s22 [redacted]

From: s22 [redacted] @sandoz.com>
Sent: Friday, July 26, 2024 10:34 AM
To: Medicine Shortages <medicine.shortages@health.gov.au>
Subject: RE: Sandoz estradiol patches market assessment [SEC=OFFICIAL]

Dear s2 [redacted]

s22 [redacted].

Please disregard the information provided in the email sent previously.

Please don't hesitate to contact me if you have any questions.

Many thanks and kind regards,

s22 [redacted]
s22 [redacted]

SANDOZ PTY LTD
Suite 1501, 100 Pacific Highway
North Sydney, NSW 2060
AUSTRALIA

s22 [redacted]
s22 [redacted] @sandoz.com

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From: s22 [redacted]
Sent: Friday, July 26, 2024 12:01 AM
To: Medicine Shortages <medicine.shortages@health.gov.au>
Subject: RE: Sandoz estradiol patches market assessment [SEC=OFFICIAL]

Dear s2 [redacted]

Please see our response of the currently available information for the below products:

Product	Estimated normal monthly demand levels	Estimated market share	Current stock levels at the sponsor/manufacturing level (as at 18/07/2024)	Current stock levels at the wholesaler/distributor level (as at 17/07/2024)	Dates of expected deliveries (importations) for the next 6 months and quantities expected for each order
s22 [redacted]					
ESTRADOT 100 estradiol 100 microgram transdermal drug delivery system sachet (338060)	s47 [redacted]				

Please let me know if you have any questions.

Many thanks and kind regards,

s22
s22

SANDOZ PTY LTD
Suite 1501, 100 Pacific Highway
North Sydney, NSW 2060
AUSTRALIA

M s22
s22 @sandoz.com

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From: s22
Sent: Thursday, July 18, 2024 3:33 PM
To: Medicine Shortages <medicine.shortages@health.gov.au>
Cc: s22 @sandoz.com>
Subject: RE: Sandoz estradiol patches market assessment [SEC=OFFICIAL]

Dear s2

Thank you for providing the background to your query.
We will provide the information by 25 July.

Kind regards,

s22
s22

SANDOZ PTY LTD
Suite 1501, 100 Pacific Highway
North Sydney, NSW 2060
AUSTRALIA

M s22
s22 @sandoz.com

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From: Medicine Shortages <medicine.shortages@health.gov.au>
Sent: Thursday, July 18, 2024 3:03 PM
To: s22 @sandoz.com>
Subject: Sandoz estradiol patches market assessment [SEC=OFFICIAL]

This Message Is From an External Sender
This message came from outside your organization.

Hi s22

Thank you for your email.
The reason behind my phone call was that we had received signals that the approved S19a Estradiol patches were unobtainable (strengths weren't mentioned). I believe my colleague has been in touch with Sandoz and is investigating the supply status of these products, however I would appreciate if you could provide me with information on the **ARTG estradiol patches** supplied by Sandoz.

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
s22					

s22 [redacted]					
ESTRADOT 10 estradiol 100 microgram transdermal drug delivery system sachet (338060)					

A response by **COB 25 July 2024** would be greatly appreciated.

Kind regards,
s2 [redacted]

s22 [redacted]
s22 [redacted]
Medicine Shortages Section
Pharmacovigilance Branch

Phone: s22 [redacted]
Email: s22 [redacted] @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] @sandoz.com>
Sent: Thursday, July 18, 2024 10:58 AM
To: s22 [redacted] @Health.gov.au>
Cc: s22 [redacted] @sandoz.com>
Subject: Estradot/Estradiol phone call enquiry

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

Dear s2 [redacted]

Thank you for your phone call enquiry on the stock levels of Estradot and Estradiol.
Sandoz is collating the data for our response.

Would you be able to provide a background on your request, or is there additional information you would like Sandoz to provide for a more complete response?

Kind regards,

s22 [redacted]
s22 [redacted]

SANDOZ PTY LTD
Suite 1501, 100 Pacific Highway
North Sydney, NSW 2060
AUSTRALIA

M s22 [redacted]
s22 [redacted] @sandoz.com

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Document 2

From: s22
To: Medicine Shortages
Cc: s22 Section 19A Submissions; s22
Subject: RE: New notification for s22 [SEC=OFFICIAL]
Date: Friday, 4 October 2024 1:30:24 PM
Attachments: image001.png
image003.png

Dear s22

Thank you for your query. Please see our response below.

s22

Response
s22

s47

Question 2
We have received multiple enquiries from external stakeholders, as well as ongoing media spotlight on the shortages of transdermal HRT patches.
Is Sandoz reassessing its future planned orders or considering alternative management actions, such as submitting a S19A application?

Response

- The shortage management strategy is:
  - s22
  - s47

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
s22					

					s22 [redacted]
s22 [redacted]					
ESTRADOT 100 estradiol 100 microgram transdermal drug delivery system sachet (338060)	s47 [redacted]				

Please reach out if you have further questions.

Many thanks and kind regards,

s22 [redacted]
s22 [redacted]

SANDOZ PTY LTD
Suite 1501, 100 Pacific Highway
North Sydney, NSW 2060
AUSTRALIA

M s22 [redacted]
s22 [redacted] @sandoz.com

[redacted]

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From: Medicine Shortages <medicine.shortages@health.gov.au>
Sent: Tuesday, September 24, 2024 2:08 PM
To: s22 [redacted] @sandoz.com>
Cc: s22 [redacted] @sandoz.com>
Subject: RE: New notification for s22 [redacted]

This Message Is From an External Sender

This message came from outside your organization.

Good afternoon s22

s22 [redacted]

We have received multiple enquiries from external stakeholders, as well as ongoing media spotlight on the shortages of transdermal HRT patches. Is Sandoz reassessing its future planned orders or considering alternative management actions, such as submitting a S19A application?

I would also like to kindly request for the following information to be provided (in the table below) as we are undertaking a new market assessment of Estradot, s22 [redacted] and s2 [redacted] products.

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
s22 [redacted]					
ESTRADOT 10 estradiol 100 microgram transdermal drug delivery system sachet (338060)					

A response by **COB Tuesday 1 October 2024** would be greatly appreciated.

Kind Regards,

s22 [redacted]

s22 [redacted]
s22 [redacted] - Medicine Shortages Section
Pharmacovigilance Branch
Medicine Regulation Division | Health Products Regulation Group
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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s22 [redacted]

s22

[redacted]

From: s22
To: Medicine Shortages
Cc: s22 Section 19A Submissions; s22
Subject: RE: New notification for s22 [SEC=OFFICIAL]
Date: Friday, 4 October 2024 4:51:09 PM
Attachments: image005.png
image007.png

Dear s22

My sincere apologies. Please disregard the table in my previous email and see the updated table data below.

Many thanks,
s22

From: s22
Sent: Friday, October 4, 2024 1:30 PM
To: Medicine Shortages <medicine.shortages@health.gov.au>
Cc s @sandoz.com>; s22 @health.gov.au s22 @health.gov.au; s22 @sandoz.com>;
Section 19A Submissions <Section19ASubmissions@Health.gov.au>; s22 @sandoz.com>
Subject: RE: New notification for s22 [SEC=OFFICIAL]

s22

Question 2
We have received multiple enquiries from external stakeholders, as well as ongoing media spotlight on the shortages of transdermal HRT patches.
Is Sandoz reassessing its future planned orders or considering alternative management actions, such as submitting a S19A application?

Response
s22

s47

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
s22					

					s22 [redacted]
s22 [redacted]					
ESTRADOT 100 estradiol 100 microgram transdermal drug delivery system sachet (338060)	s47 [redacted]				

Please reach out if you have further questions.

Many thanks and kind regards,

s22 [redacted]
s22 [redacted]

SANDOZ PTY LTD
Suite 1501, 100 Pacific Highway
North Sydney, NSW 2060
AUSTRALIA

M s22 [redacted]
s22 [redacted] @sandoz.com

[redacted]

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From: Medicine Shortages <medicine.shortages@health.gov.au>
Sent: Tuesday, September 24, 2024 2:08 PM
To: s[redacted]@sandoz.com>
Cc: s22[redacted]@sandoz.com>
Subject: RE: New notification for s22[redacted] [SEC=OFFICIAL]

This Message Is From an External Sender
This message came from outside your organization.

Good afternoon s22

s22 [redacted]

We have received multiple enquiries from external stakeholders, as well as ongoing media spotlight on the shortages of transdermal HRT patches. Is Sandoz reassessing its future planned orders or considering alternative management actions, such as submitting a S19A application?

