

Nature of the shortage:	Anticipated	
Shortage reason:	Manufacturing	Document 1
Manufacturing site problem:	Issues/delays with product release	
Shortage reason - further information:		
Estimated period supply will be affected at wholesaler points:	From:	31/07/2023
	To:	11/08/2023
Availability:	Available	
Indicate preference for date of publication:	Date of processing	
Is this shortage related to other medicines within the same Therapeutic class?	No	
Is this shortage specific to Australia?	No	
Estimated normal demand volumes for Australia:	s47	
Estimated percentage share of the Australian market:	100 %	
Estimated current stock at sponsor / manufacturing level in Australia:	28164 units	
Estimated current stock at wholesaler / distributor level in Australia:	9626 units	
What is meant by 1 unit in this context:	A single pack of 30 capsules.	

Impact

Are there therapeutic alternatives on the Australian market?	No
Do any specific population groups use this product?	Yes
Provide details of the groups and the impact on those groups:	Pediatric or adolescents or adult patients with ADHD. Adult patients with BED,
Based on your answers above and the Assessment Framework, what is the shortage impact rating?	2 - Medium Impact

Shortage Action

What communication activities have happened or are planned?	Communication Action	Date of Communication
	Letter to Wholesalers	10-Jul-2023

Letter attached in Supporting Information:	No
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Further comments on communications:

What supply management actions have happened or are planned?	Management Action	Date of Management Action
	Working to expedite next shipment	14-Jun-2023
	Constrained Supply	20-Jun-2023

Further comments on management actions:

Supporting Information

Supporting data will be:	Attached
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Documents attached to this notification:

File Name	Created By	Description
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Sponsor website where medicine shortage information is available:

File Attachments

The following files have been attached to this notification.

From: [Medicine Shortages](#)
To: s22
Cc: s22
Subject: TRIM: RE: VYVANSE lisdexamfetamine dimesilate 30mg capsule bottle (AUST R 199227) [SEC=OFFICIAL]
Date: Tuesday, 27 June 2023 2:49:07 PM
Attachments: [image001.gif](#)

Dear s22

Thank you so much for your prompt response!

The information provided has been very helpful.

Kind regards

s22

Pharmacist

[Medicine Shortages Section](#)

[Pharmacovigilance Branch](#)

Phone: s22

Email: medicine.shortages@health.gov.au

Therapeutic Goods Administration

Department of Health and Aged Care

PO Box 100

Woden ACT 2606

www.tga.gov.au



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From: s22 <[redacted]@takeda.com>

Sent: Tuesday, 27 June 2023 2:39 PM

To: Medicine Shortages <medicine.shortages@health.gov.au>

Cc: s22 <[redacted]@takeda.com>

Subject: RE: VYVANSE lisdexamfetamine dimesilate 30mg capsule bottle (AUST R 199227)

[SEC=OFFICIAL]

Dear s22

Thank you for your email. Following is information your requested:

1. Are you confident in the return of supply date (11-Aug-2023)?

Company response: Yes, company is confident of return of supply date of 11-Aug-2023 as we have allowed a longer lead time than actual arrival of stock.

2. Do you anticipate any other strengths of VYVANSE will be affected?

Company response: Company is not anticipating other strengths to be affected at this stage.

Please contact me should you need any further information.

Kind regards

s22

From: Medicine Shortages <medicine.shortages@health.gov.au>

Sent: Tuesday, June 27, 2023 11:21 AM

To: s22 [REDACTED] <[\[REDACTED\]@takeda.com](mailto:[REDACTED]@takeda.com)>

Cc: s22 [REDACTED] <[\[REDACTED\]@takeda.com](mailto:[REDACTED]@takeda.com)>

Subject: VYVANSE lisdexamfetamine dimesilate 30mg capsule bottle (AUST R 199227)

[SEC=OFFICIAL]

Dear s22 [REDACTED]

Thank you for lodging a Medicine Shortage Notification for VYVANSE lisdexamfetamine dimesilate 30mg capsule bottle (AUST R 199227).

Noting that you have advised that the shortage is not specific to Australia, could you please answer the following questions.

1. Are you confident in the return of supply date (11-Aug-2023)?
2. Do you anticipate any other strengths of VYVANSE will be affected?

Thank you for your assistance.

Kind regards

s22 [REDACTED]

Pharmacist

Medicine Shortages Section

Pharmacovigilance Branch

Phone: s22 [REDACTED]

Email: medicine.shortages@health.gov.au

Therapeutic Goods Administration

Department of Health and Aged Care

PO Box 100

Woden ACT 2606

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From: s22
To: [Medicine Shortages](#)
Cc: s22
Subject: RE: Medicine Shortage Notification for VYVANSE lisdexamfetamine dimesilate 30mg [SEC=OFFICIAL]
Date: Tuesday, 4 July 2023 2:45:36 PM
Attachments: [image001.png](#)
[image003.jpg](#)
[image004.png](#)

Dear s22

Thank you for your email. As requested, following is company *response* to action items listed:

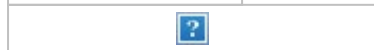
ACTION ITEMS:

- Please advise if the shortage of VYVANSE 30mg has already started and if so please update the MSN to 'current' and change the shortage dates accordingly.
 - *Company response: Wholesalers (Sigma, Symbion, API) are holding 1-2 weeks coverage nationally*
- If VYVANSE 40mg is in current or anticipated shortage, please submit a medicine shortage notification.
 - *Company response: There is no anticipated shortage for the VYVANSE 40mg*
- How confident Takeda Pharmaceuticals is in shortage resolution dates?
 - *Company response: Flights have been confirmed with batch being released. We are on schedule to meeting the timelines previously supplied.*

Please let me know if you need any further information or clarification.

Kind regards

s22



s22 PhD

s22 – Oceania Cluster

Takeda Pharmaceuticals Australia Pty Ltd

Grosvenor Place, Level 39
225 George Street
Sydney NSW 2000 Australia

Direct Line: s22

Mobile: s22

s22 [@takeda.com](#)

From: Medicine Shortages

Sent: Tuesday, July 4, 2023 12:34 PM

To: s22

Cc: s22

Subject: Medicine Shortage Notification for VYVANSE lisdexamfetamine dimesilate 30mg [SEC=OFFICIAL]

Dear s22

Many thanks for your time on the phone.

As I mentioned, the TGA has received multiple inquiries of supply disruptions of VYVANSE 30mg and VYVANSE 40mg capsules.

We understand that Takeda Pharmaceuticals has submitted a shortage notification (MSN) for VYVANSE 30mg ARTG 199227 for an anticipated shortage from 31 July 2023 to 11 August 2023. However, currently pharmacists are unable to order these medicines from their regular wholesalers.

ACTION ITEMS:

- Please advise if the shortage of VYVANSE 30mg has already started and if so please update the MSN to 'current' and change the shortage dates accordingly.
- If VYVANSE 40mg is in current or anticipated shortage, please submit a medicine shortage notification.
- How confident Takeda Pharmaceuticals is in shortage resolution dates?

Do not hesitate to reach out if you have any questions.

Kind Regards

s22

s22

Pharmacist- Medicine Shortages Section

Pharmacovigilance Branch

Medicine Regulation Division | Health Products Regulation Group

Phone: s22

Email: medicine.shortages@health.gov.au

Therapeutic Goods Administration

Department of Health and Aged Care

PO Box 100

Woden ACT 2606

www.tga.gov.au

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From: [Medicine Shortages](#)
To: §22
Cc: §22 @takeda.com
Subject: RE: Section 31 Request for Information - VYVANSE lisdexamfetamine dimesilate 30mg capsule bottle ARTG 199227 and VYVANSE lisdexamfetamine dimesilate 40 mg capsules bottle ARTG 284020 [SEC=OFFICIAL]
Date: Wednesday, 5 July 2023 4:33:39 PM
Attachments: [image006.png](#)
[image008.png](#)
[image001.png](#)

Dear §22

Many thanks for providing the requested information.
 We truly appreciate your prompt response.

Please inform us and vary the shortage notification if there are any changes in the anticipated shortage situation.

Kind Regards

§22

§22

Pharmacist- Medicine Shortages Section
 Pharmacovigilance Branch
 Medicine Regulation Division | Health Products Regulation Group
 Phone: §22
 Email: medicine.shortages@health.gov.au

Therapeutic Goods Administration
 Department of Health and Aged Care
 PO Box 100
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From: §22 @takeda.com>
Sent: Wednesday, 5 July 2023 2:43 PM
To: Medicine Shortages <medicine.shortages@health.gov.au>
Cc: §22 @takeda.com>
Subject: RE: Section 31 Request for Information – VYVANSE lisdexamfetamine dimesilate 30mg capsule bottle ARTG 199227 and VYVANSE lisdexamfetamine dimesilate 40 mg capsules bottle ARTG 284020 [SEC=OFFICIAL]

Dear §22

Thank you for your email with S31 request. Following is the information requested by the TGA:

Product	Estimated normal monthly demand levels	Estimated market share	Current stock levels at the sponsor/manufacturing level (as at 05.07.23 am)	Current stock levels at the wholesaler/distributor level (as at 03.07.23)	Dates of expected deliveries (importations) for the next 6 months and quantities expected for each order
VYVANSE lisdexamfetamine dimesilate 30mg capsule bottle ARTG 199227	§47	100 %	15,681	1,547 (approx. 16,000 in transit or waiting receipt at wholesalers/distributors)	38,000 14 th July 36,000 Aug delivery 37,000 Sep delivery 55,000 Oct delivery 95,000 Nov delivery 90,000 Dec delivery
VYVANSE lisdexamfetamine dimesilate 40 mg capsules bottle ARTG 284020		100 %	75,160	4,475 (approx. 10,000 in transit or waiting receipt at wholesaler/distributors)	123,000 Sep delivery 50,000 Oct delivery

Please contact me should you need any further information.

Kind regards

§22



Better Health, Brighter Future

§22 PhD

§22 – Oceania Cluster

Takeda Pharmaceuticals Australia Pty Ltd

Grosvenor Place, Level 39

225 George Street

Sydney NSW 2000 Australia

Direct Line: §22

Mobile: §22

§22 @takeda.com

From: Medicine Shortages <medicine.shortages@health.gov.au>
Sent: Tuesday, July 4, 2023 4:25 PM
To: §22 @takeda.com
Cc: §22 @takeda.com
Subject: Section 31 Request for Information – VYVANSE lisdexamfetamine dimesilate 30mg capsule bottle ARTG 199227 and VYVANSE lisdexamfetamine dimesilate 40 mg capsules bottle ARTG 284020 [SEC=OFFICIAL]
Importance: High

Dear §22

Many thanks for your prompt response. To assist with our investigation please provide further information as requested below.

Re: VYVANSE lisdexamfetamine dimesilate 30mg capsule bottle ARTG 199227 and VYVANSE lisdexamfetamine dimesilate 40 mg capsules bottle ARTG 284020

BACKGROUND

The TGA has received multiple inquiries from different states about the current supply disruption of Vyvanse 30mg and 40mg capsules.

In my capacity as a delegate of the Secretary of the Department of Health and Aged Care for the purposes of s 31 of the [Therapeutic Goods Act 1989](#) (the Act), I am writing to request information under s 31(1) of the Act in relation to the following medicine(s) (the **medicine(s)**):

- VYVANSE lisdexamfetamine dimesilate 30mg capsule bottle ARTG 199227
- VYVANSE lisdexamfetamine dimesilate 40 mg capsules bottle ARTG 284020

RESPONSE REQUIREMENTS

In relation to the medicines referred to above and in accordance with section 31 of the Act, please provide the required information as detailed below by email to medicine.shortages@health.gov.au. Please ensure we receive your response by: **5pm Wednesday 5 July 2023**

If you believe that the time allowed is inadequate or you have difficulties meeting the due date, please contact me as soon as possible.

INFORMATION REQUIRED

1. Stock holdings of the above medicines at the wholesaler and sponsor levels
2. Dates of expected deliveries (importations) that Takeda Pharmaceuticals expect to receive over the next six months and quantities expected for each order.
3. The date the information in 1. and 2. was collected and deemed accurate.

Please provide this information in the table provided below

Product	Estimated normal monthly demand levels	Estimated market share	Current stock levels at the sponsor/manufacturing level (as at Date)	Current stock levels at the wholesaler/distributor level (as at Date)	Dates of expected deliveries (importations) for the next 6 months and quantities expected for each order
VYVANSE lisdexamfetamine dimesilate 30mg capsule bottle ARTG 199227					
VYVANSE lisdexamfetamine dimesilate 40 mg capsules bottle ARTG 284020					

Further, if any of these products are in anticipated/current shortage, you are required to submit a medicine shortages notification in accordance with the mandatory reporting legislation that commenced on 1 January 2019. Failure to do so is a breach of the legislation.

If you do not comply with this notice by the due date or you provide false or misleading information in compliance or purported compliance with this notice, we can take further regulatory action which may include cancelling the registration of the medicines, issuing infringement notices, criminal prosecution or (if false or misleading information is provided) the commencement of civil penalty proceedings against you (see s 30(2)(caa), 31AAA, 31(4) to (8) of the Act).

Yours sincerely

Signed and authorised by

[S31 delegate]
 Delegate of the Secretary

§22

Pharmacist- Medicine Shortages Section
 Pharmacovigilance Branch
 Medicine Regulation Division | Health Products Regulation Group
 Phone: §22
 Email: medicine.shortages@health.gov.au

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

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From: s22
To: Medicine Shortages
Cc: s22
Subject: RE: Request for Information - VYVANSE lisdexamfetamine dimesilate 30mg capsule bottle ARTG 199227 [SEC=OFFICIAL]
Date: Friday, 4 August 2023 2:42:39 PM
Attachments: image001.png, image002.png, image003.jpg

Good afternoon s22

On behalf of my colleague, s22, please see below the company's responses to your questions:

- Could you please advise us if there is any current or anticipated shortage, if so please submit a shortage notification. In addition to the anticipated shortage of Vyvanse 30mg, Takeda anticipate shortage for Vyvanse 20mg and Vyvanse 40mg as well. Shortage notifications will be submitted by early next week at the very latest.
If there is no shortage please provide the reason for the delay in stock transfer to wholesalers. N/A
Please advise us if there are any changes in the below mentioned quantities and dates for the next 6 months expected deliveries. What date is August delivery expected? Delivery dates for all presentations are not confirmed yet. Possibility of date confirmation: 2 weeks prior to actual delivery.

Please see the table below for up-to-date information of supply and stock levels for the 3 Vyvanse presentations:

Table with 6 columns: Product, Estimated normal monthly demand levels, Estimated market share, Current stock levels at the sponsor/manufacturing level (as at 04.08.23), Current stock levels at the wholesaler/distributor level (as at 31.08.23), Dates of expected deliveries (importations) for the next 6 months and quantities expected for each order. Rows include Vyvanse 30mg, 40mg, and 20mg presentations.

Should you still need any further information, please don't hesitate to contact us again immediately.

Kind regards

s22
s22
s22, Oceania Cluster
Takeda Pharmaceuticals Australia Pty Ltd
Lvl 39, Grosvenor Place
225 George Street
Sydney NSW 2000
Australia
Office: +s22
Mob: +s22
s22@takeda.com

From: Medicine Shortages <medicine.shortages@health.gov.au>
Sent: Thursday, August 3, 2023 11:24 AM
To: s22@takeda.com
Cc: s22@takeda.com
Subject: RE: Request for Information - VYVANSE lisdexamfetamine dimesilate 30mg capsule bottle ARTG 199227 [SEC=OFFICIAL]

Dear s22
Thank you for your email.
We accept your proposal of response by COB 4 August 2023.
Kind Regards

s22
s22
Pharmacist- Medicine Shortages Section
Pharmacovigilance Branch
Medicine Regulation Division | Health Products Regulation Group
Phone: s22
Email: medicine.shortages@health.gov.au

Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100
Woden ACT 2606
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From: s22@takeda.com
Sent: Thursday, 3 August 2023 10:13 AM
To: Medicine Shortages <medicine.shortages@health.gov.au>
Cc: s22@takeda.com
Subject: RE: Request for Information - VYVANSE lisdexamfetamine dimesilate 30mg capsule bottle ARTG 199227 [SEC=OFFICIAL]

Dear s22
Thank you for your email. Takeda is working on providing a response to your request but need more time. Company proposes to have response to TGA by COB 4-Aug-2023, hope the TGA finds this as acceptable.
Kind regards
s22



§22 PhD
 §22 – Oceania Cluster
Takeda Pharmaceuticals Australia Pty Ltd
 Grosvenor Place, Level 39
 225 George Street
 Sydney NSW 2000 Australia
 Direct Line: §22
 Mobile: §22
 §22 @takeda.com

From: Medicine Shortages <medicine_shortages@health.gov.au>
Sent: Wednesday, August 2, 2023 2:55 PM
To: §22 @takeda.com
Cc: §22 @takeda.com
Subject: Request for Information – VYVANSE lisdexamfetamine dimesilate 30mg capsule bottle ARTG 199227 [SEC=OFFICIAL]

Dear §22
 Hope you are well.
 Thank you for providing the information about Vyvanse last month. We note that Takeda has resolved the anticipated shortage that was submitted for Vyvanse 30mg.
 However, we are receiving multiple inquiries of **current** stock unavailability of **Vyvanse 30mg**. Pharmacists are unable to order from their wholesalers portal. Please respond to following questions.

- Could you please advise us if there is any current or anticipated shortage, if so please submit a shortage notification.
- If there is no shortage please provide the reason for the delay in stock transfer to wholesalers.
- Please advise us if there are any changes in the below mentioned quantities and dates for the next 6 months expected deliveries. What date is August delivery expected?

We would appreciate your response ASAP but no later than **COB tomorrow 3 August 2023**.
 Kind Regards

§22
 §22
 Pharmacist- Medicine Shortages Section
 Pharmacovigilance Branch
 Medicine Regulation Division | Health Products Regulation Group
 Phone: §22
 Email: medicine_shortages@health.gov.au

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

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From: §22 @takeda.com
Sent: Wednesday, 5 July 2023 2:43 PM
To: Medicine Shortages <medicine_shortages@health.gov.au>
Cc: §22 @takeda.com
Subject: RE: Section 31 Request for Information – VYVANSE lisdexamfetamine dimesilate 30mg capsule bottle ARTG 199227 and VYVANSE lisdexamfetamine dimesilate 40 mg capsules bottle ARTG 284020 [SEC=OFFICIAL]

Dear §22
 Thank you for your email with S31 request. Following is the information requested by the TGA:

Product	Estimated normal monthly demand levels	Estimated market share	Current stock levels at the sponsor/manufacturing level (as at 05.07.23 am)	Current stock levels at the wholesaler/distributor level (as at 03.07.23)	Dates of expected deliveries (importations) for the next 6 months and quantities expected for each order
VYVANSE lisdexamfetamine dimesilate 30mg capsule bottle ARTG 199227	§47	100 %	15,681	1,547 (approx. 16,000 in transit or waiting receipt at wholesalers/distributors)	38,000 14 th July 36,000 Aug delivery 37,000 Sep delivery 55,000 Oct delivery 95,000 Nov delivery 90,000 Dec delivery
VYVANSE lisdexamfetamine dimesilate 40 mg capsules bottle ARTG 284020		100 %	75,160	4,475 (approx. 10,000 in transit or waiting receipt at wholesaler/distributors)	123,000 Sep delivery 50,000 Oct delivery

Please contact me should you need any further information.
 Kind regards



§22 PhD
 §22 – Oceania Cluster
Takeda Pharmaceuticals Australia Pty Ltd
 Grosvenor Place, Level 39
 225 George Street
 Sydney NSW 2000 Australia
 Direct Line: §22
 Mobile: §22
 §22 @takeda.com

From: Medicine Shortages

Sent: Tuesday, July 4, 2023 4:25 PM

To: §22

Cc: §22

Subject: Section 31 Request for Information – VYVANSE lisdexamfetamine dimesilate 30mg capsule bottle ARTG 199227 and VYVANSE lisdexamfetamine dimesilate 40 mg capsules bottle ARTG 284020 [SEC=OFFICIAL]

Importance: High

Dear §22

Many thanks for your prompt response. To assist with our investigation please provide further information as requested below.

Re: VYVANSE lisdexamfetamine dimesilate 30mg capsule bottle ARTG 199227 and VYVANSE lisdexamfetamine dimesilate 40 mg capsules bottle ARTG 284020

BACKGROUND

The TGA has received multiple inquiries from different states about the current supply disruption of Vyvanse 30mg and 40mg capsules.

In my capacity as a delegate of the Secretary of the Department of Health and Aged Care for the purposes of s 31 of the [Therapeutic Goods Act 1989](#) (the Act), I am writing to request information under s 31(1) of the Act in relation to the following medicine(s) (the **medicine(s)**):

- **VYVANSE lisdexamfetamine dimesilate 30mg capsule bottle ARTG 199227**
- **VYVANSE lisdexamfetamine dimesilate 40 mg capsules bottle ARTG 284020**

RESPONSE REQUIREMENTS

In relation to the medicines referred to above and in accordance with section 31 of the Act, please provide the required information as detailed below by email to medicine.shortages@health.gov.au. Please ensure we receive your response by: **5pm Wednesday 5 July 2023**

If you believe that the time allowed is inadequate or you have difficulties meeting the due date, please contact me as soon as possible.

INFORMATION REQUIRED

1. Stock holdings of the above medicines at the wholesaler and sponsor levels
2. Dates of expected deliveries (importations) that Takeda Pharmaceuticals expect to receive over the next six months and quantities expected for each order.
3. The date the information in 1. and 2. was collected and deemed accurate.

Please provide this information in the table provided below

Product	Estimated normal monthly demand levels	Estimated market share	Current stock levels at the sponsor/manufacturing level (as at Date)	Current stock levels at the wholesaler/distributor level (as at Date)	Dates of expected deliveries (importations) for the next 6 months and quantities expected for each order
VYVANSE lisdexamfetamine dimesilate 30mg capsule bottle ARTG 199227					
VYVANSE lisdexamfetamine dimesilate 40 mg capsules bottle ARTG 284020					

Further, if any of these products are in anticipated/current shortage, you are required to submit a medicine shortages notification in accordance with the mandatory reporting legislation that commenced on 1 January 2019. Failure to do so is a breach of the legislation.

If you do not comply with this notice by the due date or you provide false or misleading information in compliance or purported compliance with this notice, we can take further regulatory action which may include cancelling the registration of the medicines, issuing infringement notices, criminal prosecution or (if false or misleading information is provided) the commencement of civil penalty proceedings against you (see s 30(2)(caa), 31AAA, 31(4) to (8) of the Act).

Yours sincerely

Signed and authorised by

[S31 delegate]

Delegate of the Secretary

§22

Pharmacist- Medicine Shortages Section

Pharmacovigilance Branch

Medicine Regulation Division | Health Products Regulation Group

Phone: §22

Email: medicine.shortages@health.gov.au

Therapeutic Goods Administration

Department of Health and Aged Care

PO Box 100

Woden ACT 2606

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Medicine Shortage Notification

Notifier

Notifier

Sponsor Name:	Takeda Pharmaceuticals Australia Pty Ltd
Sponsor Address:	Grosvenor Place Level 39 225 George Street Sydney NSW 2000
Australian telephone number for public contact purposes:	1800012612
Medical information email for public contact purposes:	medinfoAPAC@takeda.com

Primary Contact

Name:	s22
Phone Number:	s22
Email Address:	s22@takeda.com

Secondary Contact

Name:	s22
Phone Number:	s22
Email Address:	s22@takeda.com

ARTG Entry

ARTG Entry

ARTG number of the product that has a supply disruption:

ARTG ID	ARTG Name	Active Ingredient	Strength	Dosage Form
199227	VYVANSE	lisdexamfetamine dimesilate	30mg	Capsule, hard

ATC Descriptor:	Nervous system
Are all pack sizes for this ARTG entry affected?	Yes
Is this ARTG entry listed in the PBS?	Yes
Provide the PBS number for this listing:	10486X
Do you have a designated sponsor representative within your organisation who is a point of contact on PBS matters?	Yes

PBS Contact Details

Name:	s22
Phone Number:	s22
Email Address:	s22@takeda.com

Details

Details

When was the shortage known to the sponsor?	21/06/2023
--	------------

Nature of the shortage:	Resolved	
Shortage reason:	Manufacturing	Document 7
Manufacturing site problem:	Issues/delays with product release	
Shortage reason - further information:		
Estimated period supply will be affected at wholesaler points:	From:	17/07/2023
	To:	17/07/2023
Availability:	Available	
TGA publication date:	28/07/2023	
Is this shortage related to other medicines within the same Therapeutic class?	No	
Is this shortage specific to Australia?	No	
Estimated normal demand volumes for Australia:	s47	
Estimated percentage share of the Australian market:	100 %	
Estimated current stock at sponsor / manufacturing level in Australia:	38115 units	
Estimated current stock at wholesaler / distributor level in Australia:	2186 units	
What is meant by 1 unit in this context:	A single pack of 30 capsules.	

Impact

Are there therapeutic alternatives on the Australian market?	No
Do any specific population groups use this product?	Yes
Provide details of the groups and the impact on those groups:	Pediatric or adolescents or adult patients with ADHD. Adult patients with BED,
Based on your answers above and the Assessment Framework, what is the shortage impact rating?	2 - Medium Impact

Shortage Action

What communication activities have happened or are planned?

Communication Action	Date of Communication
Letter to Wholesalers	10-Jul-2023

Letter attached in Supporting Information:

No

Further comments on communications:

What supply management actions have happened or are planned?

Management Action	Date of Management Action
Working to expedite next shipment	14-Jun-2023
Constrained Supply	20-Jun-2023

Further comments on management actions:

Supporting Information

Supporting data will be:

Sponsor website where medicine shortage information is available:


From: [Medicine Shortages](#)
To: [REDACTED]
Subject: Re: Vyvanse shortage MS-2023-NT-00735-1
Date: Thursday, 10 August 2023 10:56:44 AM
Attachments: [image001.pdf](#)
[image002.png](#)
[image003.png](#)

Dear [REDACTED]
Thank you for your email.
The requested notification has been flagged for immediate archiving. You should be able to submit your new notification shortly.
Kind regards

[REDACTED]
Pharmacist
Medicine Shortages Section
Pharmacovigilance Branch

Phone: [REDACTED]
Email: medicine.shortages@health.gov.au

Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care
PO Box 100
Woden ACT 2606
www.tga.gov.au


The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.
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From: [REDACTED] <[REDACTED]@takeda.com>
Sent: Thursday, 10 August 2023 7:32 AM
To: Medicine Shortages <medicine.shortages@health.gov.au>
Subject: Vyvanse shortage MS-2023-NT-00735-1
Importance: High

Dear team,
The medicine shortage for Vyvanse 30mg capsules with the above number (please see the snapshot below) has been resolved, yet it is still preventing us from lodging a new shortage notification for the same drug



Could you please close this one ASAP so we can lodge the new notification in time for our meeting with the TGA on Monday 14-Aug?
Should you need any information, please let me know immediately.

Kind regards
[REDACTED]
[REDACTED] MMdSc
[REDACTED], Oceania Cluster
Takeda Pharmaceuticals Australia Pty Ltd
Lvl 39, Grosvenor Place
225 George Street
Sydney NSW 2000
Australia
Office: [REDACTED]
Mob: [REDACTED]
[REDACTED] [\[REDACTED\]@takeda.com](mailto:[REDACTED]@takeda.com)

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Notifier

Notifier

Sponsor Name: Takeda Pharmaceuticals Australia Pty Ltd

Sponsor Address: Grosvenor Place Level 39 225 George Street Sydney NSW 2000

Australian telephone number for public contact purposes: 1800012612

Medical information email for public contact purposes: medinfoAPAC@takeda.com

Primary Contact

Name: §22

Phone Number: §22

Email Address: §22@takeda.com

Secondary Contact

Name: §22

Phone Number: §22

Email Address: §22@takeda.com

ARTG Entry

ARTG Entry

ARTG number of the product that has a supply disruption:

ARTG ID	ARTG Name	Active Ingredient	Strength	Dosage Form
199227	VYVANSE	lisdexamfetamine dimesilate	30mg	Capsule, hard

ATC Descriptor: Nervous system

Are all pack sizes for this ARTG entry affected? Yes

Is this ARTG entry listed in the PBS? Yes

Provide the PBS number for this listing: 10486X

Do you have a designated sponsor representative within your organisation who is a point of contact on PBS matters? Yes

PBS Contact Details

Name: §22

Phone Number: §22

Email Address: §22@takeda.com

Details

Details

When was the shortage known to the sponsor? 04/08/2023

Nature of the shortage:	Current	
Shortage reason:	Manufacturing	Document 9
Manufacturing site problem:	Issues/delays with packaging and/or labelling	
Shortage reason - further information:	Takeda are experiencing some delays related to the global supply of Vyvanse products due to the remediation actions implemented at the contract manufacturing organization site Wasdell Europe with respect to the Critical Observations identified during the HPRA health authority inspection previously communicated to the TGA. As a result the expected manufacturing time frames have been increased and committed shipments to Australia have been further delayed.	
Estimated period supply will be affected at wholesaler points:	From:	07/08/2023
	To:	31/12/2023
Availability:	Limited Availability	
Publication:	This notification will be published by the TGA under Section 61 of the Therapeutic Goods Act 1989.	
Is this shortage related to other medicines within the same Therapeutic class?	No	
Is this shortage specific to Australia?	No	
Estimated normal demand volumes for Australia:	s47	
Estimated percentage share of the Australian market:	100 %	
Estimated current stock at sponsor / manufacturing level in Australia:	8864 units	
Estimated current stock at wholesaler / distributor level in Australia:	3495 units	
What is meant by 1 unit in this context:	Single pack of 30 capsules	

Impact

Are there therapeutic alternatives on the Australian market?	Yes
What is the status of substitute options for this product in Australia?	Appropriate Therapeutic Alternatives
Are they available in adequate supplies to meet demand?	Unknown at this time
Provide details:	There are different stimulants, such as methylphenidate, belonging to the same class of psychostimulants
Do any specific population groups use this product?	Yes
Provide details of the groups and the impact on those groups:	Paediatric, adolescents, and adult patients with ADHD. Adult patients with BED
Based on your answers above and the Assessment Framework, what is the shortage impact rating?	2 - Medium Impact

Shortage Action

What communication activities have happened or are planned?

Communication Action	Date of Communication
Letter to Prescribers	14-Aug-2023
Letter to Patient Advocacy Groups	14-Aug-2023
Letter to Pharmacists	14-Aug-2023

Letter attached in Supporting Information:

No

Further comments on communications:

Communications plans includes:

1. HCP letter (all paediatricians and psychiatrists)
2. Consumer Statement to Patient Advisory Groups (ADHD Australia, ADHD Foundation)
3. Pharmacy Letter (all retail pharmacies)
4. Wholesaler Letter

What supply management actions have happened or are planned?

Management Action	Date of Management Action
Constrained Supply	07-Aug-2023
Working to expedite next shipment	07-Aug-2023

Further comments on management actions:**Supporting Information****Supporting data will be:**

Attached

Documents attached to this notification:

File Name	Created By	Description
FINAL_VYVANSE Stock Shortage_AUG2023_HCP LETTER.pdf	S22	Letter to HCPs

Sponsor website where medicine shortage information is available:**File Attachments**

The following files have been attached to this notification.

Notifier

Notifier

Sponsor Name: Takeda Pharmaceuticals Australia Pty Ltd

Sponsor Address: Grosvenor Place Level 39 225 George Street Sydney NSW 2000

Australian telephone number for public contact purposes: 1800012612

Medical information email for public contact purposes: medinfoAPAC@takeda.com

Primary Contact

Name: §22

Phone Number: §22

Email Address: §22@takeda.com

Secondary Contact

Name: §22

Phone Number: +§22

Email Address: §22@takeda.com

ARTG Entry

ARTG Entry

ARTG number of the product that has a supply disruption:

ARTG ID	ARTG Name	Active Ingredient	Strength	Dosage Form
284019	VYVANSE	lisdexamfetamine dimesilate	20mg	Capsule, hard

ATC Descriptor: Nervous system

Are all pack sizes for this ARTG entry affected? Yes

Is this ARTG entry listed in the PBS? Yes

Provide the PBS number for this listing: 11884L

Do you have a designated sponsor representative within your organisation who is a point of contact on PBS matters? Yes

PBS Contact Details

Name: §22

Phone Number: §22

Email Address: §22@takeda.com

Details

Details

When was the shortage known to the sponsor? 04/08/2023

Nature of the shortage:	Anticipated	
Shortage reason:	Manufacturing	Document 10
Manufacturing site problem:	Issues/delays with packaging and/or labelling	
Shortage reason - further information:	Takeda are experiencing some delays related to the global supply of Vyvanse products due to the remediation actions implemented at the contract manufacturing organization site Wasdell Europe with respect to the Critical Observations identified during the HPRA health authority inspection previously communicated to the TGA. As a result the expected manufacturing time frames have been increased and committed shipments to Australia have been further delayed.	
Estimated period supply will be affected at wholesaler points:	From:	16/10/2023
	To:	31/12/2023
Availability:	Available	
Indicate preference for date of publication:	Date of processing	
Is this shortage related to other medicines within the same Therapeutic class?	No	
Is this shortage specific to Australia?	No	
Estimated normal demand volumes for Australia:	s47	
Estimated percentage share of the Australian market:	100 %	
Estimated current stock at sponsor / manufacturing level in Australia:	74212 units	
Estimated current stock at wholesaler / distributor level in Australia:	7047 units	
What is meant by 1 unit in this context:	Single pack of 30 capsules	

Impact

Are there therapeutic alternatives on the Australian market?	Yes
What is the status of substitute options for this product in Australia?	Appropriate Therapeutic Alternatives
Are they available in adequate supplies to meet demand?	Unknown at this time
Provide details:	There are different stimulants, such as methylphenidate, belonging to the same class of psychostimulants
Do any specific population groups use this product?	Yes
Provide details of the groups and the impact on those groups:	Paediatric, adolescents, and adult patients with ADHD. Adult patients with BED.
Based on your answers above and the Assessment Framework, what is the shortage impact rating?	2 - Medium Impact

Shortage Action

What communication activities have happened or are planned?

Communication Action	Date of Communication
Letter to Patient Advocacy Groups	14-Aug-2023
Letter to Pharmacists	14-Aug-2023
Letter to Prescribers	14-Aug-2023
Letter to Wholesalers	14-Aug-2023

Letter attached in Supporting Information:

No

[Document 10](#)

Further comments on communications:

Communications plans includes:

1. HCP letter (all paediatricians and psychiatrists)
2. Consumer Statement to Patient Advisory Groups (ADHD Australia, ADHD Foundation)
3. Pharmacy Letter (all retail pharmacies)
4. Wholesaler Letter

What supply management actions have happened or are planned?

Management Action	Date of Management Action
Constrained Supply	07-Aug-2023
Working to expedite next shipment	07-Aug-2023

Further comments on management actions:

Supporting Information

Supporting data will be:

Attached

Documents attached to this notification:

File Name	Created By	Description
FINAL_VYVANSE Stock Shortage_AUG2023_HCP LETTER.pdf	S22	Letter to HCPs

Sponsor website where medicine shortage information is available:

File Attachments

The following files have been attached to this notification.

From: s22
To: s22
Subject: FW: TGA meeting with Takeda Pharmaceuticals re: Vyvanse shortages [SEC=OFFICIAL]
Date: Monday, 14 August 2023 1:42:20 PM
Attachments: [Takeda TGA Meeting Vyvanse Supply 14Aug23.pptx](#)

Hi team,

If you haven't seen them yet, some slides from Takeda for the meeting today.

Regards,

s22

From: Medicine Shortages <medicine.shortages@health.gov.au>
Sent: Monday, 14 August 2023 1:18 PM
To: s22 <[REDACTED]@health.gov.au>
Subject: FW: TGA meeting with Takeda Pharmaceuticals re: Vyvanse shortages [SEC=OFFICIAL]

Hey s22

This has been forwarded from Medicine Shortages Inbox. It has been moved to the action folder.

Kind Regards,

s22

From: s22 <[REDACTED]@takeda.com>
Sent: Monday, 14 August 2023 1:13 PM
To: Medicine Shortages <medicine.shortages@health.gov.au>; s22 <[REDACTED]@Health.gov.au>
Cc: s22 <[REDACTED]@takeda.com>; s22 <[REDACTED]@takeda.com>; s22 <[REDACTED]@takeda.com>
Subject: RE: TGA meeting with Takeda Pharmaceuticals re: Vyvanse shortages [SEC=OFFICIAL]

Good afternoon s22

Please find attached the presentation slides for our meeting.

Kind regards

s22

From: Medicine Shortages <medicine.shortages@health.gov.au>
Sent: Monday, August 14, 2023 9:14 AM
To: s22 <[REDACTED]@takeda.com>; Medicine Shortages <medicine.shortages@health.gov.au>; s22 <[REDACTED]@Health.gov.au>
Cc: s22 <[REDACTED]@takeda.com>; s22 <[REDACTED]@takeda.com>; s22 <[REDACTED]@takeda.com>

Subject: RE: TGA meeting with Takeda Pharmaceuticals re: Vyvanse shortages [SEC=OFFICIAL]

Good morning s22

Thank you so much for providing this agenda, I have sent an updated invite this morning, including an agenda combining your input below and some additional information from the Medicine Shortages team.

Kindest regards,

s22

Pharmacist

Medicine Shortages Section

Pharmacovigilance Branch

Phone: s22

Email: medicine.shortages@health.gov.au

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

The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community.

From: s22 <[redacted]@takeda.com>

Sent: Monday, 14 August 2023 7:56 AM

To: Medicine Shortages <medicine.shortages@health.gov.au>; s22 <[redacted]@health.gov.au>; s22 <[redacted]@Health.gov.au>

Cc: s22 <[redacted]@takeda.com>; s22 <[redacted]@takeda.com>; s22 <[redacted]@takeda.com>

Subject: RE: TGA meeting with Takeda Pharmaceuticals re: Vyvanse shortages [SEC=OFFICIAL]

Good morning,

In preparation for our meeting at 2.30pm today, please see below the agenda:

- Introduction – s22: 1min
- Overview of issues affecting supply – s22: 2-3mins max.
- – s22: 5mins max.
- Communications plan – s22: 2-3mins max.
- Mitigation plan – s22: 1mins max.
- Q&A: 15mins

Please note there is a last-minute change to one of the attendees; s22 from Medical Affairs will be attending instead of s22.

