacturer (vaping substance), or details of the manufacturers (vaping devices).
- **Evidence of compliance to applicable standards** – you will need this for each vaping good you intend to import, or supply following domestic manufacture.

Legislation

This notice is made under paragraph (a) in column 3 of item 15, and paragraph (a) in column 3 of item 16, of Schedule 5A to the *Therapeutic Goods Regulations 1990* (the TG Regulations).

This notice is also made under paragraph (a) in the column headed "Conditions" of item 2.17, and paragraph (a) in the column headed "Conditions" of item 2.18, of Part 2 of Schedule 4 to the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations)

Section 1: Sponsor information

Company name:	Mission Distribution Victoria Pty Limited
TGA client ID:	83800
Contact email:	s2 s47 [redacted]

Section 2: Vaping good category

See guidance about the definitions used in this form. Every vaping good requires a separate notice, including where those therapeutic vaping goods are contained in a therapeutic vaping kit or therapeutic vaping pack.

Select one vaping good category for this notice:

☒ A finished good that is, or contains, a vaping substance (a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a good in a ***therapeutic vaping kit*** – see item 15 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 5 and 8 below

☐ A finished good that would be a medical device except that it is for supply as part of a therapeutic vaping pack (a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** in a ***therapeutic vaping pack*** – see item 15 of Schedule 5A to the TG Regulations).[1]

Complete sections 3, 4, 5 and 8 below

☐ A finished good that does not contain a vaping substance, and is a reusable vaping device or a component of a reusable vaping device, or a reusable cartridge, capsule or pod or other vessel (a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.17 of Part 2 of Schedule 4 to the MD Regulations).

Complete sections 3, 4, 6 and 8 below.

☐ A starting material, that is not liquid nicotine, for use in the manufacture of therapeutic vaping goods that are or contain therapeutic vaping substances (see item 16 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of vaping goods in Australia (including a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a ***therapeutic vaping kit*** – see item 16 Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of other therapeutic goods in Australia (see item 16 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ A component or article intended for use in the manufacture of an unfilled vaping device (the manufacture of a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.18 of Part 2 of Schedule 4 to the MD Regulations).

Complete sections 3, 4, 7 and 8 below.

[1] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

Section 3: Vaping good details

Complete **tables 1 and 2** if your vaping good is:

- a therapeutic vaping substance;
- liquid nicotine; or
- starting material that is an ingredient for use in the manufacture of a therapeutic vaping substance or therapeutic vaping substance accessory.

Complete **table 3** if your vaping good is:

- a therapeutic vaping device, e.g. a reusable vaporiser, battery, mouthpiece, coil or other parts of a reusable therapeutic vaping device;
- a therapeutic vaping device accessory, e.g. a unfilled cartridge, capsule or pod; or
- a component or article for use in the manufacture of a therapeutic vaping device, therapeutic vaping device accessory or therapeutic vaping substance accessory.

Complete **tables 1, 2 and 3** if your vaping good is:

- a therapeutic vaping substance accessory e.g. a filled cartridge, capsule or pod.

When completing **table 2**:

- list all ingredients (except for nicotine, details of which should be included in Table 1), including flavour, using the Australian Approved Ingredient name where possible; and
- use the approved terminology in TGA Code Tables, e.g. the Australian Approved Names of ingredients, and as specified in the published guidance.

Table 1: Details of the therapeutic vaping substance, liquid nicotine or starting material

Name of good:	RELX Pod Pro2-Tobacco Red-28.5mg/mL Nicotine
Description of good:	Therapeutic vaping substance accessory
Container type:	Prefilled Pod
Volume in mL (or weight if applicable):	1.9mL
Nicotine form (if applicable):	Nicotine ID 54852
Nicotine quantity:	28.5mg/mL

Table 2: Ingredients in the therapeutic vaping substance, liquid nicotine or starting material

Ingredient name	Quantity
s47 [redacted]	[redacted]

Table 3: Details of the therapeutic vaping device, therapeutic vaping device accessory, therapeutic vaping substance accessory or articles or components for further manufacture

Vaping good name:	RELX Pod Pro2-Tobacco Red-28.5mg/mL Nicotine		
Device model:	RELX Pod Pro2		
Vaping good description:	Therapeutic vaping substance accessory		
Liquid capacity in mL:	1.9mL		
Device product identifier GMDN or UDI:	No GMDN or UDI is available		
Rechargeable battery:	☐ Yes	☒ No	
Battery capacity:	Prefilled pod, no battery included		
Battery composition: (e.g. Nickel-Cadmium, Nickel-Metal Hydride, Lithium Ion)	Prefilled pod, no battery included		
Battery voltage:	Prefilled pod, no battery included		
Battery wattage:	Prefilled pod, no battery included		
Type of heating element:	☒ Coil	☐ Wick	☐ Other
	If Other selected, please describe:		
Charging unit:	☐ USB	☒ Other Prefilled pod, no battery included	
Is the airflow adjustable?	☐ Yes	☒ No	
Type of control unit(s): (e.g. PCB, microcontroller, software, etc)	Prefilled pod, no control unit included		

Section 4: Manufacturer details

Provide details of all prior manufacturers of the therapeutic vaping goods, ingredients or components you are importing or supplying.

Manufacturers of the therapeutic vaping substance, therapeutic vaping substance accessory, liquid nicotine or starting material for further manufacture

Manufacturer name:	s47 [redacted]
TGA client ID:	s47 [redacted]
Steps in manufacture:	Vaping substance manufacturer/testing chemical manufacturer

Manufacturer name:	s47 [redacted]
TGA client ID:	s47 [redacted]
Steps in manufacture:	Finished product manufacturer/packaging manufacturer/testing physical manufacturer

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturers of the therapeutic vaping device, therapeutic vaping device accessory, therapeutic vaping substance accessory or articles or components for further manufacture

Manufacturer name:	s47 [redacted]				
Site street address:	s47 [redacted]				
Suburb/Town/City:	s47 [redacted]	**State/Territory:**	s47 [redacted]	**Post code:**	s47 [redacted]
Country:	s47 [redacted]				
Contact email:	s22 s47 [redacted]				

Manufacturer name:	s47 [redacted]				
Site street address:	s47 [redacted]				
Suburb/Town/City:	s47 [redacted]	**State/Territory:**	s47 [redacted]	**Post code:**	s47 [redacted]
Country:	s47 [redacted]				
Contact email:	s22 s47 [redacted]				

Manufacturer name:					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Manufacturer name:	
Site street address:	

Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Section 5: Compliance – vaping substances etc

Complete this section if the therapeutic vaping good is ready to be supplied in Australia and is, or contains, a therapeutic vaping substance, including a therapeutic vaping substance accessory, therapeutic vaping kit or is a good in a therapeutic vaping pack.[2].

The therapeutic vaping good:

☐ is only indicated for 'smoking cessation' or the 'management of nicotine dependence'.

The therapeutic vaping good:

☒ conforms with applicable standards, including *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021*. **Complete the TGO 110 compliance evidence below.**

OR

☐ is the subject of a consent from the Secretary under section 14 or 14A of the Therapeutic Goods Act for importation or supply. (Note: consent is only granted in exceptional circumstances).

TGO 110 compliance evidence

☒ Testing is performed on each batch of vaping goods.

- ☒ We hold an example of recent testing performed on a batch of vaping goods supplied or to be supplied in Australia:

Name of the facility:	s47 [redacted]
Address of the facility:	s47 [redacted]
Date tested: (dd/mm/yyyy)	14/12/2023

- ☒ Testing performed will confirm the nicotine concentration, which aligns with the label claim (where applicable).
- ☒ Testing will confirm the absence of prohibited ingredients.
- ☒ Batch-specific test results can be made available upon request.

☒ The good only contains mint, menthol, or tobacco flavour, if it contains a flavour.

☒ The labels comply with the requirements of TGO 110.

- ☒ The product label includes a list of all ingredients required by TGO 110.
- ☒ The product label includes quantity of nicotine as an active ingredient (if applicable).
- ☒ The product label includes applicable warning statements.
- ☒ Copies of labels can be provided upon request.

☒ The good has child-resistant packaging.

☒ For a vaping substance accessory, vaping device, vaping device accessory or vaping substance accessories in a kit, the good(s) conforms with the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023* or essential principles, as appropriate (see footnote 3 and 4).

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[2] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

Section 6: Compliance – vaping devices etc

Complete this section for a good that is a therapeutic vaping device or therapeutic vaping device accessory that does not contain a therapeutic vaping substance and is not to be imported or supplied in a therapeutic vaping pack. See footnotes 3 and 4 as to which standards apply to your vaping device.

The therapeutic vaping device or therapeutic device accessory:

☐ is only intended to administer a therapeutic vaping substance that is indicated for 'smoking cessation' or the 'management of nicotine dependence'.

The therapeutic vaping device or therapeutic device accessory:

☐ conforms with the Essential Principles[3]. **Complete the *Essential Principles* checklist available on the TGA website** (https://www.tga.gov.au/resources/resource/forms/essential-principles-checklist-medical-devices). You do not need to submit the completed checklist. **Go to section 8.**

OR

☐ is a device to which the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023*[4] (MDSO) applies and conforms with the MDSO. **Complete the vaping device compliance evidence below.**

OR

☐ is the subject of consent from the Secretary under section 41MA or 41MAA of the Act for non-compliance with the essential principles. (Note: consent is only granted in exceptional circumstances, for a limited period). **Go to section 8.**

Evidence of compliance – vaping device or vaping device accessory

If your therapeutic vaping device or therapeutic vaping device accessory does not comply with the Essential Principles and the MDSO applies, select one or more types of valid evidence held that demonstrates compliance with applicable requirements:

☐ US FDA - Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS)

☐ EU - European Tobacco Products Directive - A valid notification under Article 20 of Directive 2014/40/EU

☐ UK MHRA - notification through the Tobacco and related Products Regulations (TRPR), as listed on the notified e-cigarette products publication (database) ecig (cms.mhra.gov.uk/ecig)

☐ Certificate, licence, notification, or other approval establishing compliance for supply of therapeutic goods (TGA, US FDA, EU notified body, or designated body by UK MHRA)

☐ ISO 9001 certificate

☐ ISO13485 certificate

Based on the selection above, provide the following information as evidence (the table can be duplicated if more than one type of evidence is held or there are multiple manufacturing sites holding separate certifications):

Authorising authority / certification or notification body	
Scope of authorisation / certification / notification	
Authorisation / certificate / notification number or identifier	

[3] The essential principles apply to therapeutic vaping devices and therapeutic vaping device accessories by default under the *Therapeutic Goods Act 1989*.

[4] The MDSO applies to therapeutic vaping devices and therapeutic vaping device accessories, imported or manufactured on or after 1 March 2024, that prior to 1 January 2024 were excluded from the operation of the *Therapeutic Goods Act 1989*. Vaping devices and vaping device accessories previously excluded were those not intended to be used exclusively for the administration of a medicine.

Section 7: Ingredients or components for further manufacture in Australia

Complete this section if the good is a starting material, component or article being imported for the purpose of further manufacture in Australia.

☐ The starting material is for use in the lawful manufacture of a therapeutic vaping substance or a therapeutic vaping substance accessory or another therapeutic good by a manufacturer that holds all relevant licences or approvals. Provide details of manufacturing sites in the table below. Duplicate the table as necessary.

Manufacturer name:	
TGA licence number:	
Steps in manufacture:	

☐ The article or component is for use in the lawful manufacture of a therapeutic vaping device or a therapeutic vaping device accessory by a manufacturer that holds all relevant licences or approvals. Provide details of manufacturing sites in the table below. Duplicate the table as necessary.

Manufacturer name:					
Conformity assessment evidence					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Section 8: Declaration

Section 8.1: Privacy information

General privacy information is available on the TGA website.

The TGA is collecting personal information in this form in order to contact the sponsor to discuss the notice where necessary.

Section 8.2: Declaration

☒ I declare that the information provided in this form, is, to the best of my knowledge, current and correct.

☒ I certify that the statements made in this notice are supported by information and evidence which will be provided to the TGA upon request.

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 section 137.1 of the Commonwealth Criminal Code.

Name	s22 [redacted]		
Signature	s22 [redacted]	Date	04.03.2024

Send this completed notification form to vapenotifications@health.gov.au

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA USE ONLY

This form, when completed, will be classified as **'Official'**.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

Sponsor notice – Vaping goods

Notice to import or supply in Australia therapeutic vaping goods

About this form

You must submit this notice to the TGA prior to commencing importation or supply in Australia of unregistered therapeutic vaping goods that are intended for smoking cessation or the management of nicotine dependence, or ingredients or components used in the manufacture of those goods. The notice must be submitted before the therapeutic vaping goods are imported, or, for finished goods that are manufactured in Australia, before those goods are first supplied in Australia.

A separate form must be completed for each different type of therapeutic vaping good, ingredient or component intended to be imported or supplied. For example, if you have different flavours, concentrations of nicotine, or vaping device characteristics, you will need to submit a notice for each good.

If a notice is made for therapeutic vaping goods imported for further manufacture in Australia, a separate notice will need to be made for each good prior to supply.

Once complete, send this form to vapenotifications@health.gov.au

If information in the form relating to your therapeutic vaping good is incomplete, we may not be able to provide you a notification number.

You should be aware that the TGA may publish certain information relating to your notice – such as your name and details of your good.

Guidance

Guidance is available on the TGA website to help you to complete the form.

What you'll need to complete this form

- **Your TGA client ID** – see guidance on setting up a TGA client ID.
- **Details about your therapeutic vaping good, ingredient or component** – you will need to tell us key details about the good you intend to import, or supply following domestic manufacture.
- **Manufacturer information** – we need to know the TGA client ID for each manufacturer (vaping substance), or details of the manufacturers (vaping devices).
- **Evidence of compliance to applicable standards** – you will need this for each vaping good you intend to import, or supply following domestic manufacture.

Legislation

This notice is made under paragraph (a) in column 3 of item 15, and paragraph (a) in column 3 of item 16, of Schedule 5A to the *Therapeutic Goods Regulations 1990* (the TG Regulations).

This notice is also made under paragraph (a) in the column headed "Conditions" of item 2.17, and paragraph (a) in the column headed "Conditions" of item 2.18, of Part 2 of Schedule 4 to the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations)

Section 1: Sponsor information

Company name:	Mission Distribution Victoria Pty Limited
TGA client ID:	83800
Contact email:	s2 s47 [redacted]

Section 2: Vaping good category

See guidance about the definitions used in this form. Every vaping good requires a separate notice, including where those therapeutic vaping goods are contained in a therapeutic vaping kit or therapeutic vaping pack.

Select one vaping good category for this notice:

☐ A finished good that is, or contains, a vaping substance (a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a good in a ***therapeutic vaping kit*** – see item 15 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 5 and 8 below

☐ A finished good that would be a medical device except that it is for supply as part of a therapeutic vaping pack (a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** in a ***therapeutic vaping pack*** – see item 15 of Schedule 5A to the TG Regulations).[1]

Complete sections 3, 4, 5 and 8 below

☒ A finished good that does not contain a vaping substance, and is a reusable vaping device or a component of a reusable vaping device, or a reusable cartridge, capsule or pod or other vessel (a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.17 of Part 2 of Schedule 4 to the MD Regulations).

Complete sections 3, 4, 6 and 8 below.

☐ A starting material, that is not liquid nicotine, for use in the manufacture of therapeutic vaping goods that are or contain therapeutic vaping substances (see item 16 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of vaping goods in Australia (including a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a ***therapeutic vaping kit*** – see item 16 Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of other therapeutic goods in Australia (see item 16 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ A component or article intended for use in the manufacture of an unfilled vaping device (the manufacture of a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.18 of Part 2 of Schedule 4 to the MD Regulations).

Complete sections 3, 4, 7 and 8 below.

[1] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

Section 3: Vaping good details

Complete **tables 1 and 2** if your vaping good is:

- a therapeutic vaping substance;
- liquid nicotine; or
- starting material that is an ingredient for use in the manufacture of a therapeutic vaping substance or therapeutic vaping substance accessory.

Complete **table 3** if your vaping good is:

- a therapeutic vaping device, e.g. a reusable vaporiser, battery, mouthpiece, coil or other parts of a reusable therapeutic vaping device;
- a therapeutic vaping device accessory, e.g. a unfilled cartridge, capsule or pod; or
- a component or article for use in the manufacture of a therapeutic vaping device, therapeutic vaping device accessory or therapeutic vaping substance accessory.

Complete **tables 1, 2 and 3** if your vaping good is:

- a therapeutic vaping substance accessory e.g. a filled cartridge, capsule or pod.

When completing **table 2**:

- list all ingredients (except for nicotine, details of which should be included in Table 1), including flavour, using the Australian Approved Ingredient name where possible; and
- use the approved terminology in TGA Code Tables, e.g. the Australian Approved Names of ingredients, and as specified in the published guidance.

Table 1: Details of the therapeutic vaping substance, liquid nicotine or starting material

Name of good:	
Description of good:	
Container type:	
Volume in mL (or weight if applicable):	
Nicotine form (if applicable):	
Nicotine quantity:	

Table 2: Ingredients in the therapeutic vaping substance, liquid nicotine or starting material

Ingredient name	Quantity

Table 3: Details of the therapeutic vaping device, therapeutic vaping device accessory, therapeutic vaping substance accessory or articles or components for further manufacture

Vaping good name:	RELX Infinity 2 Device		
Device model:	P54a		
Vaping good description:	Therapeutic vaping device without vaping substance		
Liquid capacity in mL:	No applicable, it's a therapeutic vaping device without tank		
Device product identifier GMDN or UDI:	No GMDN or UDI is available		
Rechargeable battery:	☒ Yes	☐ No	
Battery capacity:	440mAh		
Battery composition: (e.g. Nickel-Cadmium, Nickel-Metal Hydride, Lithium Ion)	Lithium Ion		
Battery voltage:	3.7V~4.2V		
Battery wattage:	8W		
Type of heating element:	☐ Coil	☐ Wick	☒ Other
	If Other selected, please describe: No applicable, it's a therapeutic vaping device without tank		
Charging unit:	☒ USB	☐ Other	
Is the airflow adjustable?	☐ Yes	☒ No	
Type of control unit(s): (e.g. PCB, microcontroller, software, etc)	PCB, microcontroller, software		

Section 4: Manufacturer details

Provide details of all prior manufacturers of the therapeutic vaping goods, ingredients or components you are importing or supplying.

Manufacturers of the therapeutic vaping substance, therapeutic vaping substance accessory, liquid nicotine or starting material for further manufacture

Manufacturer name:	s47 [redacted]
TGA client ID:	s47 [redacted]
Steps in manufacture:	Finished product manufacturer/packaging manufacturer/testing physical manufacturer

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturers of the therapeutic vaping device, therapeutic vaping device accessory, therapeutic vaping substance accessory or articles or components for further manufacture

Manufacturer name:	s47 [redacted]				
Site street address:	s47 [redacted]				
Suburb/Town/City:	s47 [redacted]	**State/Territory:**	s47 [redacted]	**Post code:**	s47 [redacted]
Country:	s47 [redacted]				
Contact email:	s22 s47 [redacted]				

Manufacturer name:					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Manufacturer name:					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Manufacturer name:					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	

Country:	
Contact email:	

Section 5: Compliance – vaping substances etc

Complete this section if the therapeutic vaping good is ready to be supplied in Australia and is, or contains, a therapeutic vaping substance, including a therapeutic vaping substance accessory, therapeutic vaping kit or is a good in a therapeutic vaping pack.[2].

The therapeutic vaping good:

☐ is only indicated for 'smoking cessation' or the 'management of nicotine dependence'.

The therapeutic vaping good:

☐ conforms with applicable standards, including *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021*. **Complete the TGO 110 compliance evidence below.**

OR

☐ is the subject of a consent from the Secretary under section 14 or 14A of the Therapeutic Goods Act for importation or supply. (Note: consent is only granted in exceptional circumstances).

TGO 110 compliance evidence

☐ Testing is performed on each batch of vaping goods.

- ☐ We hold an example of recent testing performed on a batch of vaping goods supplied or to be supplied in Australia:

Name of the facility:	s47 [redacted]
Address of the facility:	s47 [redacted]
Date tested: (dd/mm/yyyy)	16/12/2023

- ☐ Testing performed will confirm the nicotine concentration, which aligns with the label claim (where applicable).
- ☐ Testing will confirm the absence of prohibited ingredients.
- ☐ Batch-specific test results can be made available upon request.

☐ The good only contains mint, menthol, or tobacco flavour, if it contains a flavour.

☐ The labels comply with the requirements of TGO 110.

- ☐ The product label includes a list of all ingredients required by TGO 110.
- ☐ The product label includes quantity of nicotine as an active ingredient (if applicable).
- ☐ The product label includes applicable warning statements.
- ☐ Copies of labels can be provided upon request.

☐ The good has child-resistant packaging.

☐ For a vaping substance accessory, vaping device, vaping device accessory or vaping substance accessories in a kit, the good(s) conforms with the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023* or essential principles, as appropriate (see footnote 3 and 4).

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[2] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

Section 6: Compliance – vaping devices etc

Complete this section for a good that is a therapeutic vaping device or therapeutic vaping device accessory that does not contain a therapeutic vaping substance and is not to be imported or supplied in a therapeutic vaping pack. See footnotes 3 and 4 as to which standards apply to your vaping device.

The therapeutic vaping device or therapeutic device accessory:

☒ is only intended to administer a therapeutic vaping substance that is indicated for 'smoking cessation' or the 'management of nicotine dependence'.

The therapeutic vaping device or therapeutic device accessory:

☒ conforms with the Essential Principles[3]. **Complete the *Essential Principles* checklist available on the TGA website** (https://www.tga.gov.au/resources/resource/forms/essential-principles-checklist-medical-devices). You do not need to submit the completed checklist. **Go to section 8.**

OR

☐ is a device to which the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023*[4] (MDSO) applies and conforms with the MDSO. **Complete the vaping device compliance evidence below.**

OR

☐ is the subject of consent from the Secretary under section 41MA or 41MAA of the Act for non-compliance with the essential principles. (Note: consent is only granted in exceptional circumstances, for a limited period). **Go to section 8.**

Evidence of compliance – vaping device or vaping device accessory

If your therapeutic vaping device or therapeutic vaping device accessory does not comply with the Essential Principles and the MDSO applies, select one or more types of valid evidence held that demonstrates compliance with applicable requirements:

☐ US FDA - Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS)

☐ EU - European Tobacco Products Directive - A valid notification under Article 20 of Directive 2014/40/EU

☐ UK MHRA - notification through the Tobacco and related Products Regulations (TRPR), as listed on the notified e-cigarette products publication (database) ecig (cms.mhra.gov.uk/ecig)

☐ Certificate, licence, notification, or other approval establishing compliance for supply of therapeutic goods (TGA, US FDA, EU notified body, or designated body by UK MHRA)

☒ ISO 9001 certificate

☐ ISO13485 certificate

Based on the selection above, provide the following information as evidence (the table can be duplicated if more than one type of evidence is held or there are multiple manufacturing sites holding separate certifications):

Authorising authority / certification or notification body	s47 [redacted]
Scope of authorisation / certification / notification	Manufacturing of Electronic Cigarette and Atomizers
Authorisation / certificate / notification number or identifier	s47 [redacted]

[3] The essential principles apply to therapeutic vaping devices and therapeutic vaping device accessories by default under the *Therapeutic Goods Act 1989*.

[4] The MDSO applies to therapeutic vaping devices and therapeutic vaping device accessories, imported or manufactured on or after 1 March 2024, that prior to 1 January 2024 were excluded from the operation of the *Therapeutic Goods Act 1989*. Vaping devices and vaping device accessories previously excluded were those not intended to be used exclusively for the administration of a medicine.

Section 7: Ingredients or components for further manufacture in Australia

Complete this section if the good is a starting material, component or article being imported for the purpose of further manufacture in Australia.