I would also like to kindly request for the following information to be provided (in the table below) as we are undertaking a new market assessment of Estradot, s22 [redacted] and s22 products.

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
s22 [redacted]					
ESTRADOT 10 estradiol 100 microgram transdermal drug delivery system sachet (338060)					

A response by **COB Tuesday 1 October 2024** would be greatly appreciated.

Kind Regards,

s22

s22 [redacted]
s22 [redacted] - Medicine Shortages Section
Pharmacovigilance Branch
Medicine Regulation Division | Health Products Regulation Group
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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s22

[redacted]

Document 3

s22

[redacted]

Document 4

From: Medicine Shortages
To: s22 [redacted]
Cc: s22 [redacted] @sandoz.com; s22 [redacted] ; Section 19A Submissions; s22 [redacted] @sandoz.com; s22 [redacted]
Subject: RE: New notification for s22 [redacted] [SEC=OFFICIAL]
Date: Thursday, 10 October 2024 10:16:05 AM
Attachments: image005.png
image007.png

Good morning s22 [redacted]

s22 [redacted]

Kind Regards,

s22 [redacted]

s22 [redacted]
s22 [redacted] - Medicine Shortages Section
Pharmacovigilance Branch
Medicine Regulation Division | Health Products Regulation Group
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] @sandoz.com>
Sent: Friday, October 4, 2024 4:51 PM
To: Medicine Shortages <medicine.shortages@health.gov.au>
Cc: s22 [redacted] @sandoz.com>; s22 [redacted] @health.gov.au>; s22 [redacted] @health.gov.au>; s22 [redacted] @sandoz.com>; Section 19A Submissions <Section19ASubmissions@Health.gov.au>; s22 [redacted] @sandoz.com>
Subject: RE: New notification for s22 [redacted] [SEC=OFFICIAL]

Dear s22 [redacted]

My sincere apologies. Please disregard the table in my previous email and see the updated table data below.

Many thanks,
s22 [redacted]

From: s [redacted]
Sent: Friday, October 4, 2024 1:30 PM
To: Medicine Shortages <medicine.shortages@health.gov.au>
Cc: s22 [redacted] @sandoz.com>; s22 [redacted] @health.gov.au; s22 [redacted] @health.gov.au; s22 [redacted] @sandoz.com>; Section 19A Submissions <Section19ASubmissions@Health.gov.au>; s22 [redacted] @sandoz.com>
Subject: RE: New notification for s22 [redacted] [SEC=OFFICIAL]

Dear s22 [redacted]

Thank you for your query. Please see our response below.

s22 [redacted]

s47 [redacted]

Question 2
We have received multiple enquiries from external stakeholders, as well as ongoing media spotlight on the shortages of transdermal HRT patches.
Is Sandoz reassessing its future planned orders or considering alternative management actions, such as submitting a S19A application?

R s22 [redacted]

s47 [redacted]

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

s22 [redacted]

					s22 [redacted]
s22 [redacted]					
ESTRADOT 100 estradiol 100 microgram transdermal drug delivery system sachet (338060)	s47 [redacted]				

Please reach out if you have further questions.

Many thanks and kind regards,

s22 [redacted]
s22 [redacted]

SANDOZ PTY LTD
Suite 1501, 100 Pacific Highway
North Sydney, NSW 2060
AUSTRALIA

M s22 [redacted]
s22 [redacted] @sandoz.com

[redacted]

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From: Medicine Shortages <medicine.shortages@health.gov.au>
Sent: Tuesday, September 24, 2024 2:08 PM
To: s22 [redacted] @sandoz.com>
Cc: s22 [redacted] @sandoz.com>
Subject: RE: New notification for s22 [redacted] [SEC=OFFICIAL]

This Message Is From an External Sender
This message came from outside your organization.

Good afternoon s22 [redacted]

s22 [redacted]

s22 [redacted]

We have received multiple enquiries from external stakeholders, as well as ongoing media spotlight on the shortages of transdermal HRT patches. Is Sandoz reassessing its future planned orders or considering alternative management actions, such as submitting a S19A application?

I would also like to kindly request for the following information to be provided (in the table below) as we are undertaking a new market assessment of Estradot, s22 [redacted] and s22 products.

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
s22 [redacted]					
ESTRADOT 10 estradiol 100 microgram transdermal drug delivery system sachet (338060)					

A response by **COB Tuesday 1 October 2024** would be greatly appreciated.

Kind Regards,

s22 [redacted]

s22 [redacted]
s22 [redacted] - Medicine Shortages Section
Pharmacovigilance Branch
Medicine Regulation Division | Health Products Regulation Group
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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s22 [redacted]

s22

[redacted]

From: Medicine Shortages
To: s22
Cc: s22 @sandoz.com; s22
Subject: RE: New notification for s22 [SEC=OFFICIAL]
Date: Thursday, 24 October 2024 2:38:00 PM
Attachments: image005.png
image007.png

Hi s22

Thank you for your response. I have processed the shortage notifications s47G nd s47G for Estradot 100 (ARTG 338060) and s22

I have the following questions relating to these shortages:

- s47 .
  However, the shortage has been pushed out to s47G Have there been any changes?
- s22
-

We are appreciative of a response to the above questions by **COB Monday 28 October 2024.**

Thank you for your assistance in managing this shortage. Please let us know if there are any updates.

Kind Regards,

s22
s22
s22 - 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 @sandoz.com>
Sent: Thursday, 24 October 2024 10:00 AM
To: Medicine Shortages <medicine.shortages@health.gov.au>
Cc: s22 @sandoz.com>; s22 @sandoz.com>; s22 @sandoz.com>; s22 @health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>
Subject: RE: New notification for s22 [SEC=OFFICIAL]

Dear s22
s22

Many thanks and kind regards,

s22
s22

SANDOZ PTY LTD
Suite 1501, 100 Pacific Highway
North Sydney, NSW 2060
AUSTRALIA

M s22
s22 @sandoz.com

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From: Medicine Shortages <medicine.shortages@health.gov.au>
Sent: Thursday, October 17, 2024 3:00 PM
To: s22 @sandoz.com>
Cc: s22 @sandoz.com>; s22 @sandoz.com>; s22 @sandoz.com>; s22

s22 @health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>
Subject: RE: New notification for s22 [SEC=OFFICIAL]

This Message Is From an External Sender

This message came from outside your organization.

Good afternoon s22

Thank you for updating the MSN s22

s22

Thank you for your ongoing collaboration, your assistance is greatly appreciated.

Kind Regards,

s22
s22
s22 - Medicine Shortages Section
Pharmacovigilance Branch
Medicine Regulation Division | Health Products Regulation Group
Phone s
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 @sandoz.com>
Sent: Friday, October 11, 2024 9:39 AM
To: Medicine Shortages <medicine.shortages@health.gov.au>
Cc: s22 @sandoz.com>; s22 @sandoz.com>; Section 19A Submissions <Section19ASubmissions@Health.gov.au>; s22 @sandoz.com>; s22 @health.gov.au>; s22 @Health.gov.au>; s22 @Health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>
Subject: RE: New notification for s22 [SEC=OFFICIAL]

Dear s22

Thank you for your response s22
Please see our comments to your email below in blue.

Many thanks and kind regards,

s22
s22

SANDOZ PTY LTD
Suite 1501, 100 Pacific Highway
North Sydney, NSW 2060
AUSTRALIA

M s22
s22 @sandoz.com

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From: Medicine Shortages <medicine.shortages@health.gov.au>
Sent: Thursday, October 10, 2024 10:16 AM
To: s22 @sandoz.com>
Cc: s22 @sandoz.com>; s22 @sandoz.com>; Section 19A Submissions

Document 5

<Section19ASubmissions@Health.gov.au>; s22 @sandoz.com>; s22 @health.gov.au>; s22 @Health.gov.au>; s22 @Health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>

Subject: RE: New notification for s22 [SEC=OFFICIAL]

This Message Is From an External Sender

This message came from outside your organization.

Good morning s22

s22

- The worldwide demand for Estradot and s47 range of products has increased s47
- s47
- Root cause of s22 shortage: s47
- Locally in AU and NZ, Sandoz is the only supplier of the s47 range of products and the national shortage is addressed as follows:
  - Estradot AU: s22
  - s47
    -
    -

Please let me know if you require the notification to be pushed back for your amendments.