Should you need any further information prior to the meeting, please let me know immediately.

Kind regards

s22

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

From: Medicine Shortages <medicine.shortages@health.gov.au>

Sent: Thursday, August 10, 2023 10:06 AM

To: Medicine Shortages; s22

Cc: s22

Subject: TGA meeting with Takeda Pharmaceuticals re: Vyvanse shortages [SEC=OFFICIAL]

When: Monday, August 14, 2023 2:30 PM-3:00 PM (UTC+10:00) Canberra, Melbourne, Sydney.

Where: webex

Good morning s22

The TGA utilises Webex as the platform for our virtual meetings and teleconferences.

Please see below the virtual meeting details for Monday 14 August at 2.30pm.

If I could ask you to please forward this email to the colleagues you mentioned in your email, it is most appreciated:

- s22
-
-
-
-

Kindest regards,

s22

Pharmacist


Medicine Shortages Section

Pharmacovigilance Branch

Phone: s22

Email: medicine.shortages@health.gov.au

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



The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community.

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

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More ways to join:

Join from the meeting link

<https://health-au.webex.com/health-au/j.php?MTID=m42b60c5b81b4450601bb410c85a9cb37>

Join by meeting number

Meeting number (access code): 2652 209 6087

Meeting password: Uj2mVTmwd35

Tap to join from a mobile device (attendees only)

[+61-2-9338-2221,26522096087###](tel:+61-2-9338-2221,26522096087###) Australia Toll

Join by phone

+61-2-9338-2221 Australia Toll

[Global call-in numbers](#)

Join from a video system or application

Dial [26522096087@health-au.webex.com](tel:26522096087@health-au.webex.com)

You can also dial 210.4.202.4 and enter your meeting number.

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

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

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Takeda & TGA Meeting

Vyvanse (lisdexamphetamine) supply

14th August 2023



Vyvanse Supply – Supply Chain

Agenda:

#	Title	Lead
1	Welcome and introduction	s22 [redacted], Medicine Shortages Section, TGA s22 [redacted], Takeda Pharmaceuticals
2	Overview of issues affecting supply	s22 [redacted], Takeda Pharmaceuticals
3	Supply & Demand overview	s22 [redacted] Takeda Pharmaceuticals
4	Communication plan	s22 [redacted], Takeda Pharmaceuticals
5	Mitigation plan	s22 [redacted]
6	Q & A	All participants

Vyvanse Supply – Supply Chain



Purpose of meeting:

To confirm:

- confidence in anticipated deliveries

Review supply plan (slide 5-6) showing :

“Firm” confirmed replenishments

“Planned” replenishments that are awaiting date confirmations

- shortage dates –

As per Supply Plan on slide 5 & reported to the TGA

- whether 20mg and 40mg are affected by the shortage

20mg & 40mg demand has been uplifted to include 30mg demand (25% in Aug & 50% from Sep to Nov)

In addition 60mg demand has also been uplifted to include 25% of 30mg demand from Sep to Nov

- expected delivery dates (i.e. specific date or week) and confidence in these

Firm dates are locked in, planned replenishments are reviewed weekly with Manufacturing

Actions:

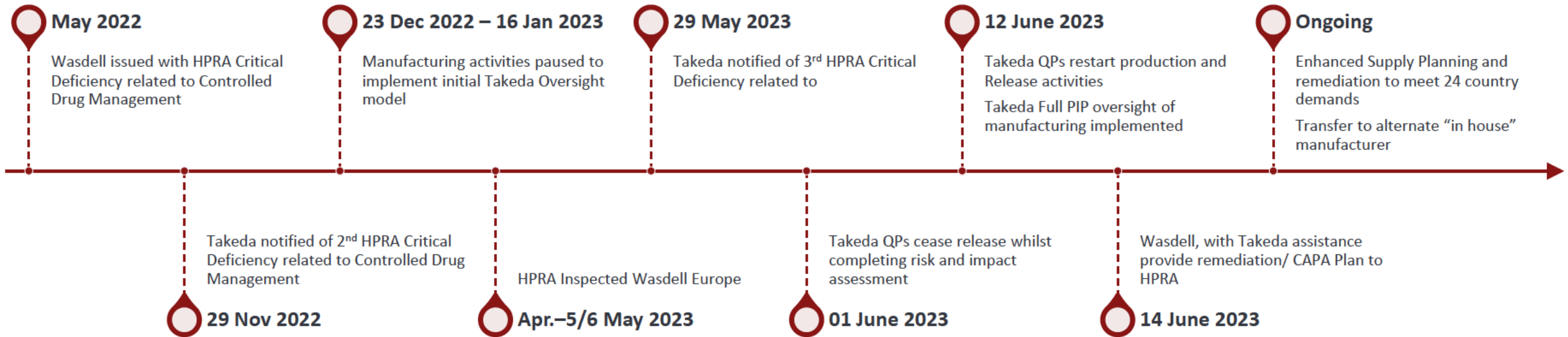
- Agree on shortage dates for publishing on the TGA website and communication plan

Takeda Contract Manufacturer (CMO)- Wasdell Europe GMP



Reason for Supply Disruptions – Vyvanse 30mg and 20mg

- Over the past 12 months CMO responsible for primary packaging of Vyvanse products - Wasdell Europe has had 3 HPRA inspections resulting in unsatisfactory GMP Compliance with the most recent inspection occurring in May 2023 resulting in additional critical observations.
- Remediation plans agreed with HPRA include full Takeda Oversight, Person in Plant (PIP) for all manufacturing steps.
- Result is ongoing reduction in packaging capacity at site and decrease in product availability across the 24 country markets impacted.
- Takeda continue to work with HPRA and Wasdell Europe to enhance production capacities.



Vyvanse 20mg, 30mg & 40mg – Supply Chain



SOH Update 14th Aug

Stock in Transit

Planned replenishments, dates to be confirmed

			Aug/23	Sep/23	Oct/23	Nov/23	Dec/23	Jan/24	Feb/24	Mar/24	Apr/24
501101	Vyvanse 20mg	Starting Inv	70639	76189	44495	62208	29127	36691	68870	100664	132075
		Monthly FC (uplifted to include 30mg demand - Aug 25%, Sep to Nov 50%)	s47								
		Stock delivery	25000		50000		25000	50000	50000	50000	50000
		EOM - month's stock cover	2.4	1.4	1.9	1.7	2.1	3.8	5.4	7.0	4.8
			* Qty 25k stock in transit ETA 29.08								
		Reported to TGA:	Anticipated shortage from 16th Oct - 31 Dec, worse case scenario due to planned shipments awaiting confirmed dates								
500735	Vyvanse 30mg	Starting Inv	5591	-24608	-19426	-13863	61581	108906	165612	221699	277167
		Monthly FC (no adjustment)	s47								
		Stock delivery		36000	37000	107500	80000	90000	90000	90000	90000
		EOM - month's stock cover	-0.8	-0.6	-0.4	1.9	3.3	4.9	6.4	7.9	5.9
			* Manufacturing advised delivery in AU end Sep								
		Reported to TGA:	Anticipated shortage from 7th Oct - 31 Dec, worse case scenario due to planned shipments awaiting confirmed dates								
501102	Vyvanse 40mg	Starting Inv	84946	59946	44497	53012	10491	33272	30327	51655	78257
		Monthly FC (uplifted to include 30mg demand - Aug 25%, Sep to Nov 50%)	s47								
		Stock delivery		25000	50000		50000	25000	50000	56000	160000
		EOM - month's stock cover	1.5	1.1	1.2	0.4	1.2	1.1	1.8	2.6	5.9
			* Qty 25k in Ireland awaiting QA release & Shipping								

Vyvanse 50mg, 60mg & 70mg – Supply Chain



SOH Update 14th Aug

Stock in Transit

Planned replenishments, dates to be confirmed

			Aug/23	Sep/23	Oct/23	Nov/23	Dec/23	Jan/24	Feb/24	Mar/24	Apr/24	
500736	Vyvanse 50mg	Starting Inv	72868	51868	24552	36619	8069	21997	80808	138356	190577	
		Monthly FC	s47									
		Stock delivery			40000		40000	90000	90000	90000		
		EOM - month's stock cover	1.9	0.9	1.3	0.3	0.7	2.5	3.7	5.9	5.1	
			Aug/23	Sep/23	Oct/23	Nov/23	Dec/23	Jan/24	Feb/24	Mar/24	Apr/24	
501103	Vyvanse 60mg	Starting Inv	99459	90459	71206	65160	44921	31413	17565	18376	93047	
		Monthly FC (uplifted to include 30mg demand - Sep to Nov 25%)	s47									
		Stock delivery			13700				15000	89200	30000	
		EOM - month's stock cover	4.7	3.6	3.2	3.3	2.3	1.2	1.3	6.3	7.7	
			Aug/23	Sep/23	Oct/23	Nov/23	Dec/23	Jan/24	Feb/24	Mar/24	Apr/24	
500737	Vyvanse 70mg	Starting Inv	61002	73414	79533	108135	90431	97421	104106	110484	141557	
		Monthly FC	s47									
		Stock delivery	25002	23212	46000		25000	25000	25000	50000		
		EOM - month's stock cover	4.3	4.6	6.1	5.0	5.3	5.6	5.8	7.4	5.0	

* 25k Stock in transit ETA 18.08.23

*23k stock available in Ireland awaiting to be dispatched

From: s22
To: [Medicine Shortages](#)
Cc: s22
Subject: RE: Meeting request - TGA Medicine Shortages team - Vyvanse (lisdexamfetamine) shortages [SEC=OFFICIAL]
Date: Thursday, 10 August 2023 7:51:50 AM
Attachments: [image001.gif](#)

Good morning s22

We are happy to meet with the TGA on **Monday 14 August 14:30 – 15:00**. Please provide the phone number to contact.

The following attendees will be available to answer any questions you might have and provide the necessary information:

- s22
-
-
-
-

We also want to bring to your attention that a shortage notification for Vyvanse 20mg was lodged earlier today with the communications letter to HCP attached to it for your information. However, the shortage notification for Vyvanse 30mg couldn't be lodged because the previous notification, although resolved, is still preventing it. An email was sent to Medicine Shortage to close the previous notification immediately.

We look forward to meeting with you on Monday; in the meantime should you need any further information, please let me know immediately.

Kind regards

s22

From: s22
Sent: Wednesday, August 9, 2023 1:09 PM
To: Medicine Shortages <medicine.shortages@health.gov.au>
Cc: s22 @takeda.com>
Subject: RE: Meeting request - TGA Medicine Shortages team - Vyvanse (lisdexamfetamine) shortages [SEC=OFFICIAL]

Good afternoon s22

I'm still gathering information from the different functions on agreed date/time of meeting next week and the final list of attendees, and will respond to you by early tomorrow 10-Aug at the latest.

On the other hand, we want to inform you that we have draft shortage notifications in the system for Vyvanse 30mg (Current) and 20mg (Anticipated) that are ready for submission. Can you please advise whether the notifications should be submitted now or after the meeting next week?

Your prompt response would be greatly appreciated.

Kind regards

s22

From: Medicine Shortages <medicine.shortages@health.gov.au>
Sent: Tuesday, August 8, 2023 5:54 PM
To: s22 @takeda.com>; s22

s22 [REDACTED]@takeda.com>; s22 [REDACTED]@takeda.com>

Subject: Meeting request - TGA Medicine Shortages team - Vyvanse (lisdexamfetamine) shortages [SEC=OFFICIAL]

Good afternoon,

The Medicine Shortages team within the Therapeutic Goods Administration (TGA) would like to organise a meeting with Takeda Pharmaceuticals to discuss the anticipated supply constraints for several strengths of VYVANSE (lisdexamphetamine) products over the coming months.

Given the number of products involved and the projected lengths of the shortages, we hope to more fully understand the current and future supply of these medicines and explore the potential risks leading into this shortage period. This information will allow us to anticipate communication and management strategies for patients and healthcare professionals.

Please advise which of the following times is most suitable:

- Monday 14 August 14:30 – 15:00
- Monday 14 August 15:00 – 15:30
- Monday 14 August 15:30 – 16:00
- Tuesday 15 August 10:00 – 10:30
- Tuesday 15 August 10:30 – 11:00

If these suggested times are not suitable, or if you have any questions, please contact the Medicines Shortages team on s22 [REDACTED] or medicine.shortages@health.gov.au

Kindest regards,

s22 [REDACTED]

Pharmacist

Medicine Shortages Section

Pharmacovigilance Branch

Phone: s22 [REDACTED]

Email: medicine.shortages@health.gov.au

Therapeutic Goods Administration

Department of Health and Aged Care

PO Box 100

Woden ACT 2606

www.tga.gov.au



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From: s22
To: [Medicine Shortages](#)
Subject: Accepted: TGA meeting with Takeda Pharmaceuticals re: Vyvanse shortages [SEC=OFFICIAL]

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From: s22
To: s22
Cc: s22
Subject: Notes from our Takeda meeting - Vyvanse shortages [SEC=OFFICIAL]
Date: Wednesday, 16 August 2023 2:30:50 PM
Attachments: [image003.png](#)

Hi all,

Vyvanse shortages Takeda presentation slides: [D23-2868823](#)

Most of the supply information of all strengths of Vyvanse including the future deliveries and whether they are planned or confirmed are included in slides.

Here are some notes from our Takeda meeting on Monday 14 August 2024 about Vyvanse shortages.

- Takeda uses manufacturing site Wasdell Europe for primary packaging. HPRa health authority identified some compliance issues during their inspection last year. Takeda usually have 3-4 months of safety stock and therefore shortages are experienced now.
- Further, end of May, the MFG site had 2 weeks shut down of production. This has resulted in reduced packaging capacity. Shipments are delayed.
- Shortage is global and 24 countries are impacted.
- Takeda is only anticipating current shortage of 30mg and anticipated shortage of 20mg until end of the year.
- Other strengths are not affected as they have confirmed deliveries as opposed to planned but not confirmed for 20 and 30mg.
- They are considering a shift in demand for other strengths and they have forecasted their future deliveries to accommodate increase in demand for other strengths.
- HCP letters went to all psychiatrists on 10/8/23. Letters were sent through email. Letters to pharmacists and wholesalers are planned to be sent out today (ie.14/8/23)
- Consumer statement to key patient advisory group is planned to be communicated tomorrow.
- As a mitigation strategy, Takeda has made a submission to the TGA to include new packaging and labelling site in Germany. Art work has already been submitted to TGA.
- We asked them to provide us submission ID so that we can request expedited review.
- We also asked them to share with us all the communication letters they are planning to send out.
- We agreed to publish both the shortages ASAP as some of the shortage communication emails had already gone out.
- Takeda confirmed that they are aware of the possibility of stock piling and therefore they are planning to do manual release of stock.
- They also will be holding emergency stock for the strengths in shortage.

Let me know if you need any further information.

Kind Regards

s22

s22

Pharmacist- Medicine Shortages Section
Pharmacovigilance Branch

Medicine Regulation Division | Health Products Regulation Group

Phone: s22

Email: medicine.shortages@health.gov.au

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

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

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Takeda & TGA Meeting

Vyvanse (lisdexamphetamine) supply

14th August 2023



Vyvanse Supply – Supply Chain

Agenda:

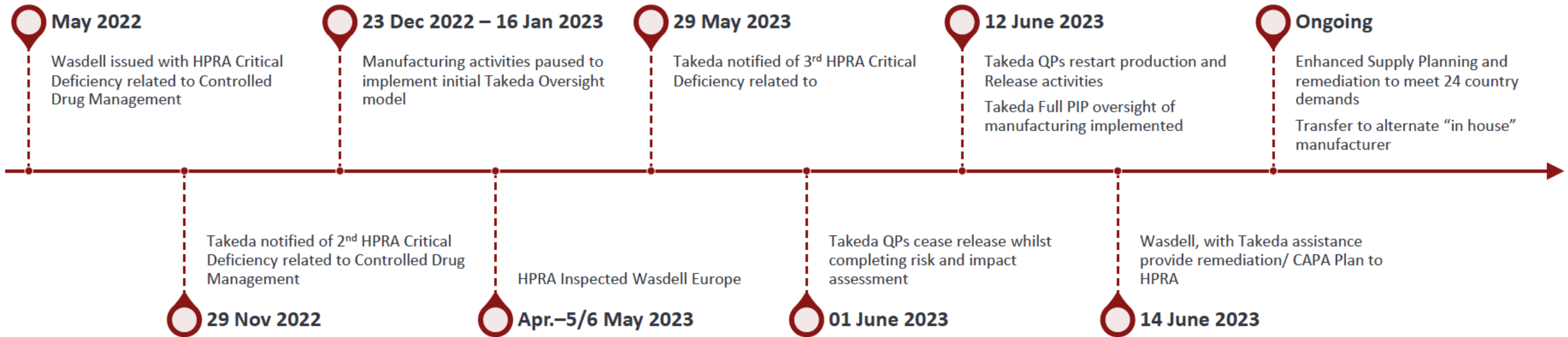
#	Title	Lead
1	Welcome and introduction	s22 [redacted], Medicine Shortages Section, TGA s22 [redacted], Takeda Pharmaceuticals
2	Overview of issues affecting supply	s22 [redacted], Takeda Pharmaceuticals
3	Supply & Demand overview	s22 [redacted], Takeda Pharmaceuticals
4	Communication plan	s22 [redacted], Takeda Pharmaceuticals
5	Mitigation plan	s22 [redacted]
6	Q & A	All participants

Takeda Contract Manufacturer (CMO)- Wasdell Europe GMP



Reason for Supply Disruptions – Vyvanse 30mg and 20mg

- Over the past 12 months CMO responsible for primary packaging of Vyvanse products - Wasdell Europe has had 3 HPRA inspections resulting in unsatisfactory GMP Compliance with the most recent inspection occurring in May 2023 resulting in additional critical observations.
- Remediation plans agreed with HPRA include full Takeda Oversight, Person in Plant (PIP) for all manufacturing steps.
- Result is ongoing reduction in packaging capacity at site and decrease in product availability across the 24 country markets impacted.
- Takeda continue to work with HPRA and Wasdell Europe to enhance production capacities.



Vyvanse Supply – Supply Chain

Purpose of meeting:

To confirm:

- confidence in anticipated deliveries

Review supply plan (slide 5-6) showing :

“Firm” confirmed replenishments

“Planned” replenishments that are awaiting date confirmations

- shortage dates –

As per Supply Plan on next slide & reported to the TGA

- whether 20mg and 40mg are affected by the shortage

20mg & 40mg demand has been uplifted to include 30mg demand (25% in Aug & 50% from Sep to Nov)

In addition 60mg demand has also been uplifted to include 25% of 30mg demand from Sep to Nov

- expected delivery dates (i.e. specific date or week) and confidence in these

“Firm” dates are locked in, planned replenishments are reviewed weekly with Manufacturing

Actions:

- Agree on shortage dates for publishing on the TGA website and communication plan

Vyvanse 20mg, 30mg & 40mg – Supply Chain



SOH Update 14th Aug

Stock in Transit

Planned replenishments, dates to be confirmed

			Aug/23	Sep/23	Oct/23	Nov/23	Dec/23	Jan/24	Feb/24	Mar/24	Apr/24
501101	Vyvanse 20mg	Starting Inv	70639	76189	44495	62208	29127	36691	68870	100664	132075
		Monthly FC (uplifted to include 30mg demand - Aug 25%, Sep to Nov 50%)	s47								
		Stock delivery	25000		50000		25000	50000	50000	50000	
		EOM - month's stock cover	2.4	1.4	1.9	1.7	2.1	3.8	5.4	7.0	4.8
			* Qty 25k stock in transit ETA 29.08								
		Reported to TGA: Anticipated shortage from 16th Oct - 31 Dec, worse case scenario due to planned shipments awaiting confirmed dates									
500735	Vyvanse 30mg	Starting Inv	5591	-24608	-19426	-13863	61581	108906	165612	221699	277167
		Monthly FC (no adjustment)	s47								
		Stock delivery		36000	37000	107500	80000	90000	90000	90000	
		EOM - month's stock cover	-0.8	-0.6	-0.4	1.9	3.3	4.9	6.4	7.9	5.9
			* Manufacturing advised delivery in AU end Sep								
		Reported to TGA: Anticipated shortage from 7th Aug - 31 Dec, worse case scenario due to planned shipments awaiting confirmed dates									
501102	Vyvanse 40mg	Starting Inv	84946	59946	44497	53012	10491	33272	30327	51655	78257
		Monthly FC (uplifted to include 30mg demand - Aug 25%, Sep to Nov 50%)	s47								
		Stock delivery		25000	50000		50000	25000	50000	56000	160000
		EOM - month's stock cover	1.5	1.1	1.2	0.4	1.2	1.1	1.8	2.6	5.9
			* Qty 25k in Ireland awaiting QA release & Shipping								
			* Qty 50K is stock in transit SEA ETA 2nd Oct								

Vyvanse 50mg, 60mg & 70mg – Supply Chain



SOH Update 14th Aug

Stock in Transit
Planned replenishments, dates to be confirmed

			Aug/23	Sep/23	Oct/23	Nov/23	Dec/23	Jan/24	Feb/24	Mar/24	Apr/24	
500736	Vyvanse 50mg	Starting Inv	72868	51868	24552	36619	8069	21997	80808	138356	190577	
		Monthly FC	s47									
		Stock delivery			40000		40000	90000	90000	90000		
		EOM - month's stock cover	1.9	0.9	1.3	0.3	0.7	2.5	3.7	5.9	5.1	
			Aug/23	Sep/23	Oct/23	Nov/23	Dec/23	Jan/24	Feb/24	Mar/24	Apr/24	
501103	Vyvanse 60mg	Starting Inv	99459	90459	71206	65160	44921	31413	17565	18376	93047	
		Monthly FC (uplifted to include 30mg demand - Sep to Nov 25%)	s47									
		Stock delivery			13700				15000	89200	30000	
		EOM - month's stock cover	4.7	3.6	3.2	3.3	2.3	1.2	1.3	6.3	7.7	
			Aug/23	Sep/23	Oct/23	Nov/23	Dec/23	Jan/24	Feb/24	Mar/24	Apr/24	
500737	Vyvanse 70mg	Starting Inv	61002	73414	79533	108135	90431	97421	104106	110484	141557	
		Monthly FC	s47									
		Stock delivery	25002	23212	46000		25000	25000	25000	50000		
		EOM - month's stock cover	4.3	4.6	6.1	5.0	5.3	5.6	5.8	7.4	5.0	

* 25k Stock in transit ETA 18.08.23

*23k stock available in Ireland awaiting to be dispatched

From: s22
To: [Medicine Shortages](#)
Cc: s22
Subject: RE: Meeting request - TGA Medicine Shortages team - Vyvanse (lisdexamfetamine) shortages [SEC=OFFICIAL]
Date: Thursday, 17 August 2023 8:58:02 AM
Attachments: [image001.gif](#)
[Meetings docs.zip](#)

Dear s22

Thank you very much for the constructive discussion at the meeting on Monday 14-Aug. Please find attached the following documents:

- Meeting minutes. Please let me know if you have any comments or want to make any changes.
- Copies of the final communications:
 - HCP letter – sent on 10 August via email and due to arrive hard copy via post this week to all psychiatrist & paediatricians
 - Pharmacy letter – sent on 15 August via email and due to arrive hard copy via post in coming weeks to all pharmacies
 - Wholesaler communications – sent on 16 August via email
 - Consumer Statement – will be shared to patient organisations (ADHD Australia & ADHD Foundation) by 18 August.

As mentioned at the meeting, an application to register the artworks to be used at the new packaging site is currently under review; the Submission number is: **PM-2023-02348-1**. A S31 request for minor changes to the artwork was raised and the response will be submitted to the TGA by Fri 18-Aug at the very latest.

Should you need any further information, please let me know immediately.

Kind regards

s22

From: Medicine Shortages <medicine.shortages@health.gov.au>

Sent: Tuesday, August 8, 2023 5:54 PM

To: s22 <[REDACTED]@takeda.com>; s22 <[REDACTED]@takeda.com>; s22 <[REDACTED]@takeda.com>

Subject: Meeting request - TGA Medicine Shortages team - Vyvanse (lisdexamfetamine) shortages [SEC=OFFICIAL]

Good afternoon,

The Medicine Shortages team within the Therapeutic Goods Administration (TGA) would like to organise a meeting with Takeda Pharmaceuticals to discuss the anticipated supply constraints for several strengths of VYVANSE (lisdexamphetamine) products over the coming months.

Given the number of products involved and the projected lengths of the shortages, we hope to more fully understand the current and future supply of these medicines and explore the potential risks leading into this shortage period. This information will allow us to anticipate communication and management strategies for patients and healthcare professionals.

Please advise which of the following times is most suitable:

- Monday 14 August 14:30 – 15:00
- Monday 14 August 15:00 – 15:30
- Monday 14 August 15:30 – 16:00
- Tuesday 15 August 10:00 – 10:30

Tuesday 15 August 10:30 – 11:00

If these suggested times are not suitable, or if you have any questions, please contact the Medicines Shortages team on s22 or medicine.shortages@health.gov.au

Kindest regards,

s22

Pharmacist

Medicine Shortages Section

Pharmacovigilance Branch

Phone: s22

Email: medicine.shortages@health.gov.au

Therapeutic Goods Administration

Department of Health and Aged Care

PO Box 100

Woden ACT 2606

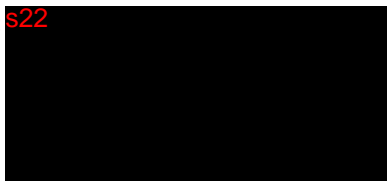
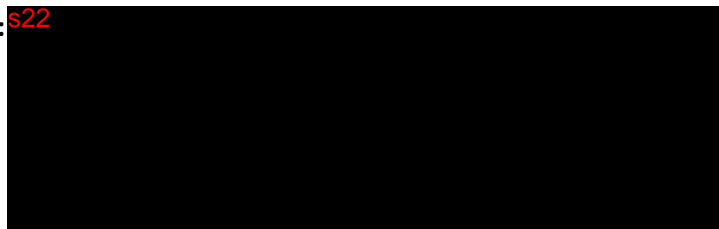
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TGA meeting with Takeda Pharmaceuticals re: Vyvanse shortages**Date: 14-Aug-2023****Time: 2.30-3.00pm****Attendees:****TGA – Medicine Shortages Section:** s22**Takeda:** s22

Meeting started at 2.30pm with the introduction of both teams.

Quality

s22 provided an overview of the shortage situation and the contributing factors, mainly the primary packaging site for Vyvanse (Wasdell – Ireland) had unsatisfactory GMP compliance, and despite the remediation plans, which was agreed with HPRA, packaging capacity has been impacted and product availability decreased across the 24 countries impacted.

Supply Chain

s22 presented a review of the supply plan (all strengths) that includes both ‘confirmed’ replenishments and ‘planned’ replenishments that are still awaiting confirmation. To compensate for the shortage of the 30mg, demand for the 20mg, 40mg, and 60mg has been uplifted. s22 also confirmed that planned replenishments are reviewed weekly with manufacturing.

Commercial

s22 presented the communications plan, which include letters to the following stakeholders:

- HCPs (Psychiatrists & Paediatricians), distributed 10-Aug-2023
- Pharmacists
- Wholesalers (email communication)
- Statement to Patient Advisory Groups

Regulatory

s22 informed the TGA of the long-term mitigation plan. A new packaging site (Takeda GmbH – Germany) has been registered as an alternative to Wasdell. TGA requested minor changes to the artworks and those will be submitted to the TGA 18-Aug-2023.

Points of Discussion

- TGA queried the draft shortage notification for Vyvanse 40mg and whether this will be submitted. s22 explained the draft was created before the company received a confirmation of a new shipment that’s on its way; therefore, the draft will not be submitted.
- TGA agreed the communications plan is sufficient and asked whether Takeda has any reason for withholding back publication of the shortage notifications on the TGA website. TGA did not agree to any delays because the letters to stakeholders either were distributed already

(HCPs) or will be distributed soon. The shortage notifications will be published on the TGA website once they are processed.

- TGA offered their assistance with expediting approval of the outstanding artworks to help production from the new site starting earlier.
- The length of shortage notifications for the 20mg and 30mg is conservative (until 31-Dec). If confirmed information is received that shortage will be resolved earlier, Takeda will send subsequent communications to notify the same stakeholders and update the notifications on the TGA website.

Action items:

Takeda to provide the following to the TGA:

- Copies of all communication letters
- The current submission number for the artworks

Meeting ended at 3.00pm.



15th August 2023

Dear Pharmacist,

RE: SUPPLY INTERRUPTION OF VYVANSE® (lisdexamfetamine dimesilate)

We are writing to inform you of an interruption to supply that will affect the availability of VYVANSE in Australia **from August 2023 until December 2023**. This interruption is expected to intermittently impact the **20mg and 30mg strengths**, with VYVANSE 30mg experiencing the greatest impact.

Based on typical usage patterns, Takeda anticipates that remaining inventory at warehouses and wholesalers will be exhausted as follows:

- VYVANSE 30mg – middle of August 2023
- VYVANSE 20mg – end of October 2023

From August 2023 through to December 2023 there will be ongoing disruptions to regular supply and whilst we anticipate some deliveries during this time, we do not anticipate that these will be sufficient to meet usual demand. As of the date of this letter, the supplies of Vyvanse 40mg, 50mg, 60mg, 70mg capsules are not impacted.

To mitigate potential stock shortages for patients, our supply team will be closely overseeing the inventory for VYVANSE 20mg and 30mg over the coming months. Please expect some orders not to be supplied in full and intermittent periods where there will be no stock available.

This stock shortage is undoubtedly going to cause inconvenience to you and to customers. We will provide regular updates on the availability of VYVANSE and will continue to work on resolving the shortage as a matter of priority.

Any urgent enquiries should be directed to:

- Takeda Medical Information: telephone 1800 012 612 or email: medinfoAPAC@takeda.com
- Takeda Customer Service: telephone 1800 812 734

Yours sincerely,

s22 [Redacted]

s22 [Redacted] PhD
s22 [Redacted]



Please review **Product Information before prescribing**. Product Information is available from Takeda Pharmaceuticals Australia Pty Ltd. Phone: 1800 012 612. Email: medinfoAPAC@takeda.com

For further information about the appropriate selection of patients and prescribing of VYVANSE, please visit <http://www.idxguide.com/au> (password: onetakeda)

VYVANSE has a potential for abuse, misuse, dependence, or diversion for non-therapeutic uses. Physicians should assess the risk of abuse prior to prescribing and monitor for signs of abuse and dependence while on therapy. VYVANSE should be prescribed cautiously to patients with a history of substance abuse or dependence. Careful supervision is required during withdrawal from abusive use since severe depression may occur. Withdrawal following chronic therapeutic use may unmask symptoms of the underlying disorder that may require follow-up.

Minimum Product Information. VYVANSE® (lisdexamfetamine dimesilate).

Indication: Attention Deficit Hyperactivity Disorder (ADHD): Indicated for treatment of ADHD. Treatment should be commenced by a specialist as part of a comprehensive treatment program and re-evaluated periodically during long-term use. Binge Eating Disorder (BED): Indicated for treatment of moderate to severe BED in adults when non-pharmacological treatment is unsuccessful or unavailable. Treatment should be commenced and managed by a psychiatrist. **Dosage and Administration:** VYVANSE should be initiated at 30 mg once daily in the morning (avoid afternoon doses due to potential for insomnia) and slowly adjusted to the lowest effective dose (no more frequently than weekly). Capsules may be taken whole, or opened and the contents emptied and mixed with a soft food such as yogurt or in a glass of water or orange juice.

Contraindications: Advanced arteriosclerosis; symptomatic cardiovascular disease (eg cardiac arrhythmia, ischaemic heart disease); moderate to severe hypertension; hyperthyroidism; hypersensitivity or idiosyncratic reaction to sympathomimetic amines or any of the excipients; glaucoma; agitated states (eg severe anxiety, tension and agitation); administration during or within 14 days of cessation of MAOIs; pheochromocytoma; tics, Tourette's syndrome; patients who exhibit severe depression, anorexia nervosa, psychotic symptoms or suicidal tendency; drug dependence or alcohol abuse. **Precautions:** Cardiovascular disease; psychiatric disorders (psychosis, bipolar disease, aggression); seizures; visual disturbance; long-term suppression of growth, peripheral vasculopathy including Raynaud's phenomenon. Renal impairment (severe renal insufficiency max dose 50mg/day; dose reduction for dialysis patients). No data in hepatic impairment. Pregnancy: Category B3. Women taking VYVANSE should refrain from breast feeding. Not studied in children <6 years or adults >55 years of age. **Interactions:** MAOIs (see Contraindications), antihypertensives, narcotic analgesics, antipsychotics, agents that alter urinary pH, serotonergic drugs. **Adverse Effects:** Very Common reactions: decreased appetite, insomnia, headache, dry mouth, upper abdominal pain, weight decreased. Common reactions: anorexia, agitation, anxiety, libido decreased, tic, affect lability, psychomotor hyperactivity, bruxism, aggression, dizziness, restlessness, tremor, somnolence, mydriasis, tachycardia, palpitation, dyspnoea, diarrhoea, nausea, vomiting, hyperhidrosis, rash, irritability, fatigue, feeling jittery, pyrexia, blood pressure increased, erectile dysfunction. Note: where frequency of adverse reactions varies across age groups (children, adolescents, adults), the adverse reaction is listed according to the highest frequency.

(pi-01047. V1.0)



Vyvanse Stock Shortage – Consumer Statement August 2023

RE: SUPPLY INTERRUPTION OF VYVANSE® (lisdexamfetamine dimesilate) 20mg & 30mg capsules

Takeda Pharmaceuticals Australia Pty Ltd (“Takeda”), the supplier of VYVANSE, is currently experiencing a supply interruption which will affect the availability of VYVANSE 20mg and 30mg capsules in Australia from **August 2023 until December 2023**.

This interruption is expected to impact **VYVANSE 20mg and 30mg** strengths intermittently over this time. This means that your pharmacist may not be able to get stock of VYVANSE to fill your prescription. As of the date of this notice, the supplies of Vyvanse 40mg, 50mg, 60mg, 70mg capsules are not impacted.

Takeda acknowledges the inconvenience and disruption to patients and is working to resolve this shortage as a matter of priority.

If you have any questions, please contact your doctor or pharmacist, or Takeda Medical Information via phone on 1800 012 612 or email: medinfoAPAC@takeda.com.



10th August 2023

Dear Doctor,

RE: SUPPLY INTERRUPTION OF VYVANSE® (lisdexamfetamine dimesilate) 20mg & 30mg

We are writing to inform you of an interruption to supply that will affect the availability of VYVANSE in Australia **from August 2023 until December 2023**. This interruption is expected to intermittently impact the **20mg and 30mg strengths** during this time, with VYVANSE 30mg experiencing the greatest impact.

Based on typical usage patterns, Takeda anticipates that remaining inventory at warehouses and wholesalers of will be exhausted as follows:

- VYVANSE 30mg – middle of August 2023
- VYVANSE 20mg – end of October 2023

Further disruptions to regular supply of the 20mg and 30mg capsules are expected until December 2023. This stock limitation may have an impact of availability across different locations, and patients may need to explore alternative pharmacies to obtain VYVANSE. As of the date of this letter, the supplies of Vyvanse 40mg, 50mg, 60mg, 70mg capsules are not impacted.

Takeda understands the importance of maintaining consistent treatment with VYVANSE and recognises the need to preserve this limited stock to prioritise ongoing care. Therefore, clinicians are asked to exercise their clinical judgement by being aware of this stock limitation when considering treatment with VYVANSE. Limiting new initiations to ease demands on these strengths of VYVANSE may help preserve available stock for stable patients and maintain treatment continuity.

This stock shortage is undoubtedly going to cause inconvenience to you and your patients. We will continue to provide regular updates on the availability of VYVANSE as information is available and will continue to work on resolving the shortage as priority. In the meantime, any urgent enquiries should be directed to:

- Takeda customer service: telephone 1800 812 734
- Takeda Medical Information: telephone 1800 012 612 or email: medinfoAPAC@takeda.com

Yours sincerely,

s22
[Redacted signature]

s22 [Redacted name] PhD
s22 [Redacted name]



Please review Product Information before prescribing. Product Information is available from Takeda Pharmaceuticals Australia Pty Ltd. Phone: 1800 012 612. Email: medinfoAPAC@takeda.com

For further information about the appropriate selection of patients and prescribing of VYVANSE, please visit <http://www.idxguide.com/au> (password: onetakeda)

VYVANSE has a potential for abuse, misuse, dependence, or diversion for non-therapeutic uses. Physicians should assess the risk of abuse prior to prescribing and monitor for signs of abuse and dependence while on therapy. VYVANSE should be prescribed cautiously to patients with a history of substance abuse or dependence. Careful supervision is required during withdrawal from abusive use since severe depression may occur. Withdrawal following chronic therapeutic use may unmask symptoms of the underlying disorder that may require follow-up.

Minimum Product Information. VYVANSE® (lisdexamfetamine dimesilate).

Indication: Attention Deficit Hyperactivity Disorder (ADHD): Indicated for treatment of ADHD. Treatment should be commenced by a specialist as part of a comprehensive treatment program and re-evaluated periodically during long-term use. Binge Eating Disorder (BED): Indicated for treatment of moderate to severe BED in adults when non-pharmacological treatment is unsuccessful or unavailable. Treatment should be commenced and managed by a psychiatrist. **Dosage and Administration:** VYVANSE should be initiated at 30 mg once daily in the morning (avoid afternoon doses due to potential for insomnia) and slowly adjusted to the lowest effective dose (no more frequently than weekly). Capsules may be taken whole, or opened and the contents emptied and mixed with a soft food such as yogurt or in a glass of water or orange juice. **Contraindications:** Advanced arteriosclerosis; symptomatic cardiovascular disease (eg cardiac arrhythmia, ischaemic heart disease); moderate to severe hypertension; hyperthyroidism; hypersensitivity or idiosyncratic reaction to sympathomimetic amines or any of the excipients; glaucoma; agitated states (eg severe anxiety, tension and agitation); administration during or within 14 days of cessation of MAOIs; pheochromocytoma; tics, Tourette's syndrome; patients who exhibit severe depression, anorexia nervosa, psychotic symptoms or suicidal tendency; drug dependence or alcohol abuse. **Precautions:** Cardiovascular disease; psychiatric disorders (psychosis, bipolar disease, aggression); seizures; visual disturbance; long-term suppression of growth, peripheral vasculopathy including Raynaud's phenomenon. Renal impairment (severe renal insufficiency max dose 50mg/day; dose reduction for dialysis patients). No data in hepatic impairment. Pregnancy: Category B3. Women taking VYVANSE should refrain from breast feeding. Not studied in children <6 years or adults >55 years of age. **Interactions:** MAOIs (see Contraindications), antihypertensives, narcotic analgesics, antipsychotics, agents that alter urinary pH, serotonergic drugs. **Adverse Effects:** Very Common reactions: decreased appetite, insomnia, headache, dry mouth, upper abdominal pain, weight decreased. Common reactions: anorexia, agitation, anxiety, libido decreased, tic, affect lability, psychomotor hyperactivity, bruxism, aggression, dizziness, restlessness, tremor, somnolence, mydriasis, tachycardia, palpitation, dyspnoea, diarrhoea, nausea, vomiting, hyperhidrosis, rash, irritability, fatigue, feeling jittery, pyrexia, blood pressure increased, erectile dysfunction. Note: where frequency of adverse reactions varies across age groups (children, adolescents, adults), the adverse reaction is listed according to the highest frequency.