☐ The starting material is for use in the lawful manufacture of a therapeutic vaping substance or a therapeutic vaping substance accessory or another therapeutic good by a manufacturer that holds all relevant licences or approvals. Provide details of manufacturing sites in the table below. Duplicate the table as necessary.

Manufacturer name:	
TGA licence number:	
Steps in manufacture:	

☐ The article or component is for use in the lawful manufacture of a therapeutic vaping device or a therapeutic vaping device accessory by a manufacturer that holds all relevant licences or approvals. Provide details of manufacturing sites in the table below. Duplicate the table as necessary.

Manufacturer name:					
Conformity assessment evidence					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Section 8: Declaration

Section 8.1: Privacy information

General privacy information is available on the TGA website.

The TGA is collecting personal information in this form in order to contact the sponsor to discuss the notice where necessary.

Section 8.2: Declaration

☒ I declare that the information provided in this form, is, to the best of my knowledge, current and correct.

☒ I certify that the statements made in this notice are supported by information and evidence which will be provided to the TGA upon request.

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 section 137.1 of the Commonwealth Criminal Code.

Name	s22 [redacted]		
Signature	s22 [redacted]	Date	04.03.2024

Send this completed notification form to vapenotifications@health.gov.au

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA USE ONLY

This form, when completed, will be classified as **'Official'**.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

Sponsor notice – Vaping goods

Notice to import or supply in Australia therapeutic vaping goods

About this form

You must submit this notice to the TGA prior to commencing importation or supply in Australia of unregistered therapeutic vaping goods that are intended for smoking cessation or the management of nicotine dependence, or ingredients or components used in the manufacture of those goods. The notice must be submitted before the therapeutic vaping goods are imported, or, for finished goods that are manufactured in Australia, before those goods are first supplied in Australia.

A separate form must be completed for each different type of therapeutic vaping good, ingredient or component intended to be imported or supplied. For example, if you have different flavours, concentrations of nicotine, or vaping device characteristics, you will need to submit a notice for each good.

If a notice is made for therapeutic vaping goods imported for further manufacture in Australia, a separate notice will need to be made for each good prior to supply.

Once complete, send this form to vapenotifications@health.gov.au

If information in the form relating to your therapeutic vaping good is incomplete, we may not be able to provide you a notification number.

You should be aware that the TGA may publish certain information relating to your notice – such as your name and details of your good.

Guidance

Guidance is available on the TGA website to help you to complete the form.

What you'll need to complete this form

- **Your TGA client ID** – see guidance on setting up a TGA client ID.
- **Details about your therapeutic vaping good, ingredient or component** – you will need to tell us key details about the good you intend to import, or supply following domestic manufacture.
- **Manufacturer information** – we need to know the TGA client ID for each manufacturer (vaping substance), or details of the manufacturers (vaping devices).
- **Evidence of compliance to applicable standards** – you will need this for each vaping good you intend to import, or supply following domestic manufacture.

Legislation

This notice is made under paragraph (a) in column 3 of item 15, and paragraph (a) in column 3 of item 16, of Schedule 5A to the *Therapeutic Goods Regulations 1990* (the TG Regulations).

This notice is also made under paragraph (a) in the column headed "Conditions" of item 2.17, and paragraph (a) in the column headed "Conditions" of item 2.18, of Part 2 of Schedule 4 to the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations)

Section 1: Sponsor information

Company name:	Mission Distribution Victoria Pty Limited
TGA client ID:	83800
Contact email:	s2 s47 [redacted]

Section 2: Vaping good category

See guidance about the definitions used in this form. Every vaping good requires a separate notice, including where those therapeutic vaping goods are contained in a therapeutic vaping kit or therapeutic vaping pack.

Select one vaping good category for this notice:

☒ A finished good that is, or contains, a vaping substance (a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a good in a ***therapeutic vaping kit*** – see item 15 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 5 and 8 below

☐ A finished good that would be a medical device except that it is for supply as part of a therapeutic vaping pack (a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** in a ***therapeutic vaping pack*** – see item 15 of Schedule 5A to the TG Regulations).[1]

Complete sections 3, 4, 5 and 8 below

☐ A finished good that does not contain a vaping substance, and is a reusable vaping device or a component of a reusable vaping device, or a reusable cartridge, capsule or pod or other vessel (a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.17 of Part 2 of Schedule 4 to the MD Regulations).

Complete sections 3, 4, 6 and 8 below.

☐ A starting material, that is not liquid nicotine, for use in the manufacture of therapeutic vaping goods that are or contain therapeutic vaping substances (see item 16 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of vaping goods in Australia (including a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a ***therapeutic vaping kit*** – see item 16 Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of other therapeutic goods in Australia (see item 16 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ A component or article intended for use in the manufacture of an unfilled vaping device (the manufacture of a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.18 of Part 2 of Schedule 4 to the MD Regulations).

Complete sections 3, 4, 7 and 8 below.

[1] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

Section 3: Vaping good details

Complete **tables 1 and 2** if your vaping good is:

- a therapeutic vaping substance;
- liquid nicotine; or
- starting material that is an ingredient for use in the manufacture of a therapeutic vaping substance or therapeutic vaping substance accessory.

Complete **table 3** if your vaping good is:

- a therapeutic vaping device, e.g. a reusable vaporiser, battery, mouthpiece, coil or other parts of a reusable therapeutic vaping device;
- a therapeutic vaping device accessory, e.g. a unfilled cartridge, capsule or pod; or
- a component or article for use in the manufacture of a therapeutic vaping device, therapeutic vaping device accessory or therapeutic vaping substance accessory.

Complete **tables 1, 2 and 3** if your vaping good is:

- a therapeutic vaping substance accessory e.g. a filled cartridge, capsule or pod.

When completing **table 2**:

- list all ingredients (except for nicotine, details of which should be included in Table 1), including flavour, using the Australian Approved Ingredient name where possible; and
- use the approved terminology in TGA Code Tables, e.g. the Australian Approved Names of ingredients, and as specified in the published guidance.

Table 1: Details of the therapeutic vaping substance, liquid nicotine or starting material

Name of good:	RELX Pod Pro2-Tobacco Red-28.5mg/mL Nicotine
Description of good:	Therapeutic vaping substance accessory
Container type:	Prefilled Pod
Volume in mL (or weight if applicable):	1.9mL
Nicotine form (if applicable):	Nicotine ID 54852
Nicotine quantity:	28.5mg/mL

Table 2: Ingredients in the therapeutic vaping substance, liquid nicotine or starting material

Ingredient name	Quantity
s47	

Table 3: Details of the therapeutic vaping device, therapeutic vaping device accessory, therapeutic vaping substance accessory or articles or components for further manufacture

Vaping good name:	RELX Pod Pro2-Tobacco Red-28.5mg/mL Nicotine		
Device model:	RELX Pod Pro2		
Vaping good description:	Therapeutic vaping substance accessory		
Liquid capacity in mL:	1.9mL		
Device product identifier GMDN or UDI:	No GMDN or UDI is available		
Rechargeable battery:	☐ Yes	☒ No	
Battery capacity:	Prefilled pod, no battery included		
Battery composition: (e.g. Nickel-Cadmium, Nickel-Metal Hydride, Lithium Ion)	Prefilled pod, no battery included		
Battery voltage:	Prefilled pod, no battery included		
Battery wattage:	Prefilled pod, no battery included		
Type of heating element:	☒ Coil	☐ Wick	☐ Other
	If Other selected, please describe:		
Charging unit:	☐ USB	☒ Other Prefilled pod, no battery included	
Is the airflow adjustable?	☐ Yes	☒ No	
Type of control unit(s): (e.g. PCB, microcontroller, software, etc)	Prefilled pod, no control unit included		

Section 4: Manufacturer details

Provide details of all prior manufacturers of the therapeutic vaping goods, ingredients or components you are importing or supplying.

Manufacturers of the therapeutic vaping substance, therapeutic vaping substance accessory, liquid nicotine or starting material for further manufacture

Manufacturer name:	s47 [redacted]
TGA client ID:	s47 [redacted]
Steps in manufacture:	Vaping substance manufacturer/testing chemical manufacturer

Manufacturer name:	s47 [redacted]
TGA client ID:	s47 [redacted]
Steps in manufacture:	Finished product manufacturer/packaging manufacturer/testing physical manufacturer

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturers of the therapeutic vaping device, therapeutic vaping device accessory, therapeutic vaping substance accessory or articles or components for further manufacture

Manufacturer name:	s47 [redacted]				
Site street address:	s47 [redacted]				
Suburb/Town/City:	s47 [redacted]	**State/Territory:**	s47 [redacted]	**Post code:**	s47 [redacted]
Country:	s47 [redacted]				
Contact email:	s22 s47 [redacted]				

Manufacturer name:	s47 [redacted]				
Site street address:	s47 [redacted]				
Suburb/Town/City:	s47 [redacted]	**State/Territory:**	s47 [redacted]	**Post code:**	s47 [redacted]
Country:	s47 [redacted]				
Contact email:	s22 s47 [redacted]				

Manufacturer name:					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Manufacturer name:	
Site street address:	

Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Section 5: Compliance – vaping substances etc

Complete this section if the therapeutic vaping good is ready to be supplied in Australia and is, or contains, a therapeutic vaping substance, including a therapeutic vaping substance accessory, therapeutic vaping kit or is a good in a therapeutic vaping pack.[2].

The therapeutic vaping good:

☐ is only indicated for 'smoking cessation' or the 'management of nicotine dependence'.

The therapeutic vaping good:

☒ conforms with applicable standards, including *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021*. **Complete the TGO 110 compliance evidence below.**

OR

☐ is the subject of a consent from the Secretary under section 14 or 14A of the Therapeutic Goods Act for importation or supply. (Note: consent is only granted in exceptional circumstances).

TGO 110 compliance evidence

☒ Testing is performed on each batch of vaping goods.

☒ We hold an example of recent testing performed on a batch of vaping goods supplied or to be supplied in Australia:

Name of the facility:	s47 [redacted]
Address of the facility:	s47 [redacted]
Date tested: (dd/mm/yyyy)	14/12/2023

☒ Testing performed will confirm the nicotine concentration, which aligns with the label claim (where applicable).

☒ Testing will confirm the absence of prohibited ingredients.

☒ Batch-specific test results can be made available upon request.

☒ The good only contains mint, menthol, or tobacco flavour, if it contains a flavour.

☒ The labels comply with the requirements of TGO 110.

☒ The product label includes a list of all ingredients required by TGO 110.

☒ The product label includes quantity of nicotine as an active ingredient (if applicable).

☒ The product label includes applicable warning statements.

☒ Copies of labels can be provided upon request.

☒ The good has child-resistant packaging.

☒ For a vaping substance accessory, vaping device, vaping device accessory or vaping substance accessories in a kit, the good(s) conforms with the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023* or essential principles, as appropriate (see footnote 3 and 4).

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[2] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

Section 6: Compliance – vaping devices etc

Complete this section for a good that is a therapeutic vaping device or therapeutic vaping device accessory that does not contain a therapeutic vaping substance and is not to be imported or supplied in a therapeutic vaping pack. See footnotes 3 and 4 as to which standards apply to your vaping device.

The therapeutic vaping device or therapeutic device accessory:

☐ is only intended to administer a therapeutic vaping substance that is indicated for 'smoking cessation' or the 'management of nicotine dependence'.

The therapeutic vaping device or therapeutic device accessory:

☐ conforms with the Essential Principles[3]. **Complete the *Essential Principles* checklist available on the TGA website** (https://www.tga.gov.au/resources/resource/forms/essential-principles-checklist-medical-devices). You do not need to submit the completed checklist. **Go to section 8.**

OR

☐ is a device to which the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023*[4] (MDSO) applies and conforms with the MDSO. **Complete the vaping device compliance evidence below.**

OR

☐ is the subject of consent from the Secretary under section 41MA or 41MAA of the Act for non-compliance with the essential principles. (Note: consent is only granted in exceptional circumstances, for a limited period). **Go to section 8.**

Evidence of compliance – vaping device or vaping device accessory

If your therapeutic vaping device or therapeutic vaping device accessory does not comply with the Essential Principles and the MDSO applies, select one or more types of valid evidence held that demonstrates compliance with applicable requirements:

☐ US FDA - Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS)

☐ EU - European Tobacco Products Directive - A valid notification under Article 20 of Directive 2014/40/EU

☐ UK MHRA - notification through the Tobacco and related Products Regulations (TRPR), as listed on the notified e-cigarette products publication (database) ecig (cms.mhra.gov.uk/ecig)

☐ Certificate, licence, notification, or other approval establishing compliance for supply of therapeutic goods (TGA, US FDA, EU notified body, or designated body by UK MHRA)

☐ ISO 9001 certificate

☐ ISO13485 certificate

Based on the selection above, provide the following information as evidence (the table can be duplicated if more than one type of evidence is held or there are multiple manufacturing sites holding separate certifications):

Authorising authority / certification or notification body	
Scope of authorisation / certification / notification	
Authorisation / certificate / notification number or identifier	

[3] The essential principles apply to therapeutic vaping devices and therapeutic vaping device accessories by default under the *Therapeutic Goods Act 1989*.

[4] The MDSO applies to therapeutic vaping devices and therapeutic vaping device accessories, imported or manufactured on or after 1 March 2024, that prior to 1 January 2024 were excluded from the operation of the *Therapeutic Goods Act 1989*. Vaping devices and vaping device accessories previously excluded were those not intended to be used exclusively for the administration of a medicine.

Section 7: Ingredients or components for further manufacture in Australia

Complete this section if the good is a starting material, component or article being imported for the purpose of further manufacture in Australia.

☐ The starting material is for use in the lawful manufacture of a therapeutic vaping substance or a therapeutic vaping substance accessory or another therapeutic good by a manufacturer that holds all relevant licences or approvals. Provide details of manufacturing sites in the table below. Duplicate the table as necessary.

Manufacturer name:	
TGA licence number:	
Steps in manufacture:	

☐ The article or component is for use in the lawful manufacture of a therapeutic vaping device or a therapeutic vaping device accessory by a manufacturer that holds all relevant licences or approvals. Provide details of manufacturing sites in the table below. Duplicate the table as necessary.

Manufacturer name:					
Conformity assessment evidence					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Section 8: Declaration

Section 8.1: Privacy information

General privacy information is available on the TGA website.

The TGA is collecting personal information in this form in order to contact the sponsor to discuss the notice where necessary.

Section 8.2: Declaration

☒ I declare that the information provided in this form, is, to the best of my knowledge, current and correct.

☒ I certify that the statements made in this notice are supported by information and evidence which will be provided to the TGA upon request.

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 section 137.1 of the Commonwealth Criminal Code.

Name	s22 [redacted]		
Signature	s22 [redacted]	Date	04.03.2024

Send this completed notification form to vapenotifications@health.gov.au

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA USE ONLY

This form, when completed, will be classified as **'Official'**.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

Sponsor notice – Vaping goods

Notice to import or supply in Australia therapeutic vaping goods

About this form

You must submit this notice to the TGA prior to commencing importation or supply in Australia of unregistered therapeutic vaping goods that are intended for smoking cessation or the management of nicotine dependence, or ingredients or components used in the manufacture of those goods. The notice must be submitted before the therapeutic vaping goods are imported, or, for finished goods that are manufactured in Australia, before those goods are first supplied in Australia.

A separate form must be completed for each different type of therapeutic vaping good, ingredient or component intended to be imported or supplied. For example, if you have different flavours, concentrations of nicotine, or vaping device characteristics, you will need to submit a notice for each good.

If a notice is made for therapeutic vaping goods imported for further manufacture in Australia, a separate notice will need to be made for each good prior to supply.

Once complete, send this form to vapenotifications@health.gov.au

If information in the form relating to your therapeutic vaping good is incomplete, we may not be able to provide you a notification number.

You should be aware that the TGA may publish certain information relating to your notice – such as your name and details of your good.

Guidance

Guidance is available on the TGA website to help you to complete the form.

What you'll need to complete this form

- **Your TGA client ID** – see guidance on setting up a TGA client ID.
- **Details about your therapeutic vaping good, ingredient or component** – you will need to tell us key details about the good you intend to import, or supply following domestic manufacture.
- **Manufacturer information** – we need to know the TGA client ID for each manufacturer (vaping substance), or details of the manufacturers (vaping devices).
- **Evidence of compliance to applicable standards** – you will need this for each vaping good you intend to import, or supply following domestic manufacture.

Legislation

This notice is made under paragraph (a) in column 3 of item 15, and paragraph (a) in column 3 of item 16, of Schedule 5A to the *Therapeutic Goods Regulations 1990* (the TG Regulations).

This notice is also made under paragraph (a) in the column headed "Conditions" of item 2.17, and paragraph (a) in the column headed "Conditions" of item 2.18, of Part 2 of Schedule 4 to the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations)

Section 1: Sponsor information

Company name:	Mission Distribution Victoria Pty Limited
TGA client ID:	83800
Contact email:	s2 s47 [redacted]

Section 2: Vaping good category

See guidance about the definitions used in this form. Every vaping good requires a separate notice, including where those therapeutic vaping goods are contained in a therapeutic vaping kit or therapeutic vaping pack.

Select one vaping good category for this notice:

☒ A finished good that is, or contains, a vaping substance (a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a good in a ***therapeutic vaping kit*** – see item 15 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 5 and 8 below

☐ A finished good that would be a medical device except that it is for supply as part of a therapeutic vaping pack (a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** in a ***therapeutic vaping pack*** – see item 15 of Schedule 5A to the TG Regulations).[1]

Complete sections 3, 4, 5 and 8 below

☐ A finished good that does not contain a vaping substance, and is a reusable vaping device or a component of a reusable vaping device, or a reusable cartridge, capsule or pod or other vessel (a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.17 of Part 2 of Schedule 4 to the MD Regulations).

Complete sections 3, 4, 6 and 8 below.

☐ A starting material, that is not liquid nicotine, for use in the manufacture of therapeutic vaping goods that are or contain therapeutic vaping substances (see item 16 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of vaping goods in Australia (including a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a ***therapeutic vaping kit*** – see item 16 Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of other therapeutic goods in Australia (see item 16 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ A component or article intended for use in the manufacture of an unfilled vaping device (the manufacture of a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.18 of Part 2 of Schedule 4 to the MD Regulations).

Complete sections 3, 4, 7 and 8 below.

[1] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

Section 3: Vaping good details

Complete **tables 1 and 2** if your vaping good is:

- a therapeutic vaping substance;
- liquid nicotine; or
- starting material that is an ingredient for use in the manufacture of a therapeutic vaping substance or therapeutic vaping substance accessory.

Complete **table 3** if your vaping good is:

- a therapeutic vaping device, e.g. a reusable vaporiser, battery, mouthpiece, coil or other parts of a reusable therapeutic vaping device;
- a therapeutic vaping device accessory, e.g. a unfilled cartridge, capsule or pod; or
- a component or article for use in the manufacture of a therapeutic vaping device, therapeutic vaping device accessory or therapeutic vaping substance accessory.

Complete **tables 1, 2 and 3** if your vaping good is:

- a therapeutic vaping substance accessory e.g. a filled cartridge, capsule or pod.

When completing **table 2**:

- list all ingredients (except for nicotine, details of which should be included in Table 1), including flavour, using the Australian Approved Ingredient name where possible; and
- use the approved terminology in TGA Code Tables, e.g. the Australian Approved Names of ingredients, and as specified in the published guidance.

Table 1: Details of the therapeutic vaping substance, liquid nicotine or starting material

Name of good:	RELX Pod Pro2-Tobacco Gold-28.5mg/mL Nicotine
Description of good:	Therapeutic vaping substance accessory
Container type:	Prefilled Pod
Volume in mL (or weight if applicable):	1.9mL
Nicotine form (if applicable):	Nicotine ID 54852
Nicotine quantity:	28.5mg/mL

Table 2: Ingredients in the therapeutic vaping substance, liquid nicotine or starting material

Ingredient name	Quantity
s47	

Table 3: Details of the therapeutic vaping device, therapeutic vaping device accessory, therapeutic vaping substance accessory or articles or components for further manufacture

Vaping good name:	RELX Pod Pro2-Tobacco Gold-28.5mg/mL Nicotine		
Device model:	RELX Pod Pro2		
Vaping good description:	Therapeutic vaping substance accessory		
Liquid capacity in mL:	1.9mL		
Device product identifier GMDN or UDI:	No GMDN or UDI is available		
Rechargeable battery:	☐ Yes	☒ No	
Battery capacity:	Prefilled pod, no battery included		
Battery composition: (e.g. Nickel-Cadmium, Nickel-Metal Hydride, Lithium Ion)	Prefilled pod, no battery included		
Battery voltage:	Prefilled pod, no battery included		
Battery wattage:	Prefilled pod, no battery included		
Type of heating element:	☒ Coil	☐ Wick	☐ Other
	If Other selected, please describe:		
Charging unit:	☐ USB	☒ Other Prefilled pod, no battery included	
Is the airflow adjustable?	☐ Yes	☒ No	
Type of control unit(s): (e.g. PCB, microcontroller, software, etc)	Prefilled pod, no control unit included		

Section 4: Manufacturer details

Provide details of all prior manufacturers of the therapeutic vaping goods, ingredients or components you are importing or supplying.

Manufacturers of the therapeutic vaping substance, therapeutic vaping substance accessory, liquid nicotine or starting material for further manufacture

Manufacturer name:	s47 [redacted]
TGA client ID:	s47 [redacted]
Steps in manufacture:	Vaping substance manufacturer/testing chemical manufacturer

Manufacturer name:	s47 [redacted]
TGA client ID:	s47 [redacted]
Steps in manufacture:	Finished product manufacturer/packaging manufacturer/testing physical manufacturer

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturers of the therapeutic vaping device, therapeutic vaping device accessory, therapeutic vaping substance accessory or articles or components for further manufacture

Manufacturer name:	s47 [redacted]				
Site street address:	s47 [redacted]				
Suburb/Town/City:	s47 [redacted]	**State/Territory:**	s47 [redacted]	**Post code:**	s47 [redacted]
Country:	s47 [redacted]				
Contact email:	s22 s47 [redacted]				

Manufacturer name:	s47 [redacted]				
Site street address:	s47 [redacted]				
Suburb/Town/City:	s47 [redacted]	**State/Territory:**	s47 [redacted]	**Post code:**	s47 [redacted]
Country:	s47 [redacted]				
Contact email:	s22 s47 [redacted]				

Manufacturer name:					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Manufacturer name:	
Site street address:	

Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Section 5: Compliance – vaping substances etc

Complete this section if the therapeutic vaping good is ready to be supplied in Australia and is, or contains, a therapeutic vaping substance, including a therapeutic vaping substance accessory, therapeutic vaping kit or is a good in a therapeutic vaping pack.[2].

The therapeutic vaping good:

☐ is only indicated for 'smoking cessation' or the 'management of nicotine dependence'.

The therapeutic vaping good:

☒ conforms with applicable standards, including *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021*. **Complete the TGO 110 compliance evidence below.**

OR

☐ is the subject of a consent from the Secretary under section 14 or 14A of the Therapeutic Goods Act for importation or supply. (Note: consent is only granted in exceptional circumstances).

TGO 110 compliance evidence

☒ Testing is performed on each batch of vaping goods.

- ☒ We hold an example of recent testing performed on a batch of vaping goods supplied or to be supplied in Australia:

Name of the facility:	s47 [redacted]
Address of the facility:	s47 [redacted]
Date tested: (dd/mm/yyyy)	26/01/2024

- ☒ Testing performed will confirm the nicotine concentration, which aligns with the label claim (where applicable).
- ☒ Testing will confirm the absence of prohibited ingredients.
- ☒ Batch-specific test results can be made available upon request.

☒ The good only contains mint, menthol, or tobacco flavour, if it contains a flavour.

☒ The labels comply with the requirements of TGO 110.