Kind Regards,

s22

s22
s22 - 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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Document 5

s22

[redacted]

s22

Document 5

s22

Document 5

s22

Document 5

Document 5

s22

[redacted]

From: Medicine Shortages
To: s22
Cc: s22 @sandoz.com; s22 @sandoz.com; s22
Subject: RE: New notification for s22 [SEC=OFFICIAL]
Date: Tuesday, 29 October 2024 12:27:40 PM
Attachments: image002.png
image004.png

Dear s22

Thank you for your response. We are happy to have a meeting with Sandoz anytime between 11.30am-2pm on Thursday, 29 October 2024. Would this work for your team?
In terms of best contacts to invite from Medicine Shortages Section, please include everyone in this email from the TGA.
We would also appreciate if you could provide the meeting agenda prior to the meeting, noting we have some questions regarding the supply of Estradot, s22 products and the s47

Kind Regards,

s22
s22
s22 - 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 @sandoz.com>
Sent: Monday, October 28, 2024 5:13 PM
To: Medicine Shortages <medicine.shortages@health.gov.au>
Cc: s22 @sandoz.com>; s22 @sandoz.com>; s22 @sandoz.com>; s22 @health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>
Subject: RE: New notification for s22 [SEC=OFFICIAL]

Dear s22 and s22

Please see our responses to your queries below.

- **Information provided in s31 request in October, indicated that there is delivery s47 due for Estradot 100 (ARTG 338060) in s47G However, the shortage has been pushed out to s47G . Have there been any changes?**
  - Sandoz is experiencing a long-term shortage due to a global shortage for Estradot, s22 , and s22 products. This has led to:
    - s47
    - s47
  - During this long-term shortage limited registered stock will become available via the allocation. s47 delivery in s47G is still expected, however this is not a complete resolution of the shortage due to backorders and increased demand.
  - A S19 is currently under evaluation which is needed to address the shortage in Australia (and indirectly, in New Zealand). Therefore, the shortage was extended to allow for the evaluation of the S19.
    s47 .
  - Sandoz is proposing a call with the TGA this week to address the medicine shortage reporting for Estradot, s22 , and s22 products s47
    - Please advise who from the TGA should be invited to the call. (E.g. Head of Medicine Shortages)

s22

s22

  - Sandoz is proposing a call with the TGA this week to discuss proposals to address the medicine shortage in the long term for s22 s22 , and s22 products.
    - Please advise who from the TGA should be invited to the call. (E.g. Head of Medicine Shortages)
  - Pending this call, Sandoz will review the shortage resolution date and update the notification accordingly.

We will look forward to your response regarding the best contacts to invite to the call to discuss the proposals to address the medicine shortages for Estradot, s22 , and s22

Many thanks and kind regards,

s22 [redacted]
s22 [redacted]

SANDOZ PTY LTD
Suite 1501, 100 Pacific Highway
North Sydney, NSW 2060
AUSTRALIA

M s22 [redacted]
s22 [redacted] @sandoz.com

[redacted]

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s22

[redacted]

Document 6

s22

[redacted]

s22

Document 6

s22

Document 6

s22

Document 6

s22

Document 6

s22

[redacted]

Document 6

s22

[redacted]

From: s22 [redacted]
To: Medicine Shortages
Cc: s22 [redacted]
Subject: RE: Urgent request: Please push back notifications [SEC=OFFICIAL]
Date: Wednesday, 6 November 2024 12:31:21 PM
Attachments: image002.png

Dear s22 [redacted]

s22 [redacted] has just had another alignment call with s22 [redacted] on the reporting of the medicine shortages for the Estradot products.
Could I please request that you push back what was submitted for s22 [redacted] and Estradot 100, and I will update all strengths of Estradot s22 [redacted] for processing today.

Thank you so much for your cooperation and support!

Many thanks and kind regards,

s22 [redacted]
s22 [redacted]

SANDOZ PTY LTD
Suite 1501, 100 Pacific Highway
North Sydney, NSW 2060
AUSTRALIA

M s22 [redacted]
s22 [redacted] @sandoz.com

SANDOZ

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From: Medicine Shortages <medicine.shortages@health.gov.au>
Sent: Wednesday, November 6, 2024 9:44 AM
To: s22 [redacted] @sandoz.com>
Cc: s22 [redacted] @health.gov.au>; s22 [redacted] @Health.gov.au>
Subject: RE: Urgent request: Please push back notifications [SEC=OFFICIAL]
Importance: High

This Message Is From an External Sender

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Good morning s22

Thank you for submitting the amended notifications for s22 and Estradot 100 s22

s22

We would appreciate if these notifications can be processed today. Please reach out if you have any questions and if the notifications need to be pushed back.

Kind Regards,

s22
s22
s22 - 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 <medicine.shortages@health.gov.au>
Sent: Tuesday, November 5, 2024 5:05 PM
To: s22 @sandoz.com
Subject: RE: Urgent request: Please push back notifications [SEC=OFFICIAL]
Importance: High

Hi s22

I've pushed back the notification to you for your amendments.

Kind Regards,

s22
s22
s22 - 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
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From: s22 @sandoz.com>
Sent: Tuesday, November 5, 2024 4:41 PM
To: Medicine Shortages <medicine.shortages@health.gov.au>
Subject: Urgent request: Please push back notifications
Importance: High

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

Dear Medicine Shortages Team,

I have submitted the following notifications for the Estradot range of products, however unfortunately this was inaccurate information.
Could I please request that these are "pushed back" into draft status and I will provide the update.

s22

s22 [redacted]

Thank you so much!

Kind regards,

s22 [redacted]
s22 [redacted]

SANDOZ PTY LTD
Suite 1501, 100 Pacific Highway
North Sydney, NSW 2060
AUSTRALIA

M s22 [redacted]
s22 [redacted] @sandoz.com

SANDOZ

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From: s22 [redacted]
To: Medicine Shortages
Cc: s22 [redacted]
Subject: RE: Urgent request: Please push back notifications [SEC=OFFICIAL]
Date: Wednesday, 6 November 2024 2:50:22 PM
Attachments: image003.png
image004.png
image006.png
image007.png

Dear s22 [redacted]

I have submitted the updated notifications for all the Estradot and Estalis products.

ARTG	Description	Medicine Shortage - To (Re-visit date) (in ascending order)	MS identifier
s22 [redacted]			
338060	ESTRADOT 100MCG 8TTS AU	31/12/2025	MS-2024-04765-1

s22 [redacted]

Thank you so much for your understanding and support.

Many thanks and kind regards,

s22 [redacted]
s22 [redacted]

SANDOZ PTY LTD
Suite 1501, 100 Pacific Highway
North Sydney, NSW 2060
AUSTRALIA

M s22 [redacted]
s22 [redacted] @sandoz.com

[redacted]

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From: Medicine Shortages <medicine.shortages@health.gov.au>
Sent: Wednesday, November 6, 2024 1:44 PM
To: s22 [redacted] @sandoz.com>
Cc: s22 [redacted] @health.gov.au>; s22 [redacted] @Health.gov.au>; s22 [redacted] @sandoz.com>
Subject: RE: Urgent request: Please push back notifications [SEC=OFFICIAL]

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Hi s22

I have already processed the updates for Estrado s2 and 100, please see the Medicine shortage reports database for further information. If you require these notifications to be updated, you should be able to submit it now.

s22

Please call me on the below number if you have any questions.

Kind Regards,

s22

s22
s22 – Medicine Shortages Section

Medicines Regulation Division | Health Products Regulation Group
Pharmacovigilance Branch
Australian Government Department of Health and Aged Care
T: s22
| E: s22 @health.gov.au
Location: Parramatta
GPO Box 9848, Sydney NSW 2001

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s22

s22

[redacted]

s22

[redacted]

s22

Document 8

From: Medicine Shortages
To: s22 [redacted]
Subject: RE: Medicine Shortage Database - Estradot s19a statement [SEC=OFFICIAL]
Date: Thursday, 7 November 2024 10:46:00 AM
Attachments: image001.png
image002.png
image006.png
image004.png

Hi s22 [redacted],

Apologies regarding that, I can quickly add these back in. Please allow a couple of hours for the MSRD to update.

Kind Regards,

s22 [redacted]
s22 [redacted]
s22 [redacted] - Medicine Shortages Section
Pharmacovigilance Branch
Medicine Regulation Division | Health Products Regulation Group
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] @sandoz.com>
Sent: Thursday, November 7, 2024 10:42 AM
To: Medicine Shortages <medicine.shortages@health.gov.au>
Subject: Medicine Shortage Database - Estradot s19a statement

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

Dear Team,

Thank you so much for processing the medicine shortage updates for the Estradot and s22 products.