(pi-01047. V1.0)

From: s22
Cc: s22; s22; s22; s22; s22
Subject: SUPPLY INTERRUPTION OF VYVANSE 20mg & 30mg
Date: Wednesday, 16 August 2023 10:57:30 AM
Attachments: [image004.png](#)
[image005.jpg](#)
Importance: High

Dear Wholesaler,

We are writing to inform you of an interruption to supply that will affect the availability of VYVANSE in Australia from August 2023 until December 2023. This interruption is expected to intermittently impact the 20mg and 30mg strengths, with VYVANSE 30mg experiencing the greatest impact.

Based on typical usage patterns, Takeda anticipates that remaining inventory at DHL will be exhausted as follows:

- VYVANSE 30mg – effective immediately
- VYVANSE 20mg – end of October 2023

From August 2023 through to December 2023 there will be ongoing disruptions to regular supply and whilst we anticipate some deliveries during this time, we do not anticipate that these will be sufficient to meet usual demand. The supplies of Vyvanse 40mg, 50mg, 60mg, 70mg capsules are not impacted.

To mitigate potential stock shortages for patients, our supply team will be closely overseeing the inventory for VYVANSE 20mg and 30mg over the coming months. Please expect some orders not to be supplied in full and intermittent periods where there will be no stock available.

This stock shortage is undoubtedly going to cause inconvenience to you and to customers. We will provide regular updates on the availability of VYVANSE and will continue to work on resolving the shortage as a matter of priority.

Any urgent enquiries should be directed to:

- Takeda Medical Information: telephone 1800 012 612 or email: medinfoAPAC@takeda.com

Otherwise, please contact our Supply Chain Specialists s22@takeda.com

Yours sincerely,



s22
s22 - Neuroscience
Takeda Pharmaceuticals Australia Pty Ltd
Suite 3901, Level 39, Grosvenor Place
225 George Street
Sydney, NSW 2000

Mobile **s22**
s22 [@takeda.com](mailto:s22@takeda.com)

From: [Medicine Shortages](#)
To: s22
Subject: RE: MS-2023-NT-00980-1. VYVANSE 30 mg medicines shortage. [SEC=OFFICIAL]
Date: Thursday, 28 September 2023 4:04:57 PM
Attachments: [image003.png](#)
[image006.png](#)
[image008.png](#)
[image009.png](#)

Dear s22

No problems at all.

I will be available to chat at 1:00 pm on Tuesday 3 October and I'm happy to call you on your mobile.

Look forward to speaking to you then.

Kind regards,

s22

s22
Pharmacist – Medicine Shortages Section
Pharmacovigilance Branch
 Medicines Regulation Division | Health Products Regulation Group
 Australian Government, Department of Health and Aged Care
 T: s22 | E: medicine.shortages@health.gov.au
 Location: Fairbairn
 PO Box 100, Woden ACT 2606, Australia

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From: s22 <@takeda.com>
Sent: Thursday, 28 September 2023 3:41 PM
To: Medicine Shortages <medicine.shortages@health.gov.au>
Subject: RE: MS-2023-NT-00980-1. VYVANSE 30 mg medicines shortage. [SEC=OFFICIAL]

Dear s22

Thank you for your email. Could I suggest Tue 3rd Oct either at 11:30 am or 1:00 pm, would that suit you? Let me know, also if you can confirm if I should call you on the number listed in your email or if you choose to call on my mobile.

Kind regards

s22



Better Health, Brighter Future

s22 PhD
 s22 – Oceania Cluster
Takeda Pharmaceuticals Australia Pty Ltd
 Grosvenor Place, Level 39
 225 George Street
 Sydney NSW 2000 Australia
 Mobile: s22
 s22 @takeda.com

From: Medicine Shortages <medicine.shortages@health.gov.au>
Sent: Thursday, September 28, 2023 3:25 PM
To: s22 @takeda.com>
Subject: RE: MS-2023-NT-00980-1. VYVANSE 30 mg medicines shortage. [SEC=OFFICIAL]

Dear s22

Thank you for your follow up questions. I think the best course of action to respond to these queries will be a phone call.

I am happy to contact you between 1pm and 4pm tomorrow if there is a time within this that suits you? Otherwise we can arrange a different time to discuss these matters. Please let me know your preference.

Kind regards,

s22

s22
Pharmacist – Medicine Shortages Section
Pharmacovigilance Branch
 Medicines Regulation Division | Health Products Regulation Group
 Australian Government, Department of Health and Aged Care
 T: s22 | E: medicine.shortages@health.gov.au
 Location: Fairbairn
 PO Box 100, Woden ACT 2606, Australia

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them and their cultures, and to all Elders both past and present

From: §22 <§22@takeda.com>
Sent: Thursday, 28 September 2023 2:25 PM
To: Medicine Shortages <medicine.shortages@health.gov.au>
Subject: RE: MS-2023-NT-00980-1. VYVANSE 30 mg medicines shortage. [SEC=OFFICIAL]

Dear §22

Further to our recent interaction, Takeda would like to seek some further clarifications please, hope you are able to assist.

- As a normal course of action, does the TGA proactively advise the sponsor of the medicine under shortage about S19A approval granted to someone? If not the case, then for future, could the TGA consider informing the sponsor as it would help align sharing the message in case of queries from healthcare professionals.
- In a scenario such as this shortage, we believe it becomes more complex since the S19A approval happens to be for the same brand sourced from overseas. What would the pharmacovigilance reporting arrangements be for the S19A approval holder? Does TGA instruct them to report safety information to the Australian sponsor of the medicine, and how does the S19A approval holder ensure routine and additional risk minimisation activities are implemented?
- The medicine shortage duration is until Dec-2023. Takeda chose a conservative date of end of Dec-2023 but it is likely the shortage may be resolved earlier. Could we please check the reason why the S19A approval granted to Medsurge is valid until 29-Feb-2024? According to the TGA S19A guidance document the approval should not exceed by more than one month of shortage.
- Once the shortage is resolved by Takeda, would the TGA rescind the S19A approval granted to Medsurge? If so, what is the process for this - should we advise the TGA that the shortage is resolved? What evidence will the TGA need from us in order to be satisfied it can rescind the S19A approval?
- We understand the pack size approved for supply by Medsurge is for 100 capsules whereas the registered VYVANSE 30 mg pack size is 30 capsules. Please could the TGA clarify whether the S19A dispensed product to the patient is 100 capsules?
- Finally, what will be the status of any Medsurge supplied products which are already with wholesalers once the s19A approval lapses? Will these be capable of further sale by wholesalers, even after the s19A approval has lapsed?

I look forward to your feedback. Let me know if you wish to have a discussion on phone.

Thank you.
 Kind regards

§22



Better Health, Brighter Future

§22 PhD
 §22 – Oceania Cluster
Takeda Pharmaceuticals Australia Pty Ltd
 Grosvenor Place, Level 39
 225 George Street
 Sydney NSW 2000 Australia
 Mobile: §22
 §22 @takeda.com

From: Medicine Shortages <medicine.shortages@health.gov.au>
Sent: Tuesday, September 26, 2023 9:16 AM
To: §22 <§22@takeda.com>
Subject: RE: MS-2023-NT-00980-1. VYVANSE 30 mg medicines shortage. [SEC=OFFICIAL]

Dear §22

Thank you for pointing this out. You're correct, it should mention the 30mg strength and not the 20mg.

I will let the appropriate area know of this error, and we will get this updated.

Kind regards,

§22

§22
Pharmacist – Medicine Shortages Section
Pharmacovigilance Branch
 Medicines Regulation Division | Health Products Regulation Group
 Australian Government, Department of Health and Aged Care
 T: §22 | E: medicine.shortages@health.gov.au
 Location: Fairbairn
 PO Box 100, Woden ACT 2606, Australia

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From: §22 <§22@takeda.com>
Sent: Tuesday, 26 September 2023 7:17 AM
To: Medicine Shortages <medicine.shortages@health.gov.au>
Subject: RE: MS-2023-NT-00980-1. VYVANSE 30 mg medicines shortage. [SEC=OFFICIAL]

Dear §22

Thank you for your prompt response and hope all well with you too. I noticed in the s19A link provided in your email the shortage mentioned is VYVANSE lisdexamfetamine dimesilate 20mg (ARTG 284019), could you please let me know the reason given the shortage is for the 30 mg strength.

Section 19A approved medicine	Vyvanse lisdexamfetamine dimesylate capsules 30mg (USA)
--------------------------------------	---

Section 19A approval holder	Medsurge Healthcare Pty Ltd ABN 92 124 728 892
------------------------------------	--

Phone	1300 788 261
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Approved until	29 February 2024
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Status	Current
---------------	---------

Medicines in short supply/unavailable	VYVANSE lisdexamfetamine dimesilate 20 mg capsules bottle - ARTG 284019
--	---

Kind regards

§22

From: Medicine Shortages <medicine.shortages@health.gov.au>

Sent: Monday, September 25, 2023 3:11 PM

To: §22 <§22@takeda.com>

Subject: RE: MS-2023-NT-00980-1. VYVANSE 30 mg medicines shortage. [SEC=OFFICIAL]

Dear §22

I hope all is well.

Yes, the product approved for supply under section 19A of the *Therapeutic Goods Act 1989* (Act) is a Vyvanse branded product from another country, namely the United States of America (USA). Specifically, the product approved is Vyvanse lisdexamfetamine dimesylate capsules 30mg (USA). More information about the product approved for supply under section 19A is available on our Section 19A database from <https://www.tga.gov.au/resources/section-19a-approvals/vyvanse-lisdexamfetamine-dimesylate-capsules-30mg-usa>

Please let me know if you require any further information to assist.

Kind regards,

§22

§22

**Pharmacist – Medicine Shortages Section
Pharmacovigilance Branch**

Medicines Regulation Division | Health Products Regulation Group

Australian Government, Department of Health and Aged Care

T: §22 | E: medicine.shortages@health.gov.au

Location: Fairbairn

PO Box 100, Woden ACT 2606, Australia

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From: §22 <§22@takeda.com>

Sent: Monday, 25 September 2023 2:46 PM

To: Medicine Shortages <medicine.shortages@health.gov.au>

Subject: MS-2023-NT-00980-1. VYVANSE 30 mg medicines shortage.

Dear TGA Medicine Shortage Section

I hope you can assist with Takeda's query in regard to the following entry in TGA's Medicines Shortage database. A section 19A application from Medsurge has been approved by the TGA for supply of an unregistered 30 mg lisdexamfetamine dimesilate product. Could we please check whether the unapproved product is 'VYVANSE' brand product sourced from another country? We wish to know this since Takeda has pharmacovigilance activity obligations for VYVANSE brand.

Enter an active ingredient or trade name

[Current \(1\)](#)
[Anticipated \(1\)](#)
[Resolved \(0\)](#)
[Discontinuations \(0\)](#)

Current shortages

Sort by: [Updated date](#) | [Active ingredient](#) | [Trade name](#) | [Therapeutic class](#)

[lisdexamfetamine dimesilate](#)

Updated 15-09-2023

VYVANSE lisdexamfetamine dimesilate 30mg capsule bottle

AUST R: 199227

Expected supply: 31 Dec 2023

Availability: Limited Availability

Management action: The sponsor is closely controlling the supply and working to expedite the next shipment. An unregistered product has been approved for supply under Section 19A. The approval holder, Medsurge can be contacted for details on supply on: 1300 788 261 or sales@medsurge.com.au

Thank you.

Kind regards

\$22



Better Health, Brighter Future

\$22 PhD

\$22 – Oceania Cluster

Takeda Pharmaceuticals Australia Pty Ltd

Grosvenor Place, Level 39

225 George Street

Sydney NSW 2000 Australia

Direct Line: **\$22**

Mobile: **\$22**

\$22 [@takeda.com](mailto:>@takeda.com)

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From: [Medicine Shortages](#)
 To: s22
 Subject: RE: MS-2023-NT-00980-1. VYVANSE 30 mg medicines shortage. [SEC=OFFICIAL]
 Date: Wednesday, 4 October 2023 2:25:07 PM
 Attachments: [image003.png](#)
[image007.png](#)
[image008.png](#)
[image009.png](#)
[image010.png](#)
[image002.png](#)
[image005.png](#)

Dear s22

Thank you for providing this synopsis of our conversation. I've just added in some small edits in green, but I agree with the overall notes made.

Thank you also for providing the follow up information regarding the risk management requirements, as well as the updates for the 30mg emergency stock and 40mg availability. It is greatly appreciated.

Regarding the 30mg emergency stock, we wish to reference the availability of this in our management actions on our Medicine Shortages Reports Database (with Takeda's contact phone number) so that (as mentioned in our conversation yesterday) healthcare professionals can enquire about availability for patients who can only use the ARTG product. Are you ok for us to add this information into our management actions (location shown below)?

Enter an active ingredient or trade name

Current (1)

Anticipated (1)

Resolved (0)

Discontinuations (0)

Current shortages

Sort by: Updated date | Active ingredient | Trade name | Therapeutic class

Shortage	Updated
lisdexamfetamine dimesilate VYVANSE lisdexamfetamine dimesilate 30mg capsule bottle AUST R: 199227 Expected supply: 31 Dec 2023 Availability: Limited Availability Management action: The sponsor is closely controlling the supply and working to expedite the next shipment. An unregistered product has been approved for supply under Section 19A. The approval holder, Medsurge can be contacted for details on supply on: 1300 788 261 or sales@medsurge.com.au	Updated 15-09-2023

Thank you again for your cooperation.

Kind regards,

s22

s22
 Pharmacist – Medicine Shortages Section
 Pharmacovigilance Branch
 Medicines Regulation Division | Health Products Regulation Group
 Australian Government, Department of Health and Aged Care
 T: s22 | E: medicine.shortages@health.gov.au
 Location: Fairbairn
 PO Box 100, Woden ACT 2606, Australia

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From: s22@takeda.com>
 Sent: Wednesday, 4 October 2023 12:54 PM
 To: Medicine Shortages <medicine.shortages@health.gov.au>
 Subject: RE: MS-2023-NT-00980-1. VYVANSE 30 mg medicines shortage. [SEC=OFFICIAL]

Dear s22

Thank you too for the discussion on phone and for providing additional information in your email below. Following are notes I made from your feedback, please let me know of any errors or if I missed anything.

- As a normal course of action, does the TGA proactively advise the sponsor of the medicine under shortage about S19A approval granted to someone? If not the case, then for future, could the TGA consider informing the sponsor as it would help align sharing the message in case of queries from healthcare professionals.
TGA's feedback: Normally, the TGA does not advise the sponsor of the medicine under shortage about S19A approval. It is a challenge presented for such communications especially when there are multiple ARTG sponsors involved. S19A approval holder provides Dear Healthcare Professional Letters as part of their S19A application process.
- In a scenario such as this shortage, we believe it becomes more complex since the S19A approval happens to be for the same brand sourced from overseas. What would the pharmacovigilance reporting arrangements be for the S19A approval holder? Does TGA instruct them to report safety information to the Australian sponsor of the medicine, and how does the S19A approval holder ensure routine and additional risk minimisation

activities are implemented?

TGA's feedback: The S19A approval holder has the responsibility of over labelling the product supplied with their name and contact details. They had to arrange additional documents needed for supply of S8 – Controlled Drug (import permits). Any pharmacovigilance reporting to the TGA is their responsibility.

Note: Post-discussion, the TGA provided advice in email below confirming the S19A holder has no requirement as part of this approval to supply education material.

In response to the query in the email about background to requirement of additional risk minimisation activities, Takeda can confirm it is not just related to marketing/advertising. A condition of approval of VYVANSE is to implement the RMP as agreed with TGA.

- *Educational tools, in the form of Physician's guide to prescribing, are utilized in Australia as an additional risk minimization measure. These are described in the RMP. The tools are presented by a website with downloadable checklists and charts to enable healthcare professionals in the appropriate selection of patients and prescription of VYVANSE for the treatment of patients with ADHD, and separate tools for the treatment of patients with BED. The checklists and charts for ADHD and BED are aligned with the Australian PI and are accessed via a local website. www.idxguide.com/au. Links and passwords are included in the minimum PI of promotional materials The Link can be accessed from Products page of Takeda website. Link and password are communicated with psychiatrists by representatives.*
- The medicine shortage duration is until Dec-2023. Takeda chose a conservative date of end of Dec-2023 but it is likely the shortage may be resolved earlier. Could we please check the reason why the S19A approval granted to Medsurge is valid until 29-Feb-2024? According to the TGA S19A guidance document the approval should not exceed by more than one month of shortage.
TGA's feedback: In general, the requested duration of a S19A approval is one month post the shortage resolving. The decision is made by the Delegate. Over past 12 months the TGA have observed volatility in the shortage end date and therefore allow a bit more buffer for the duration granted for a S19A approval, this is not reflective of Takeda as a company.
- Once the shortage is resolved by Takeda, would the TGA rescind the S19A approval granted to Medsurge? If so, what is the process for this - should we advise the TGA that the shortage is resolved? What evidence will the TGA need from us in order to be satisfied it can rescind the S19A approval?
TGA's feedback: S19A approval can be lapsed once the shortage notification is updated on TGA's eBS as resolved. Though not required, Takeda may send an email confirming shortage has been resolved by a follow-up email. Once the resolved notification is received, Medicine shortages would then need to reach out to the S19A sponsor advising them of the approval lapsing (via written notice).
- We understand the pack size approved for supply by Medsurge is for 100 capsules whereas the registered VYVANSE 30 mg pack size is 30 capsules. Please could the TGA clarify whether the S19A dispensed product to the patient is 100 capsules?
TGA's feedback: The quantity dispensed by the pharmacy for the patient is the quantity prescribed by the Dr which is normally 30 capsules. The pack size of 100 capsules is not meant for patients. TGA cannot assure the dispensed pack will bear the name and contact details of the S19A holder. For any product complaint, the patient would most probably contact the pharmacy.
- Finally, what will be the status of any Medsurge supplied products which are already with wholesalers once the s19A approval lapses? Will these be capable of further sale by wholesalers, even after the s19A approval has lapsed?
TGA's feedback: Once S19A approval is lapsed, Medsurge can no longer supply the product. The same applies to wholesalers. Pharmacies are allowed to supply to patients.
Note: Post-discussion, the TGA provided information below regarding applicable legislation.

I will separately respond to your query soon about 30 mg and 40 mg Vyvanse supplies status.

Kind regards

S22



Better Health, Brighter Future

S22 PhD

S22 – Oceania Cluster

Takeda Pharmaceuticals Australia Pty Ltd

Grosvenor Place, Level 39

225 George Street

Sydney NSW 2000 Australia

Mobile: S22

S22 @takeda.com

From: Medicine Shortages <medicine.shortages@health.gov.au>

Sent: Wednesday, October 4, 2023 10:02 AM

To: S22 @takeda.com>

Subject: RE: MS-2023-NT-00980-1. VYVANSE 30 mg medicines shortage. [SEC=OFFICIAL]

Dear S22

Thank you for your time on the phone yesterday, regarding your follow-up questions about the approval of overseas-registered Vyvanse under section 19A.

As discussed, there were two points from our discussion I was required to follow up on. I wish to provide you with the following information on these two issues:

- Regarding the requirements for supplying risk minimisation education material as part of the approval, I have confirmed that there is no requirement as part of this approval for the sponsor to supply education material.

I apologise for not asking this in our discussion, but are you able to provide any information on the specific legislation (or condition of approval) requiring ARTG Vyvanse to supply this material? Or is the provision of this educational material specifically related to the marketing (e.g. advertising) of the product to prescribers and healthcare professionals? I have been looking at the conditions for registration for ARTG Vyvanse and I cannot seem to see anything that requires the provision of this as a condition of registration, so apologies if I have missed this. If the provision of this material is related to the advertising of the product, then Medsurge are still required to follow the same legislation for advertising prescription medicines as

outlined in the [Therapeutic Goods \(Therapeutic Goods Advertising Code\) Instrument 2021](#).

- Regarding the section of legislation which stipulates sponsors cannot supply section 19A approved good past their approval date, it is in [section 21 of the Therapeutic Goods Act 1989](#). I have taken a screen shot (below) of the legislation as well for your convenience. As discussed yesterday, section 19A products can be supplied past the expiry of the approval, but only to the ultimate consumer (e.g. pharmacists can supply S19A product to patients past the expiry of the approval, as patients are the ultimate consumer of the product). However, for anyone else to supply a product which they do not sponsor (e.g. wholesalers, companies wanting to supply overseas products under section 19A, etc.) there must be a current S19A approval in place before they can supply the product.

21 Offence relating to wholesale supply

A person must not supply in Australia therapeutic goods for use in humans, being goods of which the person is not a sponsor, to another person who is not the ultimate consumer of the goods unless:

- (a) the goods are registered goods or listed goods; or
- (b) the goods are exempt goods; or
- (ba) the goods are exempt under section 18A; or
- (c) the goods are the subject of an approval or authority under section 19; or
- (d) the goods are the subject of an approval under section 19A.

Penalty: 120 penalty units.

As a side note, I can now confirm the [S19A approval for Vyvanse 30mg \(USA\)](#) on our website has been amended to reflect the correct Vyvanse product that is in shortage. Thank you again for pointing out this error.

Thank you again for the discussion, and I look forward to receiving your updates regarding the availability of emergency supply for the 30mg product, and the availability of the 40mg product.

Kind regards,

s22

s22

Pharmacist – Medicine Shortages Section
Pharmacovigilance Branch
 Medicines Regulation Division | Health Products Regulation Group
 Australian Government, Department of Health and Aged Care
 T: s22 | E: medicine.shortages@health.gov.au
 Location: Fairbairn
 PO Box 100, Woden ACT 2606, Australia

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From: s22 <[redacted]@takeda.com>
Sent: Thursday, 28 September 2023 2:25 PM
To: Medicine Shortages <medicine.shortages@health.gov.au>
Subject: RE: MS-2023-NT-00980-1. VYVANSE 30 mg medicines shortage. [SEC=OFFICIAL]

Dear s22,

Further to our recent interaction, Takeda would like to seek some further clarifications please, hope you are able to assist.

- As a normal course of action, does the TGA proactively advise the sponsor of the medicine under shortage about S19A approval granted to someone? If not the case, then for future, could the TGA consider informing the sponsor as it would help align sharing the message in case of queries from healthcare professionals.
- In a scenario such as this shortage, we believe it becomes more complex since the S19A approval happens to be for the same brand sourced from overseas. What would the pharmacovigilance reporting arrangements be for the S19A approval holder? Does TGA instruct them to report safety information to the Australian sponsor of the medicine, and how does the S19A approval holder ensure routine and additional risk minimisation activities are implemented?
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- Once the shortage is resolved by Takeda, would the TGA rescind the S19A approval granted to Medsurge? If so, what is the process for this - should we advise the TGA that the shortage is resolved? What evidence will the TGA need from us in order to be satisfied it can rescind the S19A approval?
- We understand the pack size approved for supply by Medsurge is for 100 capsules whereas the registered VYVANSE 30 mg pack size is 30 capsules. Please could the TGA clarify whether the S19A dispensed product to the patient is 100 capsules?
- Finally, what will be the status of any Medsurge supplied products which are already with wholesalers once the S19A approval lapses? Will these be capable of further sale by wholesalers, even after the S19A approval has lapsed?

I look forward to your feedback. Let me know if you wish to have a discussion on phone.

Thank you.
 Kind regards

s22



Better Health, Brighter Future

s22 PhD
 s22 – Oceania Cluster

Takeda Pharmaceuticals Australia Pty Ltd

Grosvenor Place, Level 39
 225 George Street
 Sydney NSW 2000 Australia
 Mobile: s22
 s22@takeda.com

From: Medicine Shortages <medicine.shortages@health.gov.au>
Sent: Tuesday, September 26, 2023 9:16 AM
To: s22@takeda.com
Subject: RE: MS-2023-NT-00980-1. VYVANSE 30 mg medicines shortage. [SEC=OFFICIAL]

Dear s22

Thank you for pointing this out. You're correct, it should mention the 30mg strength and not the 20mg.

I will let the appropriate area know of this error, and we will get this updated.

Kind regards,

s22

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Pharmacist – Medicine Shortages Section
Pharmacovigilance Branch
 Medicines Regulation Division | Health Products Regulation Group
 Australian Government, Department of Health and Aged Care
 T: s22 | E: medicine.shortages@health.gov.au
 Location: Fairbairn
 PO Box 100, Woden ACT 2606, Australia

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From: s22@takeda.com
Sent: Tuesday, 26 September 2023 7:17 AM
To: Medicine Shortages <medicine.shortages@health.gov.au>
Subject: RE: MS-2023-NT-00980-1. VYVANSE 30 mg medicines shortage. [SEC=OFFICIAL]

Dear s22

Thank you for your prompt response and hope all well with you too. I noticed in the s19A link provided in your email the shortage mentioned is VYVANSE lisdexamfetamine dimesilate 20mg (ARTG 284019), could you please let me know the reason given the shortage is for the 30 mg strength.

Section 19A approved medicine	Vyvanse lisdexamfetamine dimesylate capsules 30mg (USA)
Section 19A approval holder	Medsurge Healthcare Pty Ltd ABN 92 124 728 892
Phone	1300 788 261
Approved until	29 February 2024
Status	Current
Medicines in short supply/unavailable	VYVANSE lisdexamfetamine dimesilate 20 mg capsules bottle - ARTG 284019

Kind regards

s22

From: Medicine Shortages <medicine.shortages@health.gov.au>
Sent: Monday, September 25, 2023 3:11 PM
To: s22@takeda.com
Subject: RE: MS-2023-NT-00980-1. VYVANSE 30 mg medicines shortage. [SEC=OFFICIAL]

Dear s22

I hope all is well.

Yes, the product approved for supply under section 19A of the *Therapeutic Goods Act 1989* (Act) is a Vyvanse branded product from another country, namely the United States of America (USA). Specifically, the product approved is Vyvanse lisdexamfetamine dimesylate capsules 30mg (USA). More information about the product approved for supply under section 19A is available on our Section 19A database from <https://www.tga.gov.au/resources/section-19a-approvals/vyvanse-lisdexamfetamine-dimesylate-capsules-30mg-usa>

Please let me know if you require any further information to assist.

Kind regards,

§22

§22

Pharmacist – Medicine Shortages Section
Pharmacovigilance Branch
 Medicines Regulation Division | Health Products Regulation Group
 Australian Government, Department of Health and Aged Care
 T: §22 | E: medicine.shortages@health.gov.au
 Location: Fairbairn
 PO Box 100, Woden ACT 2606, Australia

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From: §22 <§22@takeda.com>
Sent: Monday, 25 September 2023 2:46 PM
To: Medicine Shortages <medicine.shortages@health.gov.au>
Subject: MS-2023-NT-00980-1. VYVANSE 30 mg medicines shortage.

Dear TGA Medicine Shortage Section

I hope you can assist with Takeda's query in regard to the following entry in TGA's Medicines Shortage database. A section 19A application from Medsurge has been approved by the TGA for supply of an unregistered 30 mg lisdexamfetamine dimesilate product. Could we please check whether the unapproved product is 'VYVANSE' brand product sourced from another country? We wish to know this since Takeda has pharmacovigilance activity obligations for VYVANSE brand.

vyvanse

Enter an active ingredient or trade name

Current (1)
Anticipated (1)
Resolved (0)
Discontinuations (0)

Current shortages

Sort by: Updated date | Active ingredient | Trade name | Therapeutic class

<p>lisdexamfetamine dimesilate VYVANSE lisdexamfetamine dimesilate 30mg capsule bottle AUST R: 199227 Expected supply: 31 Dec 2023 Availability: Limited Availability Management action: The sponsor is closely controlling the supply and working to expedite the next shipment. An unregistered product has been approved for supply under Section 19A. The approval holder, Medsurge can be contacted for details on supply on: 1300 788 261 or sales@medsurge.com.au</p>	<p>Updated 15-09-2023</p>
--	---------------------------

Thank you.
 Kind regards

§22



Better Health, Brighter Future

§22 PhD
 §22 – Oceania Cluster
Takeda Pharmaceuticals Australia Pty Ltd
 Grosvenor Place, Level 39
 225 George Street
 Sydney NSW 2000 Australia
 Direct Line: §22
 Mobile: §22
 §22 @takeda.com

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Notifier

Notifier

Sponsor Name: Takeda Pharmaceuticals Australia Pty Ltd

Sponsor Address: Grosvenor Place Level 39 225 George Street Sydney NSW 2000

Australian telephone number for public contact purposes: 1800012612

Medical information email for public contact purposes: medinfoAPAC@takeda.com

Primary Contact

Name: §22

Phone Number: §22

Email Address: §22 @takeda.com

Secondary Contact

Name: §22

Phone Number: §22

Email Address: §22 @takeda.com

ARTG Entry

ARTG Entry

ARTG number of the product that has a supply disruption:

ARTG ID	ARTG Name	Active Ingredient	Strength	Dosage Form
284019	VYVANSE	lisdexamfetamine dimesilate	20mg	Capsule, hard
	lisdexamfetamine dimesilate			
	20 mg capsules			
	bottle			

ATC Descriptor: Nervous system

Are all pack sizes for this ARTG entry affected? Yes

Is this ARTG entry listed in the PBS? Yes

Provide the PBS number for this listing: 11884L

Do you have a designated sponsor representative within your organisation who is a point of contact on PBS matters? Yes

PBS Contact Details

Name: §22

Phone Number: §22

Email Address: §22 @takeda.com

Details

Details

When was the shortage known to the sponsor? 04/08/2023

Nature of the shortage:	Resolved	
Shortage reason:	Manufacturing	Document 18
Manufacturing site problem:	Issues/delays with packaging and/or labelling	
Shortage reason - further information:	Takeda are experiencing some delays related to the global supply of Vyvanse products due to the remediation actions implemented at the contract manufacturing organization site Wasdell Europe with respect to the Critical Observations identified during the HPRA health authority inspection previously communicated to the TGA. As a result the expected manufacturing time frames have been increased and committed shipments to Australia have been further delayed.	
Estimated period supply will be affected at wholesaler points:	From:	09/10/2023
	To:	09/10/2023
Availability:	Available	
TGA publication date:	14/08/2023	
Is this shortage related to other medicines within the same Therapeutic class?	No	
Is this shortage specific to Australia?	No	
Estimated normal demand volumes for Australia:	S47	
Estimated percentage share of the Australian market:	100 %	
Estimated current stock at sponsor / manufacturing level in Australia:	41798 units	
Estimated current stock at wholesaler / distributor level in Australia:	8791 units	
What is meant by 1 unit in this context:	Single pack of 30 capsules	

Impact

Are there therapeutic alternatives on the Australian market?	Yes
What is the status of substitute options for this product in Australia?	Appropriate Therapeutic Alternatives
Are they available in adequate supplies to meet demand?	Unknown at this time
Provide details:	There are different stimulants, such as methylphenidate, belonging to the same class of psychostimulants
Do any specific population groups use this product?	Yes
Provide details of the groups and the impact on those groups:	Paediatric, adolescents, and adult patients with ADHD. Adult patients with BED.
Based on your answers above and the Assessment Framework, what is the shortage impact rating?	2 - Medium Impact

Shortage Action

What communication activities have happened or are planned?

Communication Action	Date of Communication
Letter to Patient Advocacy Groups	14-Aug-2023
Letter to Pharmacists	14-Aug-2023
Letter to Prescribers	14-Aug-2023
Letter to Wholesalers	14-Aug-2023

Letter attached in Supporting Information:

No

[Document 18](#)

Further comments on communications:

Communications plans includes:

1. HCP letter (all paediatricians and psychiatrists)
 2. Consumer Statement to Patient Advisory Groups (ADHD Australia, ADHD Foundation)
 3. Pharmacy Letter (all retail pharmacies)
 4. Wholesaler Letter
-

What supply management actions have happened or are planned?

Management Action	Date of Management Action
Constrained Supply	07-Aug-2023
Working to expedite next shipment	07-Aug-2023

Further comments on management actions:

Supporting Information

Supporting data will be:

Sponsor website where medicine shortage information is available:

From: [Medicine Shortages](#)
To: s22
Subject: RE: VYVANSE 30 mg and 40 mg query from TGA medicines Shortage Section [SEC=OFFICIAL]
Date: Monday, 9 October 2023 1:25:23 PM
Attachments: [image001.png](#)
[image003.png](#)

Dear s22

Thank you for your update regarding the proposed management action.

I will include the provided email address, and will attempt at separating out the information on the Section 19A. I have put in a separate line at present, The system we use is a bit clunky so I will see how it looks published on the database, and if it is not separated out then I will attempt other measures to try and separate the two pieces of information.

Thank you again for your assistance with this.

Kind regards,

s22

s22

**Pharmacist – Medicine Shortages Section
Pharmacovigilance Branch**

Medicines Regulation Division | Health Products Regulation Group
Australian Government, Department of Health and Aged Care

T: s22 | E: medicine.shortages@health.gov.au

Location: Fairbairn

PO Box 100, Woden ACT 2606, Australia

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From: s22 <s22@takeda.com>
Sent: Monday, 9 October 2023 12:57 PM
To: Medicine Shortages <medicine.shortages@health.gov.au>
Subject: RE: VYVANSE 30 mg and 40 mg query from TGA medicines Shortage Section

Dear s22

Thank you for email. Takeda would like to propose the following text to update the management action for Vyvanse 30mg. Takeda would ideally also prefer that the Medsurge related information be on a separate line so people don't skim over it and think its related to Takeda.

'Emergency Supply of VYVANSE lisdexamfetamine dimesilate 30mg capsule bottle AUST R: 199227 is available from the sponsor. Please contact Takeda Pharmaceuticals Australia Pty Ltd on 1800 012 612 or medinfoapac@takeda.com for details on supply.

An unregistered product has also been approved for supply under Sec 19A. The approval holder, Medsurge can be contacted for details on supply on: 1300 788 261 or

sales@medsurge.com.au

Please let me know your feedback.

Kind regards

s22



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s22

PhD

s22

– Oceania Cluster

Takeda Pharmaceuticals Australia Pty Ltd

Grosvenor Place, Level 39
225 George Street
Sydney NSW 2000 Australia
Mobile: s22

s22

[@takeda.com](mailto:s22@takeda.com)

From: Medicine Shortages <medicine.shortages@health.gov.au>

Sent: Friday, October 6, 2023 11:37 AM

To: s22 <s22@takeda.com>

Subject: [SEC=OFFICIAL] RE: VYVANSE 30 mg and 40 mg query from TGA medicines Shortage Section

Dear s22

We have standard words that we use across all of our management actions on the [database](#), such as when we reference a section 19A product or if the TGA has published a web statement about a shortage. This is so that the wording across all of our shortages remains as consistent as possible.

I am proposing to update the management action for Vyvanse 30mg to the following:

'Emergency Supply of VYVANSE lisdexamfetamine dimesilate 30mg capsule bottle AUST R: 199227 is available from the sponsor. Please contact Takeda Pharmaceuticals Australia Pty Ltd on 1800 012 612 for details on supply. An unregistered product has also been approved for supply under Section 19A. The approval holder, Medsurge can be contacted for details on supply on: 1300 788 261 or sales@medsurge.com.au'

For reference, we always include a reference to any approved S19A in our management actions, so that healthcare professionals (HCPs) and consumer are aware of this action should they not be able to access any ARTG Vyvanse.

If you have any issues with this wording (specific to the reference to emergency stock), including if the contact phone number is correct or if there is an alternative way you would prefer HCPs to contact Takeda, please let me know.

Kind regards,

s22

s22

**Pharmacist – Medicine Shortages Section
Pharmacovigilance Branch**Medicines Regulation Division | Health Products Regulation Group
Australian Government, Department of Health and Aged CareT: s22 | E: medicine.shortages@health.gov.au

Location: Fairbairn

PO Box 100, Woden ACT 2606, Australia

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From: s22 <s22@takeda.com>**Sent:** Friday, 6 October 2023 7:26 AM**To:** Medicine Shortages <medicine.shortages@health.gov.au>**Subject:** RE: VYVANSE 30 mg and 40 mg query from TGA medicines Shortage Section

Dear s22

Regarding the 30mg emergency stock, could Takeda determine the wording to use in TGA's management section of Medicines Shortage Database. Please let me know.

Thank you.

Kind regards

s22

From: s22**Sent:** Wednesday, October 4, 2023 12:56 PM**To:** Medicine Shortages <medicine.shortages@health.gov.au>**Subject:** VYVANSE 30 mg and 40 mg query from TGA medicines Shortage Section

Dear s22

I am responding to your phone query asking for information on 30 mg strength for emergency supplies; and if any issues with 40 mg supplies. I can confirm:

- 30 mg strength: Yes – 6,000 units are reserved for emergency supplies.
This strength will continue to be on allocation until supply is 'healthy'
- 40 mg supplies:
Based on current Stock On Hand & replenishment plan, there is no foreseeable issue.
We will continue to monitor sales closely.

Let me know if you need any further information.