- ☒ The product label includes a list of all ingredients required by TGO 110.
- ☒ The product label includes quantity of nicotine as an active ingredient (if applicable).
- ☒ The product label includes applicable warning statements.
- ☒ Copies of labels can be provided upon request.

☒ The good has child-resistant packaging.

☒ For a vaping substance accessory, vaping device, vaping device accessory or vaping substance accessories in a kit, the good(s) conforms with the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023* or essential principles, as appropriate (see footnote 3 and 4).

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[2] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

Section 6: Compliance – vaping devices etc

Complete this section for a good that is a therapeutic vaping device or therapeutic vaping device accessory that does not contain a therapeutic vaping substance and is not to be imported or supplied in a therapeutic vaping pack. See footnotes 3 and 4 as to which standards apply to your vaping device.

The therapeutic vaping device or therapeutic device accessory:

☐ is only intended to administer a therapeutic vaping substance that is indicated for 'smoking cessation' or the 'management of nicotine dependence'.

The therapeutic vaping device or therapeutic device accessory:

☐ conforms with the Essential Principles[3]. **Complete the *Essential Principles* checklist available on the TGA website** (https://www.tga.gov.au/resources/resource/forms/essential-principles-checklist-medical-devices). You do not need to submit the completed checklist. **Go to section 8.**

OR

☐ is a device to which the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023*[4] (MDSO) applies and conforms with the MDSO. **Complete the vaping device compliance evidence below.**

OR

☐ is the subject of consent from the Secretary under section 41MA or 41MAA of the Act for non-compliance with the essential principles. (Note: consent is only granted in exceptional circumstances, for a limited period). **Go to section 8.**

Evidence of compliance – vaping device or vaping device accessory

If your therapeutic vaping device or therapeutic vaping device accessory does not comply with the Essential Principles and the MDSO applies, select one or more types of valid evidence held that demonstrates compliance with applicable requirements:

☐ US FDA - Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS)

☐ EU - European Tobacco Products Directive - A valid notification under Article 20 of Directive 2014/40/EU

☐ UK MHRA - notification through the Tobacco and related Products Regulations (TRPR), as listed on the notified e-cigarette products publication (database) ecig (cms.mhra.gov.uk/ecig)

☐ Certificate, licence, notification, or other approval establishing compliance for supply of therapeutic goods (TGA, US FDA, EU notified body, or designated body by UK MHRA)

☐ ISO 9001 certificate

☐ ISO13485 certificate

Based on the selection above, provide the following information as evidence (the table can be duplicated if more than one type of evidence is held or there are multiple manufacturing sites holding separate certifications):

Authorising authority / certification or notification body	
Scope of authorisation / certification / notification	
Authorisation / certificate / notification number or identifier	

[3] The essential principles apply to therapeutic vaping devices and therapeutic vaping device accessories by default under the *Therapeutic Goods Act 1989*.

[4] The MDSO applies to therapeutic vaping devices and therapeutic vaping device accessories, imported or manufactured on or after 1 March 2024, that prior to 1 January 2024 were excluded from the operation of the *Therapeutic Goods Act 1989*. Vaping devices and vaping device accessories previously excluded were those not intended to be used exclusively for the administration of a medicine.

Section 7: Ingredients or components for further manufacture in Australia

Complete this section if the good is a starting material, component or article being imported for the purpose of further manufacture in Australia.

☐ The starting material is for use in the lawful manufacture of a therapeutic vaping substance or a therapeutic vaping substance accessory or another therapeutic good by a manufacturer that holds all relevant licences or approvals. Provide details of manufacturing sites in the table below. Duplicate the table as necessary.

Manufacturer name:	
TGA licence number:	
Steps in manufacture:	

☐ The article or component is for use in the lawful manufacture of a therapeutic vaping device or a therapeutic vaping device accessory by a manufacturer that holds all relevant licences or approvals. Provide details of manufacturing sites in the table below. Duplicate the table as necessary.

Manufacturer name:					
Conformity assessment evidence					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Section 8: Declaration

Section 8.1: Privacy information

General privacy information is available on the TGA website.

The TGA is collecting personal information in this form in order to contact the sponsor to discuss the notice where necessary.

Section 8.2: Declaration

☒ I declare that the information provided in this form, is, to the best of my knowledge, current and correct.

☒ I certify that the statements made in this notice are supported by information and evidence which will be provided to the TGA upon request.

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 section 137.1 of the Commonwealth Criminal Code.

Name	s22 [redacted]		
Signature	s22 [redacted]	Date	04.03.2024

Send this completed notification form to vapenotifications@health.gov.au

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA USE ONLY

This form, when completed, will be classified as **'Official'**.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

Sponsor notice – Vaping goods

Notice to import or supply in Australia therapeutic vaping goods

About this form

You must submit this notice to the TGA prior to commencing importation or supply in Australia of unregistered therapeutic vaping goods that are intended for smoking cessation or the management of nicotine dependence, or ingredients or components used in the manufacture of those goods. The notice must be submitted before the therapeutic vaping goods are imported, or, for finished goods that are manufactured in Australia, before those goods are first supplied in Australia.

A separate form must be completed for each different type of therapeutic vaping good, ingredient or component intended to be imported or supplied. For example, if you have different flavours, concentrations of nicotine, or vaping device characteristics, you will need to submit a notice for each good.

If a notice is made for therapeutic vaping goods imported for further manufacture in Australia, a separate notice will need to be made for each good prior to supply.

Once complete, send this form to vapenotifications@health.gov.au

If information in the form relating to your therapeutic vaping good is incomplete, we may not be able to provide you a notification number.

You should be aware that the TGA may publish certain information relating to your notice – such as your name and details of your good.

Guidance

Guidance is available on the TGA website to help you to complete the form.

What you'll need to complete this form

- **Your TGA client ID** – see guidance on setting up a TGA client ID.
- **Details about your therapeutic vaping good, ingredient or component** – you will need to tell us key details about the good you intend to import, or supply following domestic manufacture.
- **Manufacturer information** – we need to know the TGA client ID for each manufacturer (vaping substance), or details of the manufacturers (vaping devices).
- **Evidence of compliance to applicable standards** – you will need this for each vaping good you intend to import, or supply following domestic manufacture.

Legislation

This notice is made under paragraph (a) in column 3 of item 15, and paragraph (a) in column 3 of item 16, of Schedule 5A to the *Therapeutic Goods Regulations 1990* (the TG Regulations).

This notice is also made under paragraph (a) in the column headed "Conditions" of item 2.17, and paragraph (a) in the column headed "Conditions" of item 2.18, of Part 2 of Schedule 4 to the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations)

Section 1: Sponsor information

Company name:	Mission Distribution Victoria Pty Limited
TGA client ID:	83800
Contact email:	s2 s47 [redacted]

Section 2: Vaping good category

See guidance about the definitions used in this form. Every vaping good requires a separate notice, including where those therapeutic vaping goods are contained in a therapeutic vaping kit or therapeutic vaping pack.

Select one vaping good category for this notice:

☒ A finished good that is, or contains, a vaping substance (a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a good in a ***therapeutic vaping kit*** – see item 15 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 5 and 8 below

☐ A finished good that would be a medical device except that it is for supply as part of a therapeutic vaping pack (a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** in a ***therapeutic vaping pack*** – see item 15 of Schedule 5A to the TG Regulations).[1]

Complete sections 3, 4, 5 and 8 below

☐ A finished good that does not contain a vaping substance, and is a reusable vaping device or a component of a reusable vaping device, or a reusable cartridge, capsule or pod or other vessel (a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.17 of Part 2 of Schedule 4 to the MD Regulations).

Complete sections 3, 4, 6 and 8 below.

☐ A starting material, that is not liquid nicotine, for use in the manufacture of therapeutic vaping goods that are or contain therapeutic vaping substances (see item 16 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of vaping goods in Australia (including a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a ***therapeutic vaping kit*** – see item 16 Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of other therapeutic goods in Australia (see item 16 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ A component or article intended for use in the manufacture of an unfilled vaping device (the manufacture of a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.18 of Part 2 of Schedule 4 to the MD Regulations).

Complete sections 3, 4, 7 and 8 below.

[1] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

Section 3: Vaping good details

Complete **tables 1 and 2** if your vaping good is:

- a therapeutic vaping substance;
- liquid nicotine; or
- starting material that is an ingredient for use in the manufacture of a therapeutic vaping substance or therapeutic vaping substance accessory.

Complete **table 3** if your vaping good is:

- a therapeutic vaping device, e.g. a reusable vaporiser, battery, mouthpiece, coil or other parts of a reusable therapeutic vaping device;
- a therapeutic vaping device accessory, e.g. a unfilled cartridge, capsule or pod; or
- a component or article for use in the manufacture of a therapeutic vaping device, therapeutic vaping device accessory or therapeutic vaping substance accessory.

Complete **tables 1, 2 and 3** if your vaping good is:

- a therapeutic vaping substance accessory e.g. a filled cartridge, capsule or pod.

When completing **table 2**:

- list all ingredients (except for nicotine, details of which should be included in Table 1), including flavour, using the Australian Approved Ingredient name where possible; and
- use the approved terminology in TGA Code Tables, e.g. the Australian Approved Names of ingredients, and as specified in the published guidance.

Table 1: Details of the therapeutic vaping substance, liquid nicotine or starting material

Name of good:	RELX Pod Pro2-Tobacco Red-28.5mg/mL Nicotine
Description of good:	Therapeutic vaping substance accessory
Container type:	Prefilled Pod
Volume in mL (or weight if applicable):	1.9mL
Nicotine form (if applicable):	Nicotine ID 54852
Nicotine quantity:	28.5mg/mL

Table 2: Ingredients in the therapeutic vaping substance, liquid nicotine or starting material

Ingredient name	Quantity
s47 [redacted]	

Table 3: Details of the therapeutic vaping device, therapeutic vaping device accessory, therapeutic vaping substance accessory or articles or components for further manufacture

Vaping good name:	RELX Pod Pro2-Tobacco Red-28.5mg/mL Nicotine		
Device model:	RELX Pod Pro2		
Vaping good description:	Therapeutic vaping substance accessory		
Liquid capacity in mL:	1.9mL		
Device product identifier GMDN or UDI:	No GMDN or UDI is available		
Rechargeable battery:	☐ Yes	☒ No	
Battery capacity:	Prefilled pod, no battery included		
Battery composition: (e.g. Nickel-Cadmium, Nickel-Metal Hydride, Lithium Ion)	Prefilled pod, no battery included		
Battery voltage:	Prefilled pod, no battery included		
Battery wattage:	Prefilled pod, no battery included		
Type of heating element:	☒ Coil	☐ Wick	☐ Other
	If Other selected, please describe:		
Charging unit:	☐ USB	☒ Other Prefilled pod, no battery included	
Is the airflow adjustable?	☐ Yes	☒ No	
Type of control unit(s): (e.g. PCB, microcontroller, software, etc)	Prefilled pod, no control unit included		

Section 4: Manufacturer details

Provide details of all prior manufacturers of the therapeutic vaping goods, ingredients or components you are importing or supplying.

Manufacturers of the therapeutic vaping substance, therapeutic vaping substance accessory, liquid nicotine or starting material for further manufacture

Manufacturer name:	s47 [redacted]
TGA client ID:	s47 [redacted]
Steps in manufacture:	Vaping substance manufacturer/testing chemical manufacturer

Manufacturer name:	s47 [redacted]
TGA client ID:	s47 [redacted]
Steps in manufacture:	Finished product manufacturer/packaging manufacturer/testing physical manufacturer

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturers of the therapeutic vaping device, therapeutic vaping device accessory, therapeutic vaping substance accessory or articles or components for further manufacture

Manufacturer name:	s47 [redacted]				
Site street address:	s47 [redacted]				
Suburb/Town/City:	s47 [redacted]	**State/Territory:**	s47 [redacted]	**Post code:**	s47 [redacted]
Country:	s47 [redacted]				
Contact email:	s22 s47 [redacted]				

Manufacturer name:	s47 [redacted]				
Site street address:	s47 [redacted]				
Suburb/Town/City:	s47 [redacted]	**State/Territory:**	s47 [redacted]	**Post code:**	s47 [redacted]
Country:	s47 [redacted]				
Contact email:	s22 s47 [redacted]				

Manufacturer name:					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Manufacturer name:	
Site street address:	

Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Section 5: Compliance – vaping substances etc

Complete this section if the therapeutic vaping good is ready to be supplied in Australia and is, or contains, a therapeutic vaping substance, including a therapeutic vaping substance accessory, therapeutic vaping kit or is a good in a therapeutic vaping pack.[2].

The therapeutic vaping good:

☐ is only indicated for 'smoking cessation' or the 'management of nicotine dependence'.

The therapeutic vaping good:

☒ conforms with applicable standards, including *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021*. **Complete the TGO 110 compliance evidence below.**

OR

☐ is the subject of a consent from the Secretary under section 14 or 14A of the Therapeutic Goods Act for importation or supply. (Note: consent is only granted in exceptional circumstances).

TGO 110 compliance evidence

☒ Testing is performed on each batch of vaping goods.

- ☒ We hold an example of recent testing performed on a batch of vaping goods supplied or to be supplied in Australia:

Name of the facility:	s47 [redacted]
Address of the facility:	s47 [redacted]
Date tested: (dd/mm/yyyy)	14/12/2023

- ☒ Testing performed will confirm the nicotine concentration, which aligns with the label claim (where applicable).
- ☒ Testing will confirm the absence of prohibited ingredients.
- ☒ Batch-specific test results can be made available upon request.

☒ The good only contains mint, menthol, or tobacco flavour, if it contains a flavour.

☒ The labels comply with the requirements of TGO 110.

- ☒ The product label includes a list of all ingredients required by TGO 110.
- ☒ The product label includes quantity of nicotine as an active ingredient (if applicable).
- ☒ The product label includes applicable warning statements.
- ☒ Copies of labels can be provided upon request.

☒ The good has child-resistant packaging.

☒ For a vaping substance accessory, vaping device, vaping device accessory or vaping substance accessories in a kit, the good(s) conforms with the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023* or essential principles, as appropriate (see footnote 3 and 4).

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[2] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

Section 6: Compliance – vaping devices etc

Complete this section for a good that is a therapeutic vaping device or therapeutic vaping device accessory that does not contain a therapeutic vaping substance and is not to be imported or supplied in a therapeutic vaping pack. See footnotes 3 and 4 as to which standards apply to your vaping device.

The therapeutic vaping device or therapeutic device accessory:

☐ is only intended to administer a therapeutic vaping substance that is indicated for 'smoking cessation' or the 'management of nicotine dependence'.

The therapeutic vaping device or therapeutic device accessory:

☐ conforms with the Essential Principles[3]. **Complete the *Essential Principles* checklist available on the TGA website** (https://www.tga.gov.au/resources/resource/forms/essential-principles-checklist-medical-devices). You do not need to submit the completed checklist. **Go to section 8.**

OR

☐ is a device to which the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023*[4] (MDSO) applies and conforms with the MDSO. **Complete the vaping device compliance evidence below.**

OR

☐ is the subject of consent from the Secretary under section 41MA or 41MAA of the Act for non-compliance with the essential principles. (Note: consent is only granted in exceptional circumstances, for a limited period). **Go to section 8.**

Evidence of compliance – vaping device or vaping device accessory

If your therapeutic vaping device or therapeutic vaping device accessory does not comply with the Essential Principles and the MDSO applies, select one or more types of valid evidence held that demonstrates compliance with applicable requirements:

☐ US FDA - Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS)

☐ EU - European Tobacco Products Directive - A valid notification under Article 20 of Directive 2014/40/EU

☐ UK MHRA - notification through the Tobacco and related Products Regulations (TRPR), as listed on the notified e-cigarette products publication (database) ecig (cms.mhra.gov.uk/ecig)

☐ Certificate, licence, notification, or other approval establishing compliance for supply of therapeutic goods (TGA, US FDA, EU notified body, or designated body by UK MHRA)

☐ ISO 9001 certificate

☐ ISO13485 certificate

Based on the selection above, provide the following information as evidence (the table can be duplicated if more than one type of evidence is held or there are multiple manufacturing sites holding separate certifications):

Authorising authority / certification or notification body	
Scope of authorisation / certification / notification	
Authorisation / certificate / notification number or identifier	

[3] The essential principles apply to therapeutic vaping devices and therapeutic vaping device accessories by default under the *Therapeutic Goods Act 1989*.

[4] The MDSO applies to therapeutic vaping devices and therapeutic vaping device accessories, imported or manufactured on or after 1 March 2024, that prior to 1 January 2024 were excluded from the operation of the *Therapeutic Goods Act 1989*. Vaping devices and vaping device accessories previously excluded were those not intended to be used exclusively for the administration of a medicine.

Section 7: Ingredients or components for further manufacture in Australia

Complete this section if the good is a starting material, component or article being imported for the purpose of further manufacture in Australia.

☐ The starting material is for use in the lawful manufacture of a therapeutic vaping substance or a therapeutic vaping substance accessory or another therapeutic good by a manufacturer that holds all relevant licences or approvals. Provide details of manufacturing sites in the table below. Duplicate the table as necessary.

Manufacturer name:	
TGA licence number:	
Steps in manufacture:	

☐ The article or component is for use in the lawful manufacture of a therapeutic vaping device or a therapeutic vaping device accessory by a manufacturer that holds all relevant licences or approvals. Provide details of manufacturing sites in the table below. Duplicate the table as necessary.

Manufacturer name:					
Conformity assessment evidence					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Section 8: Declaration

Section 8.1: Privacy information

General privacy information is available on the TGA website.

The TGA is collecting personal information in this form in order to contact the sponsor to discuss the notice where necessary.

Section 8.2: Declaration

☒ I declare that the information provided in this form, is, to the best of my knowledge, current and correct.

☒ I certify that the statements made in this notice are supported by information and evidence which will be provided to the TGA upon request.

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 section 137.1 of the Commonwealth Criminal Code.

Name	s22 [redacted]		
Signature	s22 [redacted]	Date	04.03.2024

Send this completed notification form to vapenotifications@health.gov.au

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA USE ONLY

This form, when completed, will be classified as **'Official'**.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

Sponsor notice – Vaping goods

Notice to import or supply in Australia therapeutic vaping goods

About this form

You must submit this notice to the TGA prior to commencing importation or supply in Australia of unregistered therapeutic vaping goods that are intended for smoking cessation or the management of nicotine dependence, or ingredients or components used in the manufacture of those goods. The notice must be submitted before the therapeutic vaping goods are imported, or, for finished goods that are manufactured in Australia, before those goods are first supplied in Australia.

A separate form must be completed for each different type of therapeutic vaping good, ingredient or component intended to be imported or supplied. For example, if you have different flavours, concentrations of nicotine, or vaping device characteristics, you will need to submit a notice for each good.

If a notice is made for therapeutic vaping goods imported for further manufacture in Australia, a separate notice will need to be made for each good prior to supply.

Once complete, send this form to vapenotifications@health.gov.au

If information in the form relating to your therapeutic vaping good is incomplete, we may not be able to provide you a notification number.

You should be aware that the TGA may publish certain information relating to your notice – such as your name and details of your good.

Guidance

Guidance is available on the TGA website to help you to complete the form.

What you'll need to complete this form

- **Your TGA client ID** – see guidance on setting up a TGA client ID.
- **Details about your therapeutic vaping good, ingredient or component** – you will need to tell us key details about the good you intend to import, or supply following domestic manufacture.
- **Manufacturer information** – we need to know the TGA client ID for each manufacturer (vaping substance), or details of the manufacturers (vaping devices).
- **Evidence of compliance to applicable standards** – you will need this for each vaping good you intend to import, or supply following domestic manufacture.

Legislation

This notice is made under paragraph (a) in column 3 of item 15, and paragraph (a) in column 3 of item 16, of Schedule 5A to the *Therapeutic Goods Regulations 1990* (the TG Regulations).

This notice is also made under paragraph (a) in the column headed "Conditions" of item 2.17, and paragraph (a) in the column headed "Conditions" of item 2.18, of Part 2 of Schedule 4 to the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations)

Section 1: Sponsor information

Company name:	Mission Distribution Victoria Pty Limited
TGA client ID:	83800
Contact email:	s2 s47 [redacted]

Section 2: Vaping good category

See guidance about the definitions used in this form. Every vaping good requires a separate notice, including where those therapeutic vaping goods are contained in a therapeutic vaping kit or therapeutic vaping pack.

Select one vaping good category for this notice:

☒ A finished good that is, or contains, a vaping substance (a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a good in a ***therapeutic vaping kit*** – see item 15 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 5 and 8 below

☐ A finished good that would be a medical device except that it is for supply as part of a therapeutic vaping pack (a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** in a ***therapeutic vaping pack*** – see item 15 of Schedule 5A to the TG Regulations).[1]

Complete sections 3, 4, 5 and 8 below

☐ A finished good that does not contain a vaping substance, and is a reusable vaping device or a component of a reusable vaping device, or a reusable cartridge, capsule or pod or other vessel (a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.17 of Part 2 of Schedule 4 to the MD Regulations).

Complete sections 3, 4, 6 and 8 below.

☐ A starting material, that is not liquid nicotine, for use in the manufacture of therapeutic vaping goods that are or contain therapeutic vaping substances (see item 16 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of vaping goods in Australia (including a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a ***therapeutic vaping kit*** – see item 16 Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of other therapeutic goods in Australia (see item 16 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ A component or article intended for use in the manufacture of an unfilled vaping device (the manufacture of a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.18 of Part 2 of Schedule 4 to the MD Regulations).

Complete sections 3, 4, 7 and 8 below.

[1] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

Section 3: Vaping good details

Complete **tables 1 and 2** if your vaping good is:

- a therapeutic vaping substance;
- liquid nicotine; or
- starting material that is an ingredient for use in the manufacture of a therapeutic vaping substance or therapeutic vaping substance accessory.

Complete **table 3** if your vaping good is:

- a therapeutic vaping device, e.g. a reusable vaporiser, battery, mouthpiece, coil or other parts of a reusable therapeutic vaping device;
- a therapeutic vaping device accessory, e.g. a unfilled cartridge, capsule or pod; or
- a component or article for use in the manufacture of a therapeutic vaping device, therapeutic vaping device accessory or therapeutic vaping substance accessory.

Complete **tables 1, 2 and 3** if your vaping good is:

- a therapeutic vaping substance accessory e.g. a filled cartridge, capsule or pod.

When completing **table 2**:

- list all ingredients (except for nicotine, details of which should be included in Table 1), including flavour, using the Australian Approved Ingredient name where possible; and
- use the approved terminology in TGA Code Tables, e.g. the Australian Approved Names of ingredients, and as specified in the published guidance.

Table 1: Details of the therapeutic vaping substance, liquid nicotine or starting material

Name of good:	RELX Pod Pro2-Menthol-28.5mg/mL Nicotine
Description of good:	Therapeutic vaping substance accessory
Container type:	Prefilled Pod
Volume in mL (or weight if applicable):	1.9mL
Nicotine form (if applicable):	Nicotine ID 54852
Nicotine quantity:	28.5mg/mL

Table 2: Ingredients in the therapeutic vaping substance, liquid nicotine or starting material

Ingredient name	Quantity
s47	

Table 3: Details of the therapeutic vaping device, therapeutic vaping device accessory, therapeutic vaping substance accessory or articles or components for further manufacture

Vaping good name:	RELX Pod Pro2-Menthol-28.5mg/mL Nicotine		
Device model:	RELX Pod Pro2		
Vaping good description:	Therapeutic vaping substance accessory		
Liquid capacity in mL:	1.9mL		
Device product identifier GMDN or UDI:	No GMDN or UDI is available		
Rechargeable battery:	☐ Yes	☒ No	
Battery capacity:	Prefilled pod, no battery included		
Battery composition: (e.g. Nickel-Cadmium, Nickel-Metal Hydride, Lithium Ion)	Prefilled pod, no battery included		
Battery voltage:	Prefilled pod, no battery included		
Battery wattage:	Prefilled pod, no battery included		
Type of heating element:	☒ Coil	☐ Wick	☐ Other
	If Other selected, please describe:		
Charging unit:	☐ USB	☒ Other Prefilled pod, no battery included	
Is the airflow adjustable?	☐ Yes	☒ No	
Type of control unit(s): (e.g. PCB, microcontroller, software, etc)	Prefilled pod, no control unit included		

Section 4: Manufacturer details

Provide details of all prior manufacturers of the therapeutic vaping goods, ingredients or components you are importing or supplying.