For s22 and Estradot 100mcg, the S19a statement that was previously there has been removed.
Would it be possible for these to be added back?

s22

estradiol
ESTRADOT 100 estradiol 100 microgram transdermal drug delivery system sachet
AUST R: 338060
Expected supply: 31 Dec 2025
Availability: Unavailable
Management action: Sponsor is working to expedite the next shipment

s22

Thank you so much!

Kind regards,

s22
s22

SANDOZ PTY LTD
Suite 1501, 100 Pacific Highway
North Sydney, NSW 2060
AUSTRALIA

M s22
s22 @sandoz.com

SANDOZ

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Document 10

From: Medicine Shortages
To: s22
Cc: s22
Subject: RE: Request for information - Market assessment - Estradot and s22 transdermal patches [SEC=OFFICIAL]
Date: Friday, 31 January 2025 2:09:12 PM
Attachments: image002.png

Dear s22

Thank you for your response. We will grant Sandoz an extension until 10 February 2025 to provide the missing delivery/planned orders information.

Kind Regards,

s22
s22
s22 - 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 @sandoz.com>
Sent: Thursday, 30 January 2025 2:48 PM
To: Medicine Shortages <medicine.shortages@health.gov.au>
Cc: s22 @Health.gov.au>
Subject: RE: Request for information - Market assessment - Estradot and s22 transdermal patches [SEC=OFFICIAL]

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

Dear s22

Please see below the information available so far.

Regarding the delivery information, the person managing this is currently on annual leave. Would it be possible for us to have an extension until 10th February 2025? Many thanks for your understanding – will look forward to your response. We will endeavor to provide the information as soon as possible.

ARTG product	Pack Size	Estimated normal monthly demand levels	Estimated market share	Current stock levels at the sponsor/manufacturing level (as at 28/01/2025)	Current stock levels at the wholesaler/distributor level (as at 28/01/2025)	Dates of expected deliveries (importations) for the next 6 months and quantities expected for each order
s22 [redacted]						
ESTRADOT 100 estradiol 100 microgram transdermal drug delivery system sachet ARTG 338060	8 patches	s47 [redacted]				TBC
s22 [redacted]						

s22 [redacted]

Many thanks and kind regards,

s22 [redacted]
s22 [redacted]

SANDOZ PTY LTD
Suite 1501, 100 Pacific Highway
North Sydney, NSW 2060
AUSTRALIA

M s22 [redacted]
s22 [redacted] @sandoz.com

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From: Medicine Shortages <medicine.shortages@health.gov.au>
Sent: Friday, January 24, 2025 11:42 AM
To: s22 [redacted] @sandoz.com>
Cc: s22 [redacted] @Health.gov.au>; s22 [redacted] @sandoz.com>
Subject: Request for information - Market assessment - Estradot and Estalis transdermal patches [SEC=OFFICIAL]

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Dear s22 [redacted]

I hope this email finds you well.

As we continue to monitor the availability of transdermal HRT patches to ensure patients can readily access their medicine, we kindly request for an update regarding the current and upcoming supply of all ARTG estradiol-containing patches marketed by Sandoz Pty Ltd.

Appreciate if you can complete the table and respond by **COB Friday, 31 January 2025.**

ARTG product	Pack Size	Estimated normal monthly demand levels	Estimated market share	Current stock levels at the sponsor/manufacturing level (as at XX/XX/XXXX)	Current stock levels at the wholesaler/distributor level (as at XX/XX/XXXX)	Dates of expected deliveries (importations) for the next 6 months and quantities expected for each order
s22 [redacted]						
ESTRADOT 100 estradiol 100 microgram transdermal drug delivery system sachet ARTG 338060						
s22 [redacted]						

Kind Regards,

s22
s22
s22 - 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
To: Section 19A Submissions; s22
Cc: Medicine Shortages; s22
Subject: S19 / Estradiol Transdermal System s22 and 100mcg/day (0.1mg/day) (Sandoz, USA)
Date: Friday, 1 November 2024 3:04:07 PM
Attachments: image002.gif
image003.jpg

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Dear s22
Further to the emails below and feedback received from TGA s22
Sandoz has updated medicine shortages for ESTRADOT 100 mcg (AUST R 338060) and s22 s22 today until 30/04/2025 to support Sandoz' application to continue supply of estradiol transdermal products under the section 19A pathway.
s22
Please advise if you require any further information to evaluate and approve S19 application currently under review.
Many thanks
s22

From: s22

From: Section 19A Submissions <Section19ASubmissions@Health.gov.au>
Sent: Thursday, 24 October 2024 12:48 PM
To: s22 @sandoz.com>
Subject: RE: Amended DHCPL - Estradiol Transdermal System s22 and 100mcg/day (0.1mg/day) (Sandoz, USA) [SEC=OFFICIAL]

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Dear s22
Thank you for following up the shortage dates of Estradot products.
Once the medicine shortages notifications are updated, we will progress the renewal application for Estradiol Transdermal System s22 and 100mcg/day (0.1mg/day) (Sandoz, USA). We will endeavour to have a decision from the delegate by 31/10/24.
Kind regards
s22
s22
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] @sandoz.com>
Sent: Wednesday, 23 October 2024 5:37 PM
To: Section 19A Submissions <Section19ASubmissions@Health.gov.au>
Subject: RE: Amended DHCPL - Estradiol Transdermal System s22 [redacted] and 100mcg/day (0.1mg/day) (Sandoz, USA) [SEC=OFFICIAL]

Dear s22 [redacted]

Thank you again for your time over the phone today.

I've spoken to s47G [redacted] in regards to the information that Sandoz would like to communicate in regards to our stock of Estradot. We will be receiving the final feedback on Monday afternoon and will action accordingly. However, I would like to confirm with you if the proposed timeframe would still allow for a decision of our S19A application to be made by the 31-Oct-2024? I do apologise for the short time frame.

Thank you again for all your support in regards to this application.

Kind regards,

s22 [redacted]
s22 [redacted]

SANDOZ PTY LTD
Suite 1501, 100 Pacific Highway
North Sydney, NSW 2060
Australia
T s22 [redacted]
M s22 [redacted]
s22 [redacted] @sandoz.com

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From: Section 19A Submissions <Section19ASubmissions@Health.gov.au>
Sent: Wednesday, 23 October 2024 12:42 PM
To: s22 [redacted] @sandoz.com>
Subject: RE: Amended DHCPL - Estradiol Transdermal System s22 [redacted] and 100mcg/day (0.1mg/day) (Sandoz, USA) [SEC=OFFICIAL]

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Dear s22

Thank you for your reply and updating the MSN for ESTRADOT 100 estradiol 100 microgram transdermal drug delivery system sachet ARTG 338060.

Can we please further discuss the published shortage dates? Is there a convenient time this afternoon for me to call? Please also confirm the best phone number to contact you on.

Kind regards

s22
s22
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 @sandoz.com>
Sent: Wednesday, 23 October 2024 11:44 AM
To: Section 19A Submissions <Section19ASubmissions@Health.gov.au>
Subject: RE: Amended DHCPL - Estradiol Transdermal System s22 and 100mcg/day (0.1mg/day) (Sandoz, USA) [SEC=OFFICIAL]

Dear s22 ,

Thank you for your email.

We reviewed the MSN database and have submitted an extension for ESTRADOT 100 mcg. The submission number for your reference is: **MS-2024-04548-1.**

Please let me know if there are any further discrepancies or any further information required for the approval of the S19A extension application.

Thank you again for all your support in this application.

Kind regards,

s22
s22

SANDOZ PTY LTD
Suite 1501, 100 Pacific Highway
North Sydney, NSW 2060
Australia
T s22
M s22
s22 @sandoz.com

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From: Section 19A Submissions <Section19ASubmissions@Health.gov.au>
Sent: Tuesday, 22 October 2024 12:59 PM
To: s22 [redacted] @sandoz.com>
Subject: RE: Amended DHCPL - Estradiol Transdermal System s22 [redacted] and 100mcg/day (0.1mg/day) (Sandoz, USA) [SEC=OFFICIAL]

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Dear s22 [redacted]
Thank you for your email.
I would like to ensure that the expiry of the section 19A renewal approvals align with the shortage dates, to ensure continuity in supply of estradiol patches. Please see my email attached from the 17/10/24 regarding the medicine shortage notifications for Estradot products.
From the information provided in the market assessment, there is not sufficient stock to resolve all the Estradot shortages within s47G [redacted].
Please update the shortage notifications as soon as possible. Once this is done the section 19A renewal application can then be finalised and sent to the delegate for review.
Kind regards
s22 [redacted]
s22 [redacted]
Medicine Shortages Section
Pharmacovigilance Branch

Phone: s22 [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

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From: s22 [redacted] @sandoz.com>
Sent: Tuesday, October 22, 2024 11:33 AM
To: Section 19A Submissions <Section19ASubmissions@Health.gov.au>
Subject: RE: Amended DHCPL - Estradiol Transdermal System s22 [redacted] and

100mcg/day (0.1mg/day) (Sandoz, USA) [SEC=OFFICIAL]

Dear s22

I hope you are well.