Kind regards

s22



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s22 PhD

s22 – Oceania Cluster

Takeda Pharmaceuticals Australia Pty Ltd

Grosvenor Place, Level 39
225 George Street
Sydney NSW 2000 Australia
Mobile: s22

s22 [@takeda.com](mailto:s22@takeda.com)

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Notifier

Notifier

Sponsor Name: Takeda Pharmaceuticals Australia Pty Ltd

Sponsor Address: Grosvenor Place Level 39 225 George Street Sydney NSW 2000

Australian telephone number for public contact purposes: 1800012612

Medical information email for public contact purposes: medinfoAPAC@takeda.com

Primary Contact

Name: s22

Phone Number: s22

Email Address: s22@takeda.com

Secondary Contact

Name: s22

Phone Number: s22

Email Address: s22@takeda.com

ARTG Entry

ARTG Entry

ARTG number of the product that has a supply disruption:

ARTG ID	ARTG Name	Active Ingredient	Strength	Dosage Form
199226	VYVANSE	lisdexamfetamine dimesilate	50mg	Capsule, hard

ATC Descriptor: Nervous system

Are all pack sizes for this ARTG entry affected? Yes

Is this ARTG entry listed in the PBS? Yes

Provide the PBS number for this listing: 10474G

Do you have a designated sponsor representative within your organisation who is a point of contact on PBS matters? Yes

PBS Contact Details

Name: s22

Phone Number: s22

Email Address: s22@takeda.com

Details

Details

When was the shortage known to the sponsor? 18/10/2023

Nature of the shortage:	Anticipated	
Shortage reason:	Manufacturing	Document 20
Manufacturing site problem:	Issues/delays with packaging and/or labelling	
Shortage reason - further information:		
Estimated period supply will be affected at wholesaler points:	From:	04/11/2023
	To:	25/12/2023
Availability:	Available	
Indicate preference for date of publication:	Date of processing	
Is this shortage related to other medicines within the same Therapeutic class?	No	
Is this shortage specific to Australia?	No	
Estimated normal demand volumes for Australia:	s47	
Estimated percentage share of the Australian market:	100 %	
Estimated current stock at sponsor / manufacturing level in Australia:	13388 units	
Estimated current stock at wholesaler / distributor level in Australia:	8441 units	
What is meant by 1 unit in this context:	1 bottle of 30 capsules	

Impact

Are there therapeutic alternatives on the Australian market?	Yes
What is the status of substitute options for this product in Australia?	Appropriate Therapeutic Alternatives
Are they available in adequate supplies to meet demand?	Unknown at this time
Provide details:	Alternative treatments include; methylphenidate, dexamfetamine, other strengths of lisdexamfetamine
Do any specific population groups use this product?	Yes
Provide details of the groups and the impact on those groups:	Paediatric, adolescents, and adult patients with Attention Deficit Hyperactivity Disorder (ADHD). Adult patients with Binge Eating Disorder (BED).
Based on your answers above and the Assessment Framework, what is the shortage impact rating?	2 - Medium Impact

Shortage Action

What communication activities have happened or are planned?	Communication Action	Date of Communication
	Letter to Prescribers	01-Nov-2023
	Letter to Pharmacists	01-Nov-2023
	Letter to Wholesalers	31-Oct-2023

Letter attached in Supporting Information:	No
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Further comments on communications:

What supply management actions have happened or are planned?	Management Action	Date of Management Action
	Constrained Supply	23-Oct-2023

Working to expedite next shipment	18-Oct-2023
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[Document 20](#)

Further comments on management actions:

Supporting Information

Supporting data will be: Attached

Documents attached to this notification:

File Name	Created By	Description
Vyvanse 50mg - Replenishment Plan - Takeda Australia.pdf	Takeda	Stock order quantities

Sponsor website where medicine shortage information is available:

File Attachments

The following files have been attached to this notification.

	Oct-23	Nov-23	Dec-23	Jan-24	Feb-24	Mar-24	Apr-24
Replenishment Qty	0	0	40,000	130,000	115,000	55,000	0
Estimated ETA			w/c 11 Dec	TBC	TBC	TBC	

From: [Medicine Shortages](#)
To: s22
Subject: FW: MSII case requires updating - VYVANSE lisdexamfetamine dimesilate 50mg capsule bottle - ARTG 199226 - (MS-2023-NT-01341-1) [SEC=OFFICIAL]
Date: Monday, 30 October 2023 2:10:00 PM
Attachments: [image001.png](#)
[image002.jpg](#)
[FINAL_VYVANSE Stock Shortage_OCT2023_HCP LETTER.pdf](#)
[FINAL_VYVANSE Stockout Letter_OCT2023_PHARMACY.pdf](#)
[FINAL_VYVANSE Stock Shortage_OCT2023_CONSUMER.pdf](#)

FYI

From: s22 @takeda.com>
Sent: Monday, 30 October 2023 1:59 PM
To: Medicine Shortages <medicine.shortages@health.gov.au>
Cc: s22 @takeda.com>
Subject: FW: MSII case requires updating - VYVANSE lisdexamfetamine dimesilate 50mg capsule bottle - ARTG 199226 - (MS-2023-NT-01341-1) [SEC=OFFICIAL]

Dear TGA Medicines Shortages

Please find attached here copies of letters for prescribers, pharmacists, and consumer statement that Takeda will be dispatching this week. These communications are in relation to VYVANSE 50 mg (MS-2023-NT-01341-1) and VYVANSE 30 mg (MS-2023-NT-00980-1) shortages.

Thank you
Kind regards

s22



s22 PhD

s22 – Oceania Cluster

Takeda Pharmaceuticals Australia Pty Ltd

Grosvenor Place, Level 39
225 George Street
Sydney NSW 2000 Australia
Mobile: s22

s22 @takeda.com

From: tga medicine shortages <medicine.shortages@health.gov.au>
Sent: Saturday, October 28, 2023 9:03 PM
To: s22 @takeda.com>
Cc: s22 @takeda.com>
Subject: MSII case requires updating - VYVANSE lisdexamfetamine dimesilate 50mg capsule bottle - ARTG 199226 - (MS-2023-NT-01341-1) [SEC=OFFICIAL]

Dear Regulatory Affairs Consultant,

The TGA is contacting you regarding the Medicine Shortage notification for your product VYVANSE lisdexamfetamine dimesilate 50mg capsule bottle - ARTG 199226 - (MS-2023-NT-01341-1).

The shortage status is anticipated. The date which the shortage is anticipated to begin is approaching: 04/11/2023.

ACTION REQUIRED:

If this shortage is still ongoing please submit an updated Medicine Shortage notification with current information.

If the shortage has been resolved please submit a Medicine Shortage notification advising that the shortage has been resolved.

If you require assistance with this process please do not hesitate to contact us via email at medicine.shortages@health.gov.au.

Kind regards,

Medicine Shortages Section
Pharmacovigilance Branch
Phone: s22 [REDACTED]
Email: medicine.shortages@health.gov.au

Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100
Woden ACT 2606
[https://urldefense.com/v3/___https://www.tga.gov.au___!!KDurfCY!8GVDxVOUI4QQ2xVni6jz8VPcllfPTxx-AVgX8gzFU2ouyDMxs1TmCTdkz3X9xa1WiQw9_BH_LqLC5YoYkvZfS39fZb6QrGCHb6-fJw\\$](https://urldefense.com/v3/___https://www.tga.gov.au___!!KDurfCY!8GVDxVOUI4QQ2xVni6jz8VPcllfPTxx-AVgX8gzFU2ouyDMxs1TmCTdkz3X9xa1WiQw9_BH_LqLC5YoYkvZfS39fZb6QrGCHb6-fJw$)

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31st October 2023

Dear Doctor,

RE: SUPPLY INTERRUPTION OF VYVANSE® (lisdexamfetamine dimesilate) 30mg and 50mg

We are writing to inform you of an interruption to supply that will affect the availability of VYVANSE in Australia **until late December 2023**. This interruption is expected to intermittently impact the **30mg and 50mg strengths** during this time.

Based on typical usage patterns, Takeda anticipates that remaining inventory at warehouses and wholesalers of will be exhausted as follows:

- VYVANSE 30mg – early December 2023
- VYVANSE 50mg – early November 2023

As of the date of this letter, the supply of Vyvanse 20mg, 40mg, 60mg, 70mg capsules are not impacted.

Takeda understands the importance of maintaining consistent treatment with VYVANSE and recognises the need to preserve this limited stock to prioritise ongoing care. We ask you to exercise your clinical judgement and take this stock limitation into account when considering treatment with VYVANSE for your patients.

We understand that supply interruptions are challenging for both you and your patients and are working to resolve these interruptions as quickly as possible.

We will continue to monitor the situation closely and will keep you informed with regards to any supply updates. In the meantime, if you have any urgent enquiries, please contact:

- Takeda Medical Information: telephone 1800 012 612 or email: medinfoAPAC@takeda.com

Yours sincerely,

s22
[Redacted signature]

s22
[Redacted name] PhD
s22
[Redacted contact information]



Please review Product Information before prescribing. Product Information is available from Takeda Pharmaceuticals Australia Pty Ltd. Phone: 1800 012 612. Email: medinfoAPAC@takeda.com

For further information about the appropriate selection of patients and prescribing of VYVANSE, please visit <http://www.lfxguide.com/au> (password: onetakeda)

VYVANSE has a potential for abuse, misuse, dependence, or diversion for non-therapeutic uses. Physicians should assess the risk of abuse prior to prescribing and monitor for signs of abuse and dependence while on therapy. VYVANSE should be prescribed cautiously to patients with a history of substance abuse or dependence. Careful supervision is required during withdrawal from abusive use since severe depression may occur. Withdrawal following chronic therapeutic use may unmask symptoms of the underlying disorder that may require follow-up.

Minimum Product Information. VYVANSE® (lisdexamfetamine dimesilate).

Indication: Attention Deficit Hyperactivity Disorder (ADHD): Indicated for treatment of ADHD. Treatment should be commenced by a specialist as part of a comprehensive treatment program and re-evaluated periodically during long-term use. Binge Eating Disorder (BED): Indicated for treatment of moderate to severe BED in adults when non-pharmacological treatment is unsuccessful or unavailable. Treatment should be commenced and managed by a psychiatrist. **Dosage and Administration:** VYVANSE should be initiated at 30 mg once daily in the morning (avoid afternoon doses due to potential for insomnia) and slowly adjusted to the lowest effective dose (no more frequently than weekly). Capsules may be taken whole, or opened and the contents emptied and mixed with a soft food such as yogurt or in a glass of water or orange juice. **Contraindications:** Advanced arteriosclerosis; symptomatic cardiovascular disease (eg cardiac arrhythmia, ischaemic heart disease); moderate to severe hypertension; hyperthyroidism; hypersensitivity or idiosyncratic reaction to sympathomimetic amines or any of the excipients; glaucoma; agitated states (eg severe anxiety, tension and agitation); administration during or within 14 days of cessation of MAOIs; pheochromocytoma; tics, Tourette's syndrome; patients who exhibit severe depression, anorexia nervosa, psychotic symptoms or suicidal tendency; drug dependence or alcohol abuse. **Precautions:** Cardiovascular disease; psychiatric disorders (psychosis, bipolar disease, aggression); seizures; visual disturbance; long-term suppression of growth, peripheral vasculopathy including Raynaud's phenomenon. Renal impairment (severe renal insufficiency max dose 50mg/day; dose reduction for dialysis patients). No data in hepatic impairment. Pregnancy: Category B3. Women taking VYVANSE should refrain from breast feeding. Not studied in children <6 years or adults >55 years of age. **Interactions:** MAOIs (see Contraindications), antihypertensives, narcotic analgesics, antipsychotics, agents that alter urinary pH, serotonergic drugs. **Adverse Effects:** Very Common reactions: decreased appetite, insomnia, headache, dry mouth, upper abdominal pain, weight decreased. Common reactions: anorexia, agitation, anxiety, libido decreased, tic, affect lability, psychomotor hyperactivity, bruxism, aggression, dizziness, restlessness, tremor, somnolence, mydriasis, tachycardia, palpitation, dyspnoea, diarrhoea, nausea, vomiting, hyperhidrosis, rash, irritability, fatigue, feeling jittery, pyrexia, blood pressure increased, erectile dysfunction. Note: where frequency of adverse reactions varies across age groups (children, adolescents, adults), the adverse reaction is listed according to the highest frequency.

(pi-01047. V1.0)



31st October 2023

Dear Pharmacist,

RE: SUPPLY INTERRUPTION OF VYVANSE® (lisdexamfetamine dimesilate) 30mg and 50mg

We are writing to inform you of an interruption to supply that will affect the availability of VYVANSE in Australia **until late December 2023**. This interruption is expected to intermittently impact the **30mg and 50mg strengths** during this time.

Based on typical usage patterns, Takeda anticipates that remaining inventory at warehouses and wholesalers will be exhausted as follows:

- VYVANSE 30mg – early December 2023
- VYVANSE 50mg – early November 2023

As of the date of this letter, the supply of Vyvanse 20mg, 40mg, 60mg, 70mg capsules are not impacted.

While we are expecting some deliveries during this time, we do not anticipate that these will be sufficient to meet usual demand. To mitigate potential stock shortages for patients, our supply team will be closely overseeing the inventory for VYVANSE 30mg and 50mg over the coming months. Please expect some orders not to be supplied in full and intermittent periods where there will be no stock available.

We understand that supply interruptions are challenging for both you and your customers and are working to resolve these interruptions as quickly as possible.

We will continue to monitor the situation closely and will keep you informed with regards to any supply updates. In the meantime, if you have any urgent enquiries, please contact:

- Takeda Medical Information: telephone 1800 012 612 or email: medinfoAPAC@takeda.com

Yours sincerely,

s22

s22

PhD

s22



Please review Product Information before prescribing. Product Information is available from Takeda Pharmaceuticals Australia Pty Ltd. Phone: 1800 012 612. Email: medinfoAPAC@takeda.com

For further information about the appropriate selection of patients and prescribing of VYVANSE, please visit <http://www.idxguide.com/au> (password: onetakeda)

VYVANSE has a potential for abuse, misuse, dependence, or diversion for non-therapeutic uses. Physicians should assess the risk of abuse prior to prescribing and monitor for signs of abuse and dependence while on therapy. VYVANSE should be prescribed cautiously to patients with a history of substance abuse or dependence. Careful supervision is required during withdrawal from abusive use since severe depression may occur. Withdrawal following chronic therapeutic use may unmask symptoms of the underlying disorder that may require follow-up.

Minimum Product Information. VYVANSE® (lisdexamfetamine dimesilate).

Indication: Attention Deficit Hyperactivity Disorder (ADHD): Indicated for treatment of ADHD. Treatment should be commenced by a specialist as part of a comprehensive treatment program and re-evaluated periodically during long-term use. Binge Eating Disorder (BED): Indicated for treatment of moderate to severe BED in adults when non-pharmacological treatment is unsuccessful or unavailable. Treatment should be commenced and managed by a psychiatrist. **Dosage and Administration:** VYVANSE should be initiated at 30 mg once daily in the morning (avoid afternoon doses due to potential for insomnia) and slowly adjusted to the lowest effective dose (no more frequently than weekly). Capsules may be taken whole, or opened and the contents emptied and mixed with a soft food such as yogurt or in a glass of water or orange juice. **Contraindications:** Advanced arteriosclerosis; symptomatic cardiovascular disease (eg cardiac arrhythmia, ischaemic heart disease); moderate to severe hypertension; hyperthyroidism; hypersensitivity or idiosyncratic reaction to sympathomimetic amines or any of the excipients; glaucoma; agitated states (eg severe anxiety, tension and agitation); administration during or within 14 days of cessation of MAOIs; pheochromocytoma; tics, Tourette's syndrome; patients who exhibit severe depression, anorexia nervosa, psychotic symptoms or suicidal tendency; drug dependence or alcohol abuse. **Precautions:** Cardiovascular disease; psychiatric disorders (psychosis, bipolar disease, aggression); seizures; visual disturbance; long-term suppression of growth, peripheral vasculopathy including Raynaud's phenomenon. Renal impairment (severe renal insufficiency max dose 50mg/day; dose reduction for dialysis patients). No data in hepatic impairment. Pregnancy: Category B3. Women taking VYVANSE should refrain from breast feeding. Not studied in children <6 years or adults >55 years of age. **Interactions:** MAOIs (see Contraindications), antihypertensives, narcotic analgesics, antipsychotics, agents that alter urinary pH, serotonergic drugs. **Adverse Effects:** Very Common reactions: decreased appetite, insomnia, headache, dry mouth, upper abdominal pain, weight decreased. Common reactions: anorexia, agitation, anxiety, libido decreased, tic, affect lability, psychomotor hyperactivity, bruxism, aggression, dizziness, restlessness, tremor, somnolence, mydriasis, tachycardia, palpitation, dyspnoea, diarrhoea, nausea, vomiting, hyperhidrosis, rash, irritability, fatigue, feeling jittery, pyrexia, blood pressure increased, erectile dysfunction. Note: where frequency of adverse reactions varies across age groups (children, adolescents, adults), the adverse reaction is listed according to the highest frequency.

(pi-01047. V1.0)



**Vyvanse Stock Shortage – Consumer Statement
October 2023**

RE: SUPPLY INTERRUPTION OF VYVANSE® (lisdexamfetamine dimesilate) 30mg & 50mg capsules

Dear XXXX

I am writing to inform you that Takeda Pharmaceuticals Australia, the supplier of VYVANSE, is currently experiencing temporary supply interruptions which will affect the availability of VYVANSE 30mg and 50mg capsules in Australia **until late December 2023**.

This means that pharmacists may not be able to get stock of VYVANSE to fill the prescriptions of those individuals prescribed the doses above.

We understand that supply interruptions are challenging for people impacted and their families and are working to resolve these interruptions as quickly as possible.

If members of your community or organisation have any questions, please direct them to contact their doctor or pharmacist. They can also contact Takeda Medical Information via phone on 1800 012 612 or email: medinfoAPAC@takeda.com.

From: s22
To: [Medicine Shortages](#): s22
Subject: RE: MSII case requires updating - VYVANSE lisdexamfetamine dimesilate 50mg capsule bottle - ARTG 199226 - (MS-2023-NT-01341-1) [SEC=OFFICIAL]
Date: Tuesday, 31 October 2023 4:15:59 PM
Attachments: [image001.png](#)
[image002.png](#)
[image003.jpg](#)

Dear s22

Thank you for contacting us; Takeda have no objection to your proposal.

Should you need any further information, please let us know.

Kind regards

s22

From: Medicine Shortages <medicine.shortages@health.gov.au>
Sent: Tuesday, October 31, 2023 1:59 PM
To: s22 @takeda.com>
Cc: s22 @takeda.com>
Subject: RE: MSII case requires updating - VYVANSE lisdexamfetamine dimesilate 50mg capsule bottle - ARTG 199226 - (MS-2023-NT-01341-1) [SEC=OFFICIAL]

Dear s22

Many thanks for sharing Takeda's communication letters about the Vyvanse shortages. We wanted to inquire if Takeda is planning to keep an emergency stock aside for Vyvanse 50mg and if so are you happy for us to publish that as a management action on our [Medicine Shortages Reports Database](#), similar to Vyvanse 30mg capsules?

I am proposing to update the management action for Vyvanse 50mg to the following:

"The sponsor is closely controlling the supply and working to expedite the next shipment. Emergency Supply of VYVANSE lisdexamfetamine dimesilate 50mg capsule bottle AUST R: 199226 is available from the sponsor. Please contact Takeda Pharmaceuticals Australia Pty Ltd on 1800 012 612 or medinfoapac@takeda.com for details on supply."

If you have any issues with this wording (specific to the reference to emergency stock), including if the contact phone number is correct or if there is an alternative way you would prefer HCPs to contact Takeda, please let me know.

Kind regards,

s22

Pharmacist- Medicine Shortages Section
Pharmacovigilance Branch

Medicine Regulation Division | Health Products Regulation Group

Phone: s22

Email: medicine.shortages@health.gov.au

Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100
Woden ACT 2606

www.tga.gov.au

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and

delete all copies of this transmission.

From: s22 [redacted] <[redacted]@takeda.com>

Sent: Monday, 30 October 2023 1:59 PM

To: Medicine Shortages <medicine.shortages@health.gov.au>

Cc: s22 [redacted] <[redacted]@takeda.com>

Subject: FW: MSII case requires updating - VYVANSE lisdexamfetamine dimesilate 50mg capsule bottle - ARTG 199226 - (MS-2023-NT-01341-1) [SEC=OFFICIAL]

Dear TGA Medicines Shortages

Please find attached here copies of letters for prescribers, pharmacists, and consumer statement that Takeda will be dispatching this week. These communications are in relation to VYVANSE 50 mg (MS-2023-NT-01341-1) and VYVANSE 30 mg (MS-2023-NT-00980-1) shortages.

Thank you

Kind regards

s22 [redacted]



s22 [redacted] PhD

s22 [redacted] – Oceania Cluster

Takeda Pharmaceuticals Australia Pty Ltd

Grosvenor Place, Level 39

225 George Street

Sydney NSW 2000 Australia

Mobile: s22 [redacted]

s22 [redacted] <[\[redacted\]@takeda.com](mailto:[redacted]@takeda.com)>

From: tga medicine shortages <medicine.shortages@health.gov.au>

Sent: Saturday, October 28, 2023 9:03 PM

To: s22 [redacted] <[redacted]@takeda.com>

Cc: s22 [redacted] <[redacted]@takeda.com>

Subject: MSII case requires updating - VYVANSE lisdexamfetamine dimesilate 50mg capsule bottle - ARTG 199226 - (MS-2023-NT-01341-1) [SEC=OFFICIAL]

Dear Regulatory Affairs Consultant,

The TGA is contacting you regarding the Medicine Shortage notification for your product VYVANSE lisdexamfetamine dimesilate 50mg capsule bottle - ARTG 199226 - (MS-2023-NT-01341-1).

The shortage status is anticipated. The date which the shortage is anticipated to begin is approaching: 04/11/2023.

ACTION REQUIRED:

If this shortage is still ongoing please submit an updated Medicine Shortage notification with current information.

If the shortage has been resolved please submit a Medicine Shortage notification advising that the shortage has been resolved.

If you require assistance with this process please do not hesitate to contact us via email at medicine.shortages@health.gov.au.

Kind regards,

Medicine Shortages Section
Pharmacovigilance Branch
Phone: s22
Email: medicine.shortages@health.gov.au

Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100
Woden ACT 2606
[https://urldefense.com/v3/__https://www.tga.gov.au__!!KDurfCY!8GVDxVOUI4QQ2xVni6jz8VPcllfPTxx-AVgX8gzFU2ouyDMxs1TmCTdkz3X9xa1WiQw9_BH_LqLC5YoYkvZfS39fZb6QrGCHb6-fJw\\$](https://urldefense.com/v3/__https://www.tga.gov.au__!!KDurfCY!8GVDxVOUI4QQ2xVni6jz8VPcllfPTxx-AVgX8gzFU2ouyDMxs1TmCTdkz3X9xa1WiQw9_BH_LqLC5YoYkvZfS39fZb6QrGCHb6-fJw$)

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"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

The content of this email and of any files transmitted may contain confidential, proprietary or legally privileged information and is intended solely for the use of the person/s or entity/ies to whom it is addressed. If you have received this email in error you have no permission whatsoever to use, copy, disclose or forward all or any of its contents. Please immediately notify the sender and thereafter delete this email and any attachments.

Notifier

Notifier

Sponsor Name: Takeda Pharmaceuticals Australia Pty Ltd

Sponsor Address: Grosvenor Place Level 39 225 George Street Sydney NSW 2000

Australian telephone number for public contact purposes: 1800012612

Medical information email for public contact purposes: medinfoAPAC@takeda.com

Primary Contact

Name: s22

Phone Number: s22

Email Address: s22@takeda.com

Secondary Contact

Name:

Phone Number: s22

Email Address: s22@takeda.com

ARTG Entry

ARTG Entry

ARTG number of the product that has a supply disruption:

ARTG ID	ARTG Name	Active Ingredient	Strength	Dosage Form
199226	VYVANSE	lisdexamfetamine dimesilate	50mg	Capsule, hard

ATC Descriptor: Nervous system

Are all pack sizes for this ARTG entry affected? Yes

Is this ARTG entry listed in the PBS? Yes

Provide the PBS number for this listing: 10474G

Do you have a designated sponsor representative within your organisation who is a point of contact on PBS matters? Yes

PBS Contact Details

Name: s22

Phone Number: s22

Email Address: s22@takeda.com

Details

Details

When was the shortage known to the sponsor? 18/10/2023

Nature of the shortage:	Current	
Shortage reason:	Manufacturing	Document 24
Manufacturing site problem:	Issues/delays with packaging and/or labelling	
Shortage reason - further information:		
Estimated period supply will be affected at wholesaler points:	From:	03/11/2023
	To:	25/12/2023
Availability:	Limited Availability	
TGA publication date:	31/10/2023	
Is this shortage related to other medicines within the same Therapeutic class?	No	
Is this shortage specific to Australia?	No	
Estimated normal demand volumes for Australia:	s47	
Estimated percentage share of the Australian market:	100 %	
Estimated current stock at sponsor / manufacturing level in Australia:	13388 units	
Estimated current stock at wholesaler / distributor level in Australia:	8441 units	
What is meant by 1 unit in this context:	1 bottle of 30 capsules	

Impact

Are there therapeutic alternatives on the Australian market?	Yes
What is the status of substitute options for this product in Australia?	Appropriate Therapeutic Alternatives
Are they available in adequate supplies to meet demand?	Unknown at this time
Provide details:	Alternative treatments include; methylphenidate, dexamfetamine, other strengths of lisdexamfetamine
Do any specific population groups use this product?	Yes
Provide details of the groups and the impact on those groups:	Paediatric, adolescents, and adult patients with Attention Deficit Hyperactivity Disorder (ADHD). Adult patients with Binge Eating Disorder (BED).
Based on your answers above and the Assessment Framework, what is the shortage impact rating?	2 - Medium Impact

Shortage Action

What communication activities have happened or are planned?	Communication Action	Date of Communication
	Letter to Prescribers	01-Nov-2023
	Letter to Pharmacists	01-Nov-2023
	Letter to Wholesalers	31-Oct-2023

Letter attached in Supporting Information:	No
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Further comments on communications:

What supply management actions have happened or are planned?	Management Action	Date of Management Action
	Constrained Supply	23-Oct-2023

Further comments on management actions:**Supporting Information**

Supporting data will be:

Attached

Documents attached to this notification:

File Name	Created By	Description
FINAL_VYVANSE Stock Shortage_OCT2023_CONSUMER.pdf	§22	Consumers statement
FINAL_VYVANSE Stock Shortage_OCT2023_HCP LETTER.pdf	§22	Letter to HCPs
FINAL_VYVANSE Stockout Letter_OCT2023_PHARMACY.pdf	§22	Letter to Pharmacists

Sponsor website where medicine shortage information is available:**File Attachments**

The following files have been attached to this notification.

Therapeutic Goods Administration | eBusiness Services

Medicine Shortage Notification**Notification ID:** MS-2023-NT-01486-1**Submission ID:** MS-2023-05050-1**Status:** Completed**Client Reference:** VYVANSE 60mg shortage

Notifier

Notifier**Sponsor Name:** Takeda Pharmaceuticals Australia Pty Ltd**Sponsor Address:** Grosvenor Place Level 39 225 George Street Sydney NSW 2000**Australian telephone number for public contact purposes:** 1800012612**Medical information email for public contact purposes:** medinfoAPAC@takeda.com**Primary Contact****Name:** s22**Phone Number:** s22**Email Address:** s22@takeda.com**Secondary Contact****Name:** s22**Phone Number:** s22**Email Address:** s22@takeda.com

ARTG Entry

ARTG Entry**ARTG number of the product that has a supply disruption:**

ARTG ID	ARTG Name	Active Ingredient	Strength	Dosage Form
284021	VYVANSE lisdexamfetamine dimesilate 60 mg capsules	lisdexamfetamine dimesilate	60mg	Capsule, hard

	bottle
ATC Descriptor:	Nervous system
Are all pack sizes for this ARTG entry affected?	Yes
Is this ARTG entry listed in the PBS?	Yes
Provide the PBS number for this listing:	11897E
Do you have a designated sponsor representative within your organisation who is a point of contact on PBS matters?	Yes
PBS Contact Details	
Name:	s22
Phone Number:	s22
Email Address:	s22 @takeda.com

Details

Details	
When was the shortage known to the sponsor?	21/11/2023
Nature of the shortage:	Anticipated
Shortage reason:	Manufacturing
Manufacturing site problem:	Issues/delays with packaging and/or labelling
Shortage reason - further information:	
Estimated period supply will be affected at wholesaler points:	From: 18-Dec-2023 To: 19-Apr-2024
Availability:	Available
TGA publication date:	24-Nov-2023
Indicate preference for date of publication:	<input checked="" type="radio"/> Date of processing <input type="radio"/> Deferred publication
Is this shortage related to other medicines	No

within the same Therapeutic class?

Is this shortage specific to Australia?	No
Estimated normal demand volumes for Australia:	547
Estimated percentage share of the Australian market:	100 %
Estimated current stock at sponsor / manufacturing level in Australia:	40543 units
Estimated current stock at wholesaler / distributor level in Australia:	5400 units
What is meant by 1 unit in this context:	A single pack of 30 capsules.

Impact

Impact

Are there therapeutic alternatives on the Australian market?	Yes
What is the status of substitute options for this product in Australia?	Appropriate Therapeutic Alternatives
Are they available in adequate supplies to meet demand?	Yes
Provide details:	Alternative treatments include: methylphenidate, dexamfetamine, other strengths of lisdexafetamine
Do any specific population groups use this product?	Yes
Provide details of the groups and the impact on those groups:	Paediatric, adolescents, and adult patients with Attention Deficit Hyperactivity Disorder (ADHD), adult patients with Binge Eating Disorder (BED).
Based on your answers above and the Assessment Framework, what is the shortage impact rating?	2 - Medium Impact

Shortage Action

Shortage Action

What communication activities have happened or are planned?

Communication Action	Date of Communication
Letter to Wholesalers	01-Dec-2023
Letter to Prescribers	01-Dec-2023
Letter to Pharmacists	01-Dec-2023
Letter to Patient Advocacy Groups	01-Dec-2023

Letter attached in Supporting Information: No

Further comments on communications:

What supply management actions have happened or are planned?

Management Action	Date of Management Action
Constrained Supply	23-Nov-2023
Working to expedite next shipment	23-Nov-2023

Further comments on management actions:

Supporting Information

Supporting Information

Supporting data will be: Or Both

Documents attached to this notification:

File Name	Created By	Description
Vyvanse 60mg - Replenishment Plan - Takeda Australia 23112023.pdf	Takeda	Replishment Plan

Documents to be sent to TGA:

Proposed Send Date	Description	Send By
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04-Dec-2023

Copies of letters

Email

Sponsor website where medicine shortage information is available:

Work Management

Work Management Information

TGA Management Actions: The sponsor is closely controlling the supply and working to expedite the next shipment

Activity Logs

Notification Activity Logs

View: AuditLogsByNotificationID

File Attachments

The following files have been attached to this notification.



- Vyvanse 60mg - Replenishment Plan - Takeda Australia 23112023.pdf

Vyvanse 60mg	Nov-23	Dec-23	Jan-24	Feb-24	Mar-24	Apr-24
Replenishment Qty		13,713				82,200
Estimated ETA		w/c 15 Dec				w/c 15 April

May-24

Therapeutic Goods Administration | eBusiness Services

Medicine Shortage Notification

Notification ID: MS-2023-NT-00980-1

Submission ID: MS-2023-05051-1

Status: Completed

Client Reference: Vyvanse 30mg shortage

Notifier

Notifier

Sponsor Name: Takeda Pharmaceuticals Australia Pty Ltd

Sponsor Address: Grosvenor Place Level 39 225 George Street Sydney NSW 2000

Australian telephone number for public contact purposes: 1800012612

Medical information email for public contact purposes: medinfoAPAC@takeda.com

Primary Contact

Name: s22

Phone Number: s22

Email Address: s22@takeda.com

Secondary Contact

Name: s22

Phone Number: s22

Email Address: s22@takeda.com

ARTG Entry

ARTG Entry

ARTG number of the product that has a supply disruption:

ARTG ID	ARTG Name	Active Ingredient	Strength	Dosage Form
199227	VYVANSE lisdexamfetamine dimesilate 30mg capsule bottle	lisdexamfetamine dimesilate	30mg	Capsule, hard

ATC Descriptor:	Nervous system
Are all pack sizes for this ARTG entry affected?	Yes
Is this ARTG entry listed in the PBS?	Yes
Provide the PBS number for this listing:	10486X
Do you have a designated sponsor representative within your organisation who is a point of contact on PBS matters?	Yes
PBS Contact Details	
Name:	s22
Phone Number:	s22
Email Address:	s22 @takeda.com

Details

Details

When was the shortage known to the sponsor?	04/08/2023
Nature of the shortage:	Current
Shortage reason:	Manufacturing
Manufacturing site problem:	Issues/delays with packaging and/or labelling
Shortage reason - further information:	Takeda are experiencing some delays related to the global supply of Vyvanse products due to the remediation actions implemented at the contract manufacturing organization site Wasdell Europe with respect to the Critical Observations identified during the HPRA health authority inspection previously communicated to the TGA. As a result the expected manufacturing time frames have been increased and committed shipments to Australia have been further delayed.
Estimated period supply will be affected at wholesaler points:	From: 07-Aug-2023 To: 07-Mar-2024
Availability:	Limited Availability
TGA publication date:	14-Aug-2023
Is this shortage related to other medicines	No

within the same Therapeutic class?

Is this shortage specific to Australia?	No
Estimated normal demand volumes for Australia:	s47
Estimated percentage share of the Australian market:	100 %
Estimated current stock at sponsor / manufacturing level in Australia:	265 units
Estimated current stock at wholesaler / distributor level in Australia:	10465 units
What is meant by 1 unit in this context:	Single pack of 30 capsules

Impact

Impact

Are there therapeutic alternatives on the Australian market?	Yes
What is the status of substitute options for this product in Australia?	Appropriate Therapeutic Alternatives
Are they available in adequate supplies to meet demand?	Unknown at this time
Provide details:	There are different stimulants, such as methylphenidate, belonging to the same class of psychostimulants
Do any specific population groups use this product?	Yes
Provide details of the groups and the impact on those groups:	Paediatric, adolescents, and adult patients with ADHD. Adult patients with BED
Based on your answers above and the Assessment Framework, what is the shortage impact rating?	2 - Medium Impact

Shortage Action

Shortage Action

What communication activities have happened or are planned?

Communication Action	Date of Communication
Letter to Prescribers	14-Aug-2023
Letter to Patient Advocacy Groups	14-Aug-2023
Letter to Pharmacists	14-Aug-2023
Letter to Wholesalers	14-Aug-2023

Letter attached in Supporting Information:

No

Further comments on communications:

Communications plans includes:
 1. HCP letter (all paediatricians and psychiatrists)
 2. Consumer Statement to Patient Advisory Groups (ADHD Australia, ADHD Foundation)
 3. Pharmacy Letter (all retail pharmacies)
 4. Wholesaler Letter

What supply management actions have happened or are planned?

Management Action	Date of Management Action
Constrained Supply	07-Aug-2023
Working to expedite next shipment	07-Aug-2023

Further comments on management actions:

Supporting Information

Supporting Information

Supporting data will be:

Or Both

Documents attached to this notification:

File Name	Created By	Description
Vyvanse 30mg & 50mg - Replenishment Plan - Takeda Australia 24112023.pdf	Takeda	Replishment Plan

Documents to be sent to TGA:

Proposed Send Date	Description	Send By
01-Dec-2023	Letters to prescribers, wholesalers, pharmacies and patient advocacy groups	Email

Sponsor website where medicine shortage information is available:

Work Management

Work Management Information**TGA Management Actions:**

Emergency Supply of VYVANSE lisdexamfetamine dimesilate 30mg capsule bottle AUST R: 199227 is available from the sponsor. Please contact Takeda Pharmaceuticals Australia Pty Ltd on 1800 012 612 or medinfoapac@takeda.com for details on supply.

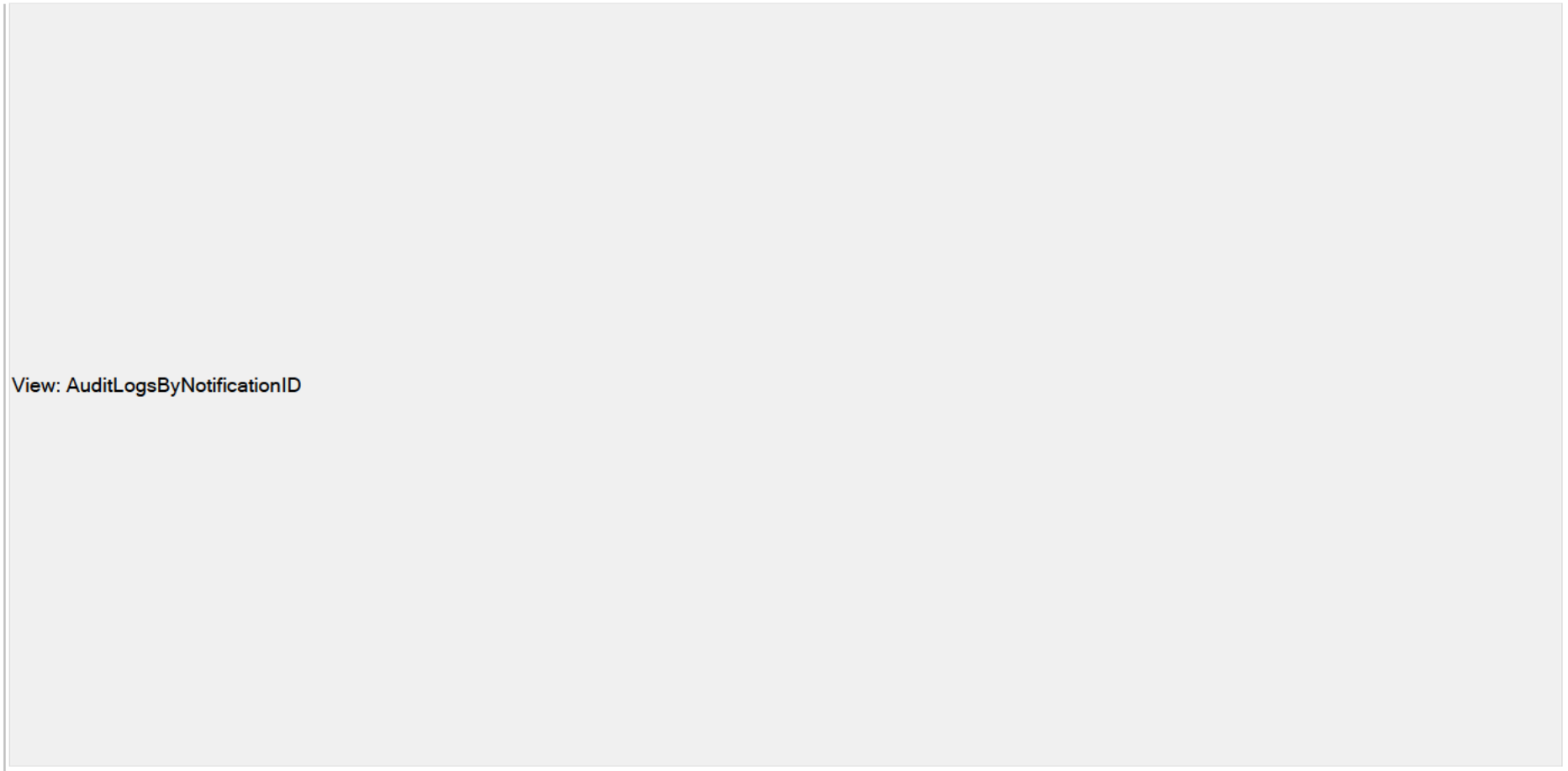
An unregistered product has also been approved for supply under Section 19A. The approval holder, Medsurge can be contacted for details on supply on: 1300 788 261 or sales@medsurge.com.au

A TGA web alert is available at:
<https://www.tga.gov.au/safety/shortages/information-about-major-medicine-shortages/about-shortages-vyvanse-lisdexamfetamine-dimesilate-capsules>

Activity Logs

Notification Activity Logs

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View: AuditLogsByNotificationID

Changes Made

Changes Made

The following changes were made between this version and the latest update of the previous version.