Manufacturers of the therapeutic vaping substance, therapeutic vaping substance accessory, liquid nicotine or starting material for further manufacture

Manufacturer name:	s47 [redacted]
TGA client ID:	s47 [redacted]
Steps in manufacture:	Vaping substance manufacturer/testing chemical manufacturer

Manufacturer name:	s47 [redacted]
TGA client ID:	s47 [redacted]
Steps in manufacture:	Finished product manufacturer/packaging manufacturer/testing physical manufacturer

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturers of the therapeutic vaping device, therapeutic vaping device accessory, therapeutic vaping substance accessory or articles or components for further manufacture

Manufacturer name:	s47 [redacted]				
Site street address:	s47 [redacted]				
Suburb/Town/City:	s47 [redacted]	**State/Territory:**	s47 [redacted]	**Post code:**	s47 [redacted]
Country:	s47 [redacted]				
Contact email:	s22 s47 [redacted]				

Manufacturer name:	s47 [redacted]				
Site street address:	s47 [redacted]				
Suburb/Town/City:	s47 [redacted]	**State/Territory:**	s47 [redacted]	**Post code:**	s47 [redacted]
Country:	s47 [redacted]				
Contact email:	s22 s47 [redacted]				

Manufacturer name:					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Manufacturer name:	
Site street address:	

Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Section 5: Compliance – vaping substances etc

Complete this section if the therapeutic vaping good is ready to be supplied in Australia and is, or contains, a therapeutic vaping substance, including a therapeutic vaping substance accessory, therapeutic vaping kit or is a good in a therapeutic vaping pack.[2].

The therapeutic vaping good:

☐ is only indicated for 'smoking cessation' or the 'management of nicotine dependence'.

The therapeutic vaping good:

☒ conforms with applicable standards, including *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021*. **Complete the TGO 110 compliance evidence below.**

OR

☐ is the subject of a consent from the Secretary under section 14 or 14A of the Therapeutic Goods Act for importation or supply. (Note: consent is only granted in exceptional circumstances).

TGO 110 compliance evidence

☒ Testing is performed on each batch of vaping goods.

- ☒ We hold an example of recent testing performed on a batch of vaping goods supplied or to be supplied in Australia:

Name of the facility:	s47 [redacted]
Address of the facility:	s47 [redacted]
Date tested: (dd/mm/yyyy)	16/12/2023

- ☒ Testing performed will confirm the nicotine concentration, which aligns with the label claim (where applicable).
- ☒ Testing will confirm the absence of prohibited ingredients.
- ☒ Batch-specific test results can be made available upon request.

☒ The good only contains mint, menthol, or tobacco flavour, if it contains a flavour.

☒ The labels comply with the requirements of TGO 110.

- ☒ The product label includes a list of all ingredients required by TGO 110.
- ☒ The product label includes quantity of nicotine as an active ingredient (if applicable).
- ☒ The product label includes applicable warning statements.
- ☒ Copies of labels can be provided upon request.

☒ The good has child-resistant packaging.

☒ For a vaping substance accessory, vaping device, vaping device accessory or vaping substance accessories in a kit, the good(s) conforms with the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023* or essential principles, as appropriate (see footnote 3 and 4).

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[2] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

Section 6: Compliance – vaping devices etc

Complete this section for a good that is a therapeutic vaping device or therapeutic vaping device accessory that does not contain a therapeutic vaping substance and is not to be imported or supplied in a therapeutic vaping pack. See footnotes 3 and 4 as to which standards apply to your vaping device.

The therapeutic vaping device or therapeutic device accessory:

☐ is only intended to administer a therapeutic vaping substance that is indicated for 'smoking cessation' or the 'management of nicotine dependence'.

The therapeutic vaping device or therapeutic device accessory:

☐ conforms with the Essential Principles[3]. **Complete the *Essential Principles* checklist available on the TGA website** (https://www.tga.gov.au/resources/resource/forms/essential-principles-checklist-medical-devices). You do not need to submit the completed checklist. **Go to section 8.**

OR

☐ is a device to which the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023*[4] (MDSO) applies and conforms with the MDSO. **Complete the vaping device compliance evidence below.**

OR

☐ is the subject of consent from the Secretary under section 41MA or 41MAA of the Act for non-compliance with the essential principles. (Note: consent is only granted in exceptional circumstances, for a limited period). **Go to section 8.**

Evidence of compliance – vaping device or vaping device accessory

If your therapeutic vaping device or therapeutic vaping device accessory does not comply with the Essential Principles and the MDSO applies, select one or more types of valid evidence held that demonstrates compliance with applicable requirements:

☐ US FDA - Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS)

☐ EU - European Tobacco Products Directive - A valid notification under Article 20 of Directive 2014/40/EU

☐ UK MHRA - notification through the Tobacco and related Products Regulations (TRPR), as listed on the notified e-cigarette products publication (database) ecig (cms.mhra.gov.uk/ecig)

☐ Certificate, licence, notification, or other approval establishing compliance for supply of therapeutic goods (TGA, US FDA, EU notified body, or designated body by UK MHRA)

☐ ISO 9001 certificate

☐ ISO13485 certificate

Based on the selection above, provide the following information as evidence (the table can be duplicated if more than one type of evidence is held or there are multiple manufacturing sites holding separate certifications):

Authorising authority / certification or notification body	
Scope of authorisation / certification / notification	
Authorisation / certificate / notification number or identifier	

[3] The essential principles apply to therapeutic vaping devices and therapeutic vaping device accessories by default under the *Therapeutic Goods Act 1989*.

[4] The MDSO applies to therapeutic vaping devices and therapeutic vaping device accessories, imported or manufactured on or after 1 March 2024, that prior to 1 January 2024 were excluded from the operation of the *Therapeutic Goods Act 1989*. Vaping devices and vaping device accessories previously excluded were those not intended to be used exclusively for the administration of a medicine.

Section 7: Ingredients or components for further manufacture in Australia

Complete this section if the good is a starting material, component or article being imported for the purpose of further manufacture in Australia.

☐ The starting material is for use in the lawful manufacture of a therapeutic vaping substance or a therapeutic vaping substance accessory or another therapeutic good by a manufacturer that holds all relevant licences or approvals. Provide details of manufacturing sites in the table below. Duplicate the table as necessary.

Manufacturer name:	
TGA licence number:	
Steps in manufacture:	

☐ The article or component is for use in the lawful manufacture of a therapeutic vaping device or a therapeutic vaping device accessory by a manufacturer that holds all relevant licences or approvals. Provide details of manufacturing sites in the table below. Duplicate the table as necessary.

Manufacturer name:					
Conformity assessment evidence					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Section 8: Declaration

Section 8.1: Privacy information

General privacy information is available on the TGA website.

The TGA is collecting personal information in this form in order to contact the sponsor to discuss the notice where necessary.

Section 8.2: Declaration

☒ I declare that the information provided in this form, is, to the best of my knowledge, current and correct.

☒ I certify that the statements made in this notice are supported by information and evidence which will be provided to the TGA upon request.

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 section 137.1 of the Commonwealth Criminal Code.

Name	s22 [redacted]		
Signature	s22 [redacted]	Date	04.03.2024

Send this completed notification form to vapenotifications@health.gov.au

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA USE ONLY

This form, when completed, will be classified as **'Official'**.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

Sponsor notice – Vaping goods

Notice to import or supply in Australia therapeutic vaping goods

About this form

You must submit this notice to the TGA prior to commencing importation or supply in Australia of unregistered therapeutic vaping goods that are intended for smoking cessation or the management of nicotine dependence, or ingredients or components used in the manufacture of those goods. The notice must be submitted before the therapeutic vaping goods are imported, or, for finished goods that are manufactured in Australia, before those goods are first supplied in Australia.

A separate form must be completed for each different type of therapeutic vaping good, ingredient or component intended to be imported or supplied. For example, if you have different flavours, concentrations of nicotine, or vaping device characteristics, you will need to submit a notice for each good.

If a notice is made for therapeutic vaping goods imported for further manufacture in Australia, a separate notice will need to be made for each good prior to supply.

Once complete, send this form to vapenotifications@health.gov.au

If information in the form relating to your therapeutic vaping good is incomplete, we may not be able to provide you a notification number.

You should be aware that the TGA may publish certain information relating to your notice – such as your name and details of your good.

Guidance

Guidance is available on the TGA website to help you to complete the form.

What you'll need to complete this form

- **Your TGA client ID** – see guidance on setting up a TGA client ID.
- **Details about your therapeutic vaping good, ingredient or component** – you will need to tell us key details about the good you intend to import, or supply following domestic manufacture.
- **Manufacturer information** – we need to know the TGA client ID for each manufacturer (vaping substance), or details of the manufacturers (vaping devices).
- **Evidence of compliance to applicable standards** – you will need this for each vaping good you intend to import, or supply following domestic manufacture.

Legislation

This notice is made under paragraph (a) in column 3 of item 15, and paragraph (a) in column 3 of item 16, of Schedule 5A to the *Therapeutic Goods Regulations 1990* (the TG Regulations).

This notice is also made under paragraph (a) in the column headed "Conditions" of item 2.17, and paragraph (a) in the column headed "Conditions" of item 2.18, of Part 2 of Schedule 4 to the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations)

Section 1: Sponsor information

Company name:	Mission Distribution Victoria Pty Limited
TGA client ID:	83800
Contact email:	s2 s47 [redacted]

Section 2: Vaping good category

See guidance about the definitions used in this form. Every vaping good requires a separate notice, including where those therapeutic vaping goods are contained in a therapeutic vaping kit or therapeutic vaping pack.

Select one vaping good category for this notice:

☐ A finished good that is, or contains, a vaping substance (a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a good in a ***therapeutic vaping kit*** – see item 15 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 5 and 8 below

☐ A finished good that would be a medical device except that it is for supply as part of a therapeutic vaping pack (a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** in a ***therapeutic vaping pack*** – see item 15 of Schedule 5A to the TG Regulations).[1]

Complete sections 3, 4, 5 and 8 below

☒ A finished good that does not contain a vaping substance, and is a reusable vaping device or a component of a reusable vaping device, or a reusable cartridge, capsule or pod or other vessel (a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.17 of Part 2 of Schedule 4 to the MD Regulations).

Complete sections 3, 4, 6 and 8 below.

☐ A starting material, that is not liquid nicotine, for use in the manufacture of therapeutic vaping goods that are or contain therapeutic vaping substances (see item 16 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of vaping goods in Australia (including a ***therapeutic vaping substance***, a ***therapeutic vaping substance accessory***, or a ***therapeutic vaping kit*** – see item 16 Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ Liquid nicotine for further manufacture of other therapeutic goods in Australia (see item 16 of Schedule 5A to the TG Regulations).

Complete sections 3, 4, 7 and 8 below.

☐ A component or article intended for use in the manufacture of an unfilled vaping device (the manufacture of a ***therapeutic vaping device*** or a ***therapeutic vaping device accessory*** – see item 2.18 of Part 2 of Schedule 4 to the MD Regulations).

Complete sections 3, 4, 7 and 8 below.

[1] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

Section 3: Vaping good details

Complete **tables 1 and 2** if your vaping good is:

- a therapeutic vaping substance;
- liquid nicotine; or
- starting material that is an ingredient for use in the manufacture of a therapeutic vaping substance or therapeutic vaping substance accessory.

Complete **table 3** if your vaping good is:

- a therapeutic vaping device, e.g. a reusable vaporiser, battery, mouthpiece, coil or other parts of a reusable therapeutic vaping device;
- a therapeutic vaping device accessory, e.g. a unfilled cartridge, capsule or pod; or
- a component or article for use in the manufacture of a therapeutic vaping device, therapeutic vaping device accessory or therapeutic vaping substance accessory.

Complete **tables 1, 2 and 3** if your vaping good is:

- a therapeutic vaping substance accessory e.g. a filled cartridge, capsule or pod.

When completing **table 2**:

- list all ingredients (except for nicotine, details of which should be included in Table 1), including flavour, using the Australian Approved Ingredient name where possible; and
- use the approved terminology in TGA Code Tables, e.g. the Australian Approved Names of ingredients, and as specified in the published guidance.

Table 1: Details of the therapeutic vaping substance, liquid nicotine or starting material

Name of good:	
Description of good:	
Container type:	
Volume in mL (or weight if applicable):	
Nicotine form (if applicable):	
Nicotine quantity:	

Table 2: Ingredients in the therapeutic vaping substance, liquid nicotine or starting material

Ingredient name	Quantity

Table 3: Details of the therapeutic vaping device, therapeutic vaping device accessory, therapeutic vaping substance accessory or articles or components for further manufacture

Vaping good name:	RELX Infinity 2 Device		
Device model:	P54a		
Vaping good description:	Therapeutic vaping device without vaping substance		
Liquid capacity in mL:	No applicable, it's a therapeutic vaping device without tank		
Device product identifier GMDN or UDI:	No GMDN or UDI is available		
Rechargeable battery:	☒ Yes	☐ No	
Battery capacity:	440mAh		
Battery composition: (e.g. Nickel-Cadmium, Nickel-Metal Hydride, Lithium Ion)	Lithium Ion		
Battery voltage:	3.7V~4.2V		
Battery wattage:	8W		
Type of heating element:	☐ Coil	☐ Wick	☒ Other
	If Other selected, please describe: No applicable, it's a therapeutic vaping device without tank		
Charging unit:	☒ USB	☐ Other	
Is the airflow adjustable?	☐ Yes	☒ No	
Type of control unit(s): (e.g. PCB, microcontroller, software, etc)	PCB, microcontroller, software		

Section 4: Manufacturer details

Provide details of all prior manufacturers of the therapeutic vaping goods, ingredients or components you are importing or supplying.

Manufacturers of the therapeutic vaping substance, therapeutic vaping substance accessory, liquid nicotine or starting material for further manufacture

Manufacturer name:	s47 [redacted]
TGA client ID:	s47 [redacted]
Steps in manufacture:	Finished product manufacturer/packaging manufacturer/testing physical manufacturer

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturer name:	
TGA client ID:	
Steps in manufacture:	

Manufacturers of the therapeutic vaping device, therapeutic vaping device accessory, therapeutic vaping substance accessory or articles or components for further manufacture

Manufacturer name:	s47 [redacted]				
Site street address:	s47 [redacted]				
Suburb/Town/City:	s47 [redacted]	**State/Territory:**	s47 [redacted]	**Post code:**	s47 [redacted]
Country:	s47 [redacted]				
Contact email:	s22 s47 [redacted]				

Manufacturer name:					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Manufacturer name:					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Manufacturer name:					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	

Country:	
Contact email:	

Section 5: Compliance – vaping substances etc

Complete this section if the therapeutic vaping good is ready to be supplied in Australia and is, or contains, a therapeutic vaping substance, including a therapeutic vaping substance accessory, therapeutic vaping kit or is a good in a therapeutic vaping pack.[2].

The therapeutic vaping good:

☐ is only indicated for 'smoking cessation' or the 'management of nicotine dependence'.

The therapeutic vaping good:

☐ conforms with applicable standards, including *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021*. **Complete the TGO 110 compliance evidence below.**

OR

☐ is the subject of a consent from the Secretary under section 14 or 14A of the Therapeutic Goods Act for importation or supply. (Note: consent is only granted in exceptional circumstances).

TGO 110 compliance evidence

☐ Testing is performed on each batch of vaping goods.

- ☐ We hold an example of recent testing performed on a batch of vaping goods supplied or to be supplied in Australia:

Name of the facility:	s47 [redacted]
Address of the facility:	s47 [redacted]
Date tested: (dd/mm/yyyy)	16/12/2023

- ☐ Testing performed will confirm the nicotine concentration, which aligns with the label claim (where applicable).
- ☐ Testing will confirm the absence of prohibited ingredients.
- ☐ Batch-specific test results can be made available upon request.

☐ The good only contains mint, menthol, or tobacco flavour, if it contains a flavour.

☐ The labels comply with the requirements of TGO 110.

- ☐ The product label includes a list of all ingredients required by TGO 110.
- ☐ The product label includes quantity of nicotine as an active ingredient (if applicable).
- ☐ The product label includes applicable warning statements.
- ☐ Copies of labels can be provided upon request.

☐ The good has child-resistant packaging.

☐ For a vaping substance accessory, vaping device, vaping device accessory or vaping substance accessories in a kit, the good(s) conforms with the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023* or essential principles, as appropriate (see footnote 3 and 4).

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[2] The *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* declares therapeutic vaping devices or therapeutic vaping device accessories in a therapeutic vaping pack not to be medical devices.

Section 6: Compliance – vaping devices etc

Complete this section for a good that is a therapeutic vaping device or therapeutic vaping device accessory that does not contain a therapeutic vaping substance and is not to be imported or supplied in a therapeutic vaping pack. See footnotes 3 and 4 as to which standards apply to your vaping device.

The therapeutic vaping device or therapeutic device accessory:

☒ is only intended to administer a therapeutic vaping substance that is indicated for 'smoking cessation' or the 'management of nicotine dependence'.

The therapeutic vaping device or therapeutic device accessory:

☒ conforms with the Essential Principles[3]. **Complete the *Essential Principles* checklist available on the TGA website** (https://www.tga.gov.au/resources/resource/forms/essential-principles-checklist-medical-devices). You do not need to submit the completed checklist. **Go to section 8.**

OR

☐ is a device to which the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023*[4] (MDSO) applies and conforms with the MDSO. **Complete the vaping device compliance evidence below.**

OR

☐ is the subject of consent from the Secretary under section 41MA or 41MAA of the Act for non-compliance with the essential principles. (Note: consent is only granted in exceptional circumstances, for a limited period). **Go to section 8.**

Evidence of compliance – vaping device or vaping device accessory

If your therapeutic vaping device or therapeutic vaping device accessory does not comply with the Essential Principles and the MDSO applies, select one or more types of valid evidence held that demonstrates compliance with applicable requirements:

☐ US FDA - Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS)

☐ EU - European Tobacco Products Directive - A valid notification under Article 20 of Directive 2014/40/EU

☐ UK MHRA - notification through the Tobacco and related Products Regulations (TRPR), as listed on the notified e-cigarette products publication (database) ecig (cms.mhra.gov.uk/ecig)

☐ Certificate, licence, notification, or other approval establishing compliance for supply of therapeutic goods (TGA, US FDA, EU notified body, or designated body by UK MHRA)

☒ ISO 9001 certificate

☐ ISO13485 certificate

Based on the selection above, provide the following information as evidence (the table can be duplicated if more than one type of evidence is held or there are multiple manufacturing sites holding separate certifications):

Authorising authority / certification or notification body	s47 [redacted]
Scope of authorisation / certification / notification	Manufacturing of Electronic Cigarette and Atomizers
Authorisation / certificate / notification number or identifier	s47 [redacted]

[3] The essential principles apply to therapeutic vaping devices and therapeutic vaping device accessories by default under the *Therapeutic Goods Act 1989*.

[4] The MDSO applies to therapeutic vaping devices and therapeutic vaping device accessories, imported or manufactured on or after 1 March 2024, that prior to 1 January 2024 were excluded from the operation of the *Therapeutic Goods Act 1989*. Vaping devices and vaping device accessories previously excluded were those not intended to be used exclusively for the administration of a medicine.

Section 7: Ingredients or components for further manufacture in Australia

Complete this section if the good is a starting material, component or article being imported for the purpose of further manufacture in Australia.

☐ The starting material is for use in the lawful manufacture of a therapeutic vaping substance or a therapeutic vaping substance accessory or another therapeutic good by a manufacturer that holds all relevant licences or approvals. Provide details of manufacturing sites in the table below. Duplicate the table as necessary.

Manufacturer name:	
TGA licence number:	
Steps in manufacture:	

☐ The article or component is for use in the lawful manufacture of a therapeutic vaping device or a therapeutic vaping device accessory by a manufacturer that holds all relevant licences or approvals. Provide details of manufacturing sites in the table below. Duplicate the table as necessary.

Manufacturer name:					
Conformity assessment evidence					
Site street address:					
Suburb/Town/City:		**State/Territory:**		**Post code:**	
Country:					
Contact email:					

Section 8: Declaration

Section 8.1: Privacy information

General privacy information is available on the TGA website.

The TGA is collecting personal information in this form in order to contact the sponsor to discuss the notice where necessary.

Section 8.2: Declaration

☒ I declare that the information provided in this form, is, to the best of my knowledge, current and correct.

☒ I certify that the statements made in this notice are supported by information and evidence which will be provided to the TGA upon request.

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 section 137.1 of the Commonwealth Criminal Code.

Name	s22 [redacted]		
Signature	s22 [redacted]	Date	04.03.2024

Send this completed notification form to vapenotifications@health.gov.au

From: s22
To: GILMOUR-WALSH, Bridget; s22
Cc: NVP
Subject: RE: Chinese laws for export [SEC=OFFICIAL]
Date: Friday, 12 May 2023 6:22:25 PM
Attachments: Submission by email - s22 (2).pdf

Hi both s22 – s22 submission is attached. I'll send it to s22 in a moment.

s22

From: GILMOUR-WALSH, Bridget <Bridget.GILMOUR-WALSH@Health.gov.au>
Sent: Friday, 12 May 2023 6:18 PM
To: s22 @Health.gov.au>
Cc: s22 @health.gov.au>; NVP <NVP@Health.gov.au>
Subject: RE: Chinese laws for export [SEC=OFFICIAL]

Can you also cc s22 and s22 into the email because it is an enforcement matter. THnx

---

From: GILMOUR-WALSH, Bridget
Sent: Friday, 12 May 2023 6:18 PM
To: s22 @Health.gov.au>
Cc: s22 @health.gov.au>; NVP <NVP@Health.gov.au>
Subject: RE: Chinese laws for export [SEC=OFFICIAL]

HI s22

On Mon, would you be able to find s22 PDF submission and send it to s22 with page ref to where he talks about Chinese export laws being utilised to prevent the export from China of vapes that would be prohibited in Australia. ABF have people they can follow this up with in China and it may be a good way to stem unlawful Chinese vapes if it is an option.

I could not get his submission to download from the consultation hub.

Thanks v much.

Bridget

From: s22 @abf.gov.au>
Sent: Friday, 12 May 2023 3:19 PM
To: GILMOUR-WALSH, Bridget <Bridget.GILMOUR-WALSH@Health.gov.au>
Subject: Chinese laws for export [SEC=OFFICIAL]

OFFICIAL

Reminder to send the consultation report that explains Chinese export laws.

Thanks

s22

s22 (she/her) | **Director**
Permits and Strategic Goods Section
Customs and Trade Policy Branch
Customs Division | National Operations Group
Australian Border Force
t: s22 | m: s22 | e: s22 @abf.gov.au

OFFICIAL

Submission

Potential reforms to the regulation of nicotine vaping products

s22 s22
s22 , University of Sydney

16 Jan 2023

Relevant career highlights of author

s22

Contents

Comments on the regulatory challenges of NVPs

1 Safety of NVPs

First commercialised in China in 2003 Nicotine Vaping Products (NVPs) have been in widespread use in many nations for only a decade or less. While there is little doubt that head-to-head comparisons of emissions from NVPs with those from combusted tobacco (principally cigarettes) suggest NVPs are likely to be significantly less toxic than cigarettes, it is critical that the framing of debate about the regulation of NVPs should not be circumscribed only by this simplistic comparison.