I was hoping to receive an update from you in regards to the processing of the renewal S19A application for Estradiol Transdermal System s22 and 100 mcg/day.

Your advice would be greatly appreciated.

Thanks and kind regards,

s22

s22

SANDOZ PTY LTD

Suite 1501, 100 Pacific Highway

North Sydney, NSW 2060

Australia

T s22

M s22

s22 @sandoz.com

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From: s22

Sent: Tuesday, 15 October 2024 9:18 PM

To: 'Section 19A Submissions' <Section19ASubmissions@Health.gov.au>

Subject: RE: Amended DHCPL - Estradiol Transdermal System s22 and 100mcg/day (0.1mg/day) (Sandoz, USA) [SEC=OFFICIAL]

Dear s22

Thank you for sending through the revised of the DHCPL.

We have reviewed and accepted the changes. Please find attached the clean copy of the DHCPL.

Should you require any further information, please let me know.

Thanks and kind regards,

s22

s22

SANDOZ PTY LTD

Suite 1501, 100 Pacific Highway

North Sydney, NSW 2060

Australia

T s22

M s22

s22 @sandoz.com

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From: Section 19A Submissions <Section19ASubmissions@Health.gov.au>

Sent: Tuesday, 15 October 2024 4:16 PM

To: s22 @sandoz.com>

Subject: Amended DHCPL - Estradiol Transdermal System s22 and

100mcg/day (0.1mg/day) (Sandoz, USA) [SEC=OFFICIAL]

This Message Is From an External Sender

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Dear s22

Please find attached the revised DHCPL for review for Estradiol Transdermal System s22 s22 and 100mcg/day (0.1mg/day) (Sandoz, USA).

I have advised that patients can use the enclosed package leaflet for application instructions.

Please review and accept the changes and send it back as a **PDF** clean copy at your earliest convenience.

Let me know if you have any questions.

Kind regards

s22
s22
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]
To: s22 [redacted]
Cc: s22 [redacted]
Subject: RE: Market assessment request - Estradiol transdermal products [SEC=OFFICIAL]
Date: Thursday, 29 May 2025 2:37:44 PM
Attachments: image001.png
image002.png
image003.gif
image004.png

Hi all,

Just spoke to s2 – Q regarding whether we would still progress their s19A now that s22 is going to be in supply again. I confirmed we would be progressing their s19A's for Estramon, s was grateful to hear this as s said they still need the s19A to support their supply.

Thank you for sending me the info s22 that was so helpful

s2

From: s22 [redacted]
Sent: Thursday, 29 May 2025 12:31 PM
To: s22 [redacted]
Subject: FW: Market assessment request - Estradiol transdermal products [SEC=OFFICIAL]

From: Medicine Shortages <medicine.shortages@health.gov.au>
Sent: Thursday, 29 May 2025 8:01 AM
To: s22 [redacted] @Health.gov.au>
Subject: FW: Market assessment request - Estradiol transdermal products [SEC=OFFICIAL]

In @ action for you

s22

From: s22 [redacted] @sandoz.com>
Sent: Wednesday, 28 May 2025 10:36 PM
To: Medicine Shortages <medicine.shortages@health.gov.au>
Cc: s22 [redacted] @sandoz.com>; s22 [redacted] @sandoz.com>
Subject: RE: Market assessment request - Estradiol transdermal products [SEC=OFFICIAL]

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Dear s22

Please find our response below.

Comments to give more background to the data provided in the tables below:

- Sandoz is committed to ensure consistent patient access to treatment and therefore need to secure supply of S19 s22 stock for s47G before S19 extension.
  - s47G [redacted], the lead time of supply chain needs to be considered and planned well in advance.
- We are still expecting supply of registered stock to come in and out for the remainder of 2025 and due to this inconsistency of supply we require the S19 extension to ensure treatment availability.
- s47 [redacted]

ARTG product	Pack Size	Estimated monthly demand	Estimated market share	Current stock levels at the sponsor/manufacturing level (as at 23/5/25)	Current stock levels at the wholesaler/distributor level (as at 22/5/25)	Dates of expected deliveries (importations) for the next 6 months and quantities expected for each order
s22 [redacted]						
ESTRADOT 100 estradiol 100 microgram transdermal drug delivery system sachet ARTG 338060	8 patches	s47 [redacted]		(S19 Estradiol US stock available)	s47 [redacted]	

Section 19A product	Pack size	Estimated monthly demand	Current stock levels at the sponsor/manufacturing level (as at 23/5/25)	Current stock levels at the wholesaler/distributor level (as at 22/5/25)	Dates of expected deliveries (importations) for the next 6 months and quantities expected for each order
s22 [redacted]					

Please don't hesitate to reach out with further questions.
Many thanks and kind regards,

s22
s22

SANDOZ PTY LTD
Suite 1501, 100 Pacific Highway
North Sydney, NSW 2060
AUSTRALIA
M s22
s22 @sandoz.com

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From: Medicine Shortages <medicine.shortages@health.gov.au>
Sent: Wednesday, 21 May 2025 3:41 PM
To: s22 @sandoz.com>
Cc: s22 @sandoz.com>
Subject: Market assessment request - Estradiol transdermal products [SEC=OFFICIAL]

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Dear Regulatory Affairs Team,
Thank you for your ongoing assistance in managing the shortages of transdermal HRT patches.
We continue to monitor the availability of the products to ensure appropriate management actions are in place for patients to access their medicines.
Can you please fill in the tables below to assist us in our assessment.

ARTG product	Pack Size	Estimated monthly demand	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
s22						
ESTRADOT 100 estradiol 100 microgram transdermal drug delivery system sachet ARTG 338060						

Section 19A product	Pack size	Estimated monthly demand	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
s22					

A response by **COB Wednesday 28 May** would be greatly appreciated.

Kindest regards,

s22
s22

Medicine Shortages Section | Pharmacovigilance Branch
Australian Government, Department of Health, Disability and Ageing
Therapeutic Goods Administration

Location: Canberra
Phone: s22

This email comes to you from Ngunnawal and Ngambri Country

PO Box 100, Woden ACT 2606
www.tga.gov.au

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Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

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Note for file

Date and time	23 October 2024 1550
Type of event (e.g. meeting/ telephone conversation)	Telephone conversation
Topic	MSNs for Estradot – ARTG s22 [redacted], 338060 and section 19A renewal approvals for Estradiol Transdermal System s22 [redacted] and 100mcg/day (0.1mg/day) (Sandoz, USA)
Participants	s22 [redacted] Medicine Shortages Section) s22 [redacted] Sandoz Pty Ltd)

Key points

- Discussed the published expected resolution dates of all ARTG Estradot patches vs the market assessment information provided under section 31 in October 2024. The market assessment indicates that the patches will remain in shortage s47G [redacted] when the shortages are due to resolve.
- Asked s22 [redacted] if the situation had changed since the section 31 request and if the shortages will resolve as per the current dates. s22 [redacted] confirmed that the shortages will not resolve on 20/01/25, however s22 [redacted] does not know when the shortages will resolve. s47 [redacted] s22 [redacted]
- s22 [redacted] confirmed that there are ongoing global issues with the supply of estradiol patches. s47 [redacted]
- s22 [redacted] said that updating the MSNs to reflect the current situation is difficult as s47 [redacted] Told s22 [redacted] that it would be more appropriate to have a longer shortage duration published and to update the availability to limited when supply allows.
- s22 [redacted] confirmed that the supply of estradiol patches has been unstable for a long period of time due to the global demand and the discontinuation of Climara patches.
- Discussed that the section 19A renewal approvals need to be justified to the delegate against current approvals and current shortage dates.
- Ensured Sandoz was aware that the delegate could still consider renewing the approvals and that given the shortage of HRT products is a high-profile shortage and the products have high usage, we would ideally like to make

	sure that there is supply available for the expected shortage duration which according to the market assessment will be longer than 20/01/25.
Decision	s22 [redacted] agreed to talk to s22 [redacted] team about extending the shortage dates of Estradot patches and will let me know of the decision as soon as possible.
Author details	Signed: s22 [redacted] 23/10/24.