Primary Contact Name has been altered from 's22 [REDACTED]' to 's22 [REDACTED]'

Primary Contact Phone Number has been altered from 's22 [REDACTED]' to '+s22 [REDACTED]'

Primary Contact Email Address has been altered from 's22 [REDACTED]@takeda.com' to 's22 [REDACTED]@takeda.com'

Estimated period supply will be affected at wholesaler points - To has been altered from '31/12/2023' to '07/03/2024'

Estimated normal demand volumes for Australia has been altered from 's47 [REDACTED]'

Estimated current stock at sponsor/manufacturing level in Australia has been altered from '8864' to '265'

Estimated current stock at wholesaler/distributor level in Australia has been altered from '3495' to '10465'

Supporting data will be has been altered from 'Attached' to 'Both'

File Attachments

The following files have been attached to this notification.



- Vyvanse 30mg & 50mg - Replenishment Plan - Takeda Australia 24112023.pdf

Vyvanse 30mg	Nov-23	Dec-23	Jan-24	Feb-24	Mar-24	Apr-24
Replenishment Qty				40,000	107,500	90,000
Estimated ETA				w/c 08 Feb	w/c 26 Feb	w/c 03 Apr

Vyvanse 50mg	Nov-23	Dec-23	Jan-24	Feb-24	Mar-24	Apr-24
Replenishment Qty		36,874		40,000	106,000	90,000
Estimated ETA		w/c 15 Dec		w/c 19 Feb	w/c 11 Mar	w/c 01 Apr

Therapeutic Goods Administration | eBusiness Services

Medicine Shortage Notification**Notification ID:** MS-2023-NT-01341-1**Submission ID:** MS-2023-05052-1**Status:** Completed**Client Reference:** Vyvanse 50 mg shortage

Notifier

Notifier**Sponsor Name:** Takeda Pharmaceuticals Australia Pty Ltd**Sponsor Address:** Grosvenor Place Level 39 225 George Street Sydney NSW 2000**Australian telephone number for public contact purposes:** 1800012612**Medical information email for public contact purposes:** medinfoAPAC@takeda.com**Primary Contact****Name:** s22**Phone Number:** s22**Email Address:** s22@takeda.com**Secondary Contact****Name:****Phone Number:** s22**Email Address:** s22@takeda.com

ARTG Entry

ARTG Entry**ARTG number of the product that has a supply disruption:**

ARTG ID	ARTG Name	Active Ingredient	Strength	Dosage Form
199226	VYVANSE lisdexamfetamine dimesilate 50mg capsule bottle	lisdexamfetamine dimesilate	50mg	Capsule, hard

ATC Descriptor:	Nervous system
Are all pack sizes for this ARTG entry affected?	Yes
Is this ARTG entry listed in the PBS?	Yes
Provide the PBS number for this listing:	10474G
Do you have a designated sponsor representative within your organisation who is a point of contact on PBS matters?	Yes
PBS Contact Details	
Name:	s22
Phone Number:	s22
Email Address:	s22 @takeda.com

Details

Details	
When was the shortage known to the sponsor?	18/10/2023
Nature of the shortage:	Current
Shortage reason:	Manufacturing
Manufacturing site problem:	Issues/delays with packaging and/or labelling
Shortage reason - further information:	
Estimated period supply will be affected at wholesaler points:	From: 03-Nov-2023 To: 07-Mar-2024
Availability:	Limited Availability
TGA publication date:	31-Oct-2023
Is this shortage related to other medicines within the same Therapeutic class?	No
Is this shortage specific to Australia?	No

Estimated normal demand volumes for Australia:	\$47
Estimated percentage share of the Australian market:	100 %
Estimated current stock at sponsor / manufacturing level in Australia:	11 units
Estimated current stock at wholesaler / distributor level in Australia:	9110 units
What is meant by 1 unit in this context:	1 bottle of 30 capsules

Impact

Impact	
Are there therapeutic alternatives on the Australian market?	Yes
What is the status of substitute options for this product in Australia?	Appropriate Therapeutic Alternatives
Are they available in adequate supplies to meet demand?	Unknown at this time
Provide details:	Alternative treatments include; methylphenidate, dexamfetamine, other strengths of lisdexamfetamine
Do any specific population groups use this product?	Yes
Provide details of the groups and the impact on those groups:	Paediatric, adolescents, and adult patients with Attention Deficit Hyperactivity Disorder (ADHD). Adult patients with Binge Eating Disorder (BED).
Based on your answers above and the Assessment Framework, what is the shortage impact rating?	2 - Medium Impact

Shortage Action

Shortage Action

What communication activities have happened

or are planned?

Communication Action
Date of Communication
 Letter to Prescribers
 01-Nov-2023
 Letter to Pharmacists
 01-Nov-2023
 Letter to Wholesalers
 31-Oct-2023

Letter attached in Supporting Information:

No

Further comments on communications:

What supply management actions have happened or are planned?

Management Action
Date of Management Action
 Constrained Supply
 23-Oct-2023
 Working to expedite next shipment
 18-Oct-2023

Further comments on management actions:

Supporting Information

Supporting Information

Supporting data will be:

Or Both

Documents attached to this notification:

File Name
Created By
Description
 Vyvanse 30mg & 50mg - Replenishment Plan - Takeda Australia 24112023.pdf
 Takeda
 Replishment Plan

Documents to be sent to TGA:

Proposed Send Date
Description
Send By
 01-Dec-2023

Letters to prescribers, wholesalers, pharmacies and patient advocacy groups
Email

Sponsor website where medicine shortage information is available:

Work Management

Work Management Information

TGA Management Actions:

The sponsor is closely controlling the supply and working to expedite the next shipment.

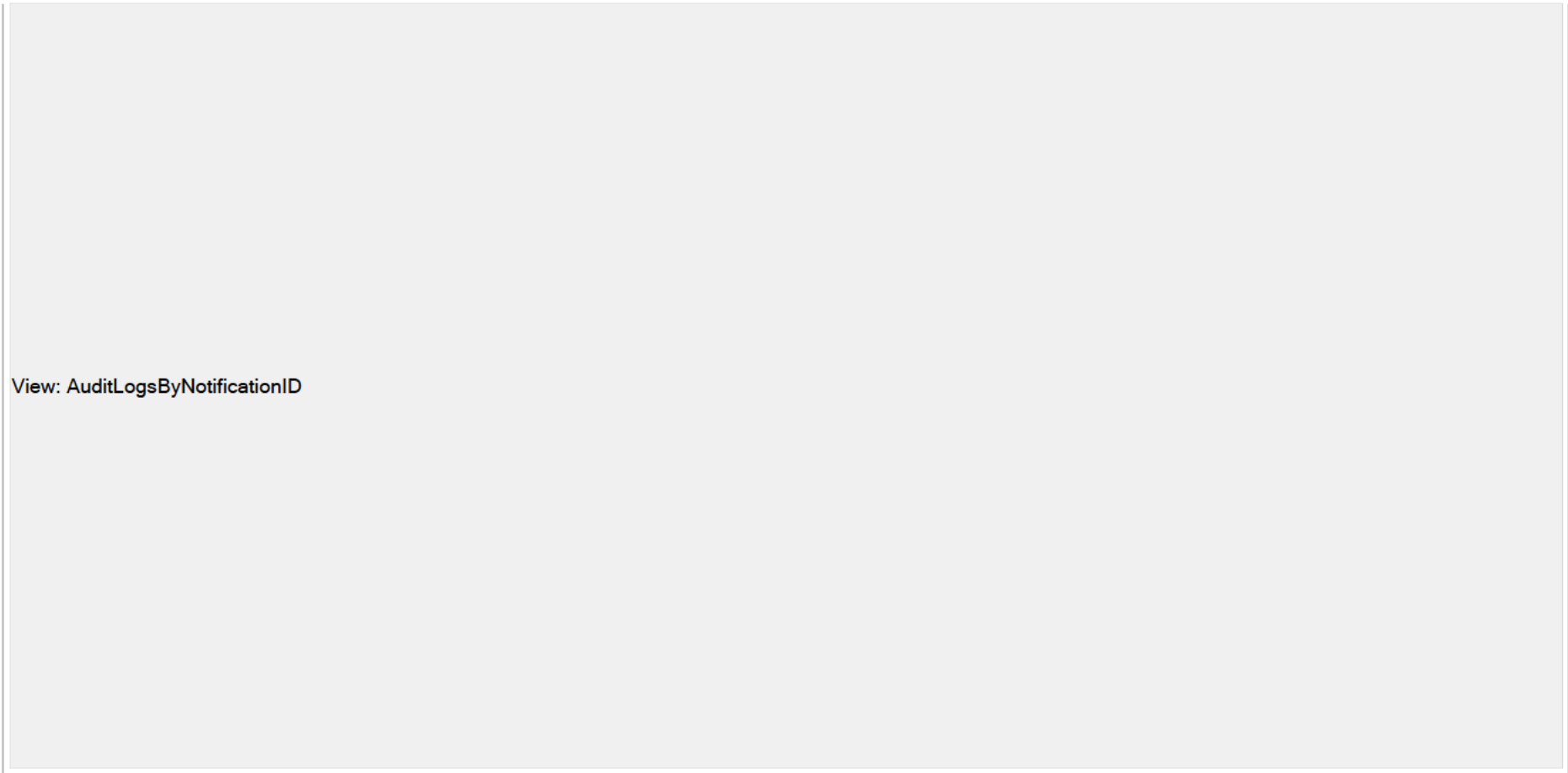
Emergency Supply of VYVANSE lisdexamfetamine dimesilate 50mg capsule bottle AUST R: 199226 is available from the sponsor. Please contact Takeda Pharmaceuticals Australia Pty Ltd on 1800 012 612 or medinfoapac@takeda.com for details on supply.

An unregistered product has also been approved for supply under Section 19A. The approval holder, Medsurge can be contacted for details on supply on: 1300 788 261 or sales@medsurge.com.au

A TGA web alert is available at:
<https://www.tga.gov.au/safety/shortages/information-about-major-medicine-shortages/about-shortages-vyvanse-lisdexamfetamine-dimesilate-capsules>

Activity Logs

Notification Activity Logs



View: AuditLogsByNotificationID

Changes Made

Changes Made

The following changes were made between this version and the latest update of the previous version.

Primary Contact Name has been altered from 's22 [REDACTED]' to 's22 [REDACTED]'

Primary Contact Phone Number has been altered from 's22 [REDACTED]' to 's22 [REDACTED]'

Primary Contact Email Address has been altered from s22 [REDACTED]@takeda.com' to s22 [REDACTED]@takeda.com'

Estimated period supply will be affected at wholesaler points - To has been altered from '25/12/2023' to '07/03/2024'

Estimated normal demand volumes for Australia has been altered from s47 [REDACTED]

Estimated current stock at sponsor/manufacturing level in Australia has been altered from '13388' to '11'

Estimated current stock at wholesaler/distributor level in Australia has been altered from '8441' to '9110'

Supporting data will be has been altered from 'Attached' to 'Both'

File Attachments

The following files have been attached to this notification.



- Vyvanse 30mg & 50mg - Replenishment Plan - Takeda Australia 24112023.pdf

From: s22
To: [Medicine Shortages](#)
Subject: RE: VYVANSE 60mg capsules anticipated shortage. Updates to current shortages for VYVANSE 30mg and 50mg capsules.
Date: Friday, 24 November 2023 11:51:31 AM
Attachments: [image001.png](#)
[image002.jpg](#)

Dear Medicines Shortage Section

A correction for submission numbers for 30 mg and 50 mg updates. These final details were available only after submissions were refreshed on TGA eBS:

30mg: MS-2023-NT-00980-1

50mg: MS-2023-NT-01341-1

Apologies for any confusion.

Thank you

Kind regards

s22

From: s22
Sent: Friday, November 24, 2023 11:32 AM
To: Medicine Shortages <medicine.shortages@health.gov.au>
Subject: VYVANSE 60mg capsules anticipated shortage. Updates to current shortages for VYVANSE 30mg and 50mg capsules.

Dear TGA Medicines Shortage Section

Takeda wish to let you know an anticipated shortage notification for VYVANSE 60 mg capsules (MS-2023-05050-1) has been submitted through the TGA's eBS portal today. Takeda has also submitted updates to current shortages notification for VYVANSE 30 mg capsules (MS-2023-05051-1) and VYVANSE 50 mg capsules (MS-2023-05052-1). The updates relate to extension of shortage end date.

Please contact me should you need any further information or if you like to discuss the shortage notifications on phone.

Thank you.

Kind regards

s22



s22 PhD

s22 – Oceania Cluster

Takeda Pharmaceuticals Australia Pty Ltd

Grosvenor Place, Level 39
225 George Street
Sydney NSW 2000 Australia
Mobile: s22

s22 [@takeda.com](#)

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From: [Medicine Shortages](#)
To: s22
Subject: RE: Vyvanse 40mg - Potential Supply Issue [SEC=OFFICIAL]
Date: Friday, 15 December 2023 11:18:03 AM
Attachments: [image001.png](#)
[image002.png](#)
[image004.png](#)

Dear s22

Thank you so much for providing this information and explaining the current landscape very clearly. It really is greatly appreciated.

Kind regards,

s22

s22
Pharmacist – Medicine Shortages Section
Pharmacovigilance Branch

Medicines Regulation Division | Health Products Regulation Group
 Australian Government, Department of Health and Aged Care
 T: s22 | E: medicine.shortages@health.gov.au
 Location: Fairbairn
 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@takeda.com>
Sent: Friday, 15 December 2023 10:44 AM
To: Medicine Shortages <medicine.shortages@health.gov.au>
Subject: RE: Vyvanse 40mg - Potential Supply Issue [SEC=OFFICIAL]

Dear s22

Thank you for your email and hope all well. Following is the information your requested:

- There is no stock shortage issue with Vyvanse 20mg, 40mg and 70mg, please refer to current stock position at Takeda.

Code	Description	Total SOH (15/12)	Average Monthly (Normal) Demand	Month Stock Cover
501102	Vyvanse 40mg Capsules	71,766	s47	
501101	Vyvanse 20mg Capsules	57,079		
500737	Vyvanse 70mg Capsules	78,987		

- Wholesalers are at low stock or OOS due to non-compliance regarding the return of the S8 receipt document, as required by NSW Ministry of Health.

Until the hard copy of the S8 document is received (via post) by our 4PL provider, orders are placed on dispatch hold.

- Takeda Australia has been in contact with wholesalers, requesting their support to ensure the mandatory S8 documents are returned in timely manner.
- As there is high risk of delay in posted mails deliveries during the holiday period, Takeda Australia has instructed our 4PL to include an Express Post envelope with each delivery at Takeda's cost.

This will hopefully lower the risk on the delay of the S8 documents returns.

- As of today, 15th December our 4PL provider has dispatched a large number of orders to various wholesalers.

We are expecting these deliveries to be received in their respective Distribution Centres next week.

Please contact me should you need any clarification or further information.

Kind regards

s22



Better Health, Brighter Future

s22

PhD

s22

– Oceania Cluster

Takeda Pharmaceuticals Australia Pty Ltd

Grosvenor Place, Level 39

225 George Street

Sydney NSW 2000 Australia

Mobile: s22

s22

@takeda.com

From: Medicine Shortages <medicine.shortages@health.gov.au>

Sent: Thursday, December 14, 2023 10:13 AM

To: s22 @takeda.com>

Subject: Vyvanse 40mg - Potential Supply Issue [SEC=OFFICIAL]

Dear s22

I hope all is well.

Thank you for providing the copies of the communication letters sent to healthcare professionals about the shortage of Vyvanse products.

We have recently received an enquiry stating patients are now unable to obtain the 40mg strength of Vyvanse.

Noting that the communications you recently sent through stated that (as of 1 December 2023) that there was no issues with the supply of 40mg Vyvanse, are you able to provide any update on the current supply of this strength? Any information that you could provide regarding this would be greatly appreciated.

If there is any potential supply issues with this strength, it would be greatly appreciated if a shortage notification could be submitted so that we can continue to keep consumers and health professionals informed.

Kind regards,

s22

s22

**Pharmacist – Medicine Shortages Section
Pharmacovigilance Branch**

Medicines Regulation Division | Health Products Regulation Group
Australian Government, Department of Health and Aged Care

T: s22 | E: medicine.shortages@health.gov.au

Location: Fairbairn

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 <[redacted]@takeda.com>

Sent: Monday, 4 December 2023 7:39 AM

To: Medicine Shortages <medicine.shortages@health.gov.au>

Subject: VYVANSE communication letters: 30mg (MS-2023-NT-00980-1), 50mg (MS-2023-NT-01341-1) and 60 mg (MS-2023-NT-01486-1).

Dear s22

Please find attached here copies of communication letters sent to prescribers, wholesalers, pharmacies, and patient organisations. The shortage notifications details are as follows:

VYVANSE 30mg capsule: MS-2023-NT-00980-1

VYVANSE 50mg capsule: MS-2023-NT-01341-1

VYVANSE 60mg capsule: MS-2023-NT-01486-1.

Please contact me should you need any clarification.

Thank you

Kind regards

s22



Better Health, Brighter Future

s22

PhD

s22

– Oceania Cluster

Takeda Pharmaceuticals Australia Pty Ltd

Grosvenor Place, Level 39

225 George Street
Sydney NSW 2000 Australia
Mobile: s22 [REDACTED]
s22 [REDACTED]@takeda.com

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1 December 2023

Dear Doctor,

RE: SUPPLY INTERRUPTION OF VYVANSE® (lisdexamfetamine dimesilate) 30mg, 50mg and 60mg capsules

We are writing to inform you that the intermittent interruption to the supply of VYVANSE will continue to affect its availability in Australia **until late April 2024**.

The interruption to supply has been caused by manufacturing delays compounded by increased demand. We are working hard to resolve the interruptions as soon as possible and are taking steps to help improve future supply continuity, including moving to an upgraded internal facility in mid-2024.

Based on typical usage patterns, Takeda anticipates that supply will be impacted for the following strengths as follows:

- VYVANSE 30mg – Now until mid-March 2024
- VYVANSE 50mg – Now until mid-March 2024
- VYVANSE 60mg – Mid-December until late April 2024

As of the date of this letter, the supply of VYVANSE 20mg, 40mg and 70mg capsules are not impacted.

Takeda understands the importance of maintaining consistent treatment with VYVANSE and recognises the need to preserve this limited stock to prioritise ongoing care. We ask you to exercise your clinical judgement and take this stock limitation into account when considering treatment with VYVANSE for your patients.

Takeda has a limited emergency supply at our warehouse which has been reserved for instances of urgent patient need. Requests for emergency stock can be made by pharmacists by calling Takeda Medical Information on 1800 012 612. All requests for emergency supply will be reviewed individually and are subject to stock availability.

We understand that supply interruptions are challenging for both you and your patients, and we want to assure you that we are doing everything we can to resolve these interruptions as quickly as possible. We will continue to monitor the situation closely and keep you informed about any supply updates.

In the meantime, if you have any urgent enquiries, please contact:

- Takeda Medical Information: telephone **1800 012 612** or email: medinfoAPAC@takeda.com

We sincerely appreciate the understanding of the ADHD community during this period.

Yours sincerely,

s22

s22

PhD

s22



Please review Product Information before prescribing. Product Information is available from Takeda Pharmaceuticals Australia Pty Ltd. Phone: 1800 012 612. Email: medinfoAPAC@takeda.com

For further information about the appropriate selection of patients and prescribing of VYVANSE, please visit <http://www.lfxguide.com/au> (password: onetakeda)

VYVANSE has a potential for abuse, misuse, dependence, or diversion for non-therapeutic uses. Physicians should assess the risk of abuse prior to prescribing and monitor for signs of abuse and dependence while on therapy. VYVANSE should be prescribed cautiously to patients with a history of substance abuse or dependence. Careful supervision is required during withdrawal from abusive use since severe depression may occur. Withdrawal following chronic therapeutic use may unmask symptoms of the underlying disorder that may require follow-up.

Minimum Product Information. VYVANSE® (lisdexamfetamine dimesilate).

Indication: Attention Deficit Hyperactivity Disorder (ADHD): Indicated for treatment of ADHD. Treatment should be commenced by a specialist as part of a comprehensive treatment program and re-evaluated periodically during long-term use. Binge Eating Disorder (BED): Indicated for treatment of moderate to severe BED in adults when non-pharmacological treatment is unsuccessful or unavailable. Treatment should be commenced and managed by a psychiatrist. **Dosage and Administration:** VYVANSE should be initiated at 30 mg once daily in the morning (avoid afternoon doses due to potential for insomnia) and slowly adjusted to the lowest effective dose (no more frequently than weekly). Capsules may be taken whole, or opened and the contents emptied and mixed with a soft food such as yogurt or in a glass of water or orange juice. **Contraindications:** Advanced arteriosclerosis; symptomatic cardiovascular disease (eg cardiac arrhythmia, ischaemic heart disease); moderate to severe hypertension; hyperthyroidism; hypersensitivity or idiosyncratic reaction to sympathomimetic amines or any of the excipients; glaucoma; agitated states (eg severe anxiety, tension and agitation); administration during or within 14 days of cessation of MAOIs; pheochromocytoma; tics, Tourette's syndrome; patients who exhibit severe depression, anorexia nervosa, psychotic symptoms or suicidal tendency; drug dependence or alcohol abuse. **Precautions:** Cardiovascular disease; psychiatric disorders (psychosis, bipolar disease, aggression); seizures; visual disturbance; long-term suppression of growth, peripheral vasculopathy including Raynaud's phenomenon. Renal impairment (severe renal insufficiency max dose 50mg/day; dose reduction for dialysis patients). No data in hepatic impairment. Pregnancy: Category B3. Women taking VYVANSE should refrain from breast feeding. Not studied in children <6 years or adults >55 years of age. **Interactions:** MAOIs (see Contraindications), antihypertensives, narcotic analgesics, antipsychotics, agents that alter urinary pH, serotonergic drugs. **Adverse Effects:** Very Common reactions: decreased appetite, insomnia, headache, dry mouth, upper abdominal pain, weight decreased. Common reactions: anorexia, agitation, anxiety, libido decreased, tic, affect lability, psychomotor hyperactivity, bruxism, aggression, dizziness, restlessness, tremor, somnolence, mydriasis, tachycardia, palpitation, dyspnoea, diarrhoea, nausea, vomiting, hyperhidrosis, rash, irritability, fatigue, feeling jittery, pyrexia, blood pressure increased, erectile dysfunction. Note: where frequency of adverse reactions varies across age groups (children, adolescents, adults), the adverse reaction is listed according to the highest frequency.

(pi-01047. V1.0)



1st December 2023

Dear Pharmacist,

RE: SUPPLY INTERRUPTION OF VYVANSE® (lisdexamfetamine dimesilate) 30mg, 50mg and 60mg capsules

We are writing to inform you that the intermittent interruption to the supply of VYVANSE will continue to affect its availability in Australia **until late April 2024**.

The interruption to supply has been caused by manufacturing delays compounded by increased demand. We are working hard to resolve the interruptions as soon as possible and are taking steps to help improve future supply continuity, including moving to an upgraded internal facility in mid-2024.

Based on typical usage patterns, Takeda anticipates that supply will be impacted for the following strengths as follows:

- VYVANSE 30mg – Now until mid-March 2024
- VYVANSE 50mg – Now until mid-March 2024
- VYVANSE 60mg – Mid-December until late April 2024

As of the date of this letter, the supply of VYVANSE 20mg, 40mg and 70mg capsules are not impacted.

While we are expecting some deliveries during this time, we do not anticipate that these will be sufficient to meet usual demand. To mitigate potential stock shortages for patients, our supply team will be closely overseeing the inventory for VYVANSE over the coming months. Please expect some orders not to be supplied in full and intermittent periods where there will be no stock available.

We understand that supply interruptions are challenging for both you and your customers and are working to resolve these interruptions as quickly as possible. **Takeda has a limited emergency supply at our warehouse which has been reserved for instances of urgent patient need.** Requests for emergency stock can be made by pharmacists by calling Takeda Medical Information on 1800 012 612. All requests for emergency supply will be reviewed individually and are subject to stock availability.

We will continue to monitor the situation closely and will keep you informed with regards to any supply updates. In the meantime, if you have any urgent enquiries, please contact:

- Takeda Medical Information: telephone **1800 012 612** or email: medinfoAPAC@takeda.com

We sincerely appreciate the patience and understanding of the ADHD community during this period.

Yours sincerely,

s22 [Redacted]

s22 [Redacted] PhD

s22 [Redacted]



Please review Product Information before prescribing. Product Information is available from Takeda Pharmaceuticals Australia Pty Ltd. Phone: 1800 012 612. Email: medinfoAPAC@takeda.com

For further information about the appropriate selection of patients and prescribing of VYVANSE, please visit <http://www.lxdguide.com/au> (password: onetakeda)

VYVANSE has a potential for abuse, misuse, dependence, or diversion for non-therapeutic uses. Physicians should assess the risk of abuse prior to prescribing and monitor for signs of abuse and dependence while on therapy. VYVANSE should be prescribed cautiously to patients with a history of substance abuse or dependence. Careful supervision is required during withdrawal from abusive use since severe depression may occur. Withdrawal following chronic therapeutic use may unmask symptoms of the underlying disorder that may require follow-up.

Minimum Product Information. VYVANSE® (lisdexamfetamine dimesilate).

Indication: Attention Deficit Hyperactivity Disorder (ADHD): Indicated for treatment of ADHD. Treatment should be commenced by a specialist as part of a comprehensive treatment program and re-evaluated periodically during long-term use. Binge Eating Disorder (BED): Indicated for treatment of moderate to severe BED in adults when non-pharmacological treatment is unsuccessful or unavailable. Treatment should be commenced and managed by a psychiatrist. **Dosage and Administration:** VYVANSE should be initiated at 30 mg once daily in the morning (avoid afternoon doses due to potential for insomnia) and slowly adjusted to the lowest effective dose (no more frequently than weekly). Capsules may be taken whole, or opened and the contents emptied and mixed with a soft food such as yogurt or in a glass of water or orange juice.

Contraindications: Advanced arteriosclerosis; symptomatic cardiovascular disease (eg cardiac arrhythmia, ischaemic heart disease); moderate to severe hypertension; hyperthyroidism; hypersensitivity or idiosyncratic reaction to sympathomimetic amines or any of the excipients; glaucoma; agitated states (eg severe anxiety, tension and agitation); administration during or within 14 days of cessation of MAOIs; pheochromocytoma; tics, Tourette's syndrome; patients who exhibit severe depression, anorexia nervosa, psychotic symptoms or suicidal tendency; drug dependence or alcohol abuse. **Precautions:** Cardiovascular disease; psychiatric disorders (psychosis, bipolar disease, aggression); seizures; visual disturbance; long-term suppression of growth, peripheral vasculopathy including Raynaud's phenomenon. Renal impairment (severe renal insufficiency max dose 50mg/day; dose reduction for dialysis patients). No data in hepatic impairment. Pregnancy: Category B3. Women taking VYVANSE should refrain from breast feeding. Not studied in children <6 years or adults >55 years of age. **Interactions:** MAOIs (see Contraindications), antihypertensives, narcotic analgesics, antipsychotics, agents that alter urinary pH, serotonergic drugs. **Adverse Effects:** Very Common reactions: decreased appetite, insomnia, headache, dry mouth, upper abdominal pain, weight decreased. Common reactions: anorexia, agitation, anxiety, libido decreased, tic, affect lability, psychomotor hyperactivity, bruxism, aggression, dizziness, restlessness, tremor, somnolence, mydriasis, tachycardia, palpitation, dyspnoea, diarrhoea, nausea, vomiting, hyperhidrosis, rash, irritability, fatigue, feeling jittery, pyrexia, blood pressure increased, erectile dysfunction. Note: where frequency of adverse reactions varies across age groups (children, adolescents, adults), the adverse reaction is listed according to the highest frequency.

(pi-01047. V1.0)



1st December 2023

Dear Wholesaler,

RE: SUPPLY INTERRUPTION OF VYVANSE® (lisdexamfetamine dimesilate) 30mg, 50mg and 60mg capsules

We are writing to inform you that the intermittent interruption to the supply of VYVANSE will continue to affect its availability in Australia **until late April 2024**.

The interruption to supply has been caused by manufacturing delays compounded by increased demand. We are working hard to resolve the interruptions as soon as possible and are taking steps to help improve future supply continuity, including moving to an upgraded internal facility in mid-2024.

Based on typical usage patterns, Takeda anticipates that supply will be impacted for the following strengths:

- VYVANSE 30mg – Now until mid-March 2024
- VYVANSE 50mg – Now until mid-March 2024
- VYVANSE 60mg – Mid-December until late April 2024

As of the date of this letter, the supply of VYVANSE 20mg, 40mg and 70mg capsules are not impacted.

While we are expecting some deliveries during this time, we do not anticipate that these will be sufficient to meet usual demand. To mitigate the impact of potential stock shortages for patients, all VYVANSE orders have been placed on manual release and will be reviewed by the supply team, who will be closely monitoring inventory levels.

Please expect some orders not to be supplied in full and intermittent periods where there will be no stock available. We also kindly request you to consider this supply interruption when dispensing your stock to ensure fair distribution across the country and continued access for patients.

We understand that supply interruptions are challenging for both you and your customers and are working to resolve these as quickly as possible.

We are monitoring the situation closely and will keep you informed with regards to any supply updates. In the meantime, if you have any urgent enquiries, please contact:

- Takeda Medical Information: telephone **1800 012 612** or email: medinfoAPAC@takeda.com



Vyvanse Stock Shortage – Patient Advocacy Groups

RE: SUPPLY INTERRUPTION OF VYVANSE® (lisdexamfetamine dimesilate) 30mg, 50mg and 60mg capsules

Dear XXXX

I am writing to inform you that Takeda Pharmaceuticals Australia, the supplier of VYVANSE, is continuing to experience temporary interruptions to the supply of VYVANSE which will intermittently impact the 30mg and 50mg strengths until mid-March 2024 and 60mg strength until late April 2024.

This means that pharmacists may not be able to get stock of VYVANSE to fill the prescriptions of those individuals prescribed the doses above.

Currently, the supply of VYVANSE 20mg, 40mg and 70mg capsules are not impacted.

The interruption to supply has been caused by manufacturing delays compounded by increased demand. Takeda understands the importance of maintaining consistent treatment with VYVANSE and that supply interruptions are challenging for impacted people and their families. We are working to resolve these interruptions as quickly as possible and are taking steps to help improve future supply continuity, including moving to an upgraded internal facility in mid-2024.

If members of your community or organisation have any questions, please direct them to contact their doctor or pharmacist. They can also contact Takeda Medical Information via phone on 1800 012 612 or email: medinfoAPAC@takeda.com.

We sincerely appreciate the understanding of the ADHD community during this period.

Notifier

Notifier

Sponsor Name: Takeda Pharmaceuticals Australia Pty Ltd

Sponsor Address: Grosvenor Place Level 39 225 George Street Sydney NSW 2000

Australian telephone number for public contact purposes: 1800012612

Medical information email for public contact purposes: medinfoAPAC@takeda.com

Primary Contact

Name: §22

Phone Number: §22

Email Address: §22@takeda.com

Secondary Contact

Name: §22

Phone Number: §22

Email Address: §22@takeda.com

ARTG Entry

ARTG Entry

ARTG number of the product that has a supply disruption:

ARTG ID	ARTG Name	Active Ingredient	Strength	Dosage Form
284021	VYVANSE lisdexamfetamine dimesilate 60 mg capsules bottle	lisdexamfetamine dimesilate	60mg	Capsule, hard

ATC Descriptor: Nervous system

Are all pack sizes for this ARTG entry affected? Yes

Is this ARTG entry listed in the PBS? Yes

Provide the PBS number for this listing: 11897E

Do you have a designated sponsor representative within your organisation who is a point of contact on PBS matters? Yes

PBS Contact Details

Name: §22

Phone Number: §22

Email Address: §22@takeda.com

Details

Details

When was the shortage known to the sponsor? 21/11/2023

Nature of the shortage:	Current	
Shortage reason:	Manufacturing	Document 32
Manufacturing site problem:	Issues/delays with packaging and/or labelling	
Shortage reason - further information:		
Estimated period supply will be affected at wholesaler points:	From:	18/12/2023
	To:	19/04/2024
Availability:	Limited Availability	
TGA publication date:	24/11/2023	
Is this shortage related to other medicines within the same Therapeutic class?	No	
Is this shortage specific to Australia?	No	
Estimated normal demand volumes for Australia:	s47	
Estimated percentage share of the Australian market:	100 %	
Estimated current stock at sponsor / manufacturing level in Australia:	21202 units	
Estimated current stock at wholesaler / distributor level in Australia:	5808 units	
What is meant by 1 unit in this context:	A single pack of 30 capsules.	

Impact

Are there therapeutic alternatives on the Australian market?	Yes
What is the status of substitute options for this product in Australia?	Appropriate Therapeutic Alternatives
Are they available in adequate supplies to meet demand?	Yes
Provide details:	Alternative treatments include: methylphenidate, dexamfetamine, other strengths of lisdexafetamine
Do any specific population groups use this product?	Yes
Provide details of the groups and the impact on those groups:	Paediatric, adolescents, and adult patients with Attention Deficit Hyperactivity Disorder (ADHD), adult patients with Binge Eating Disorder (BED).
Based on your answers above and the Assessment Framework, what is the shortage impact rating?	2 - Medium Impact

Shortage Action

What communication activities have happened or are planned?	Communication Action	Date of Communication
	Letter to Wholesalers	01-Dec-2023
	Letter to Prescribers	01-Dec-2023
	Letter to Pharmacists	01-Dec-2023
	Letter to Patient Advocacy Groups	01-Dec-2023

Letter attached in Supporting Information:	No
--	----

Further comments on communications:

What supply management actions have happened or are planned?

Management Action	Date of Management Action
Constrained Supply	23-Nov-2023 Document 32
Working to expedite next shipment	23-Nov-2023

Further comments on management actions:

Supporting Information

Supporting data will be: Attached

Documents attached to this notification:

File Name	Created By	Description
Vyvanse 60mg - Replenishment Plan - Takeda Australia 23112023.pdf	Takeda	Replenishment plan

Sponsor website where medicine shortage information is available:

File Attachments

The following files have been attached to this notification.

Vyvanse 60mg	Nov-23	Dec-23	Jan-24	Feb-24	Mar-24	Apr-24
Replenishment Qty		13,713				82,200
Estimated ETA		w/c 15 Dec				w/c 15 April

May-24

From: [Medicine Shortages](#)
To: s22 [REDACTED]@takeda.com; s22 [REDACTED]@takeda.com
Subject: Meeting between TGA and Takeda - Vyvanse Shortage [SEC=OFFICIAL]

Good afternoon all,

Please see below the logon details for the virtual meeting with the Medicine Shortages Section about the shortages of Vyvanse.

Attending from the TGA will be:

* Dr s22 [REDACTED]
* s22 [REDACTED]
* s22 [REDACTED]

Please feel free to forward this invite on to colleagues who wish to attend.

Kindest regards,

s22 [REDACTED]

Pharmacist

Medicine Shortages Section
Pharmacovigilance Branch

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

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

Join meeting <<https://health-au.webex.com/health-au/j.php?MTID=m5bc739ffcc414e08facc5904f81a5239>>

More ways to join:

Join from the meeting link

<https://health-au.webex.com/health-au/j.php?MTID=m5bc739ffcc414e08facc5904f81a5239> <<https://health-au.webex.com/health-au/j.php?MTID=m5bc739ffcc414e08facc5904f81a5239>>

Join by meeting number

Meeting number (access code): 2650 405 0745

Meeting password: gBcpuZJu585

Tap to join from a mobile device (attendees only)

+61-2-9338-2221,,26504050745## <tel:%2B61-2-9338-2221,,*01*26504050745%23%23*01*> Australia Toll

Join by phone

+61-2-9338-2221 Australia Toll

Global call-in numbers <<https://health-au.webex.com/health-au/globalcallin.php?MTID=m551574019bd828a867cd34cca3cadf17>>

Join from a video system or application

Dial 26504050745@health-au.webex.com <sip:26504050745@health-au.webex.com>

You can also dial 210.4.202.4 and enter your meeting number.

If you are a host, click here <<https://health-au.webex.com/health-au/j.php?MTID=m271ab1acaecb85312d65b501840497e4>> to view host

information.

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

From: s22
To: [Medicine Shortages](#)
Cc: s22
Subject: RE: Shortages of Vyvanse (lisdexamfetamine dimesilate) capsules [SEC=OFFICIAL]
Date: Friday, 5 January 2024 11:49:02 AM
Attachments: [image002.png](#)

Hi s22

Yes, the suggested time is fine. Regarding the proposed Vyvanse 40 mg shortage notification lodgement, it will be best to submit after our discussion on Tue 9th Jan as Takeda will be able to provide better context during the discussion. Hope you are fine with this.