Responsible regulation that considers the *whole-of-population impact of widespread vaping* needs to be guided not only by considering putative risk reduction for smokers who switch completely to NVPs. It must also consider:

- risks to vapers who also continue to smoke (dual users) often for many years
- whether access to vaping might hold more smokers in smoking than it tips out of it
- ex-smokers who commence vaping long after they have quit smoking
- the uptake of regular vaping by nicotine-naïve youth, many of whom would have been forecast by downward smoking trends as likely to never use *any* form of nicotine
- whether young people who vape are more likely to commence smoking than those who never vape, particularly when "propensity to smoke" variables are adjusted for in analyses of smoking uptake

Vaping advocates argue that access to NVPs should be as liberal as possible (and certainly as liberal as access is to cigarettes – see p 24 below). All but the most extreme frame their case via the importance of *adult smokers* being able to readily access NVPs as reduced harm nicotine delivery systems which they claim are also a very effective game-changing, disruptive means to quit smoking.

Again, extremist vaping advocates openly argue that children should also have the same access to NVPs. They even make this argument in the context of both reducing harm to children who already smoke and helping children who smoke to quit. They make this argument against historically declining smoking in teenagers long preceding the advent of vaping, where today we see unprecedented low smoking prevalence in Australia and elsewhere.

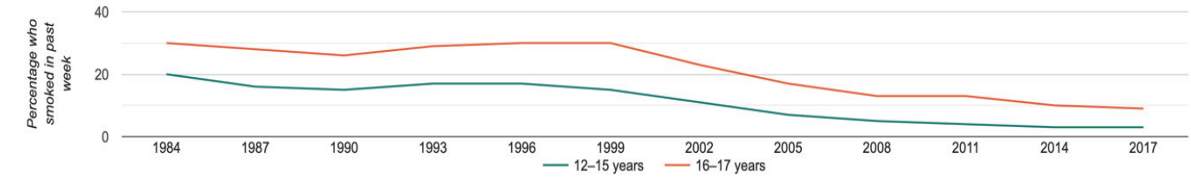


Figure 1.6.1
Prevalence of Australian secondary school students who report smoking in the last week, Australia 1984 to 2017: 12–15 year olds and 16–17 year olds

Source: Guerin and White 2020[6]

Australian youth smoking prevalence 1984 to 2017, 12-15 and 16-17 years

With an ever-diminishing proportion of children who smoke, this is an argument which makes ever-diminishing sense. With an ever-increasing proportion of children who don't smoke, ensuring that achievements in the prevention of smoking uptake are not eroded by marketing by nicotine addicting industries becomes increasingly important for tobacco control policy.

Ensuring that a large cohort of adolescents becomes nicotine dependent has long been the *sine qua non* of the tobacco industry's assessment of its future viability (see RJ Reynolds internal document below from 1973).

Younger adult smokers are the only source of replacement smokers. Repeated government studies (Appendix B) have shown that:

- Less than one-third of smokers (31%) start after age 18.
- Only 5% of smokers start after age 24.

Thus, today's younger adult smoking behavior will largely determine the trend of Industry volume over the next several decades. If younger adults turn away from smoking, the Industry must decline, just as a population which does not give birth will eventually dwindle. In such an environ-

Source: http://legacy.library.ucsf.edu/tid/fet29d00 at p10

All tobacco companies with interests in NVPs support a "consumer product" classification for NVPs which would allow them to be sold virtually anywhere, and strongly oppose the Medical Access Framework (MAF). This speaks volumes for why the MAF should be strongly supported.

Opponents of the MAF argue that it places unnecessary restrictions on a product that should be accorded exceptionalist regulatory status by having unlimited nicotine concentration, unlimited flavours, be sold anywhere to any adult, be advertised, used in almost any public setting, and minimally taxed to encourage widespread use.

Dual users have *increased* tobacco toxicant exposures

Information of immense importance to the debate about the net contribution of vaping to toxicant exposure was published in 2018 using data obtained from the US longitudinal PATH study. The authors compared concentrations of tobacco-related toxicant biomarkers among

e-cigarette users with those observed in cigarette smokers, dual users of e-cigarettes and cigarettes, and those who had never used tobacco in any form. They compared mean concentrations of 50 individual biomarkers from five major classes of tobacco product constituents: nicotine, tobacco-specific nitrosamines (TSNAs), metals, polycyclic aromatic hydrocarbons (PAHs) and volatile organic compounds (VOCs).
In summary, the data in the paper show that if you have never used tobacco in any form, unsurprisingly you are likely to have far lower biomarkers for tobacco use than those who use NVPs. If you exclusively use NVPs, you'll have far lower tobacco toxicant levels than if you smoke. But if you both smoke and vape (dual use), you'll have higher levels than those who only smoke. Dual use is not risk reduction but increases health risks.

Adding to this, another paper using PATH data found that dual users have a greater concentration of an oxidative stress marker, F2-isoprostane, than smokers. Exclusive EC users have biomarker concentrations at similar levels to those of former smokers, and lower than those of exclusive cigarette smokers.

Johns Hopkins University researchers applied liquid chromatography–high-resolution mass spectrometry (LC–HRMS) and chemical fingerprinting techniques to characterise e-liquids and aerosols from a selection of popular EC products (Mi-Salt™, Vuse™, Juul™ and Blu™). (Tehrani, Newmeyer et al. 2021) They found nearly 2,000 chemicals in these products, the vast majority of which were unidentified. Six potentially hazardous additives and contaminants, including the industrial chemical tributylphosphine oxide were identified. The authors noted "Existing research that compared e-cigarettes with normal cigarettes found that cigarette contaminants are much lower in e-cigarettes. The problem is that *e-cigarette aerosols contain other completely uncharacterized chemicals that might have health risks that we don't yet know about*." (Johns Hopkins University 2021) [my emphasis]

There is no precedent in toxicology for a mass behaviour which involves deep inhalation up to some 500+ times a day of vapourised flavouring chemicals unapproved by any regulatory authority (see p30 below)

Importantly here, the best evidence that we have about dual use is that not only does it expose smoking vapers to more toxicants, but it is also very prevalent, very enduring and is associated with higher rates of relapse to smoking than in smokers who don't vape.

Another PATH study reported that former smokers who had quit a long time ago but who vaped were far more likely than those who had never vaped to relapse back to smoking and that vapers were far more likely than those who had never vaped to have transitioned from being never smokers to smokers:

> "Distant former combustible cigarette smokers who reported e-cigarette past 30-day use (9.3%) and ever use (6.7%) *were significantly more likely than those who had never used e-cigarettes (1.3%) to have relapsed to current combustible cigarette smoking at follow-up* (*P* < .001). Never smokers who reported e-cigarette past 30-day use (25.6%) and ever use (13.9%) were significantly more likely than those who had never used e-cigarettes (2.1%) to have initiated combustible cigarette smoking (*P* < .001). A*dults who reported past 30-day e-cigarette use (7.0%) and ever e-cigarette*

> *use (1.7%) were more likely than those who had never used e-cigarettes (0.3%) to have transitioned from never smokers to current combustible cigarette smokers* (*P* < .001). E-cigarette use predicted combustible cigarette smoking in multivariable analyses controlling for covariates. [my emphasis]

A 2020 paper from the ITC four country (Australia, USA, UK, Canada) survey found that after 18 months:

> "smokers with established concurrent use [smoking and vaping or dual use] were not more likely to discontinue smoking compared to those not vaping … *it is clear that the rates of transitioning away from smoking remain unacceptably low*, and perhaps current vaping tools at best bring the likelihood of quitting up to comparable levels of less dependent smokers. The findings of our international study are consistent with the findings of the US PATH transition studies, and other observational studies, in that *most smokers remain in a persistent state of cigarette use across time, particularly the daily smokers.*"

As I wrote chapter 6 on vaping in my recent book *Quit Smoking Weapons of Mass Distraction* (Sydney University Press 2022) "if dual use is the Mount Everest of toxicant exposure, then smoking is the K2 exposure, vaping is the Matterhorn and never smoking or vaping is the toxicant exposure at sea level." Worse than that, unlike these very uncommonly climbed mountains, the prevalence of dual use, smoking and vaping are all high, exposing millions around the world.

A 2022 systematic review of the health effects of real-world dual use of electronic and conventional cigarettes versus the health effects of exclusive smoking of conventional cigarettes (ESCC) concluded "dual use is at least as, or probably even more, harmful than ESCC."

Switching not quitting

Vaping advocates and the industry have sought to reframe *quitting* as *switching to NVPs* for smokers, diminishing the primacy of quitting in public discourse about smoking. If the long-term health consequences of switching to NVPs indeed prove positively significant, regulators will be able to loosen the regulatory controls to liberalise access. This is what frequently happens with drugs which demonstrate years of effectiveness and safety, including nicotine replacement therapy which was first sold strictly via prescription and then rescheduled to OTC and supermarket sales in many formulations.

Far too early to know true risks

But in 2022 we are a long way from knowing what the long-term health consequences of vaping are. In 2021 15 past presidents of the Society for Research in Nicotine and Tobacco affirmed that "High-quality clinical and epidemiological data on vaping's health effects are relatively sparse. *There are no data on long-term health effects*, reflecting the relative novelty of vaping and the rapid evolution of vaping products." [my emphasis] Cardiovascular

and respiratory diseases and cancer seldom manifest clinically for several decades after regular exposure to causative agents commences.

Cigarette use exploded at the beginning of the 20th century after mechanisation in factories replaced handmade cigarettes. This made smoking very affordable to even those on the lowest incomes. But tobacco-caused diseases didn't start showing up in large numbers until 30–40 years later. US surgeon Alton Ochsner, recalling attendance at his first lung cancer autopsy in 1919, was told he and his fellow interns "might never see another such case as long as we lived". He saw no further cases until 17 years later in 1936 –and then saw another nine cases in six months. Since the 1960s, lung cancer has been by far the world's leading cause of cancer death with 18% of all cancer deaths in 2020, ahead of the next most frequent killer, liver cancer, with 8.3%.

As with asbestos exposure, the chronic diseases caused by smoking take many years before manifesting clinically. They are not like infectious, communicable diseases such as COVID-19, influenza or HIV where there is typically a very short period between exposure to the infectious agent and the onset of symptoms and sometimes death. Instead there are long latency periods that can stretch for several decades when smokers may not have any signs or symptoms of emerging disease.

Recent reviews have summarised increasing emerging evidence that sustained use of NVPs are associated with early signs of cardiovascular health and respiratory problems. Examples of these reviews include:

- Jonas A. Impact of vaping on respiratory health. BMJ 2022
- Keith R, Bhatnager A. Cardiorespiratory and immunologic effects of electronic cigarettes. Current Addiction Reports 2021 8:336–346 ("*The use of e-cigarettes in humans is associated with significant adverse cardiorespiratory and immunological changes. Data from animal models and in vitro studies support the notion that long-term use of e-cigarettes may pose significant health risks*.")
- Tsai M, Byun MK, Shin J, Alexander LEC. Symposium Review: Effects of e-cigarettes and vaping devices on cardiac and pulmonary physiology J Physiol 2020;588(22): 5039–5062 ("*Research thus far demonstrates that the heart and lung undergo numerous changes in response to e-cigarette use,and disease development will depend on how those changes combine with both environmental and genetic factors. E-cigarettes have been advertised as a healthy alternative to cigarette smoking, and users are under the impression that vaping of e-cigarettes is harmless, but these claims that e-cigarettes are safer and healthier are not based on evidence. Data from both humans and animal models are consistent in demonstrating that vaping of e-cigarettes causes health effects both similar to and disparate from those of cigarette smoking.*")
- Wehrli FW et al. New insights from MRI and cell biology Into the acute vascular-metabolic implications of electronic cigarette vaping. Frontiers in Physiology 21 May 2020 ("*The acute effects observed following a single vaping episode persist for 1–3 h before subsiding to baseline and are paralleled by build-up of biological markers. Sparse data exist on long-term effects of vaping, and it is likely that repeated regular exposure to e-cig aerosol during vaping will lead to chronic conditions since there*

would be no return to baseline conditions as in the case of an isolated vaping episode.")

2. Addiction and NVPs

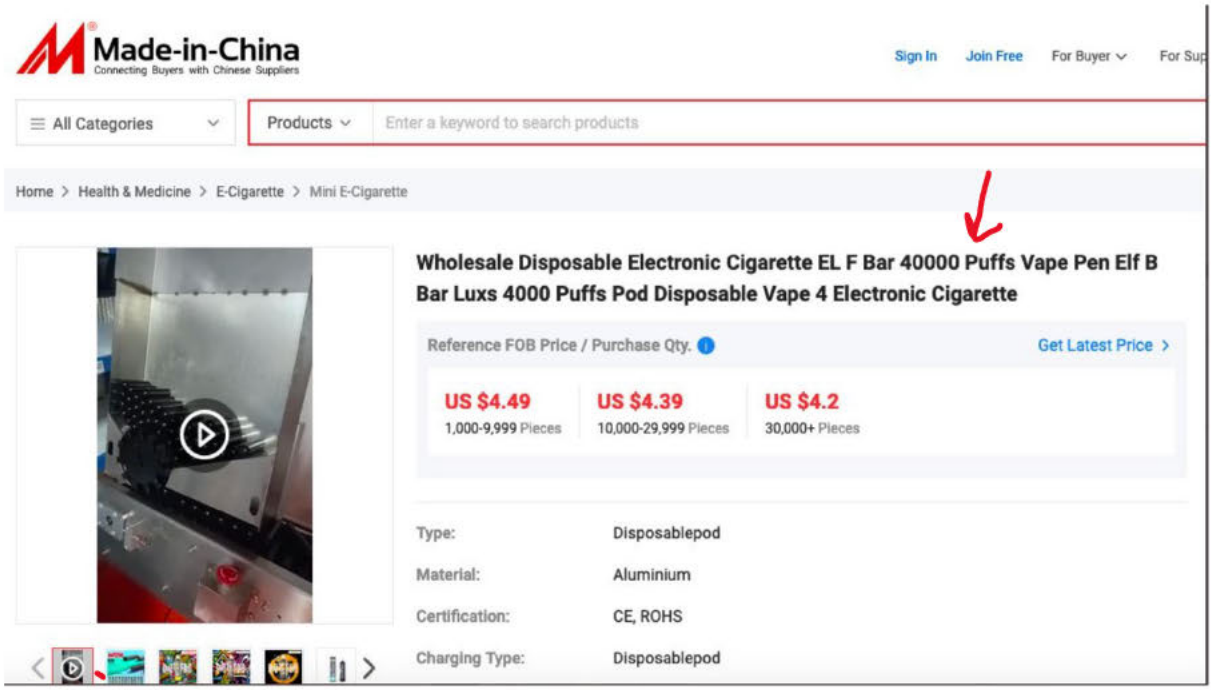
Some vaping advocates state that vapourised nicotine when inhaled via NVPs is "not terribly addictive". Such claims are frequently seen on social media. (example below)

Puff frequency is a key, easily observed parameter of nicotine addiction. A 2020 study monitoring vaping found those who were exclusive vapers pulled vape deep into their lungs on average 173 times a day – 63,188 times a year. Those who were dual users (i.e. who vaped but still smoked) basted their lungs 72 times a day with their NVPs in addition to the smoke from their smoking.

Another study found the average daily number of NVP puffs taken was 200, with a range up to 611. A third study, where researchers observed vapers using their normal vaping equipment *ad libitum* (as often as they pleased) for 90 minutes, reported the median number of puffs taken over 90 mins was 71 (i.e. 0.78 puffs per minute or 47.3 per hour). If we make the conservative assumption that a person vaped for only 12 hours a day at that rate, this would translate to 568 puffs across a 12-hour day or 207,462 times in a year.

We can contrast this with the number of puffs today's average 12-cigarettes-a-day smoker inhales. One study observing puff frequency in those smoking in social settings recorded an average of 8.7 puffs per cigarette with an average 38.6-second gap between puffs. At 12 cigarettes a day, this would translate to 104 puffs per day or 38,106 per year. So vapers' puffing compared to that with smoking occurs at an almost frantic rate, making a mockery of the bizarre denialism often seen in vaping chat rooms insisting that vaped nicotine is not addictive.

Cheap flavoured disposable vaping NVPs from China are now on sale in Australia that can deliver 40,000 puffs, the equivalent of puff numbers seen with 200 packs of 25 cigarettes where a smoker took 8 puffs per cigarette (see screenshot below).



As discussed, vaping advocates have shrugged this off as of no concern, likening teenage vaping to "fads and fashions" like hula hoops and yoyos.

Vaping advocates routinely claim that all the evidence on the harmful effects of nicotine on brain development in adolescents is from animal and cell studies, waving the dismissive "pure speculation" flag about their relevance for adolescent humans when such concerns are raised. This in in spite of the standard LD50 metric (Lethal Dose required to kill 50% of exposed laboratory animals) being used globally to rate the toxicity of chemicals for humans and the vast record of animal studies being used in the development of safety and efficacy of many life-saving drugs.

This recent longitudinal study of very young children who used any form of nicotine, using neuroimaging outcomes found "a significant association was found of early-age initiation of tobacco use with lower crystalized cognition composite score and impaired brain development in total cortical area and volume. Region of interest analysis also revealed smaller cortical area and volume across frontal, parietal, and temporal lobes."

3 Effectiveness of NVPs in smoking cessation in RCTs and in real world use

The 4th edition of the Cochrane Collaboration's review of e-cigarettes and cessation was recently published. It based its conclusions on just 6 randomised controlled trials (RCTs) which satisfied its quality standards. It concluded:

> "People are more likely to stop smoking for at least six months using nicotine e-cigarettes than using nicotine replacement therapy (6 studies, 2378 people), or e-cigarettes without nicotine (5 studies, 1447 people).
>
> For every 100 people using nicotine e-cigarettes to stop smoking, 9 to 14 might successfully stop, compared with only 6 of 100 people using nicotine-replacement therapy, 7 of 100 using e-cigarettes without nicotine, or 4 of 100 people having no support or behavioural support only."

Very critically, there are many important differences between RCTs and the ways that smoking cessation products (including NVPs) are used in the real world, away from the highly artificial constructs of RCTs.

I have reviewed these differences at length in chapter 3 of my 2022 book and summarise some key issues below.

Problems with RCTs

RCTs are revered in experimental and clinical science as being "gold standard" evidence about whether an intervention (often a drug) makes a difference to outcomes of interest, such as smoking cessation.

RCTs can compare a drug with another drug used for a similar purpose, with a placebo, or with "usual care". Usual care in smoking cessation RCTs can be the sort of advice that a doctor or other health professional might ordinarily offer to a smoker when they were not participating in a study. Given that such advice is often given, especially when a medication is involved, it is important to assess whether the medication has any additional cessation effect on top of the advice or routines to which smokers would ordinarily be exposed in their interactions with a health care provider or service.

But when smokers access drugs in real world circumstances, they may receive no support or advice (for example, when buying NRT from a supermarket or NVPs over the internet) or only brief, sometimes perfunctory advice when a health care provider or pharmacist is too busy to spend much time with a customer or patient. A NSW survey of 700 pharmacies reported that pharmacists claimed to spend an average of five minutes discussing stop smoking medications with smokers (meaning that many would spend less time than that).

Once a sufficiently large number of participants have been selected to participate in an RCT, they are randomly allocated into treatment or comparison/control arms of the trial. Ideally, the allocation should be done by randomization software and by someone not associated with the trial but by third parties with no interests of any sort in the outcomes of the trial.

Those conducting RCTs can recruit their participants in a variety of ways, some of which introduce important biases in the study population. In the smoking cessation field, we often see subjects recruited from sources like quit smoking clinics, telephone quitline callers, general practitioner and other primary health care patients, smoking cessation or vaping website and chatroom visitors. With each of these, we need to ask whether smokers recruited in such ways are different in important ways to randomly selected smokers in the

population at large. Self-selection bias is very relevant here. We are likely to be dealing with those who are more help-seeking and positively disposed to vaping. This may mean they are more motivated to quit than smokers in the general population, and it may mean they are people with lower self-efficacy (lower confidence in their ability to quit unaided).

Often researchers attempt to address this concern by demonstrating that those who have been recruited into trials are comparable to smokers in the whole population on a range of variables like demographics, smoking history, level of nicotine dependency, intention to quit and so on. But, beyond all these comparabilities, in a very important respect they *are* different: they have often taken steps at help-seeking in their hopes to stop smoking. But the great majority of smokers who quit don't seek help to do so on their final successful attempt. So those who volunteer to take part in trials recruited in these ways are help-seeking volunteers.

Trial exclusion criteria

Those running trials will often exclude people from trial participation for a variety of reasons. Those who have language problems are often excluded, as interpreters are expensive to add to study budgets. Those with drug or alcohol dependency, serious mental health problems like depression, psychosis or bipolar disorder can also be excluded, as can those with no fixed address, or who move addresses often, are in prison or who have a serious illness which might reduce their life expectancy (and so participation in the study down the track. Those with low motivation to quit can also be excluded.

One study reviewed 54 RCTs smoking cessation trials for criteria for exclusion and found 25 separate criteria being used across these trials. They then applied 12 of the most commonly used of these criteria to 4,962 adults with nicotine dependence in the past 12 months from a US national survey on alcohol use (NESARC) and to a subgroup of participants motivated to quit. (see table below).

They found two-thirds of participants with nicotine dependence would have been excluded from clinical trials by at least one criterion, with 59% of the subgroup of motivated to quit smokers also excluded.

Exclusion variable	**Current nicotine dependence (n=4962)**	**Motivated to quit smoking (n=4121)**
Pregnancy	3	3
Cardiovascular disease	7	7
Smoking <10 cigs/day	32	34
Current/past 6m use of any psychotropic medication	NA	NA
High alcohol consumption	14	13
Not motivated to quit	18	0
Use of other drugs	3	3
Current depression	17	16

Current/past 6m use of bupropion and/or NRT	NA	NA
Eating disorder	NA	NA
History of psychosis	2	2
History of bipolar disorder	10	10
Exclusion by any criterion	66	59

Table: Estimated (rounded) percentages of adults with nicotine dependence in NESARC excluded from typical trials of treatments for nicotine dependence by traditional ineligibility criteria. NA= information not available in NESARC

Trial subject retention strategies

Those running trials put a lot of effort into maximising trial cohort retention rates. If lots of people drop out of the groups being studied, this can greatly compromise the integrity of trials, as important questions can be asked about whether those who pulled out or were lost to follow-up differed in important ways to those who remained in a study across its entire course.

Real-world studies have found high levels of premature discontinuation of quit smoking medication use. A four nation study of 1,219 smokers or recent quitters who had used medication in the last year (80.5% NRT, 19.5% prescription only found most (69.1%) discontinued medication use prematurely (71.4% of NRT users and 59.6% of bupropion and varenicline. NRT users who obtained their patches or gum over-the-counter without prescription were particularly likely to discontinue (76.3%).

Lots of wisdom has accumulated in professional trial communities about cohort retention. Strategies include reducing any barriers to participation, efforts to building a sense of community and belonging among trialists, follow-up and reminder strategies, and tracing techniques. Community building strategies can be particularly important and trial staff who have good “people” skills are particularly important. This often fosters positive attitudes and a sense of responsibility among participants toward helping the trial avoid low levels of dropout. They can be made to feel important that they are contributing to the advance of science and the health of communities.

Trial staff often include young investigators whose PhD work is focussed on a trial. They have particularly strong motivation to develop good personal relationships with participants as the work they do will be assessed by their thesis and publication reviewers and major problems like high dropout rates can be fatal to publication. Someone mildly irritated with the on-going demands of a study to complete questionnaires, provide biological samples and keep personal data records may feel a sense of “that lovely young researcher who contacts me every few months would be very unhappy if I pulled out”. Strategies like sending thank you, birthday and holiday cards, trial newsletters, supplying trial logo material like caps and T-shirts are also often used. None of this happens in the real world when people start vaping or using NRT they might buy in a supermarket.