From: s22
To: Section 19A Submissions
Subject: RE: Amended DHCPL - Estradiol Transdermal System s22 and 100mcg/day (0.1mg/day) (Sandoz, USA) [SEC=OFFICIAL]
Date: Wednesday, 23 October 2024 3:48:10 PM
Attachments: image001.jpg
image002.gif

Hi s22
I think I just missed your call.
Please feel free to call me back.
Kind regards,
s22
s22

SANDOZ PTY LTD
Suite 1501, 100 Pacific Highway
North Sydney, NSW 2060
Australia
T s22
M s22
s22 @sandoz.com

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From: s22
Sent: Wednesday, 23 October 2024 2:43 PM
To: Section 19A Submissions <Section19ASubmissions@Health.gov.au>
Subject: RE: Amended DHCPL - Estradiol Transdermal System s22 and 100mcg/day (0.1mg/day) (Sandoz, USA) [SEC=OFFICIAL]

Hi s22
I'm free anytime after 3:15pm.
Please call me on s22 or a MS teams call is always helpful too, happy to provide a link.
Thanks again for your help.
Kind regards,
s22
s22

SANDOZ PTY LTD
Suite 1501, 100 Pacific Highway
North Sydney, NSW 2060
Australia
T s22
M s22
s22 @sandoz.com

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From: Section 19A Submissions <Section19ASubmissions@Health.gov.au>
Sent: Wednesday, 23 October 2024 12:42 PM

To: s22 [redacted] @sandoz.com>
Subject: RE: Amended DHCPL - Estradiol Transdermal System s22 [redacted] and 100mcg/day (0.1mg/day) (Sandoz, USA) [SEC=OFFICIAL]

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Dear s22 [redacted]
Thank you for your reply and updating the MSN for ESTRADOT 100 estradiol 100 microgram transdermal drug delivery system sachet ARTG 338060.
Can we please further discuss the published shortage dates? Is there a convenient time this afternoon for me to call? Please also confirm the best phone number to contact you on.
Kind regards

s22 [redacted]
s22 [redacted]
Medicine Shortages Section
Pharmacovigilance Branch

Phone: s22 [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

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From: s22 [redacted] @sandoz.com>
Sent: Wednesday, 23 October 2024 11:44 AM
To: Section 19A Submissions <Section19ASubmissions@Health.gov.au>
Subject: RE: Amended DHCPL - Estradiol Transdermal System s22 [redacted] and 100mcg/day (0.1mg/day) (Sandoz, USA) [SEC=OFFICIAL]
Dear s22 [redacted]
Thank you for your email.
We reviewed the MSN database and have submitted an extension for ESTRADOT 100 mcg. The submission number for your reference is: **MS-2024-04548-1.**
Please let me know if there are any further discrepancies or any further information required for the approval of the S19A extension application.
Thank you again for all your support in this application.
Kind regards,

s22 [redacted]
s22 [redacted]

SANDOZ PTY LTD
Suite 1501, 100 Pacific Highway
North Sydney, NSW 2060
Australia
T s22
M s22
s22 @sandoz.com

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From: Section 19A Submissions <Section19ASubmissions@Health.gov.au>
Sent: Tuesday, 22 October 2024 12:59 PM
To: s22 @sandoz.com>
Subject: RE: Amended DHCPL - Estradiol Transdermal System s22 and 100mcg/day (0.1mg/day) (Sandoz, USA) [SEC=OFFICIAL]

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Dear s22
Thank you for your email.
I would like to ensure that the expiry of the section 19A renewal approvals align with the shortage dates, to ensure continuity in supply of estradiol patches. Please see my email attached from the 17/10/24 regarding the medicine shortage notifications for Estradot products.
From the information provided in the market assessment, there is not sufficient stock to resolve all the Estradot shortages within s47G .
Please update the shortage notifications as soon as possible. Once this is done the section 19A renewal application can then be finalised and sent to the delegate for review.
Kind regards
s22
s22
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
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From: s22 [redacted] @sandoz.com>
Sent: Tuesday, October 22, 2024 11:33 AM
To: Section 19A Submissions <Section19ASubmissions@Health.gov.au>
Subject: RE: Amended DHCPL - Estradiol Transdermal System s22 [redacted] and 100mcg/day (0.1mg/day) (Sandoz, USA) [SEC=OFFICIAL]

Dear s22 [redacted]
I hope you are well.
I was hoping to receive an update from you in regards to the processing of the renewal S19A application for Estradiol Transdermal s22 [redacted] and 100 mcg/day.
Your advice would be greatly appreciated.
Thanks and kind regards,
s22 [redacted]
s22 [redacted]

SANDOZ PTY LTD
Suite 1501, 100 Pacific Highway
North Sydney, NSW 2060
Australia
T s22 [redacted]
M s22 [redacted]
s22 [redacted] @sandoz.com

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From: s22 [redacted]
Sent: Tuesday, 15 October 2024 9:18 PM
To: 'Section 19A Submissions' <Section19ASubmissions@Health.gov.au>
Subject: RE: Amended DHCPL - Estradiol Transdermal System s22 [redacted] and 100mcg/day (0.1mg/day) (Sandoz, USA) [SEC=OFFICIAL]

Dear s22 [redacted]
Thank you for sending through the revised of the DHCPL.
We have reviewed and accepted the changes. Please find attached the clean copy of the DHCPL.
Should you require any further information, please let me know.
Thanks and kind regards,
s22 [redacted]
s22 [redacted]

SANDOZ PTY LTD
Suite 1501, 100 Pacific Highway
North Sydney, NSW 2060
Australia
T s22 [redacted]
M s22 [redacted]
s22 [redacted] @sandoz.com

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email.

From: Section 19A Submissions <Section19ASubmissions@Health.gov.au>
Sent: Tuesday, 15 October 2024 4:16 PM
To: s22 [redacted] @sandoz.com>
Subject: Amended DHCPL - Estradiol Transdermal System s22 [redacted] and 100mcg/day (0.1mg/day) (Sandoz, USA) [SEC=OFFICIAL]

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This message came from outside your organization.

Dear s22 [redacted]
Please find attached the revised DHCPL for review for Estradiol Transdermal System s22 [redacted] and 100mcg/day (0.1mg/day) (Sandoz, USA).
I have advised that patients can use the enclosed package leaflet for application instructions.
Please review and accept the changes and send it back as a **PDF** clean copy at your earliest convenience.
Let me know if you have any questions.
Kind regards

s22 [redacted]
s22 [redacted]
Medicine Shortages Section
Pharmacovigilance Branch

Phone: s22 [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

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Document 15

From: Section 19A Submissions
To: s22
Cc: s22
Subject: RE: Market assessment request - s22 [SEC=OFFICIAL]
Date: Thursday, 17 October 2024 12:23:40 PM
Attachments: image001.jpg
image002.gif

Dear s2

Thank you for supplying the below information to assist us with the shortage situation. It is much appreciated.

I have noted that orders for ARTG stock is limited/TBA over s47G and would like to ensure that the Medicine Shortage Reports Database has the most up to date information.

As per the database, the Estradot shortages are currently due to resolve between October 2024 and s47G

Can you please update the shortage notifications to reflect the expected return to supply dates of Estradot patches as soon as possible. This will also ensure our management actions (including section 19A approvals) align with the shortage dates.

Please let me know if you have any questions.

Kind regards

s22
s22
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
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From: s22 @sandoz.com>
Sent: Tuesday, October 8, 2024 2:59 PM
To: Section 19A Submissions <Section19ASubmissions@Health.gov.au>
Cc: s22 @sandoz.com>; s22 @sandoz.com>
Subject: RE: Market assessment request - s22 [SEC=OFFICIAL]

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Dear s22 ,
I hope you are well and enjoyed the long weekend.
Please see below the information requested.