Kind regards

s22

From: Medicine Shortages <medicine.shortages@health.gov.au>
Sent: Friday, January 5, 2024 10:53 AM
To: s22 <[REDACTED]@takeda.com>; Medicine Shortages <medicine.shortages@health.gov.au>
Cc: s22 <[REDACTED]@takeda.com>
Subject: RE: Shortages of Vyvanse (lisdexamfetamine dimesilate) capsules [SEC=OFFICIAL]

Thanks s22

Would 2pm on Tuesday 9th be suitable?

If so I will send through a meeting invite.

Regards,

s22


s22

Pharmacist
Medicine Shortages Section
Pharmacovigilance Branch

Phone: s22

Email: medicine.shortages@health.gov.au

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



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From: s22 [redacted] <s22@takeda.com>
Sent: Thursday, 4 January 2024 5:18 PM
To: Medicine Shortages <medicine.shortages@health.gov.au>
Cc: s22 [redacted] <s22@takeda.com>
Subject: RE: Shortages of Vyvanse (lisdexamfetamine dimesilate) capsules [SEC=OFFICIAL]

Hi s22 [redacted]

Thank you for your prompt response. My apologies, I just found not all of my colleagues are available on Monday, therefore could we have the meeting on Tue 9th or Wed 10th Jan please at a time suitable to TGA?

I also want to let you know Takeda will be lodging a shortage notification via TGA eBS for Vyvanse 40mg soon.

Kind regards

s22 [redacted]

From: Medicine Shortages <medicine.shortages@health.gov.au>
Sent: Thursday, January 4, 2024 5:01 PM
To: s22 [redacted] <s22@takeda.com>
Cc: s22 [redacted] <s22@takeda.com>
Subject: RE: Shortages of Vyvanse (lisdexamfetamine dimesilate) capsules [SEC=OFFICIAL]

Good afternoon s22 [redacted]

Thank you for your offer, and we can forward an invite for 11am on Monday, if that suits your team?

The TGA representatives will be Dr s22 [redacted] and s22 [redacted], the s22 [redacted] of the Medicine Shortages Section (MSS) of the TGA, and s22 [redacted], one of the MSS s22 [redacted]

s22 [redacted]

Kindest regards,

s22 [redacted]

Pharmacist
Medicine Shortages Section
Pharmacovigilance Branch

Phone: s22 [redacted]

Email: medicine.shortages@health.gov.au

Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100
Woden ACT 2606

www.tga.gov.au



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From: s22 [redacted] <s22@takeda.com>
Sent: Thursday, 4 January 2024 4:09 PM
To: Medicine Shortages <medicine.shortages@health.gov.au>
Cc: s22 [redacted] <s22@takeda.com>
Subject: FW: Shortages of Vyvanse (lisdexamfetamine dimesilate) capsules [SEC=OFFICIAL]

Hi s22 [redacted] and s22 [redacted]

Takeda wish to have a meeting with the TGA to discuss the VYVANSE shortage situation. Could I request a meeting say on 8-Jan-2024, please let me know a suitable time and if you choose to send a meeting invite. From our end we will have regulatory affairs, commercial, supply chain, quality assurance and medical affairs personnel. Please if could confirm participants from TGA's end.

Thank you.
Kind regards
s22 [redacted]

From: s22 [redacted]
Sent: Wednesday, January 3, 2024 9:51 AM
To: Medicine Shortages <medicine.shortages@health.gov.au>; s22 [redacted] <s22@takeda.com>; s22 [redacted] <s22@takeda.com>; s22 [redacted] <s22@takeda.com>; s22 [redacted] <s22@takeda.com>
Subject: RE: Shortages of Vyvanse (lisdexamfetamine dimesilate) capsules [SEC=OFFICIAL]

Hi s22 [redacted]

I acknowledge receipt of TGA's request and wish to advise you company's response will be submitted early next week.

Thank you
Kind regards
s22 [redacted]



Better Health, Brighter Future

s22 [redacted] PhD
s22 [redacted] – Oceania Cluster

Takeda Pharmaceuticals Australia Pty Ltd

Grosvenor Place, Level 39
225 George Street
Sydney NSW 2000 Australia

Mobile: +s22
s22 @takeda.com

From: Medicine Shortages <medicine.shortages@health.gov.au>

Sent: Tuesday, January 2, 2024 4:16 PM

To: s22 @takeda.com>; s22 @takeda.com>;
s22 @takeda.com>; s22 @takeda.com>; s22
s22 @takeda.com>

Subject: RE: Shortages of Vyvanse (lisdexamfetamine dimesilate) capsules [SEC=OFFICIAL]

Good afternoon everyone,

I hope you all had a wonderful Christmas and New Year.

Following on from the publishing of the webpage about the shortages of Vyvanse at the very end of last year, I wanted to touch base with Takeda regarding the reasons for the extension of these shortages to now include the 60mg, and prolonging the shortage of the 30 mg product to March 2024. Given the lack of generic lisdexamfetamine products in Australia, there is marked public interest in the veracity of the resolution dates for these shortages, as well as the risk of the shortages affecting other strengths.

In August 2023, the US FDA and DEA [published a joint letter](#) outlining the quotas placed on the production of lisdexamfetamine medicines, and how these limitations may affect the shortages in that country. When the shortages of Vyvanse in Australia were first notified to the TGA, the reason given for the shortages was GMP clearance issues with a labelling facility in Ireland. If you could confirm whether these shortages are also impacted by production constraints as a result of the quotas imposed by the US jurisdictions, it would assist us greatly as we plan our mitigation activities.

We would greatly appreciate any information you can provide about:

- The impact of US FDA/DEA quotas on the production of the Vyvanse products marketed in Australia,
- Where the Australian supplies of these medicines are manufactured and shipped from, and
- The likelihood of these shortages extend to include other strengths.

Thanks so much for your assistance,

s22
Pharmacist
Medicine Shortages Section
Pharmacovigilance Branch

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

Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100

Woden ACT 2606

www.tga.gov.au



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From: Medicine Shortages <medicine.shortages@health.gov.au>

Sent: Friday, 22 December 2023 12:37 PM

Subject: Medicine shortage alert published - Shortage of Vyvanse (lisdexamfetamine dimesilate) capsules [SEC=OFFICIAL]

Good afternoon,

We have just published [About the shortages of Vyvanse \(lisdexamfetamine dimesilate\) capsules](#), which contains key information about these shortages for patients, carers and healthcare professionals.

Thank you very much for your support, advice and feedback as we navigate this difficult shortage.

Best wishes to you and your families over the holiday break.

Kindest regards,

s22

Pharmacist

Medicine Shortages Section

Pharmacovigilance Branch

Phone: s22

Email: medicine.shortages@health.gov.au

Therapeutic Goods Administration

Department of Health and Aged Care

PO Box 100

Woden ACT 2606

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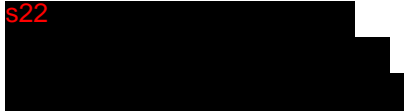
"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are

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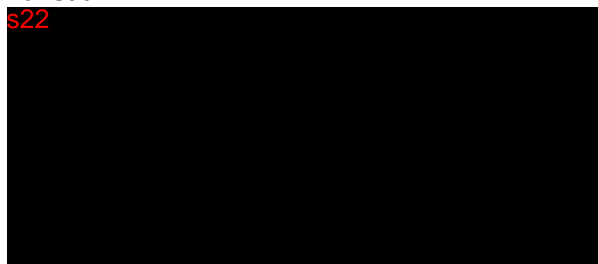
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TGA meeting with Takeda Pharmaceuticals re: Vyvanse shortages**Date: 9 Jan 2024****Time: 2.00-3.10pm****Attendees:****TGA – Medicine Shortages Section:**

s22


- pharmacist**Takeda:**

s22

**Shortage of Vyvanse 40mg capsules**

- s22 provided an update on the shortage of Vyvanse 40mg capsules. The reason for the shortage of 40mg strength is increase in demand due to the shortage of other strengths and redistribution of patients.
- They provided data and graph indicating that number of patients on Vyvanse 30mg dropped by 60% in sept 2023 whilst patient on 40mg increased by 26% and 60mg by 15%. Switch from 30mg to 40mg tripled to 6000 in sept vs July 2023 and new patient initiation on 40mg strengths increased to 1,700 in sept, double that of August 2023. They emphasized that the challenge is to understand the demand. They noticed uplift after each communication. They have access to the Medicare data indicating number of patients on each strength, however there is 3 months lag with that information. It is complicated for them to make future prediction as this increase in demand is just for this point in time. Currently they are planning to hold 10,000 units of emergency stock for the strengths in shortage.

S8 Receipt Documentation issue

- There are no shortages of 20mg and 70mg strengths. Shortage impact is considered low risk for those strengths, but it is hard for them to predict at his stage.
- There is still stock pending dispatch due to the S8 documentation not received by DHL which had compounded the issue further.
- To assist, they have explored the option of accepting email version of the S8 document but that was not successful.
- DHL are emailing and calling wholesalers and pharmacies to chase for pending documentation.
- Express pre-paid envelope is sent with each order for prompt document return.

Other points

- They confirmed that they adhered to the supply plan that manufacturer gave and the shortage of Vyvanse 40mg is not related to supply plan.

- In April 2024 they will be switching to another manufacturing plan in Germany. From April to September, they will have stock coming from both sites in Germany and Ireland and they anticipate shortages to resolve then. From September onwards, they will only be getting stock from Germany site.
- There are still constrain on the MFG site due to packaging issues. They are trying to bolster the supply with the new site in Germany which will help build the safety stock.
- We asked if they could get any stock from other markets for supply under S19A which they couldn't. They advised that Australia was allocated more stock than other countries despite the constraints.
- We asked them if they have seen any stock piling behavior which they said they do not have visibility of stock piling. We advised them to inform us if they are concerned about this so that we can assist with constraining stock at the wholesaler level.
- They also advised us that managing their emergency stock has been challenging for them. Their caveat is urgent patient need. Their current position is they do not reject any patient request, but they regularly need to monitor their emergency supply.
- s47

Communication

- Takeda is aware of the changing nature of supply situation, and they need to communicate in timely manner with the most up to date information. And the information provided from Takeda and the TGA aligns.
- They proposed to use TGA's webpage for the Vyvanse shortages as a single source of information for everyone. They are developing most frequently asked questions and they are happy to share that with us and provide most accurate shortage information so that the TGA webpage can provide patients and health care professionals with single source of information.
- For the shortage of they will be putting another communication but they will also like to use provide direction for future comms using the TGA webpage.
- Takeda is close to launching online process to request the Emergency stock which will be more efficient and less time consuming. And by having the TGA webpage they can direct pharmacists, how to order the Emergency stock.

Key areas outside of Takeda Control for consideration

- Cost of the section 19A alternative.
- MoH requirements for receipt of S8 document.
- Pharmacy substitution of alternative strengths – Pharmacist's frustration due to lack of SSSI
- Hard copy script limitations – Takeda have received feedback that some jurisdictions are required to hold the repeats for the S8 prescriptions at the particular pharmacy which is challenging in shortages and patients are not able to move to alternative pharmacy which has stock available.
- Takeda is happy to communicate these with us as they become aware of more. They said any support we can provide as an interim solution they will be happy for discussion. They would like to have an open dialogue with the team. But all agreed that the best solution is to provide the most accurate information.

US supply issues

- Takeda advised that the current interruption to supply is not related to any US FDA/DEA Aggregate Production quota for Vyvanse active pharmaceutical ingredient (API), however, it has potential to impact as the diagnosis of ADHD is increasing and they are anticipated increased demand for Vyvanse for 2024.
- The DEA indicated in Nov 2023 that the 2024 aggregate production quota for lisdexamphetamine base API would be held flat to 2023.
- In December, Takeda made a submission to the FDA/DEA on behalf of all Takeda marketing companies affected.
- Submissions were also made by certain Australian professionals and patient ADHD groups.
- Despite more than 4500 submissions being received, the DEA have not changed their position regarding the 2024 production quota.

Next steps

- Takeda to submit an anticipated MSN for Vyvanse 40mg.
- Takeda to share their slides with MSS.
- Takeda to share any communication they propose to send out to align our comms and to share their frequently asked questions to update our comms.

From: [Medicine Shortages](#)
To: s22
Cc: s22
Subject: RE: VYVANSE 40 mg medicine shortage. MS-2024-00125-1.
Date: Friday, 12 January 2024 4:41:43 PM
Attachments: [image005.png](#)
[image002.png](#)

Dear s22

I'm well thank you and hope you are too.

I appreciate you responding back to my previous email about the supply interruption of Vyvanse 20mg strengths. I confirm we have received the document, Response to TGA RFI.

In regards the MSN for Vyvanse 40mg capsules, we are happy to defer the publication until 17 Jan 2024 as requested.

Thanks so much for your ongoing collaboration.

Kind Regards

s22

s22

Pharmacist- Medicine Shortages Section

Pharmacovigilance Branch

Medicine Regulation Division | Health Products Regulation Group

Phone: s22

Email: medicine.shortages@health.gov.au

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

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From: s22@takeda.com>
Sent: Friday, 12 January 2024 3:01 PM
To: Medicine Shortages <medicine.shortages@health.gov.au>
Cc: s22@takeda.com>
Subject: VYVANSE 40 mg medicine shortage. MS-2024-00125-1.

Dear Medicines Shortage Team

An anticipated shortage notification for VYVANSE 40 mg has been submitted via TGA eBS. Since the shortage commencement date is 22-Jan-2024, the system did not allow entering a request for deferred date of publication. I wish to check with you if it possible for the TGA to delay publishing until 17-Jan-2024.

I will be grateful if you could advise as soon as possible.

Thank you.

Kind regards

s22



Better Health, Brighter Future

s22 PhD

s22 – Oceania Cluster

Takeda Pharmaceuticals Australia Pty Ltd

Grosvenor Place, Level 39
225 George Street
Sydney NSW 2000 Australia

Mobile: +s22

s22 @takeda.com

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From: s22
To: [Medicine Shortages](#)
Cc: s22
Subject: RE: Vyvanse 20mg - Potential Supply Issue [SEC=OFFICIAL]
Date: Friday, 12 January 2024 3:24:40 PM
Attachments: [image004.png](#)
[image005.png](#)
[image006.png](#)
[image007.jpg](#)
[RE Shortages of Vyvanse \(lisdexamfetamine dimesilate\) capsules_SECOFFICIAL.msg](#)

Dear s22

Hope all well with you too. Please see attached response provided to TGA's RFI in which company response to Q3 covers your query below.

I hope this addresses your request. Please contact me should you need any further clarification.

Kind regards

s22



s22 PhD

s22 – Oceania Cluster

Takeda Pharmaceuticals Australia Pty Ltd

Grosvenor Place, Level 39
225 George Street
Sydney NSW 2000 Australia

Mobile: +s22

s22 @takeda.com

From: Medicine Shortages medicine.shortages@health.gov.au

Sent: Thursday, January 4, 2024 11:44 AM

To: s22 @takeda.com>

Cc: s22 @takeda.com>

Subject: Vyvanse 20mg - Potential Supply Issue [SEC=OFFICIAL]

Dear s22

Hope you are well and had a wonderful break over holidays.

I'm reaching out as we have received an enquiry of the current supply issues Vyvanse 20mg capsules.

I note that in December wholesalers were out of stock due to non-compliance regarding the return of the S8 receipt document. Has that issue been resolved now and if not when is the stock anticipated to reach to wholesalers?

Any information that you could provide regarding this would be greatly appreciated.

Kind Regards

s22

Pharmacist- Medicine Shortages Section

Pharmacovigilance Branch

Medicine Regulation Division | Health Products Regulation Group

Phone: s22

Email: medicine.shortages@health.gov.au

Therapeutic Goods Administration

Department of Health and Aged Care
PO Box 100
Woden ACT 2606

www.tga.gov.au

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From: s22 [redacted] <s22@takeda.com>

Sent: Friday, 15 December 2023 10:44 AM

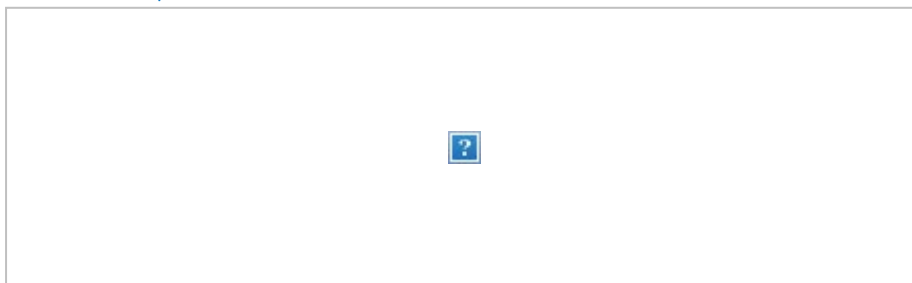
To: Medicine Shortages <medicine.shortages@health.gov.au>

Subject: RE: Vyvanse 40mg - Potential Supply Issue [SEC=OFFICIAL]

Dear s22 [redacted]

Thank you for your email and hope all well. Following is the information your requested:

- There is no stock shortage issue with Vyvanse 20mg, 40mg and 70mg, please refer to current stock position at Takeda.



- Wholesalers are at low stock or OOS due to non-compliance regarding the return of the S8 receipt document, as required by NSW Ministry of Health.
Until the hard copy of the S8 document is received (via post) by our 4PL provider, orders are placed on dispatch hold.
- Takeda Australia has been in contact with wholesalers, requesting their support to ensure the mandatory S8 documents are returned in timely manner.
- As there is high risk of delay in posted mails deliveries during the holiday period, Takeda Australia has instructed our 4PL to include an Express Post envelope with each delivery at Takeda's cost.
This will hopefully lower the risk on the delay of the S8 documents returns.
- As of today, 15th December our 4PL provider has dispatched a large number of orders to various wholesalers.
We are expecting these deliveries to be received in their respective Distribution Centres next week.

Please contact me should you need any clarification or further information.

Kind regards

s22 [redacted]



s22 [redacted] PhD

s22 [redacted] – Oceania Cluster

Takeda Pharmaceuticals Australia Pty Ltd

Grosvenor Place, Level 39
225 George Street
Sydney NSW 2000 Australia
Mobile: +s22
s22 @takeda.com

From: Medicine Shortages <medicine.shortages@health.gov.au>

Sent: Thursday, December 14, 2023 10:13 AM

To: s22 @takeda.com>

Subject: Vyvanse 40mg - Potential Supply Issue [SEC=OFFICIAL]

Dear s22

I hope all is well.

Thank you for providing the copies of the communication letters sent to healthcare professionals about the shortage of Vyvanse products.

We have recently received an enquiry stating patients are now unable to obtain the 40mg strength of Vyvanse.

Noting that the communications you recently sent through stated that (as of 1 December 2023) that there was no issues with the supply of 40mg Vyvanse, are you able to provide any update on the current supply of this strength? Any information that you could provide regarding this would be greatly appreciated.

If there is any potential supply issues with this strength, it would be greatly appreciated if a shortage notification could be submitted so that we can continue to keep consumers and health professionals informed.

Kind regards,

s22

s22

**Pharmacist – Medicine Shortages Section
Pharmacovigilance Branch**

Medicines Regulation Division | Health Products Regulation Group

Australian Government, Department of Health and Aged Care

T: s22 | E: medicine.shortages@health.gov.au

Location: Fairbairn

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 @takeda.com>

Sent: Monday, 4 December 2023 7:39 AM

To: Medicine Shortages <medicine.shortages@health.gov.au>

Subject: VYVANSE communication letters: 30mg (MS-2023-NT-00980-1), 50mg (MS-2023-NT-01341-1) and 60 mg (MS-2023-NT-01486-1).

Dear s22

Please find attached here copies of communication letters sent to prescribers, wholesalers, pharmacies, and patient organisations. The shortage notifications details are as follows:

VYVANSE 30mg capsule: MS-2023-NT-00980-1

VYVANSE 50mg capsule: MS-2023-NT-01341-1

VYVANSE 60mg capsule: MS-2023-NT-01486-1.

Please contact me should you need any clarification.

Thank you

Kind regards

s22





s22 [redacted] PhD

s22 [redacted] – Oceania Cluster

Takeda Pharmaceuticals Australia Pty Ltd

Grosvenor Place, Level 39
225 George Street
Sydney NSW 2000 Australia

Mobile: +s22 [redacted]

s22 [redacted] [@takeda.com](mailto:[redacted]@takeda.com)

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From: s22
To: [Medicine Shortages](#); s22
Subject: RE: Shortages of Vyvanse (lisdexamfetamine dimesilate) capsules [SEC=OFFICIAL]
Attachments: [image001.gif](#)
[image002.png](#)
[image003.jpg](#)
[Response to TGA RFI dated 2-Jan-2024.pdf](#)

Hi s22

Thank you for your query. Please find attached company response document attached here.
Please contact me should you require any clarification or further information.

Kind regards

s22



s22 PhD

s22 – Oceania Cluster

Takeda Pharmaceuticals Australia Pty Ltd

Grosvenor Place, Level 39
225 George Street
Sydney NSW 2000 Australia
Mobile: s22

s22 [@takeda.com](#)

From: Medicine Shortages <medicine.shortages@health.gov.au>

Sent: Tuesday, January 2, 2024 4:16 PM

To: s22 [@takeda.com](#); s22 [@takeda.com](#); s22 [@takeda.com](#); s22 [@takeda.com](#); s22 [@takeda.com](#)

Subject: RE: Shortages of Vyvanse (lisdexamfetamine dimesilate) capsules [SEC=OFFICIAL]

Good afternoon everyone,

I hope you all had a wonderful Christmas and New Year.

Following on from the publishing of the webpage about the shortages of Vyvanse at the very end of last year, I wanted to touch base with Takeda regarding the reasons for the extension of these shortages to now include the 50mg, and prolonging the shortage of the 30 mg product to March 2024. Given the lack of generic lisdexamfetamine products in Australia, there is marked public interest in the veracity of the resolution dates for these shortages, as well as the risk of the shortages affecting other strengths.

In August 2023, the US FDA and DEA [published a joint letter](#) outlining the quotas placed on the production of lisdexamfetamine medicines, and how these limitations may affect the shortages in that country. When the shortages of Vyvanse in Australia were first notified to the TGA, the reason given for the shortages was GMP clearance issues with a labelling facility in Ireland. If you could confirm whether these shortages are also impacted by production constraints as a result of the quotas imposed by the US jurisdictions, it would assist us greatly as we plan our mitigation activities.

We would greatly appreciate any information you can provide about:

- The impact of US FDA/DEA quotas on the production of the Vyvanse products marketed in Australia,
- Where the Australian supplies of these medicines are manufactured and shipped from, and

The likelihood of these shortages extend to include other strengths.

Thanks so much for your assistance,

s22

Pharmacist

Medicine Shortages Section

Pharmacovigilance Branch

Phone: s22

Email: medicine.shortages@health.gov.au

Therapeutic Goods Administration

Department of Health and Aged Care

PO Box 100

Woden ACT 2606

www.tga.gov.au



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From: Medicine Shortages <medicine.shortages@health.gov.au>

Sent: Friday, 22 December 2023 12:37 PM

Subject: Medicine shortage alert published - Shortage of Vyvanse (lisdexamfetamine dimesilate) capsules [SEC=OFFICIAL]

Good afternoon,

We have just published [About the shortages of Vyvanse \(lisdexamfetamine dimesilate\) capsules](#), which contains key information about these shortages for patients, carers and healthcare professionals.

Thank you very much for your support, advice and feedback as we navigate this difficult shortage.

Best wishes to you and your families over the holiday break.

Kindest regards,

s22

Pharmacist

Medicine Shortages Section

Pharmacovigilance Branch

Phone: s22

Email: medicine.shortages@health.gov.au

Therapeutic Goods Administration

Department of Health and Aged Care

PO Box 100

Woden ACT 2606

www.tga.gov.au



The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community.

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VYVANSE® (lisdexamfetamine dimesilate)
Responses to TGA Medicines Shortages List of Questions dated 2-Jan-2024

12-Jan-2024

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1.0 LIST OF QUESTIONS

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2.0 RESPONSES

Question 1 The impact of US FDA/DEA quotas on the production of the Vyvanse products marketed in Australia.

RESPONSE

- The current interruption to supply is NOT related to any DEA production quotas or restrictions on API.
- The DEA indicated in November 2023 that the 2024 Aggregate Production Quota for lisdexamfetamine base API would be held flat to 2023.
- In December, Takeda made a submission to the FDA/DEA on behalf of all Takeda marketing companies affected.
- Submissions were also made by certain Australian professional and consumer ADHD interest groups.
- Despite more than 4,500 submissions being received, the DEA have not changed their position regarding the 2024 production quota.

Question 2 Where the Australian supplies of these medicines are manufactured and shipped from.

RESPONSE

Finished product manufacturer:	Patheon Manufacturing Services LLC 5900 Martin Luther King Jr Highway Greenville, Nor Carolina , 27834 United States Of America OR Patheon Pharmaceuticals Inc 2110 East Galbraith Road Cincinnati , Ohio , 237-1625 United States Of America
Packaging and labelling; and shipped from	Wasdell Europe Limited IDA Dundalk Science and Technology Park Mullagharlin Dundalk , Co Louth , A91 DET0 Ireland

Question 3 The likelihood of these shortages extend to include other strengths.

RESPONSE

There has been a significant increase of VYVANSE 40mg as a result of patients who were previously on 30mg or 50mg strengths being redistributed to 40mg and we are anticipating stock to be impacted at wholesalers by the 22nd January until the end of April 2024. A shortage notification is being submitted online today.

Whilst the demand for VYVANSE 70mg has also increased as a result of patients who were previously on other strengths moving to 70mg we have assessed the risk for this strength as well as the 20mg as low but we will continue to monitor and keep you informed of any change in risk.

Notifier

Notifier

Sponsor Name: Takeda Pharmaceuticals Australia Pty Ltd

Sponsor Address: Grosvenor Place Level 39 225 George Street Sydney NSW 2000

Australian telephone number for public contact purposes: 1800012612

Medical information email for public contact purposes: medinfoAPAC@takeda.com

Primary Contact

Name: §22

Phone Number: +§22

Email Address: §22@takeda.com

Secondary Contact

Name: §22

Phone Number: §22

Email Address: §22@takeda.com

ARTG Entry

ARTG Entry

ARTG number of the product that has a supply disruption:

ARTG ID	ARTG Name	Active Ingredient	Strength	Dosage Form
284020	VYVANSE	lisdexamfetamine dimesilate	40mg	Capsule, hard

ATC Descriptor: Nervous system

Are all pack sizes for this ARTG entry affected? Yes

Is this ARTG entry listed in the PBS? Yes

Provide the PBS number for this listing: 11898F

Do you have a designated sponsor representative within your organisation who is a point of contact on PBS matters? Yes

PBS Contact Details

Name: §22

Phone Number: §22

Email Address: §22@takeda.com

Details

Details

When was the shortage known to the sponsor? 04/01/2024

Nature of the shortage:	Anticipated
Shortage reason:	Unexpected increase in consumer demand Document 39
Shortage reason - further information:	
Estimated period supply will be affected at wholesaler points:	From: 22/01/2024 To: 30/04/2024
Availability:	Available
Indicate preference for date of publication:	Date of processing
Is this shortage related to other medicines within the same Therapeutic class?	Yes
Other medicines details:	Vyvanse 30mg, 50mg, 60mg
Is this shortage specific to Australia?	No
Estimated normal demand volumes for Australia:	s47
Estimated percentage share of the Australian market:	100 %
Estimated current stock at sponsor / manufacturing level in Australia:	30000 units
Estimated current stock at wholesaler / distributor level in Australia:	823 units
What is meant by 1 unit in this context:	A single pack of 30 capsules.

Impact

Are there therapeutic alternatives on the Australian market?	Yes
What is the status of substitute options for this product in Australia?	Appropriate Therapeutic Alternatives
Are they available in adequate supplies to meet demand?	Yes
Provide details:	Alternative therapeutic alternatives include methylphenidate and dexamfetamine.
Do any specific population groups use this product?	Yes
Provide details of the groups and the impact on those groups:	Paediatric, adolescents, and adult patients with attention deficit hyperactivity disorder (ADHD), adults with binge eating disorder (BED).
Based on your answers above and the Assessment Framework, what is the shortage impact rating?	2 - Medium Impact

Shortage Action

What communication activities have happened or are planned?

Communication Action	Date of Communication
Letter to Wholesalers	12-Jan-2024
Letter to Pharmacists	22-Jan-2024
Letter to Prescribers	22-Jan-2024

Letter attached in Supporting Information: No

Further comments on communications:

What supply management actions have happened or are planned?

Management Action	Date of Management Action
Constrained Supply	04-Jan-2024

Further comments on management actions:

Document 39

Supporting Information

Supporting data will be:

Attached

Documents attached to this notification:

File Name	Created By	Description
Vyvanse 40mg - Replenishment Plan - Takeda Australia 04012024.pdf	Takeda	Replishment plan

Sponsor website where medicine shortage information is available:

File Attachments

The following files have been attached to this notification.

Vyvanse 40mg	Jan-24	Feb-24	Mar-24	Apr-24
Replenishment Qty			52,115	50,000
Estimated ETA			w/c 4 Mar	w/c 12 Apr

May-24
35,000
w/c 13 May

From: s22
To: [Medicine Shortages](#); s22
Subject: RE: VYVANSE medicine shortage meeting minutes of 9-Jan-2024 [SEC=OFFICIAL]
Date: Tuesday, 16 January 2024 2:19:19 PM
Attachments: [image001.png](#)
[image002.jpg](#)
[20240109 Takeda-TGA VYVANSE Shortage Meeting Minutes.pdf](#)
[Takeda TGA Meeting Vyvanse Supply_240109 V2.pdf](#)

Thanks s22 just copying in s22 too I think we could probably ask for s22 help updating the web statements in line with publication tomorrow – what do u all think?

From: Medicine Shortages <medicine.shortages@health.gov.au>
Sent: Tuesday, 16 January 2024 2:17 PM
To: s22 @health.gov.au; s22 @health.gov.au; s22 @Health.gov.au; s22 @health.gov.au
Subject: FW: VYVANSE medicine shortage meeting minutes of 9-Jan-2024 [SEC=OFFICIAL]

Hi team,

I'm just forwarding this to everyone in the minutes, hope this is OK.

Kind regards

s22

From: s22 @takeda.com>
Sent: Tuesday, 16 January 2024 2:13 PM
To: Medicine Shortages <medicine.shortages@health.gov.au>
Cc: s22 @takeda.com>
Subject: VYVANSE medicine shortage meeting minutes of 9-Jan-2024

Dear s22

Thank you so much for the discussion on VYVANSE medicine shortages. Please find attached here meeting minutes and copy of Takeda's presentation.

Further to this, Takeda wish to request your feedback on the following please:

- Given the shortage notification has now been lodged for VYVANSE 40mg, what is the timeframe for TGA to update information regarding this strength on the TGA's VYVANSE medicine shortage website page <https://www.tga.gov.au/safety/shortages/information-about-major-medicine-shortages/about-shortages-vyvanse-lisdexamfetamine-dimesilate-capsules>
- As proposed in the meeting, Takeda wish to provide updates to TGA's VYVANSE medicine shortage website page to help maintain latest information. Could you please let me know what the process is to meet this end.

I will be grateful if you could provide your feedback as soon as possible.

Thank you again.

Kind regards

s22



s22 PhD

s22 – Oceania Cluster

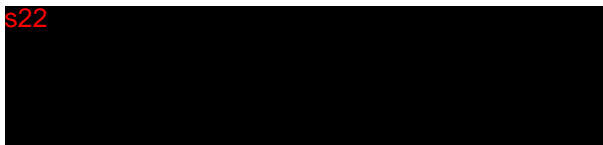
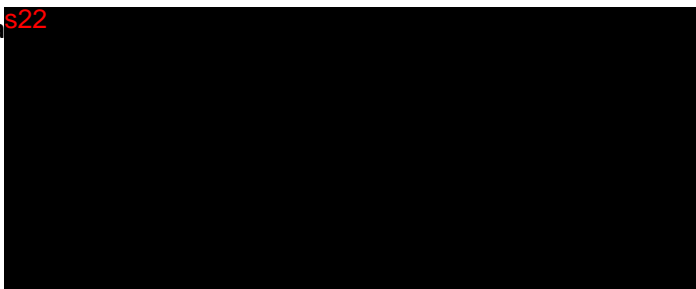
Takeda Pharmaceuticals Australia Pty Ltd

Grosvenor Place, Level 39
225 George Street
Sydney NSW 2000 Australia

Mobile: +s22

s22 @takeda.com

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TGA meeting with Takeda Pharmaceuticals re: Vyvanse Medicine Shortages**Date: 09-Jan-2024****Time: 2.00-3.00pm****Attendees:****TGA – Medicine Shortages Section: s22****Takeda s22**

Meeting started at 2.02pm with the introduction of both teams.

s22 started by giving the TGA an introduction setting the scene to how shortages started and developed leading up to the current situation. Vyvanse 30mg shortage started in August-2023 at which time it was anticipated to last to end December 2023. Takeda had a meeting with the TGA in Aug-2023 and following that, communication letters were dispatched to all stakeholders.

s22 presented the Vyvanse 40mg stock situation and the anticipated shortage. The reason for the 40mg shortage is due to the significant increase in demand following the current shortages in the 20mg, 30mg, and 50mg presentations. As with any medicine shortage, demand increases for the available presentations because i) buy-up situations vs. standard demand, and ii) patients' redistribution across remaining presentations.

s22 then presented an overview of stock levels (all presentations) at Takeda and wholesalers levels, and the expected shipments from Ireland and Germany until Jun-2024. JS also presented the following points:

- An initial 10,000 units from every impacted SKU are preserved as 'emergency supply' from the time of confirmed shortage
- There have been no changes to the supply plan for 40mg
- From Apr to Jun 2024 there will be dual supply from both Ireland and Germany
- Jul-2024 onwards, supply from Germany only
- The 40mg stock is expected to exhaust in Jan 2024
- To mitigate delays in receipt of S8 documentation, Takeda is providing an Express Pre-Paid envelope with every order for return of those documents. Takeda also explored whether emailed and/or scanned copies of receipts would be acceptable as an interim measure, but that was not accepted
- All wholesalers currently have stock of Vyvanse 20mg

s22 discussed the communication plan noting that the standard (conventional) one is becoming less efficient with each shortage notification as it's heavily impacted by the accuracy of the email and mailing lists, notifications might not be received or opened on time, etc. Therefore, there is a need to communicate in a more timely manner and to ensure consistency with the content of TGA

communications. Takeda proposed to partner with the TGA to use the Medicines Shortage page (Vyvanse-specific) on the TGA website as a single source of information and to direct stakeholders here for the most up-to-date information; for that purpose, Takeda's subsequent communication letters will include direction to the TGA website. Takeda will also provide a list of FAQs (including responses) for TGA to review before aligning on agreed content to reflect on the TGA page.

s22 then talked about the DEA quota explaining that the DEA have confirmed that the 2024 quota remain flat to 2023 despite more than 4500 submissions supporting an appropriate increase.

TGA Questions

- s22** Shortage reason - concerns that we didn't forecast/model for the increased demand in the available strengths. What is the current reason for the shortage (previously the cause of the shortage was GMP issues at Ireland site; have those been resolved?)
Response: GMP situation at Wasdell site has improved but it is not the cause for the 40mg shortage as we are experiencing more than anticipated increase in demand for the 40mg strength. Takeda has been expecting redistribution to 40mg given current shortages for 30mg, 50mg and 60 mg strengths (due to manufacturing delays), and proactively communicated with KOLs to see how patients can be managed, and then used this information to model demand forecast. However, the shortages of the strengths complicated the situation and demand outstripped modelling.
- s22** Surge in uptake of 20mg strength will now be expected after Takeda notifies 40mg shortage.
Response: Yes, that possibility is anticipated. With the current level of supplies coming through and modelling, Takeda does not anticipate shortage situation for 20mg and 70mg however we will continue to monitor this.
- s22** Has Takeda considered supply under S19A.
Response: Yes, we have considered it but, unfortunately, we have no global surplus stock for Vyvanse. Takeda was also not successful in obtaining US-labeled stock.
- s22** is Takeda aware of any signs of stockpiling at pharmacies?
Response: Takeda has no visibility at that level, only at wholesalers, but is currently exploring ways to see if this data can be obtained noting that DoH can assist with constraining wholesalers.
- s22** Does Takeda consider that we will be resolving the supply issues in March/April 2024?
Response: yes, but also noted that returning patients to their original prescriptions could take a few weeks/months, which could elongate the shortages.
- s22** S8 Receipt Documentation - Did this just start? Is it related to a single order?
Response: this is ongoing, and we'll continue to provide pre-paid (express post) envelopes with each order.
- s22** when does Takeda Australia patent for Vyvanse expire?
Response: this information is commercial in confidence however not for several years.

Takeda Questions

- s22** Takeda proposes partnering with TGA for updating TGA's Vyvanse shortage page, for e.g. Takeda would like to share commonly asked questions and responses which could be helpful to HCPs. The aim is to have aligned messaging.

Response: TGA sees the value of this proposal and it supports and welcomes the partnership with Takeda to keep the Vyvanse shortage page, including FAQs, up-to-date. There are restrictions by TGA regarding wording of responses to FAQs so will need to collaborate with Takeda before uploading.

- **s22** raised obstacles and challenges that have been shared with Takeda through our Medical Information team to date throughout the shortage, including: complexity of S8 prescription requirements, substitution of alternative strengths of Vyvanse at pharmacies, prescription hard copies being held at individual pharmacies.

Next Steps:

- Submit 40mg Notification and provide communication letters once available.
- Submit all information and FAQs to the Medicines Shortage Inbox for TGA review and upload.
- Continue to update modelling for 20mg and 70mg to anticipate impact of demand increase vs supply

Meeting ended at 3.10pm.