Trialists are often paid and drugs are free

The drugs used in trials are given free-of-charge to participants. Even where governments subsidise the cost of approved prescribed medications, the drugs are never free, and to those on low incomes, can still constitute a significant outlay. This may inhibit them being used into the medium or longer term by those who feel they need to continue using them.

It is also increasingly common for trialists to be paid for their participation in trials. This is intended to act as both fair compensation for their time and any out-of-pocket expenses like travel to the research unit, but may also act as an incentive to continue participation, particularly for those on low incomes or who are unemployed. In real world, unmonitored or unsupervised quit attempts, smokers are never paid to use quitting aids. These differences may give an extra boost to full compliance across the recommended course of smoking cessation aid use, something that is often far from the case in real world use.

Blindness integrity problems

In most RCTs, participants are not told whether they have been randomised to receive the active or placebo (control) drug. This is called subject "blinding": they are blind to whether they are getting the active drug or the dummy, inert, control drug. Sometimes, investigators are also blinded as to whether subjects have been allocated to a particular treatment arm to which each study participant has been added. This is called double blinding and is undertaken to remove the possibility of researchers actively or inadvertently communicating expectations of effects to study participants. A researcher who might have hopes that a particular treatment is efficacious and who knows that particular study participants have been allocated to the active drug, may make comments to these patients that suggest to them it is likely that they are on the active drug. Researchers with expectations that successful outcomes of a trial (ie where the active drug is shown to be far better than a placebo) might lead to valuable, career-enhancing opportunities may sometimes be tempted to compromise the integrity of the blinding of a trial.

Nicotine replacement therapy and vaping are strong candidates for a failure in blindness integrity. Nearly all smokers have often experienced interoceptive cues that they are craving nicotine. Here, we need only think of the speed with which many smokers light up a cigarette soon after waking each morning, the common sight of smokers rushing to light up after alighting from non-smoking public transport and standing outside office blocks and restaurants. These commonplace sights tell us that smokers are very familiar with sensations that remind them of their need to re-dose with nicotine and the relief and pleasant sensations they experience shortly after doing this.

So when smokers, who may have inhaled nicotine perhaps up to hundreds of times a day for years, get allocated to the placebo (non-nicotine) arm of a trial of NRT or e-cigs, many very quickly realise that they are in the control arm of the trial: they are not getting the "good stuff" that the trial is testing to see if it is effective. Their brain tells them they are not getting nicotine.

This paper looked at this issue. Of 73 trials it reviewed, only 17 made any assessment of blindness integrity (the others didn't even consider it). And of the 17, 12 reported that the participants guessed correctly which arm of the trial they had been assigned to. Knowing you have been allocated to the placebo arm would seriously erode confidence in the effectiveness of the drug, vape or NRT system to which you had been allocated, this artificially widening the likely gap between nicotine allocated subjects and those in the placebo arm.

When considered together, all the above problems make RCTs on smoking cessation a very far cry from the way smokers use NRT and ecigs in the real world. But this has not stopped headlines about effectiveness, as if these artificially constructed trials bore any resemblance to the spread and conditions of use in the real world.

Cohort studies of real world vaping and cessation

When we look at the best of the cohort studies that follow groups of smokers over time, we get a very different perspective of how well these nicotine replacement methods work in reality. I have summarised many of these studies in my 2022 book, commencing at p184.

Summaries of a couple of salutary examples follow:

A US paper by Coleman et al using PATH data reported on a 12-month follow-up of 2932 vapers. The table below shows that for every person vaping at the start of the study (wave 1) who benefited across 12 months by quitting smoking, there were 2.1 who either relapsed to or took up smoking. However, by far the most common outcome was that those who were smoking and vaping at the beginning of the 12 months study period were still vaping and smoking at the end of the 12 months. Combining the negative and "remained the same" outcomes (38% + 44% =82%) it can be argued that vaping may hold far more in smoking than it tips out of it.

Summary of e-cigarette transitions from Wave 1 to Wave 2 by cigarette smoking status (n=2932)		
Positive outcome at Wave 2 n=524 (17.9%)	**Negative outcome at Wave 2** n=1116 (38%)	**Remained the same** n=1291 (44%)
143 dual users who quit EC and smoking	886 dual users who relapsed to smoking exclusively	902 dual users continuing as dual users
104 dual users who became EC users only	109 EC only but now smoking	389 EC users continuing as exclusive EC users
277 EC only who quit EC	121 EC only who progressed to dual use	

Source: data extracted from Coleman B, *et al*. *Tob Control* doi:10.1136/tobaccocontrol-2017-054174

A PATH report by Glasser and colleagues analysed three waves of PATH data from 2013 to 2016. Like other PATH studies, the odds of quitting when all vapers were included, were found to be insignificantly different to those smokers who did not vape. But "consistent and frequent e-cigarette use over time is associated with cigarette smoking cessation among adults." So does it then follow that frequent use of e-cigarettes being associated with higher quit rates should be seen as encouraging news? Undoubtedly, except when we take a close look at the desultory numbers involved.

There were 5,894 study participants using e-cigarettes at the beginning of the study. But only 78 (1%), were "consistent and frequent" users of e-cigarettes. For that 1% of users, quitting with e-cigarettes was more successful, but this was hardly a finding signalling that we are looking at results portending a major population-wide tsunami of quitting via vaping in the USA. If we take all who vape together, there's no net story about way more quitting than when we compare smokers who don't vape.

Another question we might ask here is about how many vapers who were trying to quit smoking also stopped using e-cigarettes by the 2016 follow-up? The Glasser paper does not provide that data. But Pierce and colleagues, analysing the same PATH data sets across the same years did look at this question. Their findings?

> "None in the daily e-cigarette use group (n=56) and 45% of the no e-cigarette group (n=162) were abstinent from all tobacco (including e-cigarettes) for 12+ months at Wave 3." Not one e-cigarette user who was using e-cigarettes to quit was able to quit both cigarette and e-cigarettes after three years.

Reviews of cessation evidence published since 2017

There have been *at least* 16 reviews of the evidence of the effectiveness of vaping in smoking cessation published since 2017 by scholarly and expert groups and agencies which have concluded that the evidence for NVPs being effective for cessation are inconclusive, low quality, insufficient, weak, inadequate and very limited.

1 (2021) Wang, Bhadriraju & Glantz E-Cigarette Use and Adult Cigarette Smoking Cessation: A Meta-Analysis. Am J Public Health "*We identified 64 papers (55 observational studies and 9 randomized clinical trials [RCTs]). In observational studies of all adult smokers (odds ratio [OR] = 0.947; 95% confidence interval [CI] = 0.772, 1.160) and smokers motivated to quit smoking (OR = 0.851; 95% CI = 0.684, 1.057), e-cigarette consumer product use was not associated with quitting. Daily e-cigarette use was associated with more quitting (OR = 1.529; 95% CI = 1.158, 2.019) and less-than-daily use was associated with less quitting (OR = 0.514; 95% CI = 0.402, 0.665). The RCTs that compared quitting among smokers who were provided e-cigarettes to smokers with conventional therapy found e-cigarette use was associated with more quitting (relative risk = 1.555; 95% CI = 1.173, 2.061).* ***Conclusions.*** *As consumer products, in observational studies, e-cigarettes were not associated with increased smoking cessation in the adult population. In RCTs, provision of free e-cigarettes as a therapeutic intervention was associated with increased smoking cessation.* ***Public Health Implications.*** *E-cigarettes should not be approved as consumer products but may warrant consideration as a prescription therapy.*"

2 (2021) Pound, Zhang et al .Smoking cessation in individuals who use vaping as compared with traditional nicotine replacement therapies: a systematic review and meta-analysis. BMJ Open "*We found no difference in smoking cessation, harms and smoking reduction between e-cigarette and NRT users. However, the quality of the evidence was low. Further research is needed before widespread recommendations are made with regard to the use of ENDS*."

3 (2021) World Health Organization: *"To date, evidence on the use of ENDS as a cessation aid is inconclusive*." (World Health Organization 2021)

4 (2021) US Preventive Health Services Taskforce: "*The USPHSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of e-cigarettes for tobacco cessation in adults*."

5 (2021) World Health Organization's WHO study group on tobacco product regulation (TOBREG): "*There is insufficient evidence that HTPs (heated tobacco products) aid a switch from smoking. Therefore, claims should not be made to that effect. Even if future evidence supported HTPs as effective switching aids (i.e. substituting one tobacco product for another), they should never be considered as treatment for smoking cessation, which includes quitting nicotine use."*

6 (2020) European Commission's Scientific Committee on Health, Environmental and Emerging Risks *"there is weak evidence for the support of electronic cigarettes' effectiveness in helping smokers to quit*"

7 (2020) United States Surgeon General report on smoking cessation "*there is presently inadequate evidence to conclude that e-cigarettes, in general, increase smoking cessation*."

8 (2020) Ireland's Health Research Board "*there is no evidence of a difference in effect on incidences of smoking cessation. There is a low-level of certainty in these results due to low successful event rates and high rates lost to follow-up in all studies*".

9 (2020) Australian National University Review for Commonwealth Department of Health (preliminary report) ("*there is insufficient evidence that nicotine-delivering e-cigarettes are efficacious for smoking cessation, compared to no intervention, placebo existing nicotine-replacement therapy or other best-practice interventions*."

10 (2020) Thoracic Society of Australia and New Zealand "*Smokers who enquire about using e-cigarettes as a cessation aid should be provided with appropriate information about approved medication in conjunction with behavioural support (as these have the strongest evidence of efficacy to date). E-cigarettes are not the first-line treatment for smoking cessation.*"

11 (2020) Grebovac et al (Effectiveness of Electronic Cigarettes in Smoking Cessation: a Systematic Review and Meta-Analysis) "*nicotine-ECs may be more effective in smoking cessation when compared to placebo ECs or NRT. When compared to counselling alone, nicotine ECs are more effective short-term but its effectiveness appears to diminish with later follow-ups. Given the small number of studies, heterogeneous design and the overall moderate to low quality of evidence, it is not possible to offer clear recommendations*."

12 (2019) European Respiratory Society "*There is not enough scientific evidence to support e-cigs as an aid to smoking cessation* "

13 (2018) US National Academies of Science, Engineering and Medicine -- a "review of reviews". ("*Conclusion 17-1. Overall, there is limited evidence that e-cigarettes may be effective aids to promote smoking cessation.*")

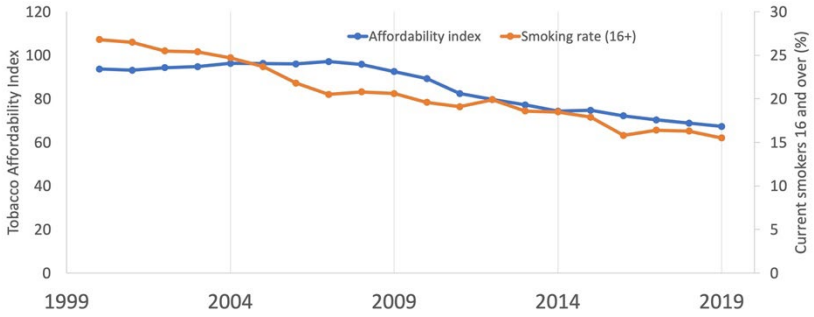
14 (2018) European Public Health Association ("*e-cigarettes may help some smokers quit but, for most, e-cigarettes depress quitting*")

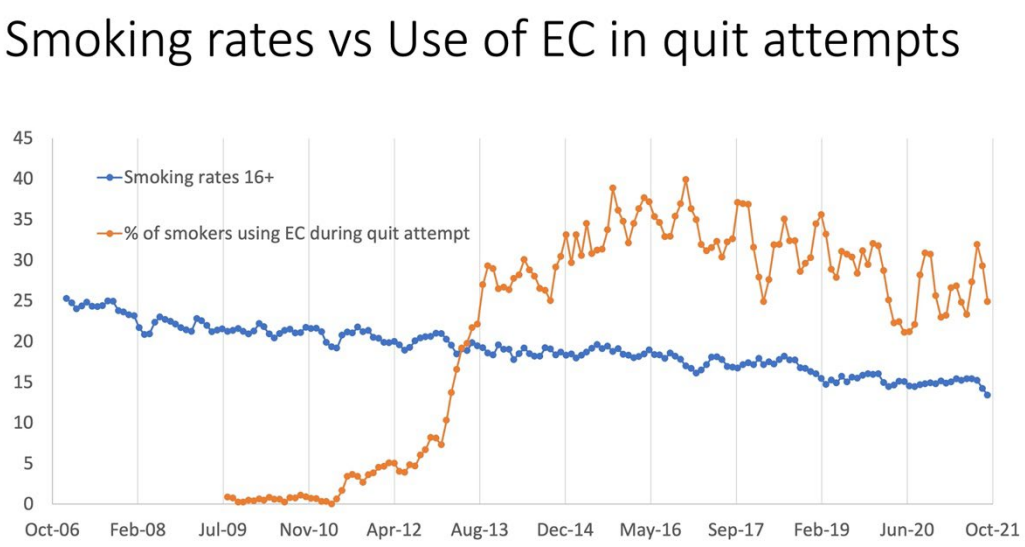
15 (2018) CSIRO "*There is currently no evidence that quit rates for smoking have decreased as a result of e-cigarette use. Long-term success with cessation was not measured in trials.*"

16 (2017) *El Dib et al* A systematic review and meta-analysis three RCTs and nine cohort studies concluded: "*There is very limited evidence regarding the impact of [e-cigarettes] on tobacco smoking cessation, reduction or adverse effects: data from RCTs are of low certainty and observational studies of very low certainty. The limitations of the cohort studies led us to a rating of very low-certainty evidence from which no credible inferences can be drawn*."

I do not expect NVPs will have a major additional impact in accelerating smoking cessation across the whole population. The two graphs below from the UK below are salutary in suggesting (1) the key role played by the decreasing affordability of smoking and (2) the slope in the decline of smoking in England which appears to have little relationship with huge increases in quit attempts using NVPs from mid 2012.

Adult Smoking vs Tobacco Affordability – UK 2000-2019





Smoking in England data

Summary of NVPs in smoking cessation

NVPs have been shown in RCTs to be superior to NRT in smoking cessation, but even in the highly artificial conditions of RCTs, approximately 9 in 10 NVP users do not quit smoking. This is hardly evidence of a revolutionary breakthrough in quitting. NRT sets a very low bar for the calibration of "success". NVP performance in RCTs is typically expressed in *relative differences* to other smoking cessation products. These comparisons often produce memorable big numbers ("70% more effective" than NRT). But its *absolute performance* is similarly desultory to that of NRT. I am unaware of any drug routinely prescribed drug that would ever be described as successful if 90% of people using it failed to improve on a primary outcome (here quitting smoking).

The performance of vaping in real world cohort studies (principally the enormously important US PATH study) are similarly dismal.

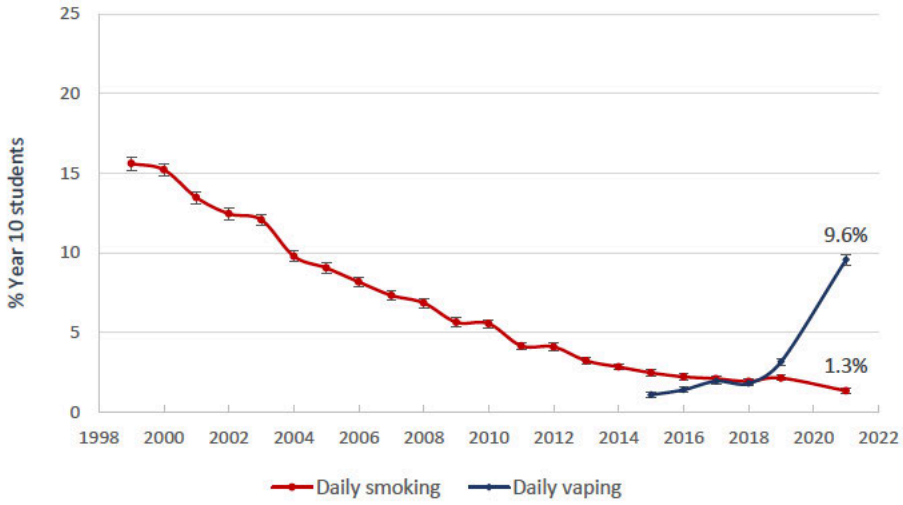
While I support the MAF policy which would restrict legal access to NVPs to those with a doctor's prescription, I emphasise that my support here is principally based on the goal of removing NVPs from open commerce where many, particularly children, are not vaping as a way to quit smoking. As I will argue below, unlawful but nevertheless open commerce has seen the Australian market deluged with unregulated products manufactured in unknown conditions with unregulated constituents. Critically here, it has seen an alarming, dramatic surge in teenage vaping. Prescription access, provided that open trading in illegal off-prescription NVPs is seriously the focus of national prosecutions with deterrent-level fines, will greatly reduce access by minors.

4 Uptake of NVP use in nicotine naïve youth

Vaping advocates often state that regular vaping by minors is at trivial levels, and that most who vape were already smoking.

The graph below is from a 2022 ASH-New Zealand report. It shows that the recent rapid growth in youth vaping far exceeded the decline in youth smoking, which had long preceded the availability of NVPs and so which could not be explained by smoking minor switching to vaping.

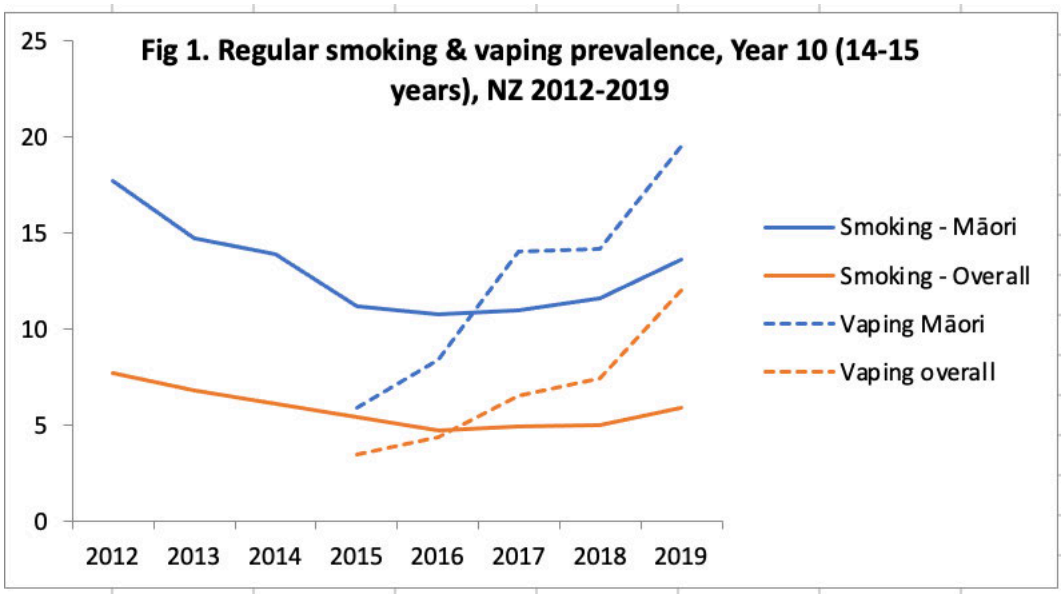
Figure 1: Youth daily smoking (1999-2021) and daily vaping prevalence (2015-2021)



Australian ASSAD data (2017) show that "Of the students who had ever used an e-cigarette (n = 2,403), 48% reported that they had never smoked a tobacco cigarette before their first vape".

AIHW/NDSHS data (2019) show that 64.5% of 14-17 year olds who had vaped were never smokers when they initiated use of e-cigarettes (Table 2.27)

An earlier graph also published by ASH NZ showed that not only was vaping rising dramatically in NZ 14-15y youth, but for the first time in many years, regular smoking (that is, smoking at least weekly) was also increasing.



Such data are concerning and have charged debate about whether vaping leads (ie increases the likelihood) to smoking in teens or whether it's simply a matter of "kids who try stuff, will always try stuff" (dignified via "common liability theory"). This debate will always be on-going because research ethics oversight would never allow a large number of randomly selected children to be randomised to vape or not vape and then followed up for several years to see if smoking rates were different.

This means the best evidence we can have on this issue must come from large, well-conducted cross-sectional cohorts and control in analyses for the very factors that common liability theorists say confound claims that vaping leads to smoking.

Perhaps the best example of this is a 2021 paper on the UK's huge Millennium Cohort. It found:

> "Among youth who had not smoked tobacco by age 14 (n = 9,046), logistic regressions estimated that teenagers who used e-cigarettes by age 14 compared with non-e-cigarette users, *had more than five times higher odds of initiating tobacco smoking by age 17 and nearly triple the odds of being a frequent tobacco smoker at age 17*, net of risk factors and demographics." [my emphasis]

Most importantly, the paper also deflated the glib 'kids who try stuff, will try stuff' common liability theory dismissal of the concern that vaping acts as training wheels or a gateway for later smoking uptake. In their analysis, the authors controlled for a rich constellation of 'propensity' factors that have been suggested to predict smoking uptake in youth. These included parental low educational attainment and employment status; parental reports of each child's behaviour during the prior 6 months using the Strengths and Difficulties Questionnaire, with indicators of externalizing behaviours (i.e. conduct problems, hyperactivity, inattention; and internalizing behaviours (i.e. emotional symptoms, peer problems) parental smoking; whether a child spent time 'most days' after school and at weekends hanging out with friends without adults or older children present. Children, via confidential self-reports, indicated whether they had ever drunk alcohol (more than a few

sips), ever engaged in delinquency (e.g. theft, vandalism) and whether their friends smoked cigarettes.

In a huge blow to common liability adherents the authors concluded:

> "we found little support that measured confounders drove the relationships between e-cigarettes and tobacco use, as the age 14 e-cigarette and tobacco cigarette estimates barely changed with the inclusion of confounders or in matched samples. Furthermore, early e-cigarette users did not share the same risk factors as early tobacco smokers, as only half the risk factors distinguished e-cigarettes users from non-users, whereas age 14 tobacco smokers were overrepresented on almost all the antecedent risk factors. If there was a common liability, we would expect similar over-representation for users of both forms of nicotine."

Vaping advocates typically ignore such evidence in their assessment of gateway effect studies.

5 The current regulatory failure

When former health minister Greg Hunt's twin proposal to combine prescription access with a ban on personal importation of NVPs was politically abandoned following internal and public lobbying by the 28 LNP backbench signatories of this letter, the prescription access arm of Hunt's policy was condemned to the wholesale failure we see today.

Before Hunt's policy announcement, NVPs were openly accessible by mail order, openly advertised on social media and available almost anywhere by retailers deciding to that the risks of ignoring and breaking the law were vanishingly small. The abandonment of the ban on personal NVP imports and the wholesale failure of governments to police undisguised, open sale of NVPs in anything but a small number of prosecutions turbo-charged the brazenness of those selling illegally.

It is hugely regrettable that the number of prosecutions undertaken against those flagrantly breaking the law and selling NVPs has trickled along at almost homeopathic proportions compared with the huge number of NVP outlets (shops of many sorts) and on-line.

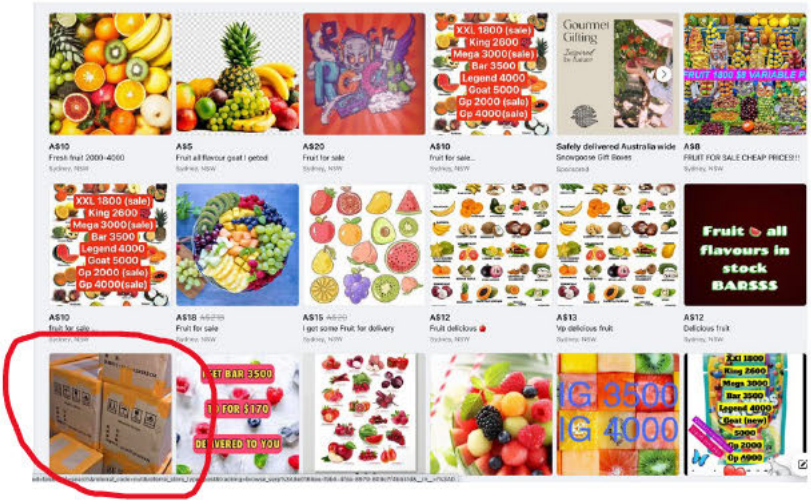
If a maverick pharmacy chain decided that it would henceforth ignore the requirement for a prescription to supply drugs which require a prescription to anyone asking for them, the chain would be closed down and those responsible almost certainly jailed.