ARTG product	Pack Size	Estimated normal monthly demand levels (when not in shortage)	Estimated market share	Current stock levels at the sponsor/manufacturing level (as at 08/10/2024)	Current stock levels at the wholesaler/distributor level (as at 07/10/2024)	Dates of expected deliveries (importations) for the next 6 months and quantities expected for each order
s22						
ESTRADOT 100 estradiol 100 microgram transdermal drug delivery system sachet ARTG 338060	8 patches	s47				

Section 19A product	Pack size	Current stock levels at the sponsor/manufacturing level (as at 08/10/2024)	Current stock levels at the wholesaler/distributor level (as at 07/10/2024)	Dates of expected deliveries (importations) for the next 6 months and quantities expected for each order
s22				

s22 [redacted]	

Should you require any further information, please let me know.
Thank you once again for all your support with our S19A applications for estradiol.
Kind regards,

s22 [redacted]
s22 [redacted]

SANDOZ PTY LTD
Suite 1501, 100 Pacific Highway
North Sydney, NSW 2060
Australia
T s22 [redacted]
M s22 [redacted]
s22 [redacted] @sandoz.com

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From: Section 19A Submissions <Section19ASubmissions@Health.gov.au>
Sent: Wednesday, October 2, 2024 3:21 PM
To: s22 [redacted] @sandoz.com>
Cc: s22 [redacted] @sandoz.com>
Subject: Market assessment request - s22 [redacted]) [SEC=OFFICIAL]

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Dear Regulatory Affairs Team,
Due to the ongoing shortages of transdermal HRT products and the associated public health impact, we are requesting supply details for your ARTG and section 19A approved products.
Can you please fill in the below tables to assist us in the management of these shortages.
I have not included all strengths of the current section 19A approved Estradiol Transdermal System (Sandoz, USA), only the strengths that a renewal application has been received for.

ARTG product	Pack Size	Estimated normal monthly demand levels (when not in shortage)	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
s22 [redacted]						
ESTRADOT 100 estradiol 100 microgram transdermal drug delivery system sachet ARTG 338060						

Section 19A product	Pack size	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
s22 [redacted]				

A response by **COB Tuesday 8 October** would be greatly appreciated.
Please let me know if you have any questions.
Kindest regards,

s22 [redacted]
s22 [redacted]
Medicine Shortages Section
Pharmacovigilance Branch

Phone: s22 [redacted]
Email: medicine.shortages@health.gov.au

Therapeutic Goods Administration

Document 15

Australian Government, 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 - Market assessment - Estradot and s22 transdermal patches [SEC=OFFICIAL]
Date: Monday, 10 February 2025 4:56:27 PM
Attachments: image001.jpg
image002.png

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Dear s22

Thank you kindly for approving the extension.

Please see the available delivery information below:

ARTG product	Pack Size	Estimated normal monthly demand levels	Estimated market share	Current stock levels at the sponsor/manufacturing level (as at 28/01/2025)	Current stock levels at the wholesaler/distributor level (as at 28/01/2025)	Dates of expected deliveries (importations) for the next 6 months and quantities expected for each order
s22 [redacted]						
ESTRADOT 100 estradiol 100 microgram transdermal drug delivery system sachet ARTG 338060	8 patches	s47 [redacted]				
s22 [redacted]						

Please let me know if you have any questions.

Many thanks and kind regards,

s22
s22

SANDOZ PTY LTD
Suite 1501, 100 Pacific Highway
North Sydney, NSW 2060
AUSTRALIA

M s22
s22 @sandoz.com

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From: Medicine Shortages <medicine.shortages@health.gov.au>
Sent: Friday, January 31, 2025 2:09 PM
To: s22 @sandoz.com>
Cc: s22 @Health.gov.au>
Subject: RE: Request for information - Market assessment - Estradot and s22 transdermal patches [SEC=OFFICIAL]

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Dear s22

Thank you for your response. We will grant Sandoz an extension until 10 February 2025 to provide the missing delivery/planned orders 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

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From: s22 @sandoz.com>
Sent: Thursday, 30 January 2025 2:48 PM
To: Medicine Shortages <medicine.shortages@health.gov.au>
Cc: s22 @Health.gov.au>
Subject: RE: Request for information - Market assessment - Estradot and s22 transdermal patches [SEC=OFFICIAL]

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Dear s22

Please see below the information available so far.

Regarding the delivery information, the s22 . Would it be possible for us to have an extension until 10th February 2025? Many thanks for your understanding – will look forward to your response. We will endeavor to provide the information as soon as possible.

ARTG product	Pack Size	Estimated normal monthly demand levels	Estimated market share	Current stock levels at the sponsor/manufacturing level (as at 28/01/2025)	Current stock levels at the wholesaler/distributor level (as at 28/01/2025)	Dates of expected deliveries (importations) for the next 6 months and quantities expected for each order
s22						
ESTRADOT 100 estradiol 100 microgram transdermal drug delivery system sachet ARTG 338060	8 patches	s47				
s22						

s22 [redacted]

Many thanks and kind regards,

s22 [redacted]
s22 [redacted]

SANDOZ PTY LTD
Suite 1501, 100 Pacific Highway
North Sydney, NSW 2060
AUSTRALIA

M s22 [redacted]
s22 [redacted] @sandoz.com

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From: Medicine Shortages <medicine.shortages@health.gov.au>
Sent: Friday, January 24, 2025 11:42 AM
To: s22 [redacted] @sandoz.com>
Cc: s22 [redacted] @Health.gov.au>; s22 [redacted] @sandoz.com>
Subject: Request for information - Market assessment - Estradot and s22 [redacted] transdermal patches [SEC=OFFICIAL]

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Dear s22 [redacted]

I hope this email finds you well.

As we continue to monitor the availability of transdermal HRT patches to ensure patients can readily access their medicine, we kindly request for an update regarding the current and upcoming supply of all ARTG estradiol-containing patches marketed by Sandoz Pty Ltd.

Appreciate if you can complete the table and respond by **COB Friday, 31 January 2025.**

ARTG product	Pack Size	Estimated normal monthly demand levels	Estimated market share	Current stock levels at the sponsor/manufacturing level (as at XX/XX/XXXX)	Current stock levels at the wholesaler/distributor level (as at XX/XX/XXXX)	Dates of expected deliveries (importations) for the next 6 months and quantities expected for each order
s22 [redacted]						
ESTRADOT 100 estradiol 100 microgram transdermal drug delivery system sachet ARTG 338060						
s22 [redacted]						

Kind Regards,

s22
s22
s22 - 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: s22
Subject: FW: Market assessment request - Estradiol transdermal products [SEC=OFFICIAL]
Date: Thursday, 29 May 2025 8:00:42 AM
Attachments: image001.png
image002.png
image003.gif
image004.png

In @ action for you
s2

From: s22
Sent: Wednesday, 28 May 2025 10:36 PM
To: Medicine Shortages
Cc: s22
Subject: RE: Market assessment request - Estradiol transdermal products [SEC=OFFICIAL]

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Dear s22
Please find our response below.
Comments to give more background to the data provided in the tables below:

- Sandoz is committed to ensure consistent patient access to treatment and therefore need to secure supply of S19 ESTRAMON stock for s47G before S19 extension.
  - s47G, the lead time of supply chain needs to be considered and planned well in advance.
- We are still expecting supply of registered stock to come in and out for the remainder of 2025 and due to this inconsistency of supply we require the S19 extension to ensure treatment availability.
- To ensure patient or pharmacies are not left out of pocket, Sandoz is supplying S19 stock at the same value as registered stock.

ARTG product	Pack Size	Estimated monthly demand	Estimated market share	Current stock levels at the sponsor/manufacturing level (as at 23/5/25)	Current stock levels at the wholesaler/distributor level (as at 22/5/25)	Dates of expected deliveries (importations) for the next 6 months and quantities expected for each order
s22						
ESTRADOT 100 estradiol 100 microgram transdermal drug delivery system sachet ARTG 338060	8 patches	s47				

Section 19A product	Pack size	Estimated monthly demand	Current stock levels at the sponsor/manufacturing level (as at 23/5/25)	Current stock levels at the wholesaler/distributor level (as at 22/5/25)	Dates of expected deliveries (importations) for the next 6 months and quantities expected for each order
s22					

Please don't hesitate to reach out with further questions.
Many thanks and kind regards,

s22
s22

SANDOZ PTY LTD
Suite 1501, 100 Pacific Highway
North Sydney, NSW 2060
AUSTRALIA
M s22
s22 @sandoz.com

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From: Medicine Shortages <medicine.shortages@health.gov.au>
Sent: Wednesday, 21 May 2025 3:41 PM
To: s22 [redacted] @sandoz.com>
Cc: s [redacted] @sandoz.com>
Subject: Market assessment request - Estradiol transdermal products [SEC=OFFICIAL]

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Dear Regulatory Affairs Team,
Thank you for your ongoing assistance in managing the shortages of transdermal HRT patches.
We continue to monitor the availability of the products to ensure appropriate management actions are in place for patients to access their medicines.
Can you please fill in the tables below to assist us in our assessment.

ARTG product	Pack Size	Estimated monthly demand	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
s22 [redacted]						
ESTRADOT 100 estradiol 100 microgram transdermal drug delivery system sachet ARTG 338060						

Section 19A product	Pack size	Estimated monthly demand	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
s22 [redacted]					

A response by **COB Wednesday 28 May** would be greatly appreciated.