Takeda & TGA Meeting

VYVANSE (lisdexamphetamine) supply

9th January 2024



Vyvanse Supply - Agenda



#	Title	Lead
1	Welcome and introduction	s22 [redacted] Medicine Shortages Section, TGA s22 [redacted] Takeda Pharmaceuticals
2	VYVANSE Supply & Demand overview	s22 [redacted] Takeda Pharmaceuticals s22 [redacted] Takeda Pharmaceuticals
3	Communication plan	s22 [redacted] Takeda Pharmaceuticals
4	Customer Feedback, Challenges and Bottlenecks	s22 [redacted] Takeda Pharmaceuticals
5	DEA Aggregate Production Quota 2024	s22 [redacted] Takeda Pharmaceuticals
6	Q & A & Next Steps	All participants

VYVANSE Stock Levels



Stock on Hand at Takeda @ 8th January

	Takeda	Emergency stock to be held at all times	Takeda / TGA notifications
Vyvanse 20mg	53,235	10,000	
Vyvanse 30mg	9,129	10,000	TGA notification Aug-23 (Disruption from Aug-23 - Dec-23) Extension to notification from Dec-23 - Apr-24
Vyvanse 40mg	29,942	10,000	Discussion on potential supply disruption
Vyvanse 50mg	24,863	10,000	TGA notification Oct-23 (Disruption from Nov-23 - Dec-23) Extension to notification from Dec-23 - Apr-24
Vyvanse 60mg	19,911	10,000	TGA notification Nov-23 (Disruption from Dec-23 - Apr-24)
Vyvanse 70mg	45,695	10,000	

Stock on Hand at Wholesalers @ 8th January

WHOLESALEERS	SYMBION				API				SIGMA			
	SOH (08.12)	Ave Weekly Normal Demand	Ave Week Cover based on Normal Demand	Pending Dispatch from Takeda (S8 document pending)	SOH (08.12)	Ave Weekly Normal Demand	Ave Week Cover based on Normal Demand	Pending Dispatch from Takeda (S8 document pending)	SOH (08.12)	Ave Weekly Normal Demand	Ave Week Cover based on Normal Demand	Pending Dispatch from Takeda (S8 document pending)
Vyvanse 20mg	s47											
Vyvanse 30mg												
Vyvanse 40mg												
Vyvanse 50mg												
Vyvanse 60mg												
Vyvanse 70mg												

Replenishment from Ireland

*** ADDITIONAL SUPPLY FROM GERMANY TO BE ADDED***

Source : Wasdell	Dec-23	Jan-24	Feb-24	Mar-24	Apr-24	May-24	Jun-24
Vyvanse 20mg	24,567	25,330		50,000			
Vyvanse 30mg		46,824		40,000	67,500	135,000	
Vyvanse 40mg	75,531			52,115	50,000	35,000	14,000
Vyvanse 50mg	36,874			85,000	151,000		55,000
Vyvanse 60mg	13,713	14,904			82,200		
Vyvanse 70mg	46,727			95,000	25,000		

Sensitive and Confidential: Not for distribution

Summary of Supply Update



Likelihood of Shortage Impact extending to other strengths

- Addition of 40mg to shortage notification
 - Stock exhausted worst case January, potentially February
- Anticipated redistribution to remaining strengths 20mg and 70mg - shortage impact considered low risk but is difficult to predict
- On schedule to provide continuity of supply for 30mg, 50mg and 60mg as planned in March / April 2024

S8 Receipt Documentation Issue

- Based on the wholesalers SOH report (8/01/24), wholesalers now have stock of Vyvanse 20mg in their DC.
- There are still stock pending dispatch due to S8 documents not yet received by DHL
- Express pre-paid envelopes are sent with every order for prompt document return
- DHL are emailing and calling wholesalers & pharmacies to chase for pending documentation
- Explored the opportunity to accept emailed versions of these S8 documents as an interim measure

Wholesalers	Wholesalers SOH (units)	Pending Dispatch at Takeda due to S8 document
Symbion	s47	
Sigma		
API		

Communication Plan



Key Principles

- Alignment and speed
- Most up to date information as quickly as possible
- One single source of truth
 - Propose TGA Medicines Shortage Vyvanse page
- Letter of notification of 40mg shortage and providing direction for future comms

Customer Feedback, Challenges and Bottlenecks

Takeda Improvement Focus

- More efficient communication method
- More efficient and sustainable approach to emergency supply management
- S8 paperwork – following up, EXPRESS paid envelopes
- Future impact modelling; prescriber and patient dynamics during and post supply impacts

Key Areas outside of Takeda Control for consideration

- MoH requirements for receipt of S8 docs
- Section 19A
- Pharmacy substitution for alternative strengths
- Hard copy script limitations

US FDA/DEA Aggregate Production Quota for Vyvanse active pharmaceutical ingredient (API)



- The current interruption to supply is NOT related to any DEA production quotas or restrictions on API.
- The DEA indicated in November 2023 that the 2024 Aggregate Production Quota for lisdexamfetamine base API would be held flat to 2023.
- In December, Takeda made a submission to the FDA/DEA on behalf of all Takeda marketing companies affected.
- Submissions were also made by certain Australian professional and patient ADHD interest groups.
- Despite more than 4,500 submissions being received, the DEA have not changed their position regarding the 2024 production quota.

From: s22
To: s22
Cc: s22; [Medicine Shortages](#)
Subject: RE: VYVANSE medicine shortage meeting minutes of 9-Jan-2024 [SEC=OFFICIAL]
Date: Thursday, 18 January 2024 7:19:54 AM
Attachments: [image001.png](#)
[image002.png](#)
[image003.jpg](#)

Hi s22

Thank you for the update, it is much appreciated. We will let you know if there are any major issues with the update.

Kind regards

s22

From: s22 @health.gov.au>
Sent: Wednesday, January 17, 2024 4:55 PM
To: s22 @takeda.com>
Cc: s22 @health.gov.au>; s22
s22 @health.gov.au>; s22 @Health.gov.au>; s22
s22 @takeda.com>; s22 @health.gov.au>
Subject: RE: VYVANSE medicine shortage meeting minutes of 9-Jan-2024 [SEC=OFFICIAL]

Hi s22

Unfortunately due to time pressure we have had to publish the alert just now:
<https://www.tga.gov.au/safety/shortages/information-about-major-medicine-shortages/about-shortages-vyvanse-lisdexamfetamine-dimesilate-capsules>

Please let me know if there are any major issues with the update.

Kind regards

s22

From: s22
Sent: Wednesday, 17 January 2024 3:39 PM
To: s22 @takeda.com>
Cc: s22 @health.gov.au>; s22
s22 @health.gov.au>; s22 @Health.gov.au>; s22
s22 @takeda.com>; Medicine Shortages <medicine.shortages@health.gov.au>
Subject: RE: VYVANSE medicine shortage meeting minutes of 9-Jan-2024 [SEC=OFFICIAL]

Hi s22

Apologies for the delay in getting back to you – the day is just flying by. The letters look great.

I have attached the draft that is currently being progressed up the line on our end for approval prior to publishing. We have incorporated the table, however slightly amended. Apologies for

the messiness, but I have left the track changes in to make it easier for you to see exactly what amendments are being made. Please let me know if all ok on your end.

Kind regards

s22

From: s22 [redacted] <[redacted]@takeda.com>
Sent: Wednesday, 17 January 2024 11:48 AM
To: s22 [redacted] <[redacted]@health.gov.au>
Cc: s22 [redacted] <[redacted]@health.gov.au>; s22 [redacted] <[redacted]@health.gov.au>; s22 [redacted] <[redacted]@Health.gov.au>; s22 [redacted] <[redacted]@takeda.com>; Medicine Shortages <[redacted]@health.gov.au>
Subject: RE: VYVANSE medicine shortage meeting minutes of 9-Jan-2024 [SEC=OFFICIAL]

Dear s22 [redacted]

Thank you for the prompt feedback. Takeda wish to request the following please:

- Request to update the web statement today with the table below as a first update. We think this is clearer to have this as a summary table up front.

VYVANSE Supply impact dates by strength

VYVANSE Strength	Supply Impact Date
VYVANSE 30mg	Now until mid-March 2024
VYVANSE 40mg	Anticipated 22 nd January until late April 2024
VYVANSE 50mg	Now until mid-March 2024
VYVANSE 60mg	Now until late April 2024

- Attached are the letters we intend to send to pharmacy and HCP today/tomorrow via email/post. In the letters, reference is made to the TGA website. We will therefore wait to receive your confirmation before sending.
- We will have additional suggestions for future updates we would like to send for consideration. However, for today the only request is to please include the table outlining impact dates by strength.

I will appreciate receiving your response at the earliest.

Thank you.

Kind regards

s22

From: s22 [redacted] <[redacted]@health.gov.au>
Sent: Wednesday, January 17, 2024 9:24 AM
To: s22 [redacted] <[redacted]@takeda.com>
Cc: s22 [redacted] <[redacted]@health.gov.au>; s22 [redacted] <[redacted]@health.gov.au>; s22 [redacted] <[redacted]@Health.gov.au>; s22 [redacted] <[redacted]@takeda.com>; Medicine Shortages <[redacted]@health.gov.au>
Subject: RE: VYVANSE medicine shortage meeting minutes of 9-Jan-2024 [SEC=OFFICIAL]

Dear s22

Thank you for sending through the minutes and presentation, really appreciate it.

We have published the 40mg Vyvanse shortage this morning, and aim to have this information updated on our web statement later today. I'll let you know ahead of publishing.

As discussed at the meeting, we are very happy to work with your team on including more information such as answers to FAQ's on the web statement etc, please send the information through when you can and we can have our team work up a draft for your review.

Happy to chat anytime

Kind regards

s22

s22 (Ms/she/her)
s22 – Medicine Shortages Section
Pharmacovigilance Branch

Medicines Regulation Division | Health Products Regulation Group
Australian Government, Department of Health and Aged Care

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

Location: Fairbairn

PO Box 100, Woden ACT 2606, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s22@takeda.com>

Sent: Tuesday, 16 January 2024 2:13 PM

To: Medicine Shortages <medicine.shortages@health.gov.au>

Cc: s22@takeda.com>

Subject: VYVANSE medicine shortage meeting minutes of 9-Jan-2024

Dear s22

Thank you so much for the discussion on VYVANSE medicine shortages. Please find attached here meeting minutes and copy of Takeda's presentation.

Further to this, Takeda wish to request your feedback on the following please:

- Given the shortage notification has now been lodged for VYVANSE 40mg, what is the timeframe for TGA to update information regarding this strength on the TGA's VYVANSE medicine shortage website page <https://www.tga.gov.au/safety/shortages/information-about-major-medicine-shortages/about-shortages-vyvanse-lisdexamfetamine-dimesilate-capsules>
- As proposed in the meeting, Takeda wish to provide updates to TGA's VYVANSE medicine shortage website page to help maintain latest information. Could you please let me know what the process is to meet this end.

I will be grateful if you could provide your feedback as soon as possible.

Thank you again.

Kind regards

s22



s22 PhD

s22 – Oceania Cluster

Takeda Pharmaceuticals Australia Pty Ltd

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Sydney NSW 2000 Australia

Mobile: s22

s22 @takeda.com

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Nature of the shortage:	Current	
Shortage reason:	Unexpected increase in consumer demand Document 43	
Shortage reason - further information:		
Estimated period supply will be affected at wholesaler points:	From:	22/01/2024
	To:	30/04/2024
Availability:	Limited Availability	
TGA publication date:	17/01/2024	
Is this shortage related to other medicines within the same Therapeutic class?	Yes	
Other medicines details:	Vyvanse 30mg, 50mg, 60mg	
Is this shortage specific to Australia?	No	
Estimated normal demand volumes for Australia:	s47	
Estimated percentage share of the Australian market:	100 %	
Estimated current stock at sponsor / manufacturing level in Australia:	24006 units	
Estimated current stock at wholesaler / distributor level in Australia:	5452 units	
What is meant by 1 unit in this context:	A single pack of 30 capsules.	

Impact

Are there therapeutic alternatives on the Australian market?	Yes
What is the status of substitute options for this product in Australia?	Appropriate Therapeutic Alternatives
Are they available in adequate supplies to meet demand?	Yes
Provide details:	Alternative therapeutic alternatives include methylphenidate and dexamfetamine.
Do any specific population groups use this product?	Yes
Provide details of the groups and the impact on those groups:	Paediatric, adolescents, and adult patients with attention deficit hyperactivity disorder (ADHD), adults with binge eating disorder (BED).
Based on your answers above and the Assessment Framework, what is the shortage impact rating?	2 - Medium Impact

Shortage Action

What communication activities have happened or are planned?

Communication Action	Date of Communication
Letter to Wholesalers	12-Jan-2024
Letter to Pharmacists	22-Jan-2024
Letter to Prescribers	22-Jan-2024

Letter attached in Supporting Information: No

Further comments on communications:

What supply management actions have happened or are planned?

Management Action	Date of Management Action
Constrained Supply	04-Jan-2024

Further comments on management actions:

Document 43

Supporting Information

Supporting data will be:

Sponsor website where medicine shortage information is available:

From: s22
To: [Medicine Shortages](#)
Cc: s22
Subject: VYVANSE shortage - feedback from HCPs regarding alternative product supplied under S19A by Medsurge.
Date: Tuesday, 23 January 2024 9:43:13 AM
Attachments: [image001.png](#)
[image002.jpg](#)
[image003.png](#)
[image004.jpg](#)

Dear TGA Medicines Shortage Team

Takeda wish to share some feedback below from an HCP (with their consent), Dr s22 s22 regarding the cost of the Medsurge section 19A product, approved as alternative to Vyvanse in Australia. As you may note from the feedback, the HCPs find the costs of product supplied by Medsurge to be impractical for majority of patients.

Thank you

Kind regards

s22



s22 PhD

s22 – Oceania Cluster

Takeda Pharmaceuticals Australia Pty Ltd

Grosvenor Place, Level 39
 225 George Street
 Sydney NSW 2000 Australia
 Mobile: +s22

s22 [@takeda.com](#)

From: s22 [@icloud.com](#)>

Sent: Thursday, January 18, 2024 6:10 PM

To: s22 [@mindcare.com.au](#)>

Cc: s22 [@takeda.com](#)>; s22 [@me.com](#)>;
 s22 [@gmail.com](#)>; s22 [@hotmail.com](#)>; s22
 s22 [@gmail.com](#)>; s22 [@gosforthclinic.com.au](#)>; s22
 s22 [@takeda.com](#)>

Subject: Re: Vyvanse stock shortage notification

Thanks s22

I agree with your points.

When I spoke to Medsurge just before Christmas (the company with access to the overseas supply) they said that:

- it was only for 30mg at the time
- the cost was s47 for 100 tablets
- the supply was 40 days away if requested.

They were apologetic about this.

As such, I haven't raised this with any patients. Maybe Takeda can inform us if the situation has changed with this. Otherwise, it seems impractical for the majority of patients. If the situation hasn't changed, I would recommend removing this as an option from the TGA notification.

I also note that Takeda has reserved an urgent supply of all doses for urgent situations. I'm wondering what the practical application of this- can one case of ADHD be considered more urgent than another?

Finally, now that 20mg and 70mg doses are only available, can Takeda provide any assurances about supply until the end of the restrictions? I imagine there is going to be high demand for what is remaining. The situation is feeling more critical to me if all options could be off the table.
Warm regards,

Dr s22 | (he/him)
Consultant Psychiatrist

Please note I work part time. I endeavour to reply to email on Thursdays.

Crisis Service: 1800 011 511 (NSW, 24 hours)

NB: Please note that email communication is not secure. Email is not a replacement for clinical review, and should never be used to communicate issues of increased risk, as a prompt reply or action cannot be expected

On Jan 18, 2024 at 1:35 PM, s22 wrote:

Hi s22

Thank you for the update - that is such a pain.

As per the TGA advice, Can you please advise:

1. how much the overseas alternate Vyvanse supply cost patients? Why can't Takeda cover this difference?
2. how do we apply to prescribe the overseas supply? Can you please provide specific instructions for clinicians?
3. I think Takeda needs to be more on the front foot, advising prescribers and pharmacists how to manage a very time consuming and frustrating problem.

TGA advice: We have approved the supply of overseas-registered alternatives to Vyvanse 30 mg, 50 mg and 60 mg under section 19A of the Therapeutic Goods Act 1989. Up-to-date information about these products is available on the [Section 19A approvals database](#).

Kind regards

s22

Dr s22 | s22, Sydney Medical School | Consultant Psychiatrist

Office hours **Monday to Thursday** 9:00am to 5:00pm

s22

. I pay my respect to all First Nation people, their cultures and connection to the land, sea, and community, and their elders, past, present, and emerging.

Office: s22

s22

| s22 | E s22

| W s22
TeleHealth Link: <https://videocall.direct> s22

From: s22 <@takeda.com>

Sent: Thursday, January 18, 2024 12:40 pm

To: s22 <@mindcare.com.au>

Subject: Vyvanse stock shortage notification

Dear s22

Happy new year and I hope you had a great Christmas and New Years!

As courtesy, I wish to update you that as of today, Takeda and the TGA has issued a new

notification which adds Vyvanse 40mg capsules to the medicines shortage list, along with 30mg, 50mg and 60mg capsules. See the notification using the weblinks below.

<https://www.tga.gov.au/safety/shortages/information-about-major-medicine-shortages/about-shortages-vyvanse-lisdexamfetamine-dimesilate-capsules>

[https://www.tga.gov.au/safety/shortages/medicine-shortage-alerts/update-about-shortages-vyvanse-lisdexamfetamine-dimesilate-](https://www.tga.gov.au/safety/shortages/medicine-shortage-alerts/update-about-shortages-vyvanse-lisdexamfetamine-dimesilate-capsules#:~:text=Update%20about%20the%20shortages%20of%20Vyvanse%20(lisdexamfetamine%20dimesilate)%20capsules,-)

[capsules#:~:text=Update%20about%20the%20shortages%20of%20Vyvanse%20\(lisdexamfetamine%20dimesilate\)%20capsules,-](https://www.tga.gov.au/safety/shortages/medicine-shortage-alerts/update-about-shortages-vyvanse-lisdexamfetamine-dimesilate-capsules#:~:text=Update%20about%20the%20shortages%20of%20Vyvanse%20(lisdexamfetamine%20dimesilate)%20capsules,-)

[Published&text=Takeda%20Pharmaceuticals%20Australia%20has%20notified,2024%20until%2030%20April%202024.](https://www.tga.gov.au/safety/shortages/medicine-shortage-alerts/update-about-shortages-vyvanse-lisdexamfetamine-dimesilate-capsules#:~:text=Update%20about%20the%20shortages%20of%20Vyvanse%20(lisdexamfetamine%20dimesilate)%20capsules,-)

Takeda has been, and will continue to work closely with the TGA regarding this issue. To help address any mis-information, we are encouraging healthcare professionals to refer to this TGA website as a source of truth, for the most up to date information.

Please don't hesitate to call me if you wish to discuss this further.

Kind regards

s22



s22

B.Pharm.

s22

Neuroscience, Gastroenterology and Vaccines

Takeda Australia Pty Ltd

Level 39 Grosvenor Place,

225 George Street,

Sydney NSW 2000

Australia

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From: [Medicine Shortages](#)
To: s22
Cc: s22
Subject: RE: MS-2024-NT-00004-1. VYVANSE 40mg shortage. [SEC=OFFICIAL]
Date: Monday, 29 January 2024 2:47:30 PM
Attachments: [image005.png](#)
[image006.png](#)

Good afternoon s22

The webpage has been updated, with the table below amended to contain information correct as of today.

Thank you again for your engagement with us on this shortage.

Kindest regards,

s22

Pharmacist


Medicine Shortages Section

Pharmacovigilance Branch

Phone: s22

Email: medicine.shortages@health.gov.au

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



The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community.

From: s22 @takeda.com>
Sent: Monday, January 29, 2024 10:42 AM
To: Medicine Shortages <medicine.shortages@health.gov.au>
Cc: s22 @takeda.com>
Subject: MS-2024-NT-00004-1. VYVANSE 40mg shortage.

Dear TGA Medicines Shortage Section

I wish to check with you when the TGA plan to update the VYVANSE shortages page to show the 40mg shortage is now current instead of anticipated:

<https://www.tga.gov.au/safety/shortages/information-about-major-medicine-shortages/about-shortages-vyvanse-lisdexamfetamine-dimesilate-capsules>

Takeda Pharmaceuticals Australia has notified us of shortages of some strengths of Vyvanse (lisdexamfetamine dimesilate) capsules because of manufacturing issues. These worldwide shortages affect Vyvanse products as follows:

Product	Estimated return date as of 17 January 2024
Vyvanse 30 mg	7 March 2024
Vyvanse 40 mg	Anticipated from 22 January 2024 until 30 April 2024
Vyvanse 50 mg	7 March 2024
Vyvanse 60 mg	19 April 2024

I look forward to your feedback.

Thank you.
Kind regards

s22



Better Health, Brighter Future

s22 PhD

s22 – Oceania Cluster

Takeda Pharmaceuticals Australia Pty Ltd

Grosvenor Place, Level 39
225 George Street
Sydney NSW 2000 Australia

Mobile: s22

s22 [@takeda.com](mailto:s22@takeda.com)

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From: [Medicine Shortages](#)
To: s22
Cc: s22
Subject: RE: VYVANSE shortages - Takeda's proposed updates to TGA's VYVANSE shortage website page [SEC=OFFICIAL]
Date: Monday, 5 February 2024 11:06:02 AM
Attachments: [image004.png](#)

Good morning s22

Thank you for this draft, and for your engagement with us on the communication of this shortage.

We will work on incorporating your recommendations to the webpage over the coming days.

s22

Pharmacist


Medicine Shortages Section

Pharmacovigilance Branch

Phone: s22

Email: medicine.shortages@health.gov.au

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



The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community.

From: s22@takeda.com>
Sent: Friday, February 2, 2024 2:54 PM
To: Medicine Shortages <medicine.shortages@health.gov.au>
Cc: s22@takeda.com>
Subject: VYVANSE shortages - Takeda's proposed updates to TGA's VYVANSE shortage website page

Dear TGA Medicine Shortages Team

Takeda proposes update to the TGA's VYVANSE shortage website page (<https://www.tga.gov.au/safety/shortages/information-about-major-medicine-shortages/about-shortages-vyvanse-lisdexamfetamine-dimesilate-capsules>). Attached here are clean and tracked copies of the proposed changes.

Summary of edits and intent

- **Update pharmacists on new way to make online requests for VYVANSE Emergency supply** instead of calling Takeda Medical Information. A hyperlink to the [TakedaPro Online](#)

- [Portal](#) has been included in the doc. The URL is takedapro.com.au/ver
- Update to the summary table and additional copy regarding the 20mg and 70mg to **clarify where we have limited availability and not a stock out.**
 - **Replacing 'stable' patients with 'existing' patients** when advising on prescribing consideration to **avoid inference to a patient's state of ADHD symptom control.**
 - Signal to **refer to the same 'About the Shortages of VYVANSE' page for updated information,** in addition to the Medicine's Shortage database.
 - **Emergency Supply summary section included.** Please add subhead to the sections list at the top of the page and include a hyperlink.
 - **Included 'Where to find more information about VYVANSE'** in the general section and links to the **PI and CMI.**
 - For all **brand reference** have replaced with **upper case to VYVANSE.**

In addition, Takeda wish to request TGA to add sentence used on About shortages page : "These products are not listed on the Pharmaceutical Benefits Scheme (PBS) and will be more expensive than the Australian products." to the webpage <https://apps.tga.gov.au/Prod/msi/Search/Details/lisdexamfetamine-dimesilate> as well for consistency.

We look forward to your consideration of the proposed changes. Please contact us if you need any further information or clarification.

Thank you.

Kind regards

s22



Better Health, Brighter Future

s22

PhD

s22

– Oceania Cluster

Takeda Pharmaceuticals Australia Pty Ltd

Grosvenor Place, Level 39
225 George Street
Sydney NSW 2000 Australia

Mobile: s22

s22

[@takeda.com](mailto:s22@takeda.com)

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Suggested Edits for the TGA website – ‘About the Shortages of VYVANSE’ *

***Content for the purpose of dissemination via the TGA website only**

(Please hyperlink the subheads highlighted in yellow)

- Information for patients
- Information for prescribers
- Information for pharmacists
- General information
- Emergency Supply

Takeda Pharmaceuticals Australia has notified us that there will be limited availability of some strengths of VYVANSE (lisdexamfetamine dimesilate) capsules until late April 2024.

Takeda has advised that this has been caused by manufacturing delays compounded by increased demand. While Takeda is expecting some deliveries during this period, these are not expected to satisfy demand for all strengths.

These shortages affect VYVANSE products as follows:

Product	Estimated return to normal supply
Vyvanse 30 mg	7 March 2024
Vyvanse 40 mg	30 April 2024
Vyvanse 50 mg	7 March 2024
Vyvanse 60 mg	19 April 2024

The 20mg and 70mg strengths are not currently impacted. Takeda continues to closely monitor stock levels and any updates will be shared on this site.

The details of these shortages and how long they may last can change. Please refer to this site and the [Medicine Shortage Reports Database - external site](#) (search for ‘Vyvanse’) for the most up-to-date information.

VYVANSE is used to treat serious conditions such as attention deficit hyperactivity disorder (ADHD) and binge eating disorder (BED). We understand the difficulties shortages of this medicine will cause, and we are responding to this issue as a priority. We are working with Takeda and other sponsors to monitor the availability and supply of this medicine.

We have approved the supply of overseas-registered alternatives to VYVANSE 30 mg, 50 mg, and 60 mg under section 19A of the Therapeutic Goods Act 1989. Up-to-date information about section 19A approvals is available on the [Section 19A approvals database](#).

Information for patients

We understand how important VYVANSE is for patients and their carers, and we appreciate the concern and difficulty these shortages may cause.

There is always someone to talk to about mental health and behavioural concerns. If you or someone close to you is experiencing an emergency, or is at immediate risk of harm, call triple zero (000). To talk to someone now, call Beyond Blue on 1300 22 4636 or Lifeline on 13 11 14.

The HealthDirect website has a full list of mental health resources at [www.healthdirect.gov.au/mental-health-resources- external site](http://www.healthdirect.gov.au/mental-health-resources-external-site).

Your pharmacist can advise you about the best way to obtain VYVANSE during these shortages. We have approved access to overseas-registered versions of VYVANSE 30 mg, 50 mg and 60 mg. Details about these products can be found on the Section 19A approvals database. These products are not listed on the Pharmaceutical Benefits Scheme (PBS) and will be more expensive than the Australian products.

If you are unable to fill your VYVANSE prescription, talk to your prescribing doctor, paediatrician or psychiatrist about other treatment options for you or the person you care for.

Information for prescribers

Please consider these shortages when initiating new patients on VYVANSE. Limiting new initiations in this shortage period will help preserve available supplies for existing patients and maintain continuity of treatment.

Please refer to this site and the [Medicine Shortage Reports database- external site](#) for the most up to date information.

Pharmacists, patients, and carers may contact you to authorise alternative strengths of VYVANSE or substitute medicines to treat their condition. We acknowledge the difficulties involved in the prescribing of controlled drugs and the extra administrative work load these shortages have caused.

We have approved the supply of overseas-registered alternatives to VYVANSE 30 mg, 50mg and 60mg under section 19A of the Therapeutic Goods Act 1989. Detailed information about these products is available on the [Section 19A approvals database](#). These products are not listed on the Pharmaceutical Benefits Scheme (PBS) and will be more expensive than the Australian products.

Emergency Supply for Urgent Patient need

Takeda Pharmaceuticals has reserved a limited emergency supply of all strengths for instances of urgent patient need. Requests for emergency stock can be made by pharmacists through the [TakedaPro online portal](#).

Information for pharmacists

Prioritising the dispensing of VYVANSE to ongoing patients where possible will help preserve available supplies for existing patients and maintain continuity of treatment.

Patients and carers may seek help in obtaining VYVANSE from alternative pharmacies or through emergency supply.

Takeda Pharmaceuticals has reserved a limited emergency supply of all strengths for instances of urgent patient need. Requests for emergency stock can be made by pharmacists through the [TakedaPro Online Portal](#).

We have also approved overseas-registered alternatives to VYVANSE 30 mg, 50 mg and 60 mg under section 19A of the Therapeutic Goods Act 1989. You can contact the approval holder, Medsurge Healthcare, on 1300 788 261 for details about ordering. Detailed information about these products is available on the [Section 19A approvals database](#). These products are not listed on the Pharmaceutical Benefits Scheme (PBS) and will be more expensive than the Australian products.

General information

Please note that while the current shortages are expected to end in April 2024, dates may change and will vary for different strengths. We encourage you to check this site or the [medicine shortage reports database-external site](#) for updates about availability.

Please keep in mind that we can suggest approaches to manage the supply of medicines during shortages, but the TGA does not have the power to regulate the clinical decisions of health professionals.

We will continue to monitor the supply of lisdexamfetamine dimesilate products and work with the suppliers and relevant health professionals to update this advice if needed.

Where to find more information about VYVANSE

Please refer to VYVANSE Product Information, and Consumer Medicines Information, for further information.

<https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2013-PI-02051-1>

<https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2013-CMI-02070-1&d=20230808172310101>

Emergency Supply for Urgent Patient Need

Takeda Pharmaceuticals has reserved a limited emergency supply of all strengths for instances of urgent patient need. Requests for emergency stock can be made by pharmacists through the [TakedaPro Online Portal](#).

On this page

- [Information for patients](#)
- [Information for prescribers](#)
- [Information for pharmacists](#)
- [General information](#)
- [Emergency Supply](#)

Takeda Pharmaceuticals Australia has notified us ~~of shortages that there will be limited availability~~ of some strengths of ~~Vyvanse-VYVANSE~~ (lisdexamfetamine dimesilate) capsules ~~because of manufacturing issues until late April 2024~~. These ~~worldwide~~ shortages affect ~~Vyvanse-VYVANSE~~ products as follows:

Product	Estimated return date as of 17 January 2024 <u>to normal supply</u>
Vyvanse 30 mg	7 March 2024
Vyvanse 40 mg	Anticipated from 22 January 2024 until 30 April 2024
Vyvanse 50 mg	7 March 2024
Vyvanse 60 mg	19 April 2024

~~Due to the increase in demand for other strengths, Vyvanse 40 mg will be in shortage in Australia from 22 January 2024 until 30 April 2024.~~

~~The 20mg and 70mg strengths are not currently impacted. Takeda continues to closely monitor stock levels and any updates will be shared on this site.~~

~~Takeda has advised that the current shortages have been caused by manufacturing delays compounded by increased demand. While Takeda is expecting some deliveries during this period, these are not expected to satisfy demand for all strengths.~~

The details of these shortages and how long they may last can change. [Please refer to this site and Check the Medicine Shortage Reports Database - external site](#) (search for 'Vyvanse') for the most up-to-date information.

~~Vyvanse-VYVANSE~~ is used to treat serious conditions such as attention deficit hyperactivity disorder (ADHD) and binge eating disorder (BED). We understand the difficulties shortages of this medicine will cause, and we are responding to this issue as a priority. We are working with Takeda Pharmaceuticals and other sponsors to monitor the availability and supply of this medicine.

We have approved the supply of overseas-registered alternatives to ~~Vyvanse~~ [VYVANSE](#) 30 mg, 50 mg and 60 mg under section 19A of the Therapeutic Goods Act 1989. Up-to-date information about section 19A approvals is available on the [Section 19A approvals database](#).

Information for patients

We understand how important a regular supply of Vyvanse is for patients and their carers, and we appreciate the concern and difficulty these shortages may cause, particularly during the holiday period when specialists may be difficult to access.

There is always someone to talk to about mental health and behavioural concerns. **If you or someone close to you is experiencing an emergency, or is at immediate risk of harm, call triple zero (000). To talk to someone now, call Beyond Blue on 1300 22 4636 or Lifeline on 13 11 14.**

The HealthDirect website has a full list of mental health resources at www.healthdirect.gov.au/mental-health-resources-external-site.

Your pharmacist can advise you about the best way to obtain [Vyvanse-VYVANSE](#) during these shortages. We have approved access to overseas-registered versions of [Vyvanse-VYVANSE](#) 30 mg, 50 mg and 60 mg. Details about these products can be found on the [Section 19A approvals database](#). These products are not listed on the Pharmaceutical Benefits Scheme (PBS) and will be more expensive than the Australian products.

If you are ~~still~~ unable to fill your [Vyvanse-VYVANSE](#) prescription, talk to your prescribing doctor, paediatrician, or psychiatrist about other treatment options for you or the person you care for.

Information for prescribers

Please consider these shortages when initiating new patients on Vyvanse. Limiting new initiations in this shortage period will help preserve available supplies for ~~stable~~[existing](#) patients and maintain continuity of treatment.

~~Please refer to this site and the~~ [The most up-to-date details about these shortages are available on the Medicine Shortage Reports database-external site for the most up to date information.](#)

Pharmacists, patients and carers may contact you to authorise alternative strengths of Vyvanse or substitute medicines to treat their condition. We acknowledge the difficulties involved in the prescribing of controlled drugs and the extra administrative workload these shortages have caused.

We have approved the supply of overseas-registered alternatives to Vyvanse 30 mg, 50 mg and 60 mg under section 19A of the Therapeutic Goods Act 1989. Detailed information about these products is available on the [Section 19A approvals database](#). These products are not listed on the Pharmaceutical Benefits Scheme (PBS) and will be more expensive than the Australian products.

Emergency Supply for urgent patient need

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Takeda Pharmaceuticals has reserved a limited emergency supply of all VYVANSE strengths for instances of urgent patient need. Requests for emergency stock can be made by pharmacists through the [TakedaPro online portal](#).

Information for pharmacists

Prioritising the dispensing of Vyvanse to ongoing patients where possible will help preserve available supplies for ~~stable~~[existing](#) patients and maintain continuity of treatment.

Patients and carers may seek help in obtaining Vyvanse from alternative pharmacies or through emergency supply.

~~Takeda Pharmaceuticals has advised us that reserved a limited~~ emergency supply of ~~Vyvanse all strengths of -~~VYVANSE ~~is available for instances of urgent patient need. Requests for emergency stock can be made by pharmacists through the TakedaPro online portal. You can contact Takeda on 1800 012 612 or medinfoapac@takeda.com for details about access and ordering.~~

We have also approved the supply of overseas-registered alternatives to ~~Vyvanse~~ [VYVANSE](#) 30 mg, 50 mg and 60 mg under section 19A of the Therapeutic Goods Act 1989. You can contact the approval holder, Medsurge Healthcare, on 1300 788 261 for details about ordering. Detailed information about these products is available on the [Section 19A approvals database](#). These products are not listed on the Pharmaceutical Benefits Scheme (PBS) and will be more expensive than the Australian products.

General information

Please note that while the current shortages are expected to end ~~by March and in~~ April 2024, ~~these~~ dates may change and ~~will vary for different strengths.~~ ~~W~~e encourage you to ~~check this site or check~~ the [medicine shortage reports database-external site](#) for updates about availability.

We can work with pharmaceutical companies to communicate information about a medicine shortage to health professionals and patients, but we cannot compel companies to increase supply or apply to have their products subsidised on the Pharmaceutical Benefits Scheme (PBS).

Please also keep in mind that we can suggest approaches to manage the supply of medicines during shortages but the TGA does not have the power to regulate the clinical decisions of health professionals.

We will continue to monitor the supply of lisdexamfetamine dimesilate products and work with the suppliers and relevant health professionals to update this advice if needed.

Where to find more information about VYVANSE

Please refer to VYVANSE Product Information, and Consumer Medicines Information, for further information.

<https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2013-PI-02051-1>

<https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2013-CMI-02070-1&d=20230808172310101>

Emergency Supply for Urgent Patient Need

Takeda Pharmaceuticals has reserved a limited emergency supply of all strengths for instances of urgent patient need. Requests for emergency stock can be made by pharmacists through the **TakedaPro Online Portal**.

Formatted: English (United States)

From: s22
To: [Medicine Shortages](#)
Cc: s22
Subject: RE: Vyvanse shortages - Takeda's proposed updates to TGA's Vyvanse shortage website page
Date: Thursday, 15 February 2024 12:57:45 PM
Attachments: [image002.png](#)
Importance: High

Good afternoon s22

We have been informed the link to the Emergency Supply Request Form for Pharmacists that the TGA included on the 'About the Shortages of Vyvanse' page is not going direct to the correct page but instead is going to the TakedaPro home page. It looks like when the name of the link we provided changed, the address to the TakedaPro homepage was changed and not the Emergency Supply Request Form. We have received feedback from pharmacists that this is confusing and implies they need to be registered, which is not the case.

Can you please update the address in the hyperlink to the following ASAP:
<https://takedapro.com.au/ver>

Should you need any further information, please let us know immediately.

Kind regards

s22

From: Medicine Shortages <medicine.shortages@health.gov.au>
Sent: Tuesday, February 13, 2024 12:34 PM
To: s22 @takeda.com>
Cc: s22 @takeda.com>
Subject: [SEC=OFFICIAL] RE: Vyvanse shortages - Takeda's proposed updates to TGA's Vyvanse shortage website page

Good afternoon s22

Thank you to s22 and yourself for putting this together, and for your responsive and collaborative approach to the communication of this shortage.

Please find attached an updated copy of the current webpage, which will be published later today.

I have recreated the bulleted points from Mr s22 original email below, with some TGA comments in green, including about some changes that we were not able to accommodate:

Summary of edits and intent

- **Update pharmacists on new way to make online requests for VYVANSE Emergency supply** instead of calling Takeda Medical Information. A hyperlink to the [TakedaPro Online Portal](#) has been included in the doc. The URL is takedapro.com.au/ver
 - Included. However, the references are to "online portal" and do not include the

'TakedaPro' name.

- Update to the summary table and additional copy regarding the 20mg and 70mg to **clarify where we have limited availability and not a stock out.**
 - Included
- **Replacing 'stable' patients with 'existing' patients** when advising on prescribing consideration to **avoid inference to a patient's state of ADHD symptom control.**
 - Included
- Signal to **refer to the same 'About the Shortages of VYVANSE' page for updated information**, in addition to the Medicine's Shortage database.
 - Included
- **Emergency Supply summary section included.** Please add subhead to the sections list at the top of the page and include a hyperlink.
 - Included
- **Included 'Where to find more information about VYVANSE'** in the general section and links to the **PI and CMI.**
 - As clinical documentation references are not traditionally included in Medicine Shortage alerts and webpages, this has **not been included**
- For all **brand reference** have replaced with **upper case to VYVANSE.**
 - This is not the preferred presentation, and to remain consistent with the [Australian Government Style Guide](#), has **not been included.**

Thank you again.

Kindest regards,

s22

Pharmacist

Medicine Shortages Section

Pharmacovigilance Branch

Phone: s22

Email: medicine.shortages@health.gov.au

Therapeutic Goods Administration

Department of Health and Aged Care

PO Box 100

Woden ACT 2606

www.tga.gov.au

The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community.

From: s22 <[redacted]@takeda.com>

Sent: Friday, February 2, 2024 2:54 PM

To: Medicine Shortages <medicine.shortages@health.gov.au>

Cc: s22 <[redacted]@takeda.com>

Subject: VYVANSE shortages - Takeda's proposed updates to TGA's VYVANSE shortage website

page

Dear TGA Medicine Shortages Team

Takeda proposes update to the TGA's VYVANSE shortage website page (<https://www.tga.gov.au/safety/shortages/information-about-major-medicine-shortages/about-shortages-vyvanse-lisdexamfetamine-dimesilate-capsules>). Attached here are clean and tracked copies of the proposed changes.