But despite the requirement for a prescription to legally access NVPs existing since Oct 1 2021 and it being illegal to sell nicotine containing vapes and liquid well before that, the wholesale failure of governments to close down and prosecute these sales has sent a clear message to criminals and retailers that they can openly advertise, display and sell NVPs with only the remotest chance of being caught and fined heavily.

Urgent need for national enforcement and prosecutions with deterrent-level fines

State and Commonwealth regulators need to mount high-profile publicised seizures and prosecutions of those importing, wholesaling and retailing NVPs. Penalties should be proportionate to the extent of sales. Without this, the prescription access policy will be fatally undermined. Few will bother to access their NVPs via prescription when they could continue do so extremely easily via existing illegal channels.

On the day I finalised this submission, entering the word "fruit" in Facebook Marketplace, a Niagara of dealers in NVPs poured down my screen. The "fruit" (flavoured vapes) come in boxes all the way from China (see photo below). Purchasers can text the traceable dealers, make traceable payments and have the NVPs delivered by a traceable courier. If ordinary citizens are capable of readily finding and transacting with illegal NVP suppliers, it is obvious that government agents with investigatory and prosecutory powers can also do this. It is equally obvious that governments have to date given this very low priority and allocated insufficient funding to their investigative authorities to allow potent deterrent effects on widespread open sales to occur.



In apparent seriousness, vaping advocates now are arguing that these “experienced” NVP retailers are best placed to be trusted with selling NVPs in a new atmosphere of “responsible” NVP retailing of just another, unremarkable “consumer good”. The submission from Dr Colin Mendelsohn sets out a typical set of tepid, anodyne controls of the sort long cynically applauded by the tobacco industry. I list them below with my comments.

“Measures to reduce youth access to vaping under a consumer model include

• Strict age verification at the time of sale

Comment: This has never prevented many retailers from totally ignoring this provision. Significant proportions of children who vape report it easy to purchase NVPs

• Legal vaping products would only be sold from licensed retail outlets

Comment: Yes, from pharmacists who would dispense only against a prescription with the MAF. But Mendelsohn here is arguing that almost anyone should be given a license to sell NVPs

• Online retailers should verify the age of the purchaser with a third-party age verification service and age verification on delivery.

Comment: How will this be policed when on-line retailers are often international? Answer: it won't be.

• Advertising should be restricted and regulated to prevent marketing appealing to adolescents.

Comment: This debate played out over 30 years ago when the tobacco industry routinely swore its advertising had no appeal children. This suggestion is profoundly naïve or ignorant about all myriad ways that such proscriptions on marketing to children can be easily circumvented. There is no magic way of stopping children seeing advertising that is supposedly intended only for adults.

• Education programs for young people should inform them with accurate information about the risks. It is then up to the adolescent to decide what to do. There is no place for exaggeration, alarmist messages and harsh sanctions.

Comment: Dr Mendelsohn appears to be arguing here that as long as adolescents "decide what to do" their decision to vape should be respected, even though it is illegal to sell cigarettes or NVPs to those age less than 18.

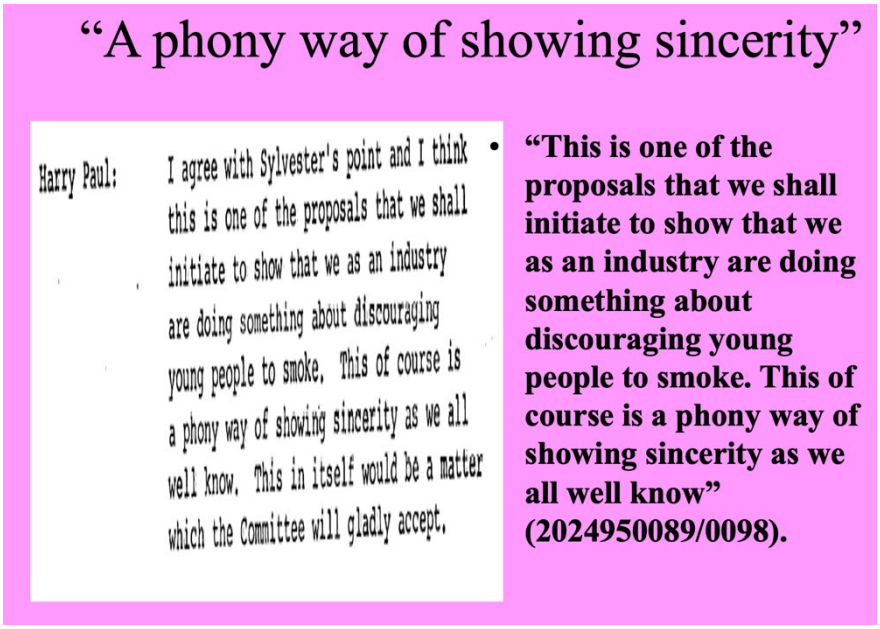
• The black-market would diminish as adult vapers migrate to legal retail outlets

Comment: this has not occurred in the UK, which is awash with illegal disposable vapes despite having the controls that Mendelsohn approves

• Substantially increased fines for illegal sales to act as a deterrent

Comment: In NSW there is currently a maximum $1650 *maximum* fine for selling illegal nicotine vapes. Fines need to be seriously increased for illegal sales and stocking of NVPs, just as huge fines and criminal penalties are set for importing commercial quantities of tax-evading tobacco or prescribable opiates. Without such serious deterrents, many would take their chances with getting a wrist-slap level fine and see such small fines as simply an irritating and highly unlikely "part of the cost of doing business".

The naivety of nearly all of these recommendations is breathtaking. Across several decades we saw boilerplate-identical, cynical calls by the tobacco industry for retailers who sold tobacco products to minors to be prosecuted, and for industry supported "children should not smoke" campaigns (see example below from 1973)



Source: https://www.industrydocuments.ucsf.edu/tobacco/docs/#id=fzjx0111

Regulate NVP selling as liberally as cigarettes are sold?

A common mantra voiced in unison by vaping promoters is to argue that it is ridiculous that deadly tobacco products are sold in thousands of outlets, while governments are seeking to limit NVP sales to prescription access. For example, in *a Medical Journal of Australia* Insight blog on e-cigarette regulation, a vaping promoter stated "ecigs are consumer products. Medicines regulation is not appropriate. Why should they be regulated more strictly than cigarettes which can be bought at every corner shop?"

However, in his very next sentence he wrote about how effective in smoking cessation NVPs are, compared to NRT. NRT is of course a medicine regulated by the Therapeutic Goods Administration, not a "consumer product", whatever that might mean.

Let's not repeat the same mistakes we made in allowing open-slather sales and promotions with cigarettes

As noted earlier, the dangers of smoking were not fully understood for at least 40-50 years after mass consumption and the commerce that facilitated it had commenced in the first decades of the twentieth century. After mechanisation of cigarette production made them cheap and readily accessible, it then took us 40 -50 years between the 1960s and today to fight for all the policies and campaign funding that have together taken smoking down to its lowest ever levels.

Out of ignorance and under sustained pressure from the tobacco industry, we began by making every regulatory mistake possible when cheap, mass-produced cigarettes appeared. Our understanding of the health risks that may be posed by NVPs is in its early infancy, given the latency periods that apply with the development of chronic disease.

It is often said that if cigarettes were invented tomorrow, and we knew now what we didn't know when they entered the market, no government in the world would permit their sale, let alone allow them to be sold in every convenience store.

With pharmaceutical products that *save* lives, treat illness and reduce severe pain, we allow only those with a 4-year pharmacy degree to sell them. And only to those with a temporary license issued by a doctor (a prescription) to use them. With cigarettes, we foolishly allowed them to be sold everywhere.

But nearly every health and medical agency in Australia and many internationally, including the WHO, are saying that NVPs should be *strongly regulated* through the TGA so that over time, as knowledge increases we could review whether looser or stronger regulation (perhaps including bans) was appropriate when that knowledge is available.

That's the way nearly every country regulates pharmaceutical products. Strict, prescription-only regulation at first, followed by evidence-driven loosening or tightening down the track as evidence accumulates about safety and effectiveness.

Many vaping advocates seem to have understood little from where we went so wrong in unleashing cigarettes and allowing them to be sold everywhere. Today they are trying to walk on both sides of the street by insisting NVPs are not therapeutic goods, but in the next breath megaphoning claims about how good they allegedly are in helping smokers quit compared to other therapeutic goods.

The MAF policy is not "prohibition"

Vaping advocates repeatedly assert that the legal requirement to have a prescription to access NVPs is "prohibition". This facile claim is as meaningful as someone claiming that Australia also "prohibits" oral contraceptives, antibiotics, anti-malarials, statins or *any* prescribed drug. The claim is typically twinned with another that accessing doctors and pharmacists is difficult and onerous. In 2020–21 there were a total of 314.8 million prescriptions supplied to patients in a population of some 25 million. These arguments thus have all the integrity of a chocolate teapot.

Comments on regulatory reform options

Before considering each of the proposed regulatory reforms, it cannot be under-emphasised that there are a set of *immediate supply-side priorities* that should be given urgent attention in choking the supply of disposable, flavoured NVPs, the main products being used by children. I acknowledge the work of the Cancer Council Australia in articulating these priorities.

Enforcement

Strong enforcement of supply side policies at a combined state and federal level against the illegal black market is the outstanding priority for addressing national concerns about ridiculously easy access by youth and non-smokers

- The primary focus needs to be on stopping domestic supply chains of illegal disposables
- High, deterrent fines, widely publicised, for both retailing and commercial quantity importing is essential
- Successful enforcement will need the Australian Border Force and state and territory public health departments to work closely together

Potential mechanisms to allow effective enforcement include the following:

- Immediately placing disposable NVPs on the Prohibited Import List may be the most effective single step.
  - Disposables form the vast majority of the illegal black market, and are unlikely to ever meet the standards required by doctors and pharmacies for distribution within the medical pathway.
  - Newly enacted domestic Chinese regulations prevent the manufacture and export of NVPs that are prohibited by domestic laws of the importer. Consequently, a ban on disposables would allow the Chinese regulators to prevent their export to Australia - this is already being seen in certain EU markets.
- Banning zero nicotine vaping products - Many illegal NVPs containing nicotine are packaged as nicotine-free, which allows their distribution through channels such as convenience stores.
- Including 'cooling agents' in Schedule 1 (Prohibited ingredients) of Therapeutic Goods Order 110 (Standard for Nicotine Vaping Products) - the cooling agents WS3 and WS23 form the basis of the 'ice' or 'cool' flavoured NVPs which are predominantly used by youth.
- High profile enforcement against illegal domestic distribution, both through stores, online and physical distribution networks
- Increased enforcement against offshore vendors marketing directly to Australian consumers via web platforms and social media. In the UK, the Advertising Standards

Authority has recently enforced against RELX for its use of social media to promote vaping products

1 Border controls

I strongly support Option 3 (which would end the personal importation scheme and introduce NVP import permits for accredited pharmaceutical wholesalers) while also agreeing that Option 4 (which would see an introduction of controls on the importation of all vaping products through the Customs Regulations) is urgently needed. Vaping products which do not contain nicotine have no therapeutic utility and in facilitating the repeated inhalation of unregulated vapourised flavouring chemicals with unknown risk profiles, constitute a potentially dangerous category of agents which ought to be prohibited as dangerous consumer goods.

2 Pre-market TGA assessment of NVPs

I support Option 3 (ARTG registration only), not the TGA preferred Options 2 and 3 together.

The Cancer Council Australia's rationale for supporting Option 3 (ARTG registration only) is:

> "Option 3 is supported as it would establish a regulated source of NVPs through the evaluation of quality, safety and efficacy (for smoking cessation). The routine use of alternative avenues for accessing unregistered NVPs already represents a significant departure from the way prescription medicines are ordinarily accessed in Australia. Requiring registration in the ARTG is Australia's 'business as usual', standard practice for ensuring the quality, safety and efficacy of prescription products. Requiring anything less than registration in the ARTG represents a significant compromise to the standards ordinarily applied under Australia's therapeutic goods framework."

I strongly agree with this. I would add two other critical reasons for my support for Option 3. First, all major tobacco transnationals now produce and market NVPs. All are implacably opposed to prescribed access and support consumer access. None have apparently ever sought TGA ARTG registration. Moreover, all are deeply affronted by Australia's prescribed medical/pharmacy access policy and fear that it may spread internationally. All have long track records in deploying vast financial and legal strategies to attacking policies they judge to not be in their interests (which is maximising addiction to nicotine, including in adolescents).

Should these companies seek ARTG registration (which is unlikely) their histories strongly suggest that they will then almost certainly play very dirty pool and unleash a wide range of strategies designed to discredit the MAF, hoping to see it dissolved into the consumer access model they desire.

For that reason, the government should heed carefully Article 5.3 of the Framework Convention on Tobacco Control about tobacco industry interference in tobacco control. It should not allow any tobacco company nor those with legal or financial connections with any tobacco company to apply for ARTG registration for NVPs.

Second, the proposed pre-market assessment process would cause utter chaos. The US FDA was so deluged by applications, it has taken three years to process them all. The same will predictably happen if the doors are opened to this in Australia where the TGA's resources would be swamped.

3. Minimum quality and safety standards for NVPs

I also *mostly* support the TGA's preferred option 7 which would:

* Prohibit all flavours (except tobacco) and additional ingredients.

* Modify labelling or packaging requirements, including to require pharmaceutical-like plain packaging and/or additional warning statements.

- Reduce the maximum nicotine concentration for both freebase nicotine and nicotine salt products to 20 mg/mL (base form or base form equivalent).
- Limit the maximum volume of liquid NVPs.
- Remove access to disposable NVPs.

Comments:

1 Prohibit flavours (except tobacco) and additional ingredients

In 2014, there were already 7,764 unique vaping flavour names being used in products sold online. In 2016–17 this had more than doubled to 15,586. In 2017 England's Professor Robert West was confident this was unlikely to be a problem: "Now some concerns have been raised about the risk that might be attending to the flavourings in e-cigarette vapour but again, these are flavourings that have been tested and the concentrations are sufficiently low that we wouldn't expect them to pose a significant health risk."

So is it indeed the case that these flavouring chemicals have all been "tested" and cleared by government food and drug regulatory bodies as safe to inhale? No. The peak flavour manufacturers association in the USA, the Flavor and Extracts Manufacturers Association (FEMA) stated in 2021

> **1.** There is no apparent direct regulatory authority in the United States to use flavors in e-cigarettes. In this context, it is important to note that the "generally recognized as safe" (GRAS) provision in Section 201(s) of the Federal Food, Drug, and Cosmetic Act (FFDCA) applies only to food as defined in Section 201(f) of the Act.
> **2.** None of the primary safety assessment programs for flavors, including the GRAS program sponsored by the Flavor and Extract Manufacturers Association of the United States (FEMA), evaluate flavor ingredients for use in products other than

human food. FEMA GRAS status for the uses of a flavor ingredient in food does not provide regulatory authority to use the flavor ingredient in e-cigarettes in the U.S.
3. E-cigarette manufacturers should not represent or suggest that the flavor ingredients used in their products are safe because they have FEMA GRAS status for use in food because such statements are false and misleading.

In summary, some flavouring chemicals likely to be used in NVP liquids may have been assessed as safe to ingest, but not to inhale.

The FEMA statement above is worth thinking about. Here is an association representing an industry which exists to promote and safeguard the interests of manufacturers of chemical flavours. Vaping would represent a massive additional source of demand for flavouring chemicals for the chemical companies in that industry. Yet here we have FEMA going out of its way to explicitly warn that no one should ever suggest that inhaling vapourised chemical flavours is safe as this would be false and misleading.

Flavours are a major factor in attracting people to vape. For example, 83% of New Zealand vapers named flavouring as a main reason they took up vaping. (Gendall and Hoek 2021) We also know that flavours are a big factor that attract children and adolescents to vaping. (Ranney 2019) Liquid nicotine manufacturers have paid close attention to these appeals. Here are a few examples of flavours that would be a big hit when announced at any five-year-old's birthday party: Cherry Crush, Vivid Vanilla, Banana Split, Cotton Candy, Rocket Pop, Gummy Bears.

Vaping advocates argue that regulators should keep their hands off flavours because they are a major factor attracting smokers to try to keep vaping, which these advocates believe should be very much encouraged. As the then head of the Foundation for a Smoke-Free World, an agency entirely funded by the tobacco company Philip Morris International, tweeted on 21 February 2021, "E-cigarette flavor bans will drive more people back to smoking – InsideSources. Responsible regulators should take note. In their zeal to address youth vaping they may well undermine the health of millions of smokers seeking to switch. @US_FDA"

So apparently, those concerned to stem the dramatic rises in regular vaping by teens in nations which have opened the e-cigarette access floodgates should get their priorities right. They should always put the interests of adult vapers ahead of preventive efforts to reduce the uptake of vaping by children. As I argued at the head of this submission, this would be plainly myopic and irresponsible.

The US Food and Drug Administration (USFDA) in late August 2021 took a decidedly different view of the risk–benefit balance when it came to flavoured vapes. Announcing that it had issued marketing denial orders over 55,000 flavoured vaping products submitted by three manufacturers, it said the applications "lacked sufficient evidence that they have a benefit to adult smokers sufficient to overcome the public health threat posed by the well-documented, alarming levels of youth use of such products". By September 2021, 295 Marketing Denial Orders had been issued by the USFDA for flavoured NVPs which impacted an estimated 1,089,000 flavours.

Jordt et al using gas chromatography, mass spectrometry and nuclear magnetic resonance spectroscopy and observed that:

> flavour aldehydes such as vanillin (vanilla flavor) and benzaldehyde (berry/fruit flavor) rapidly undergo chemical reactions with the E-liquid solvents PG and VG after mixing. The chemical adducts formed, named aldehyde PG/VG acetals, are carried over into the aerosol and are stable at physiological conditions.
>
> Toxicological tests reveal that these compounds activate the sensory irritant receptors TRPV1 and TRPA1, involved in triggering cough, secretions and cardiovascular reflexes to irritant inhalation. The aldehyde acetals activate these receptors more robustly and potently than the parent aldehydes. Comparison of the cytotoxic effects of parent aldehydes and acetals in cultured bronchial epithelial cells demonstrate that acetals induce cell death at lower concentrations. Analysis of mitochondrial respiration and glycolysis reveal that flavor aldehyde acetals suppress mitochondrial oxygen consumption and ATP production.

In summary, the authors found that "flavourings combine with solvents in e-cigarettes to produce new toxic chemicals that irritate the airways, triggering reactions that can lead to breathing and heart and blood vessel problems". The lead author commented that "This is the first demonstration that these new chemicals formed in e-liquids can damage and kill lung cells and probably do this by damaging their metabolism. Although, in some cases, more than 40% of flavour chemicals are converted into new chemicals in e-cigarettes, almost nothing was known about their toxicity until now"

These findings suggest that electronic cigarettes release unstable chemical mixtures containing a large variety of chemical products with unexpected toxicological properties. (Jordt, Caceres et al. 2020)

Despite such evidence, a 2021 review of 58 research reports on e-cigarette flavours and young people found "no included reports of adverse effects of flavours" in studies where the "quality of the evidence was very low". The authors nonetheless found that the evidence "suggested that flavours are important for initiation and continuation of vaping. Qualitative evidence shows interest and enjoyment in flavours" (Notley, Gentry et al. 2021), which explains a great deal about why vaping interest groups stridently defend flavours.

In November 2020, Clive Bates, a prominent English vaping advocate who has a low opinion of tobacco control in Australia gave evidence to the Australian Senate's inquiry into vaping (Australian Senate 2020a):

> Senator Urquhart: A lot of these flavourings are approved for ingestion in foods but not for inhalation into your lungs.
> Mr Bates: You're right. Many of them haven't been evaluated for inhalation. They are generally recognised as safe as food additives and they're added to these products to make them appealing. So you're right. They don't have —

> Senator Urquhart: I don't want to cut you off. I don't want to do that at all, but I am pressing for time. I just want to try and get the justification for how it can be safe to inhale stuff that is not meant to be inhaled into your lungs . . .
> Mr Bates: . . . With vaping, they're not moving to a situation where they're inhaling chemicals we know to be dangerous – where there are known dangers, the manufacturers tend not to put them in – but they're moving to inhaling chemicals that at least at one level have been recognised as safe for ingestion. But you're perfectly correct; most of the flavours have not been evaluated as safe for inhalation.

This is why the vaping industry and its facilitators have fought proposals for therapeutic regulation and instead want their products to bypass safety standards that they would try in vain to demonstrate.

Instead, they effectively argue that the public health and human rights imperatives to allow unimpeded access to vaping are so stratospherically important that NVPs should be accorded *exceptional* status, allowing them to be exempted from any regulations that might prevent maximum uptake. This of course is an argument that has often been made by purveyors of quack cures for a wide range of deadly diseases, including cancer, HIV and COVID-19. No sensible person believes that breathless claims and testimonies for these shonky and often dangerous treatments should raise them above regulatory scrutiny, but many evangelical vaping advocates believe NVPs are too important to be regulated.

Without the choice of thousands of untested flavours, they argue that many vapers would abandon vaping, regardless of their conviction that these products are saving their lives. Yet people living with asthma who know that salbutamol is critical for control of asthma attacks don't abandon their unflavoured puffers because they don't taste the best.

The clamour to allow thousands of unregulated and untested flavouring chemicals to be openly available is driven by commercial agenda and marketing angle opportunities. The Australian Generation Vape study found that flavours were *the single most important feature* of NVPs to teenagers.

Why aren't asthma inhalers flavoured?

Australia, with a population of some 25 million, has about 2.7 million people living with asthma, and some 464,000 with chronic obstructive pulmonary disease. Most of both groups use salbutamol inhalers ("puffers") for relief, sometimes at lifesaving moments. But significantly, none of the asthma drugs that are inhaled come in flavours which might make them more palatable. Many users, including children, do not enjoy their distinctive medicinal taste. We'd therefore understand that the manufacturers of inhaled medicines would jump at any opportunity to add flavours to puffers if this would encourage more people to use them when needed. It is unimaginable that pharmaceutical companies manufacturing them would not have long been aware of this sub-optimal taste downside to their products and tried to find any way possible to have drug regulatory agencies allow them to add flavours as we see happen with infant cough mixtures, for example.

But none has done so.

One of the big reasons for this is undoubtedly because asthma products have to go through therapeutic goods regulation. The two considerations there are efficacy and safety. Efficacy refers to how well a drug performs in doing what it is supposed to do – so here, helping smokers quit. The pharmaceutical industry knows it would struggle to demonstrate that inhaling flavours is acceptably safe in the ways they would be used by vapers.

Striking a positive balance

The dilemma for regulators is how to strike a positive balance between regulations on flavours that will act negatively on NVP uptake by ex-smoking and never-smoking adults, children and youth, while optimising willingness to use approved prescribed NVPs which pass a quality and safety standard.

The TGA discussion document notes that New Zealand allows "consumer product" NVP outlets to sell only three flavours (tobacco, menthol and mint) while "specialist" NVP outlets can sell many flavoured products. This arrangement can surely withstand no rational scrutiny and is a perfect example of "half pregnant" policy (one cannot be half pregnant). How can it be sensible from a public health perspective to restrict "consumer outlets" to three flavours, but allow virtually unlimited options in "specialist" retailers? Why would something called (say) "Coconut brandy unicorn" be OK to use if you bought it in a specialist shop but not in a convenience store?

Such absurdity invites public ridicule and threatens public respect for regulatory agencies.

Vaping advocates argue that strong regulatory limits on flavours will drive many vapers back to smoking because lack of flavouring options will make them less attractive than cigarettes. This is a bizarre argument because *most Australia cigarettes are not flavoured* except the small proportion which are mentholated.

So if flavours were a decisive factor in driving smokers to NVPs, how is it that smokers would be driven back to cigarettes which also would be unflavoured? As argued above, those with asthma do not abandon salbutamol inhalers because they are not flavoured.

The tough challenge for NVP regulation is whether to allow a very restricted range of flavours (such as the NZ 'consumer product' limit to tobacco, mint and menthol) in the hope of providing vaping products sufficiently acceptable to smokers wanting to vape) or whether to permit no added flavours at all, or as canvassed in the Discussion document, only "tobacco" flavour. If the latter option proceeded and very few smokers took these products up, would this effectively neuter the prescription model in its entirety? The submission by Liber pharmaceuticals argues strongly that this could be a serious consequence.

On Nov 30, 2022 the Minister for Health Mark Butler foreshadowed regulatory action to outlaw menthol and other flavours being used in "crush beads" in cigarettes sold in Australia. If such regulation proceeds, this will invite reasonable questions about why menthol, mint etc are unacceptable in tobacco products, but possibly acceptable in NVPs.

This dilemma is therefore certainly thorny. My view is that the New Zealand position of allowing only tobacco, mint and menthol options via prescribed vaping (but importantly not their allowing all but specifically proscribed flavours via specialist NVP shops) would be a pragmatic compromise, unacceptable to both "no flavours at all" advocates and "any flavours at all" extreme vaping advocates. It would greatly reduce the appeal of vaping to youth, although if the critically important prevention of ex-prescription sales is seriously enacted, this will be largely swept up in the effects of that exercise. But it would offer adult smokers wanting to switch a modest choice and if Liber's concerns are correct, avoid sinking the MAF.

NVPs with no flavours at all are likely to taste foul. This would be a good thing for preventing uptake but a disastrous thing for any hope that significant numbers of smokers seriously trying to quit would use the MAF channel to obtain their NVPs.

It will be important that prescribing doctors advise all to whom they prescribe NVPs that the mint, menthol and 'tobacco' flavouring chemicals available in NVPs *have not been declared risk-free*.

2 Modify labelling or packaging requirements, including to require pharmaceutical-like plain packaging and/or additional warning statements

It seems certain that few if any vapers retain or carefully examine the packaging in which their NVP apparatus is sold to them, discarding it very quickly after purchase. Unlike with cigarette and loose RYO tobacco where the pack or pouch is retained, handled and often rested on display on tables, NVP packing is ephemeral, almost always discarded and unlikely to ever represent an important vehicle for health messaging.

On a scale of 10 (vital) to 1 (marginally important) I would rank plain packaging for NVPs as a 1. However, a far clearer case could be made for "plain" regulation of the colour and shape of NVPs themselves (ie the devices). It seems self-evident that part of the attraction of vaping to (especially) teenagers but also many adults is the display or performance repertoire that is integral to vaping (the hand gestures, clouding and "oh wow, show me the one you are using" status chatter). This is much the same with the intensity of teenage interest in the latest mobile phone models, covers, apps and online games.

Of course, we must always see this proposed policy in the context huge efforts to attack illicit trade and the very few teenagers who will ever be given a prescription to access NVPs. But even if those efforts have widespread success, there will still be some illicit trade. If NVPs were to be regulated to require them to look as dull and unappealing as possible (think salbutamol inhalers used by 2.6 million Australians), this would be a considerable blow to their appeal as "recreational" products, not products sold as devices to help quitting.

The pharmaceutical industry has not tried to enhance the appeal of NRT by packaging it in attractive, conversation-starting art deco snuff boxes or wearable patches mimicking designer tattoos, or nicotine inhalers enabling retro Gatsby-era cigarette holders. Why then

should we have policies on NVP apparatus that facilitated all those appeals? I would therefore support regulation to standardise NVP devices by consumer research with young vapers (where uptake is highest) examining design variables likely to most unappealing to smokers.

3 Reduce the maximum nicotine concentration for both freebase nicotine and nicotine salt products to 20 mg/mL (base form or base form equivalent).

The dismal real-world effectiveness of NRT (~93% of smokers failing to quit) has long been argued to be principally due to the inadequate level of nicotine in NRT: many smokers find it *too low and too slow* in nicotine delivery in comparison with smoking. The same concerns may apply with NVPs if regulations were to set maximum nicotine levels too low.

The relationship between nicotine concentration and extended dual use (with cigarettes—already noted as the *most* toxic of nicotine delivery practices) should be of particular concern here. The argument that 20mg/mL maximum nicotine concentration is too low may encourage greater dual use is highly plausible and needs very careful investigation prior to final policy decision making.

20mg/mL in high-powered devices may provide acceptable nicotine delivery, but not in lower powered devices. Here, consideration should be given to prohibiting the sale or importation of high-powered vaping apparatus, and only permitting closed systems which cannot be powered up and/or nicotine added by users.

The TGA discussion document notes that there are 34 nations which set a maximum limit of 20mg/mL nicotine in NVPs. I have not followed closely the evidence on the reasoning for this limit or for other levels chosen by other nations, so do not wish to state an alternative maximum. I note that the TGA document does not elaborate on any such evidence, if it exists. My strong sense is that this is a highly specialised issue which would be amenable to research synthesis (I am unaware of any such report). Before declaring a policy, I would urge the TGA to try and summarise this evidence, perhaps commissioning international nicotine pharmacologists to also comment on the evidence status of various limits. The US FDA is likely to be the single most expert agency which might advise on this.

4 Limit the maximum volume of liquid NVPs

Comment: Having no limit or very generous limits to NVP liquid might tempt many to divert their supplies to unauthorised users. Drugs with abuse potential (codeine and other morphine derivates and analogues, prescribed amphetamines, benzodiazapines etc) all are available on prescription but always with strict maximum doses and limited repeats. Arguing that NVPs which are principally being made available as a means of quitting smoking, should have no such limits is another example of “exceptionalist” thinking about NVPs.

Policies which discourage NVP users to store and handle nicotine via the rituals of filling tank systems are to be applauded. Closed system pod systems which avoid this seem to me

eminently sensible if the TGA wants to establish a gold standard regulatory system predicated on standard dosing and user safety.

5 Remove access to disposable NVPs

Comment: Disposable NVPs are the products that dominate the purchasing of those who are vaping for fun, rather than to trying to quit smoking. They appeal because of their cheap price and their flavours. They enter Australia with zero evidence of quality manufacturing control. Those that offer many thousands of puffs carry significant concerns when it comes to degradation of the heating coils from repeated use whereby heavy metal small particles in the coils are inhaled into the lungs. In plain daily sight, it is obvious that these products are being frequently discarded in public representing a growing litter problem. I fully support a ban on these products unless individual examples were to fully assessed by any TGA approval scheme being canvassed and made available only via the MAF.

6 Clarify status as a therapeutic good

I strongly agree that this should be done

s22

From: GILMOUR-WALSH, Bridget <Bridget.GILMOUR-WALSH@Health.gov.au>
Sent: Friday, 30 June 2023 6:00 PM
To: s22
Cc: s22 EDLINGTON, Mandy; s22 s22
Subject: RE: Noetic Invoicing for Work Completed to Date and Proposed Work Order Variations [SEC=UNOFFICIAL]
Attachments: Pharmacy-available NVPs .xlsx; breakdown of 2022 NVP consultation submissions [SEC=OFFICIAL] (309 KB)

Thanks s22

We don't have any specific info re no of vape retailers.

Re manufacturers:

- we are not aware of any manufacturers lawfully supplying nicotine vapes (although there might be unlawful manufacturing which we don't know about
- we are aware of a couple of companies manufacturing e-liquid from the consultation – haven't reviewed all subs in detail but s22 seems to manufacture in Aus and so may s22
- we are not aware of local device manufacturing.

The main sponsors supplying to the pharmacy market appear to be importing products. We have identified a larger number of these from MIMs. See attached summary and link to MIMS https://www.mimsonline.com.au/Search/Search.aspx.

One of my team has done a quick search of consult submissions by supplier/manufacturer category (attached), but this won't help with no of suppliers.

Happy to discuss.

Bridget

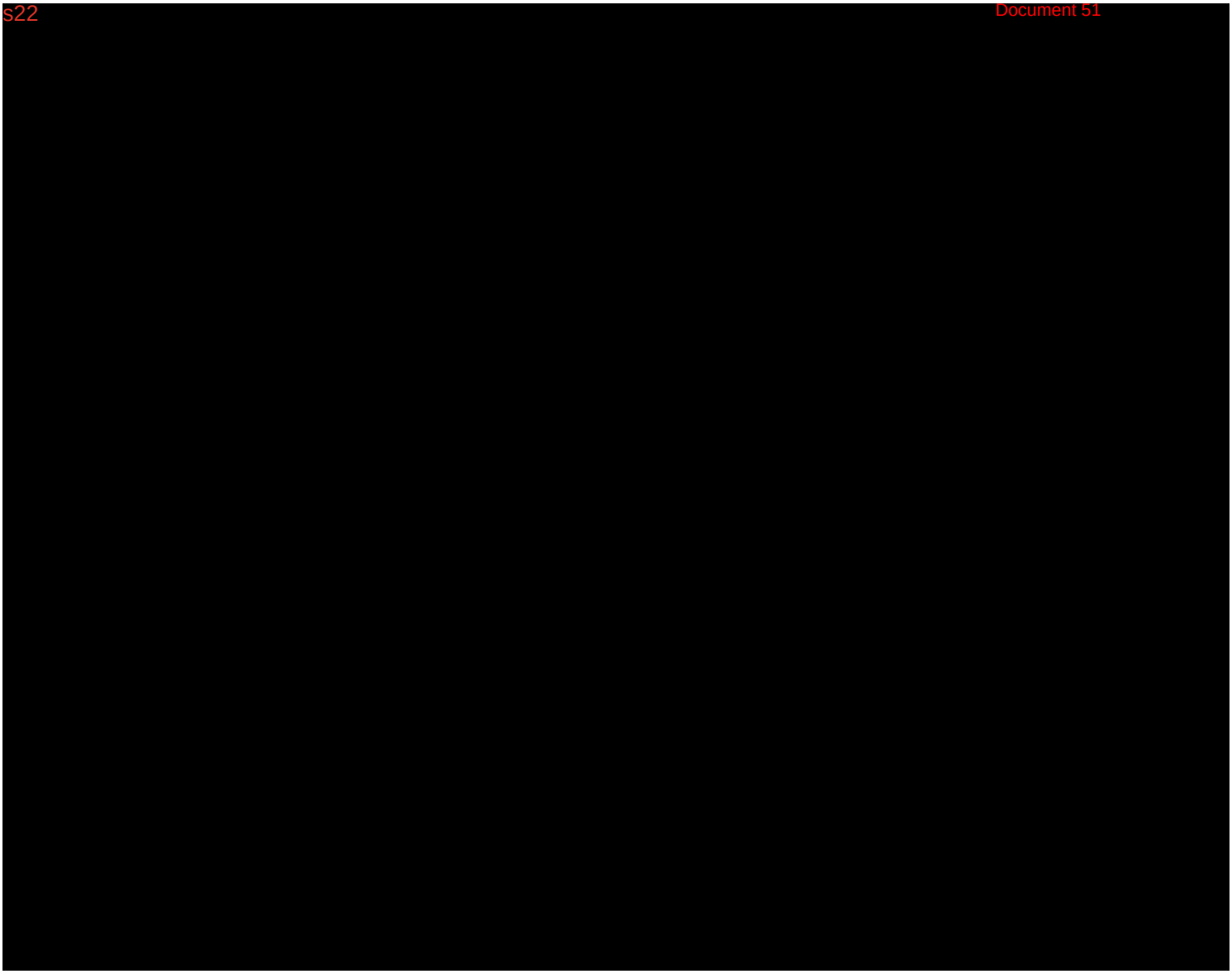
s22

s22

Document 51

s22

Document 51

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Manufacturer	Product name	Nicotine contents (mg/ml)	Pack size (ml)	Type of system (Disposable, or not)	Flavour	Only contains: Vegetable glycerine, Propylene Glycol, Nicotine and Flavour (Yes / NO (if no, what else is there))
s22						
Mission Distribution Victoria	Relx Pods	35	1.8	Pods to be used with RELX device	Flavour	NO - glycerol
	Relx Pods	46	1.8	Pods to be used with RELX device	Flavour	NO - glycerol
	Relx Pro Pods	35	1.9	Pods to be used with RELX device	Flavour	NO - glycerol
	Relx Pro Pods	46	1.9	Pods to be used with RELX device	Flavour	NO - glycerol
s22						

Manufacturer	Product name	Nicotine contents (mg/ml)	Pack size (ml)	Type of system (Disposable, or not)	Flavour	Only contains: Vegetable glycerine, Propylene Glycol, Nicotine and Flavour (Yes / NO (if no what else is there))
s22						
Mission Distribution Victoria	Relx Pods	35, 46	1.8	Pods to be used with RELX device	Flavour	NO - glycerol
	Relx Pro Pods	35, 46	1.9	Pods to be used with RELX device	Flavour	NO - glycerol
s22						

From: s22 [redacted]; GILMOUR-WALSH, Bridget
Cc: s22 [redacted]; EDLINGTON, Mandy; s22 [redacted]
Subject: RE: changes to TGO110 [SEC=OFFICIAL]
Date: Tuesday, 19 December 2023 12:17:49 PM
Attachments: image013.png
image014.png
image015.png
image016.png
image017.png
image018.png
image019.png
image020.png
image021.png
image022.png
RACGP NVP and Vaping Cessation Consultation Provisional Draft 2023_Health input 191223.docx
Response to RACGP further questions_19.12.23.docx

Hi s22 [redacted]

Please find attached in tracked some comments and suggestions from the department on the RACGP's draft interim guidance. This includes feedback from the TGA and the Population Health Division.

I have also separately attached some responses to your questions below. These responses have been prepared by my TGA colleagues.

We hope this feedback is helpful. Please reach out if we can be of further assistance before the RACGP's draft interim guidance is published later this week.

Regards

s22 [redacted] | Acting Director | E-cigarette Control Section | s22 [redacted] | s22 [redacted] |
Tobacco and E-cigarette Control Branch | Population Health Division | Department of Health and Aged Care

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From: s22 [redacted]@racgp.org.au>
Sent: Monday, 18 December 2023 9:46 AM
To: s22 [redacted]@health.gov.au>; GILMOUR-WALSH, Bridget <Bridget.GILMOUR-WALSH@Health.gov.au>
Cc: s22 [redacted]@racgp.org.au>
Subject: FW: changes to TGO110
Importance: High

Hi s22 [redacted] Bridget,
I have just been advised that the TGA have released changes to TGO110.
As per s22 [redacted] email below, can you please advise:

- When the changes come into effect?
- Any wording about the key aspects of the changes that we could consider for the NVP and Vaping cessation modules
- Is there a list of the NVPs brands most often prescribed since the October 2021?

Many thanks

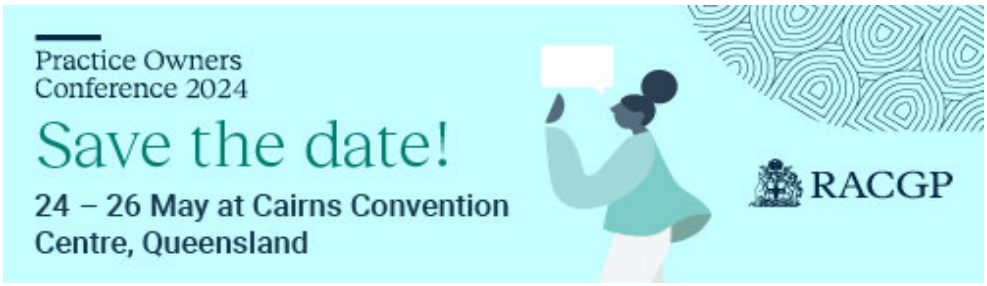
s22

s22
Senior Project Officer | Quality Care
Practice Management Standards & Quality Care | Advocacy Policy & Research

T s22
s22 @racgp.org.au | racgp.org.au

The Royal Australian College of General Practitioners Ltd
Wurundjeri Country
100 Wellington Parade, East Melbourne VIC 3002

The RACGP acknowledges Aboriginal and Torres Strait Islander peoples as the Traditional Custodians of the land and waterways in which we live and work. We recognise their continuing connection to land, water and culture and pay our respects to Elders past, present, and emerging.



From: s22 @bond.edu.au>
Sent: Monday, December 18, 2023 9:18 AM
To: s22 @racgp.org.au>
Subject: changes to TGO110
Importance: High

Hi s22

TGA have released changes to TGO110.

Can you ask them when these come into effect and if they have wording about the ley aspects of the changes that we could consider for the NVP and vaping cessation modules.

Also can you ask them if they have a list of the NVPs bands most often prescribed since the start of the medical access framework in October 2021.

Regards

s22

s22
Executive Dean

Faculty of Health Sciences and Medicine

STAND OUT BOND UNIVERSITY

Telephone: s22 [redacted] | **Fax:** s22 [redacted]
Mobile: s [redacted]
Bond University | Gold Coast, Queensland, 4229, Australia
CRICOS Provider Code 00017B

s22

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I have just been advised that the TGA have released changes to TGO110.
As per Nick's email below, can you please advise:
When the changes come into effect?

The TGO 110 commences 1 January 2024, at the same time as the *Therapeutic Goods Legislation Amendment (Vaping) Regulations 2023,* and applies in relation to goods imported or manufactured from 1 March 2024. Further substantive amendments are anticipated to be made to the quality and safety requirements in TGO 110 before the end of summer with appropriate transitional periods where applicable.

The requirements in TGO 110 apply to therapeutic vaping goods that are for use for smoking cessation or the management of nicotine dependence. The requirements apply to therapeutic vaping substances (including filled pods and cartridges) and packs that contain a combination of vaping goods (including therapeutic vaping devices and unfilled pods and cartridges).

Any wording about the key aspects of the changes that we could consider for the NVP and Vaping cessation modules

The TGA is continuously updating its web pages to provide further information relating the reforms on vaping. Some web pages that may be of particular interest are:

- New regulation of vapes starting January 2024 | Therapeutic Goods Administration (TGA)
- Next steps on vaping reforms | Health Portfolio Ministers | Australian Government Department of Health and Aged Care
- Vaping Hub | Therapeutic Goods Administration
- Vapes: information for prescribers | Therapeutic Goods Administration (TGA)

From **1 January 2024**, the importation of all disposable vapes will be banned. This means that patients will no longer be able to purchase any disposable vapes online from overseas, even if they have a prescription. Also from this time, the Special Access Scheme C (SAS C) pathway will be available to enable both medical practitioners and nurse practitioners to prescribe certain therapeutic vaping substances for smoking cessation or the management of nicotine dependence, where clinically appropriate

From **1 March 2024**, further reforms are expected to commence. Information about these reforms is available on the TGA website at New regulation of vapes starting January 2024 | Therapeutic Goods Administration (TGA). Additional about these reforms will be made available on the TGA website in 2024.

Is there a list of the NVPs brands most often prescribed since the October 2021?
The TGA does not have a list of the NVP brands that are most often prescribed since October 2021. This is because the TGA does not collect prescription data nor are sponsors of NVPs required to report on the quantities supplied.

However, sponsors of NVPs are required to submit 6 monthly reports to the TGA listing all the products supplied through the SAS and/or Authorised Prescriber pathways. Therefore, the TGA is aware from these reports that some of the brands that have been supplied to patients are:

- Aiero Nicshot
- Vuse
- VEEV
- IGET
- HQD

- Relx
- Airis Lux
- Elf bar
- WILD BY INSTINCT
- Nicovape

Also, from 1 March 2024, new pre-market requirements will apply to the importation and manufacture of all therapeutic vapes. Notification, licence and permit forms and instructions will be available prior to 1 March 2024, in order to give importers and manufacturers the opportunity to comply prior to the new requirements coming into effect.

Importers must obtain a customs licence and permit to import therapeutic vapes, and must notify the TGA that their products comply with new product standards.

These new standards:

- apply to therapeutic vapes irrespective of nicotine content,
- limit flavours to only mint, menthol or tobacco flavours, and
- specify certain requirements for vaping devices that were previously excluded from the therapeutic goods framework.

The TGA will publish a list of therapeutic vapes that have been notified by importers or manufacturers to the TGA to be indicated for the purposes of smoking cessation or the management of nicotine dependence, and compliant with the relevant product standards.

Reusable vapes that have been imported into Australia or manufactured in Australia before **1 March 2024** may continue to be lawfully supplied in Australia subject to the following requirements:

- reusable vapes containing nicotine that meet TGA requirements (including the quality requirements under the existing product standard) can continue to be lawfully supplied in Australia in pharmacy settings to a patient with a prescription in accordance with state and territory laws for prescription medicines
- reusable vapes that do **not** contain nicotine, or any other medicine, and do not make therapeutic claims, can continue to be supplied by retailers generally, including vape stores, subject to state or territory law.

This will allow legitimate retailers of reusable vapes to run down their stocks prior to the Government introducing legislation in early 2024 to prevent the domestic manufacture, advertisement, supply and commercial possession of non-therapeutic vapes to ensure comprehensive controls across all levels of the supply chain. The new notification pathway only applies to vapes imported into Australia or manufactured in Australia after 1 March 2024.

Contact details

Reporter's name:
Reporter's email:
Reporter's telephone number:
Reporter's mobile phone number:
Reporter's fax number:

Details of problem

Date problem was encountered: 2024-04-13
Name of product of concern: QuitMed
AUST R or AUST L number on product label, if known:
Name of company/person supplying the product:
Address of company/person, if known:
Contact details of company/person, if known (telephone, fax website, etc.):
Details of problem - please be as specific as possible: I am an AP and occasionally prescribe nicotine vapes to patients - I provide handsigned prescriptions to use for a number of notified products that are available in multiple pharmacies nearby.

Email sent to my patient encouraging them to doctor shop/not use their regular GP. (Including services that have treatment names in their title???

Email below:

We hope this email finds you well. We would like to inform you that your Quitmed account has been approved; however, we have encountered a slight hiccup in processing your prescription.

Upon reviewing the attached document, we noticed that it is a PDF copy rather than an eScript. We are required to adhere strictly to regulations.

Therefore, we kindly request your cooperation in obtaining an eScript from your Prescribing Doctor.

To facilitate the process and ensure seamless service, we have outlined the steps below for uploading your eScript to your Quitmed account:

Login to your Quitmed account.
Navigate to the "My Account" section.
Select "Update Prescription." (Rest assured, we will be promptly notified once this step is completed.)

Alternatively, if you encounter any challenges in obtaining an eScript, we are here to assist you. We have established partnerships with several Online Clinics dedicated to supporting individuals on their smoking cessation journey. These include:

Quit Hero
Medical Nicotine
Quit Rx
MyNicotine

We understand that this process may not be as seamless as we would like it to be at present. However, please be assured that we are actively working to enhance the user experience as we transition from personal importation to local pharmacy dispensing.

Your commitment to your health and well-being is commendable, and we appreciate your understanding and cooperation in this matter. Should you have any questions or require further assistance, please do not hesitate to reach out to us.

Thank you for choosing Quitmed to support you on your journey towards a smoke-free life.

Warm regards,

Quitmed Team
1300 634 105
dispense@quitmed.com.au
Do you have a sample of the product or any other supporting material?
[webform_submission:values:do_you_have_a_sample]