Summary of edits and intent

- **Update pharmacists on new way to make online requests for VYVANSE Emergency supply** instead of calling Takeda Medical Information. A hyperlink to the [TakedaPro Online Portal](#) has been included in the doc. The URL is takedapro.com.au/ver
- Update to the summary table and additional copy regarding the 20mg and 70mg to **clarify where we have limited availability and not a stock out.**
- **Replacing 'stable' patients with 'existing' patients** when advising on prescribing consideration to **avoid inference to a patient's state of ADHD symptom control.**
- Signal to **refer to the same 'About the Shortages of VYVANSE' page for updated information,** in addition to the Medicine's Shortage database.
- **Emergency Supply summary section included.** Please add subhead to the sections list at the top of the page and include a hyperlink.
- **Included 'Where to find more information about VYVANSE'** in the general section and links to the **PI and CMI.**
- For all **brand reference** have replaced with **upper case to VYVANSE.**

In addition, Takeda wish to request TGA to add sentence used on About shortages page : "These products are not listed on the Pharmaceutical Benefits Scheme (PBS) and will be more expensive than the Australian products." to the webpage <https://apps.tga.gov.au/Prod/msi/Search/Details/lisdexamfetamine-dimesilate> as well for consistency.

We look forward to your consideration of the proposed changes. Please contact us if you need any further information or clarification.

Thank you.

Kind regards

s22



Better Health, Brighter Future

s22

PhD

s22

– Oceania Cluster

Takeda Pharmaceuticals Australia Pty Ltd

Grosvenor Place, Level 39
225 George Street
Sydney NSW 2000 Australia

Mobile: +s22

s22

@takeda.com

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About the shortages of Vyvanse (lisdexamfetamine dimesilate)

On this page

- [Information for patients](#)
- [Information for prescribers](#)
- [Information for pharmacists](#)
 - [Emergency supply for urgent patient need](#)
- [General information](#)

Takeda Pharmaceuticals Australia has notified us that there will be limited availability of some strengths of Vyvanse (lisdexamfetamine dimesilate). These shortages affect Vyvanse products as follows:

Product	Estimated return to normal supply
Vyvanse 30 mg	7 March 2024
Vyvanse 40 mg	30 April 2024
Vyvanse 50 mg	7 March 2024
Vyvanse 60 mg	19 April 2024

Vyvanse 20 mg and 70 mg strengths are not currently impacted.

The details of these shortages and how long they may last can change. This page will be updated if Takeda notifies us of any changes to this shortage situation. Please also refer to the [Medicine Shortage Reports Database](#) (search for 'Vyvanse') for the most up-to-date information.

Takeda has advised that the current shortages have been caused by manufacturing delays compounded by increased demand. While Takeda is expecting some deliveries during this period, these are not expected to satisfy demand for all strengths.

Vyvanse is used to treat serious conditions such as attention deficit hyperactivity disorder (ADHD) and binge eating disorder (BED). We understand the difficulties shortages of this medicine will cause, and we are responding to this issue as a priority. We are working with Takeda and other sponsors to monitor the availability and supply of this medicine.

We have approved the supply of overseas-registered alternatives to Vyvanse 30 mg, 50 mg and 60 mg under section 19A of the Therapeutic Goods Act 1989. Up-to-date information about section 19A approvals is available on the [Section 19A approvals database](#).

Information for patients

We understand how important a regular supply of Vyvanse is for patients and their carers, and we appreciate the concern and difficulty these shortages may cause, particularly during the holiday period when specialists may be difficult to access.

There is always someone to talk to about mental health and behavioural concerns. **If you or someone close to you is experiencing an emergency, or is at immediate risk of harm, call triple zero (000). To talk to someone now, call Beyond Blue on 1300 22 4636 or Lifeline on 13 11 14.**

The HealthDirect website has a full list of mental health resources at www.healthdirect.gov.au/mental-health-resources.

Your pharmacist can advise you about the best way to obtain Vyvanse during these shortages. We have approved access to overseas-registered versions of Vyvanse 30 mg, 50 mg and 60 mg. Details about these products can be found on the [Section 19A database](#). These products are not listed on the Pharmaceutical Benefits Scheme (PBS) and will be more expensive than the Australian product.

If you are unable to fill your Vyvanse prescription, talk to your prescribing doctor, paediatrician or psychiatrist about other treatment options for you or the person you care for.

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Please consider these shortages when initiating new patients on Vyvanse. If you can limit initiations in this shortage period, this will help preserve available supply for existing patients to maintain continuity of their treatment.

Please refer to this webpage and the [Medicine Shortage Reports database](#) for the most up-to-date information.

Pharmacists, patients and carers may contact you to authorise alternative strengths of Vyvanse or substitute medicines to treat their condition. We acknowledge the

difficulties involved in the prescribing of controlled drugs and the extra administrative workload these shortages have caused.

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Information for pharmacists

Prioritising the dispensing of Vyvanse to ongoing patients where possible will help preserve available supplies for existing patients and maintain continuity of treatment.

Patients and carers may seek help in obtaining Vyvanse from alternative pharmacies or through emergency supply.

Emergency supply for urgent patient need

Takeda Pharmaceuticals has reserved a limited emergency supply of Vyvanse for instances of urgent patient need. Requests for emergency stock can be made by pharmacists through an [online portal](#).

We have also approved the supply of overseas-registered alternatives to Vyvanse 30 mg, 50 mg and 60 mg under section 19A of the Therapeutic Goods Act 1989. You can contact the approval holder, Medsurge Healthcare, on 1300 788 261 for details about ordering. Detailed information about these products is available on the [Section 19A approvals database](#). These products are not listed on the Pharmaceutical Benefits Scheme (PBS) and will be more expensive than the Australian product.

General information

Please note that while the current shortages are expected to end by April 2024, dates may change and will vary for different strengths. We encourage you to check this webpage and the [medicine shortage reports database](#) for updates about availability.

We can work with pharmaceutical companies to communicate information about a medicine shortage to health professionals and patients, but we cannot compel companies to increase supply or apply to have their products subsidised on the Pharmaceutical Benefits Scheme (PBS).

Please also keep in mind that we can suggest approaches to manage the supply of medicines during shortages but the TGA does not have the power to regulate the clinical decisions of health professionals.

We will continue to monitor the supply of lisdexamfetamine dimesilate products and work with the suppliers and relevant health professionals to update this advice if needed.

From: s22
To: s22 @takeda.com
Cc: s22
Bcc: s22
Subject: RE: Vyvanse shortage
Date: Thursday, 29 February 2024 5:44:00 PM
Attachments: [image003.png](#)
[image001.png](#)

Hi s22

Thank you so much for looking into these questions so promptly. I appreciate your assistance and acknowledge this is a complex situation. Please reach out if there is anything we can assist with. As discussed, the team will reach out to you regarding the edits requested to the 'About the Vyvanse shortage' web page.

Kind regards

s22

s22 B. Pharm GCertComm (Ms/she/her)
s22 – **Medicine Shortages Section**
Pharmacovigilance Branch

Medicines Regulation Division | Health Products Regulation Group

Australian Government, Department of Health and Aged Care

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

Location: Fairbairn

PO Box 100, Woden ACT 2606, Australia

Our consultation on Medicine Shortages in Australia - Challenges and opportunities is open until 12 March 2024 - [Have your say!](#)

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s22 <>
Sent: Thursday, February 29, 2024 1:41 PM
To: Medicine Shortages <medicine.shortages@health.gov.au>
Cc: s22 <>
Subject: Vyvanse shortage

Dear s22

Following up from our telephone discussion yesterday, please see below the company responses to your questions:

- Actor Pharmaceuticals has contacted Takeda. Unfortunately, any direct arrangement between a third party and Takeda in relation to the supply of lisdexamfetamine raises complex legal issues (including possible competition law issues), and we do not believe that any arrangements could be agreed and implemented before the date on which the current supply shortages for Australia are expected to be resolved.

As previously communicated, Vyvanse 40mg emergency reserve has been depleted; and unfortunately, sourcing additional stock from other countries is not possible due to worldwide supply shortage.

Should you still need any further information please do not hesitate to contact us immediately.

Kind regards

s22

s22, MMedSc
s22, Oceania Cluster

Takeda Pharmaceuticals Australia Pty Ltd

Lvl 39, Grosvenor Place
225 George Street
Sydney NSW 2000
Australia

Office: +s22

Mob: +s22

s22 [@takeda.com](mailto:s22@takeda.com)



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From: [Medicine Shortages](#)
To: s22
Cc: s22
Subject: Availability of Vyvanse 70mg [SEC=OFFICIAL]
Date: Friday, 1 March 2024 10:17:57 AM
Attachments: [image001.gif](#)

Hi s22

We have received enquiries around the availability of Vyvanse 70mg. Is Takeda experiencing any supply disruptions for that strength?

Kind Regards,

s22

s22

Pharmacist

[Medicine Shortages Section](#)

[Pharmacovigilance Branch](#)

Our consultation on Medicine Shortages in Australia - Challenges and opportunities is open until 12 March 2024.

[Have your say!](#)

Phone: s22

Email: medicine.shortages@health.gov.au

Therapeutic Goods Administration

Department of Health and Aged Care

PO Box 100

Woden ACT 2606

www.tga.gov.au



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From: Medicine Shortages <medicine.shortages@health.gov.au>

Sent: Wednesday, February 28, 2024 10:18 AM

To: s22 @takeda.com>

Cc: s22 @takeda.com>

Subject: RE: Request for information - Emergency stock for Vyvanse [SEC=OFFICIAL]

Dear s22

Thank you for your prompt response.

We appreciate the continues line of open communication with you.

Have a great day ahead.

Kind Regards,

s22

From: s22 @takeda.com>

Sent: Tuesday, February 27, 2024 6:54 PM

To: Medicine Shortages <medicine.shortages@health.gov.au>

Cc: s22 @takeda.com>

Subject: FW: Request for information - Emergency stock for Vyvanse [SEC=OFFICIAL]

Dear s22

on behalf of my colleague, s22 who is currently on leave, please find below the response to your question:

Takeda is continuing to manage requests for VYVANSE emergency stock via DHL. Requests are reviewed and approved by Takeda and subject to availability. This week we have depleted our emergency reserve of VYVANSE 40mg strength and pharmacists who have placed requests that cannot be fulfilled are being notified. We anticipate our next delivery of 40mg stock in mid-March.

Should you still need any further information, please let me know immediately,

Kind regards

s22

s22, MMedSc

s22, Oceania Cluster

Takeda Pharmaceuticals Australia Pty Ltd

Lvl 39, Grosvenor Place

225 George Street

Sydney NSW 2000

Australia

Office: +s22

Mob: s22

s22 @takeda.com

From: s22 @takeda.com>

Sent: Tuesday, February 27, 2024 1:59 PM

To: s22 @takeda.com>

Subject: Fwd: Request for information - Emergency stock for Vyvanse [SEC=OFFICIAL]

Hi s22

Hope all well with you. Please could you check with s22 and s22 and respond to TGA's request.

Thank you

Cheers

s22

From: Medicine Shortages <medicine.shortages@health.gov.au>

Sent: Monday, February 26, 2024 5:21:45 AM

To: s22 @takeda.com>

Subject: Request for information - Emergency stock for Vyvanse [SEC=OFFICIAL]

Dear s22

I hope this email finds you well.

Could you please confirm whether Takeda is currently processing emergency stock requests for Vyvanse?

I'm looking forward to hearing from you soon.

Kind Regards,

s22

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From: s22
To: [Medicine Shortages](#)
Cc: s22
Subject: RE: VYVANSE shortages - Takeda's proposed updates to TGA's VYVANSE shortage website page [SEC=OFFICIAL]
Date: Wednesday, 6 March 2024 12:53:09 PM
Attachments: [image002.png](#)

Thank you s22 much appreciated.

s22

From: Medicine Shortages <medicine.shortages@health.gov.au>
Sent: Wednesday, March 6, 2024 12:13 PM
To: s22 @takeda.com>
Cc: s22 @takeda.com>
Subject: RE: VYVANSE shortages - Takeda's proposed updates to TGA's VYVANSE shortage website page [SEC=OFFICIAL]

Good afternoon s22

The changes and updates to the [About the shortages of Vyvanse \(lisdexamfetamine dimesilate\) capsules](#) webpage were published this morning.

Thank you again for your collaborative approach to these shortages, and if you have any feedback please just let me know.

Kindest regards,


s22

Pharmacist
Medicine Shortages Section
Pharmacovigilance Branch

Phone: s22

Email: medicine.shortages@health.gov.au

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



The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community.

From: s22 @takeda.com>
Sent: Wednesday, February 28, 2024 10:03 AM
To: Medicine Shortages <medicine.shortages@health.gov.au>

Cc: s22 [REDACTED]@takeda.com>

Subject: VYVANSE shortages - Takeda's proposed updates to TGA's VYVANSE shortage website page

Dear TGA Medicine Shortages Team

Takeda proposes update to the TGA's VYVANSE shortage website page (<https://www.tga.gov.au/safety/shortages/information-about-major-medicine-shortages/about-shortages-vyvanse-lisdexamfetamine-dimesilate-capsules>).

Attached here are clean and tracked copies of the proposed changes.

Summary of edits and intent

- **Emergency supply for urgent patient need – revised copy**
 - Includes reference to requests being '**subject to availability**'. Whilst every effort is made to maintain an emergency reserve it cannot be guaranteed.
 - Change from 'request emergency stock through Takeda's online portal' to 'Information for pharmacists on how to request emergency supply can be found on Takeda's online portal'. This reflects the ability to now make requests direct through DHL to improve efficiency in processing of requests. The details for how to do this are included in the same link for Takeda's online portal.
- **Information for patients**
 - Suggest remove reference to **accessing specialist during holiday period...** as this is no longer relevant.

We look forward to your consideration of the proposed changes. Please contact us if you need any further information or clarification.

Kind regards

s22 [REDACTED]

s22 [REDACTED] MMedSc
s22 [REDACTED], Oceania Cluster

Takeda Pharmaceuticals Australia Pty Ltd

Lvl 39, Grosvenor Place
225 George Street
Sydney NSW 2000
Australia

Office: s22 [REDACTED]

Mob: s22 [REDACTED]

s22 [REDACTED]@takeda.com



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On this page

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- [Information for prescribers](#)
- [Information for pharmacists](#)
- [Emergency supply for urgent patient need](#)
- [General information](#)

Takeda Pharmaceuticals Australia has notified us that there will be limited availability of some strengths of Vyvanse (lisdexamfetamine dimesilate). These shortages affect Vyvanse products as follows:

Product	Estimated return to normal supply
Vyvanse 30 mg	7 March 2024
Vyvanse 40 mg	30 April 2024
Vyvanse 50 mg	7 March 2024
Vyvanse 60 mg	19 April 2024

Vyvanse 20 mg and 70 mg strengths are not currently impacted.

The details of these shortages and how long they may last can change. This page will be updated if Takeda notifies us of any changes to this shortage situation. Please also refer to the [Medicine Shortage Reports Database- external site](#) (search for 'Vyvanse') for the most up-to-date information.

Takeda has advised that the current shortages have been caused by manufacturing delays compounded by increased demand. While Takeda is expecting some deliveries during this period, these are not expected to satisfy demand for all strengths.

Vyvanse is used to treat serious conditions such as attention deficit hyperactivity disorder (ADHD) and binge eating disorder (BED). We understand the difficulties shortages of this medicine will cause, and we are responding to this issue as a priority. We are working with Takeda and other sponsors to monitor the availability and supply of this medicine.

We have approved the supply of overseas-registered alternatives to Vyvanse 30 mg, 50 mg and 60 mg under section 19A of the Therapeutic Goods Act 1989. Up-to-date information about section 19A approvals is available on the [Section 19A approvals database](#).

Information for patients

We understand how important a regular supply of Vyvanse is for patients and their carers, and we appreciate the concern and difficulty these shortages may cause, particularly during the holiday period when specialists may be difficult to access.

There is always someone to talk to about mental health and behavioural concerns. **If you or someone close to you is experiencing an emergency, or is at immediate risk of harm, call triple zero (000). To talk to someone now, call Beyond Blue on 1300 22 4636 or Lifeline on 13 11 14.**

The HealthDirect website has a full list of mental health resources at www.healthdirect.gov.au/mental-health-resources-external-site.

Your pharmacist can advise you about the best way to obtain Vyvanse during these shortages. We have approved access to overseas-registered versions of Vyvanse 30 mg, 50 mg and 60 mg. Details about these products can be found on the [Section 19A database](#). These products are not listed on the Pharmaceutical Benefits Scheme (PBS) and will be more expensive than the Australian product.

If you are unable to fill your Vyvanse prescription, talk to your prescribing doctor, paediatrician or psychiatrist about other treatment options for you or the person you care for.

Information for prescribers

Please consider these shortages when initiating new patients on Vyvanse. If you can limit initiations in this shortage period, this will help preserve available supply for existing patients to maintain continuity of their treatment.

Please refer to this webpage and the [Medicine Shortage Reports database-external site](#) for the most up-to-date information.

Pharmacists, patients and carers may contact you to authorise alternative strengths of Vyvanse or substitute medicines to treat their condition. We acknowledge the difficulties involved in the prescribing of controlled drugs and the extra administrative workload these shortages have caused.

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Information for pharmacists

Prioritising the dispensing of Vyvanse to ongoing patients where possible will help preserve available supplies for existing patients and maintain continuity of treatment.

Patients and carers may seek help in obtaining Vyvanse from alternative pharmacies or through emergency supply.

Emergency supply for urgent patient need

Takeda Pharmaceuticals has reserved a limited emergency supply of Vyvanse ~~is for instances which can be requested by pharmacists for instances~~ of urgent patient need. ~~All requests will be reviewed by Takeda and are subject to availability. Information for pharmacists on how to can request emergency stock through supply can be found on Takeda's online portal- external site-~~

We have also approved the supply of overseas-registered alternatives to Vyvanse 30 mg, 50 mg and 60 mg under section 19A of the Therapeutic Goods Act 1989. You can contact the approval holder, Medsurge Healthcare, on 1300 788 261 for details about ordering. Detailed information about these products is available on the [Section 19A approvals database](#). These products are not listed on the Pharmaceutical Benefits Scheme (PBS) and will be more expensive than the Australian product.

General information

Please note that while the current shortages are expected to end by April 2024, dates may change and will vary for different strengths. We encourage you to check this webpage and the [medicine shortage reports database- external site](#) for updates about availability.

We can work with pharmaceutical companies to communicate information about a medicine shortage to health professionals and patients, but we cannot compel companies to increase supply or apply to have their products subsidised on the Pharmaceutical Benefits Scheme (PBS).

Please also keep in mind that we can suggest approaches to manage the supply of medicines during shortages but the TGA does not have the power to regulate the clinical decisions of health professionals.

We will continue to monitor the supply of lisdexamfetamine dimesilate products and work with the suppliers and relevant health professionals to update this advice if needed.

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Formatted: Space After: Auto, Line spacing: Multiple 1.08 li

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On this page

- [Information for patients](#)
- [Information for prescribers](#)
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We will continue to monitor the supply of lisdexamfetamine dimesilate products and work with the suppliers and relevant health professionals to update this advice if needed.

Notifier

Notifier

Sponsor Name: Takeda Pharmaceuticals Australia Pty Ltd

Sponsor Address: Grosvenor Place Level 39 225 George Street Sydney NSW 2000

Australian telephone number for public contact purposes: 1800012612

Medical information email for public contact purposes: medinfoAPAC@takeda.com

Primary Contact

Name: s22

Phone Number: s22

Email Address: s22@takeda.com

Secondary Contact

Name:

Phone Number: s22

Email Address: s22@takeda.com

ARTG Entry

ARTG Entry

ARTG number of the product that has a supply disruption:

ARTG ID	ARTG Name	Active Ingredient	Strength	Dosage Form
199226	VYVANSE	lisdexamfetamine dimesilate	50mg	Capsule, hard

ATC Descriptor: Nervous system

Are all pack sizes for this ARTG entry affected? Yes

Is this ARTG entry listed in the PBS? Yes

Provide the PBS number for this listing: 10474G

Do you have a designated sponsor representative within your organisation who is a point of contact on PBS matters? Yes

PBS Contact Details

Name: s22

Phone Number: s22

Email Address: s22@takeda.com

Details

Details

When was the shortage known to the sponsor? 18/10/2023

Nature of the shortage:	Resolved	
Shortage reason:	Manufacturing	Document 51
Manufacturing site problem:	Issues/delays with packaging and/or labelling	
Shortage reason - further information:		
Estimated period supply will be affected at wholesaler points:	From:	03/11/2023
	To:	07/03/2024
Availability:	Available	
TGA publication date:	31/10/2023	
Is this shortage related to other medicines within the same Therapeutic class?	No	
Is this shortage specific to Australia?	No	
Estimated normal demand volumes for Australia:	s47	
Estimated percentage share of the Australian market:	100 %	
Estimated current stock at sponsor / manufacturing level in Australia:	13457 units	
Estimated current stock at wholesaler / distributor level in Australia:	47082 units	
What is meant by 1 unit in this context:	1 bottle of 30 capsules	

Impact

Are there therapeutic alternatives on the Australian market?	Yes
What is the status of substitute options for this product in Australia?	Appropriate Therapeutic Alternatives
Are they available in adequate supplies to meet demand?	Unknown at this time
Provide details:	Alternative treatments include; methylphenidate, dexamfetamine, other strengths of lisdexamfetamine
Do any specific population groups use this product?	Yes
Provide details of the groups and the impact on those groups:	Paediatric, adolescents, and adult patients with Attention Deficit Hyperactivity Disorder (ADHD). Adult patients with Binge Eating Disorder (BED).
Based on your answers above and the Assessment Framework, what is the shortage impact rating?	2 - Medium Impact

Shortage Action

What communication activities have happened or are planned?	Communication Action	Date of Communication
	Letter to Prescribers	01-Nov-2023
	Letter to Pharmacists	01-Nov-2023
	Letter to Wholesalers	31-Oct-2023

Letter attached in Supporting Information:	No
--	----

Further comments on communications:

What supply management actions have happened or are planned?	Management Action	Date of Management Action
	Constrained Supply	23-Oct-2023

Further comments on management actions:

Supporting Information

Supporting data will be:

Sponsor website where medicine shortage information is available:

Notifier

Notifier

Sponsor Name: Takeda Pharmaceuticals Australia Pty Ltd

Sponsor Address: Grosvenor Place Level 39 225 George Street Sydney NSW 2000

Australian telephone number for public contact purposes: 1800012612

Medical information email for public contact purposes: medinfoAPAC@takeda.com

Primary Contact

Name: §22

Phone Number: §22

Email Address: §22@takeda.com

Secondary Contact

Name: §22

Phone Number: §22

Email Address: §22@takeda.com

ARTG Entry

ARTG Entry

ARTG number of the product that has a supply disruption:

ARTG ID	ARTG Name	Active Ingredient	Strength	Dosage Form
199227	VYVANSE	lisdexamfetamine dimesilate	30mg	Capsule, hard

ATC Descriptor: Nervous system

Are all pack sizes for this ARTG entry affected? Yes

Is this ARTG entry listed in the PBS? Yes

Provide the PBS number for this listing: 10486X

Do you have a designated sponsor representative within your organisation who is a point of contact on PBS matters? Yes

PBS Contact Details

Name: §22

Phone Number: §22

Email Address: §22@takeda.com

Details

Details

When was the shortage known to the sponsor? 04/08/2023

Nature of the shortage:	Current	
Shortage reason:	Manufacturing	Document 52
Manufacturing site problem:	Issues/delays with packaging and/or labelling	
Shortage reason - further information:	Takeda are experiencing some delays related to the global supply of Vyvanse products due to the remediation actions implemented at the contract manufacturing organization site Wasdell Europe with respect to the Critical Observations identified during the HPRA health authority inspection previously communicated to the TGA. As a result the expected manufacturing time frames have been increased and committed shipments to Australia have been further delayed.	
Estimated period supply will be affected at wholesaler points:	From:	07/08/2023
	To:	31/03/2024
Availability:	Limited Availability	
TGA publication date:	14/08/2023	
Is this shortage related to other medicines within the same Therapeutic class?	No	
Is this shortage specific to Australia?	No	
Estimated normal demand volumes for Australia:	s47	
Estimated percentage share of the Australian market:	100 %	
Estimated current stock at sponsor / manufacturing level in Australia:	4312 units	
Estimated current stock at wholesaler / distributor level in Australia:	6406 units	
What is meant by 1 unit in this context:	Single pack of 30 capsules	

Impact

Are there therapeutic alternatives on the Australian market?	Yes
What is the status of substitute options for this product in Australia?	Appropriate Therapeutic Alternatives
Are they available in adequate supplies to meet demand?	Unknown at this time
Provide details:	There are different stimulants, such as methylphenidate, belonging to the same class of psychostimulants
Do any specific population groups use this product?	Yes
Provide details of the groups and the impact on those groups:	Paediatric, adolescents, and adult patients with ADHD. Adult patients with BED
Based on your answers above and the Assessment Framework, what is the shortage impact rating?	2 - Medium Impact

Shortage Action

What communication activities have happened or are planned?

Communication Action	Date of Communication
Letter to Prescribers	14-Aug-2023
Letter to Patient Advocacy Groups	14-Aug-2023
Letter to Pharmacists	14-Aug-2023
Letter to Wholesalers	14-Aug-2023

Letter attached in Supporting Information: No Document 52

Further comments on communications: Communications plans includes:
1. HCP letter (all paediatricians and psychiatrists)
2. Consumer Statement to Patient Advisory Groups (ADHD Australia, ADHD Foundation)
3. Pharmacy Letter (all retail pharmacies)
4. Wholesaler Letter

What supply management actions have happened or are planned?

Management Action	Date of Management Action
Constrained Supply	07-Aug-2023
Working to expedite next shipment	07-Aug-2023

Further comments on management actions:

Supporting Information

Supporting data will be: Attached

Documents attached to this notification:

File Name	Created By	Description
Updated table for Stock on Hand for VYVANSE 30mg.pdf	S22	Updated stock on hand

Sponsor website where medicine shortage information is available:

File Attachments
The following files have been attached to this notification.

Updated table for Stock on Hand for VYVANSE 30mg

Stock at company level	4,312
Stock at wholesaler level	6,406

Notifier

Notifier

Sponsor Name: Takeda Pharmaceuticals Australia Pty Ltd

Sponsor Address: Grosvenor Place Level 39 225 George Street Sydney NSW 2000

Australian telephone number for public contact purposes: 1800012612

Medical information email for public contact purposes: medinfoAPAC@takeda.com

Primary Contact

Name: §22

Phone Number: §22

Email Address: §22@takeda.com

Secondary Contact

Name: §22

Phone Number: §22

Email Address: §22@takeda.com

ARTG Entry

ARTG Entry

ARTG number of the product that has a supply disruption:

ARTG ID	ARTG Name	Active Ingredient	Strength	Dosage Form
199227	VYVANSE	lisdexamfetamine dimesilate	30mg	Capsule, hard

ATC Descriptor: Nervous system

Are all pack sizes for this ARTG entry affected? Yes

Is this ARTG entry listed in the PBS? Yes

Provide the PBS number for this listing: 10486X

Do you have a designated sponsor representative within your organisation who is a point of contact on PBS matters? Yes

PBS Contact Details

Name: §22

Phone Number: §22

Email Address: §22@takeda.com

Details

Details

When was the shortage known to the sponsor? 04/08/2023

Nature of the shortage:	Resolved	
Shortage reason:	Manufacturing	Document 54
Manufacturing site problem:	Issues/delays with packaging and/or labelling	
Shortage reason - further information:	Takeda are experiencing some delays related to the global supply of Vyvanse products due to the remediation actions implemented at the contract manufacturing organization site Wasdell Europe with respect to the Critical Observations identified during the HPRA health authority inspection previously communicated to the TGA. As a result the expected manufacturing time frames have been increased and committed shipments to Australia have been further delayed.	
Estimated period supply will be affected at wholesaler points:	From:	07/08/2023
	To:	26/03/2024
Availability:	Available	
TGA publication date:	14/08/2023	
Is this shortage related to other medicines within the same Therapeutic class?	No	
Is this shortage specific to Australia?	No	
Estimated normal demand volumes for Australia:	S47	
Estimated percentage share of the Australian market:	100 %	
Estimated current stock at sponsor / manufacturing level in Australia:	47122 units	
Estimated current stock at wholesaler / distributor level in Australia:	2453 units	
What is meant by 1 unit in this context:	Single pack of 30 capsules	

Impact

Are there therapeutic alternatives on the Australian market?	Yes
What is the status of substitute options for this product in Australia?	Appropriate Therapeutic Alternatives
Are they available in adequate supplies to meet demand?	Unknown at this time
Provide details:	There are different stimulants, such as methylphenidate, belonging to the same class of psychostimulants
Do any specific population groups use this product?	Yes
Provide details of the groups and the impact on those groups:	Paediatric, adolescents, and adult patients with ADHD. Adult patients with BED
Based on your answers above and the Assessment Framework, what is the shortage impact rating?	2 - Medium Impact

Shortage Action

What communication activities have happened or are planned?

Communication Action	Date of Communication
Letter to Prescribers	14-Aug-2023
Letter to Patient Advocacy Groups	14-Aug-2023
Letter to Pharmacists	14-Aug-2023
Letter to Wholesalers	14-Aug-2023

Letter attached in Supporting Information:

No

[Document 54](#)

Further comments on communications:

Communications plans includes:

1. HCP letter (all paediatricians and psychiatrists)
 2. Consumer Statement to Patient Advisory Groups (ADHD Australia, ADHD Foundation)
 3. Pharmacy Letter (all retail pharmacies)
 4. Wholesaler Letter
-

What supply management actions have happened or are planned?

Management Action	Date of Management Action
Constrained Supply	07-Aug-2023
Working to expedite next shipment	07-Aug-2023

Further comments on management actions:

Supporting Information

Supporting data will be:

Sponsor website where medicine shortage information is available:

From: s22
To: s22
Cc: s22
Subject: RE: Medicine shortage notification VYVANSE lisdexamfetamine dimesilate 30mg capsule bottle [199227] [SEC=OFFICIAL]
Date: Tuesday, 2 April 2024 2:48:39 PM

Thanks for your prompt reply, s22
Have a good afternoon.
Kind Regards,
s22

s22
Pharmacist
Medicine Shortages Section
Pharmacovigilance Branch

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

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

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From: s22 @takeda.com>
Sent: Tuesday, April 2, 2024 2:41 PM
To: s22 @Health.gov.au>
Cc: s22 @takeda.com>; s22 @takeda.com>
Subject: RE: Medicine shortage notification VYVANSE lisdexamfetamine dimesilate 30mg capsule bottle [199227] [SEC=OFFICIAL]

Dear s22

Please see below the breakdown of the upcoming shipments of VYVANSE 30mg covering the next 6 months; we will be receiving 3 shipments in Apr and 1 in July

Apr-24	May-24	Jun-24	Jul-24	Aug-24	Sep-24
164,456 units			138,967		
05-Apr: 30,035 units 10-Apr: 87,570 units 20-Apr: 46,851 units			1 shipment Late July		

Should you need any further information, please let us know immediately.

Kind regards
s22

From: s22 [redacted] <[redacted]@Health.gov.au>
Sent: Tuesday, April 2, 2024 2:16 PM
To: s22 [redacted] <[redacted]@takeda.com>
Cc: s22 [redacted] <[redacted]@takeda.com>
Subject: Medicine shortage notification VYVANSE lisdexamfetamine dimesilate 30mg capsule bottle [199227]
[SEC=OFFICIAL]

Dear Regulatory Affairs Team,

Thank you for submitting the medicine shortage notification for VYVANSE lisdexamfetamine dimesilate 30mg capsule bottle [199227].

Do you have information available on expected deliveries for the coming 6 months and quantities expected for each order?

A response at your earliest convenience would be greatly appreciated.

Kind Regards,

s22 [redacted]

s22 [redacted]

Pharmacist


Medicine Shortages Section

Pharmacovigilance Branch

Phone: s22 [redacted]

Email: medicine.shortages@health.gov.au

Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100
Woden ACT 2606
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From: [Medicine Shortages](#)
To: s22
Subject: FW: VYVANSE shortages - Takeda's proposed updates to TGA's VYVANSE shortage website page [SEC=OFFICIAL]
Date: Monday, 8 April 2024 10:26:16 AM
Attachments: [image003.gif](#)
[image004.gif](#)
[image005.png](#)

Good morning s22

I've moved this to your @ Action folder
regards

s22

From: s22 @takeda.com>
Sent: Saturday, April 6, 2024 7:57 AM
To: Medicine Shortages <medicine.shortages@health.gov.au>
Cc: s22 @takeda.com>
Subject: RE: VYVANSE shortages - Takeda's proposed updates to TGA's VYVANSE shortage website page [SEC=OFFICIAL]

Dear s22

To answer your question below and based on current information we are confident of current dates for resolving the shortages of the 40mg and 60mg strengths. As done with the 30mg and 50mg strengths we will confirm resolution closer to those dates.

Should you need any further information, please let us know immediately.

Kind regards

s22

From: Medicine Shortages <medicine.shortages@health.gov.au>
Sent: Wednesday, April 3, 2024 4:24 PM
To: s22 @takeda.com>
Subject: RE: VYVANSE shortages - Takeda's proposed updates to TGA's VYVANSE shortage website page [SEC=OFFICIAL]

Dear s22

Please note, the TGA webpage [About the shortages of Vyvanse \(lisdexamfetamine dimesilate\) capsules | Therapeutic Goods Administration \(TGA\)](#) has now been updated.

Are you able to share with us Takeda's confidence in resolving the shortage of the 40mg strength on 30 April 2024 and 60mg on April 19 April 2024?

Kind Regards,

s22

s22

Pharmacist
Medicine Shortages Section
Pharmacovigilance Branch

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

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



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From: s22 <[REDACTED]@takeda.com>
Sent: Tuesday, April 2, 2024 1:20 PM
To: Medicine Shortages <medicine.shortages@health.gov.au>
Subject: RE: VYVANSE shortages - Takeda's proposed updates to TGA's VYVANSE shortage website page [SEC=OFFICIAL]

Dear s22

Thank you very much for the prompt response, and my apologies as I hadn't realised the notification is still in draft; I now submitted it.

Please let me know if anything else is still needed before the TGA webpage can be updated accordingly.

Kind regards

s22

From: Medicine Shortages <medicine.shortages@health.gov.au>
Sent: Tuesday, April 2, 2024 1:13 PM
To: s22 <[REDACTED]@takeda.com>
Subject: RE: VYVANSE shortages - Takeda's proposed updates to TGA's VYVANSE shortage website page [SEC=OFFICIAL]

Dear s22

Thank you for your email.

I have had a look at the medicine shortage notification for VYVANSE lisdexamfetamine dimesilate

30mg capsule bottle – ARTG 199227. It appears that the updated notification is in draft and has not yet been submitted for us to process.

Can you please kindly check your drafts folder in eBS to see if the notification is visible. If so, can you please finalise the draft, validate and submit.

If you are unable to see the draft notification, please let me know, and I will investigate further.

Kind regards

s22

Pharmacist
Medicine Shortages Section
Pharmacovigilance Branch

Phone: s22

Email: medicine.shortages@health.gov.au

Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care
PO Box 100
Woden ACT 2606
www.tga.gov.au



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From: s22 <[redacted]@takeda.com>

Sent: Tuesday, April 2, 2024 12:23 PM

To: Medicine Shortages <medicine.shortages@health.gov.au>

Cc: s22 <[redacted]@takeda.com>

Subject: RE: VYVANSE shortages - Takeda's proposed updates to TGA's VYVANSE shortage website page [SEC=OFFICIAL]

Dear s22

I hope you had a wonderful Easter long weekend.

The VYVANSE 30mg is resolved and I updated the Shortage notification accordingly last Tue 26-Mar, yet the TGA webpage is not reflecting the updated status yet.

Can you please let us know when will the webpage be updated?

Many thanks for your support.

s22

From: Medicine Shortages <medicine.shortages@health.gov.au>

Sent: Wednesday, March 6, 2024 12:13 PM

To: s22 <[REDACTED]@takeda.com>

Cc: s22 <[REDACTED]@takeda.com>

Subject: RE: VYVANSE shortages - Takeda's proposed updates to TGA's VYVANSE shortage website page [SEC=OFFICIAL]

Good afternoon s22

The changes and updates to the [About the shortages of Vyvanse \(lisdexamfetamine dimesilate\) capsules](#) webpage were published this morning.

Thank you again for your collaborative approach to these shortages, and if you have any feedback please just let me know.

Kindest regards,

s22

Pharmacist

Medicine Shortages Section
Pharmacovigilance Branch

Phone: s22

Email: medicine.shortages@health.gov.au

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



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From: s22 <[REDACTED]@takeda.com>

Sent: Wednesday, February 28, 2024 10:03 AM

To: Medicine Shortages <medicine.shortages@health.gov.au>

Cc: s22 <[REDACTED]@takeda.com>

Subject: VYVANSE shortages - Takeda's proposed updates to TGA's VYVANSE shortage website page

Dear TGA Medicine Shortages Team

Takeda proposes update to the TGA's VYVANSE shortage website page (<https://www.tga.gov.au/safety/shortages/information-about-major-medicine-shortages/about-shortages-vyvanse-lisdexamfetamine-dimesilate-capsules>).

Attached here are clean and tracked copies of the proposed changes.

Summary of edits and intent

- **Emergency supply for urgent patient need – revised copy**
 - Includes reference to requests being '**subject to availability**'. Whilst every effort is made to maintain an emergency reserve it cannot be guaranteed.
 - Change from 'request emergency stock through Takeda's online portal' to 'Information for pharmacists on how to request emergency supply can be found on Takeda's online portal'. This reflects the ability to now make requests direct through DHL to improve efficiency in processing of requests. The details for how to do this are included in the same link for Takeda's online portal.
- **Information for patients**
 - Suggest remove reference to **accessing specialist during holiday period...** as this is no longer relevant.

We look forward to your consideration of the proposed changes. Please contact us if you need any further information or clarification.

Kind regards

s22

s22, MMedSc
Regulatory Product Lead, Oceania Cluster

Takeda Pharmaceuticals Australia Pty Ltd

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