Kindest regards,

s22 [redacted]
s22 [redacted]
Medicine Shortages Section | Pharmacovigilance Branch
Australian Government, Department of Health, Disability and Ageing
Therapeutic Goods Administration

Location: Canberra
Phone s22 [redacted]

This email comes to you from Ngunnawal and Ngambri Country
PO Box 100, Woden ACT 2606
www.tga.gov.au

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From: Section 19A Submissions
To: s22
Cc: s22
Subject: RE: Supply enquiry section 19A - estradiol transdermal system products & return to supply dates for ARTG estradiol patch products [SEC=OFFICIAL]
Date: Thursday, 21 March 2024 10:50:31 AM
Attachments: image001.jpg
image002.png

Hi s22
I hope to have a decision to you on this application either by this afternoon, or tomorrow.
Kind regards,

s22
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
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From: s22 @sandoz.com>
Sent: Thursday, March 21, 2024 10:47 AM
To: Section 19A Submissions <Section19ASubmissions@Health.gov.au>
Cc: s22 @sandoz.com>
Subject: RE: Supply enquiry section 19A - estradiol transdermal system products & return to supply dates for ARTG estradiol patch products [SEC=OFFICIAL]

Hi s22
I was just wondering whether you are in a position to confirm by when we could expect to receive s19A approval s22
Many thanks for your support.
Best regards,

s22
s22
s22
SANDOZ PTY LTD
Suite 1501, 100 Pacific Highway
North Sydney, NSW 2060
T s22
M s22
s22 @sandoz.com

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From: Section 19A Submissions <Section19ASubmissions@Health.gov.au>
Sent: Wednesday, March 20, 2024 1:44 PM
To: s22 @sandoz.com>

Cc: s22 [redacted] @sandoz.com>
Subject: RE: Supply enquiry section 19A - estradiol transdermal system products & return to supply dates for ARTG estradiol patch products [SEC=OFFICIAL]

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Hi s22 [redacted]
Many thanks for your prompt reply.
I will let you know if we require any further information.
Kind regards,

s22 [redacted]
s22 [redacted]
s22 [redacted] – **Medicine Shortages Section**
Pharmacovigilance Branch
Medicines Regulation Division | Health Products Regulation Group
Australian Government, Department of Health and Aged Care
T: s22 [redacted] | E: s22 [redacted] @health.gov.au
Location: Fairbairn
PO Box 100, Woden ACT 2606, Australia
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From: s22 [redacted] @sandoz.com>
Sent: Wednesday, March 20, 2024 1:38 PM
To: Section 19A Submissions <Section19ASubmissions@Health.gov.au>
Cc: s22 [redacted] @sandoz.com>
Subject: RE: Supply enquiry section 19A - estradiol transdermal system products & return to supply dates for ARTG estradiol patch products [SEC=OFFICIAL]

Hi s22 [redacted]
s22 [redacted]
Many thanks,

s22 [redacted]
s22 [redacted]
s22 [redacted]
SANDOZ PTY LTD
Suite 1501, 100 Pacific Highway
North Sydney, NSW 2060
T s22 [redacted]
M s22 [redacted]
s22 [redacted] @sandoz.com

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From: s22 [redacted]
Sent: Wednesday, March 20, 2024 12:56 PM

To: 'Section19ASubmissions@Health.gov.au' <Section19ASubmissions@Health.gov.au>
Cc: s22 [redacted] @sandoz.com>
Subject: RE: Supply enquiry section 19A - estradiol transdermal system products & return to supply dates for ARTG estradiol patch products [SEC=OFFICIAL]

Hi s22 [redacted]
Thanks for your time on the phone earlier.
I can confirm that we have no objection to the section 19A approvals being extended to 31 October 2024.
s22 [redacted]
Let me know if you require anything further.
Many thanks,

s22 [redacted]
s22 [redacted]
s22 [redacted]
SANDOZ PTY LTD
Suite 1501, 100 Pacific Highway
North Sydney, NSW 2060
T s22 [redacted]
M s22 [redacted]
s22 [redacted] @sandoz.com

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From: s22 [redacted]
Sent: Wednesday, March 20, 2024 10:35 AM
To: Section19ASubmissions@Health.gov.au
Subject: RE: Supply enquiry section 19A - estradiol transdermal system products & return to supply dates for ARTG estradiol patch products [SEC=OFFICIAL]

Hi s22 [redacted]
s22 [redacted], but I am available to assist you. I tried to reach you by phone just not but did not get through.
If you could call me on the mobile number below when free, I would be most grateful.
Many thanks,

s22 [redacted]
s22 [redacted]
s22 [redacted]
SANDOZ PTY LTD
Suite 1501, 100 Pacific Highway
North Sydney, NSW 2060
T s22 [redacted]
M s22 [redacted]
s22 [redacted] @sandoz.com

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From: s22 [redacted] @sandoz.com>
Sent: Wednesday, March 20, 2024 10:07 AM
To: s22 [redacted] @sandoz.com>
Subject: FW: Supply enquiry section 19A - estradiol transdermal system products & return to supply dates for ARTG estradiol patch products [SEC=OFFICIAL]

From: Section 19A Submissions <Section19ASubmissions@Health.gov.au>
Sent: Wednesday, 20 March 2024 10:06:57 am (UTC+10:00) Canberra, Melbourne, Sydney
To: s22 [redacted] @sandoz.com>
Subject: RE: Supply enquiry section 19A - estradiol transdermal system products & return to supply dates for ARTG estradiol patch products [SEC=OFFICIAL]

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Good morning s22 [redacted]
I tried calling you on the below numbers , without any luck. Can you please call me back on : s22 [redacted] in regards to Sandoz's s19A estradiol patch products.
Kind regards,

s22 [redacted]
s22 [redacted]
s22 [redacted] – **Medicine Shortages Section**
Pharmacovigilance Branch
Medicines Regulation Division | Health Products Regulation Group
Australian Government, Department of Health and Aged Care
T: s22 [redacted] | E: s22 [redacted] @health.gov.au
Location: Fairbairn
PO Box 100, Woden ACT 2606, Australia
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From: Section 19A Submissions <Section19ASubmissions@Health.gov.au>
Sent: Friday, March 15, 2024 2:52 PM
To: s22 [redacted] @sandoz.com>
Cc: s22 [redacted] @sandoz.com>; s22 [redacted] @sandoz.com>
Subject: RE: Supply enquiry section 19A - estradiol transdermal system products & return to supply dates for ARTG estradiol patch products [SEC=OFFICIAL]

Dear s22 [redacted]
Many thanks for the update.
I will be in touch if we require further information.
You have a lovely weekend also.
Kind regards,

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

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From: s22 [redacted] @sandoz.com>
Sent: Friday, March 15, 2024 1:25 PM
To: Section 19A Submissions <Section19ASubmissions@Health.gov.au>
Cc: s22 [redacted] @sandoz.com>; s22 [redacted] @sandoz.com>
Subject: RE: Supply enquiry section 19A - estradiol transdermal system products & return to supply dates for ARTG estradiol patch products [SEC=OFFICIAL]

Dear s22 [redacted],
In addition to yesterday's response, further information has become available in regards to the Medicine Shortage Notification for the other strengths of Estradot. We have submitted extensions for all strengths of ESTRADOT. Please find the table below for the information:

AUST R	Product	Resolution Date	MS extension submission reference
s22 [redacted]			
338060	ESTRADOT 100 estradiol 100 microgram transdermal drug delivery system sachet	15th July 2024	MS-2024-01135-1

I trust this information is of use.
Thank you again for your support in this application and I hope you have a wonderful weekend ahead.
Kind regards,
s22 [redacted]
s22 [redacted]

SANDOZ PTY LTD
Suite 1501, 100 Pacific Highway
North Sydney, NSW 2060
Australia
T s22 [redacted]
M s22 [redacted]
s22 [redacted] @sandoz.com

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From: s22 [redacted]
Sent: Thursday, March 14, 2024 5:11 PM
To: Section 19A Submissions <Section19ASubmissions@Health.gov.au>
Cc: s22 [redacted] @sandoz.com>; s22 [redacted]

s22 [redacted] @sandoz.com>

Subject: RE: Supply enquiry section 19A - estradiol transdermal system products & return to supply dates for ARTG estradiol patch products [SEC=OFFICIAL]

Dear s22 [redacted]

Thank you for your email and I hope you are well too.

I can confirm that we have yet to commence supply via S19A for the below mentioned products however I can provide you an estimated start date and overall quantity for each approved strength:

Product	Estimated start date of supply	Estimated total S19A stock to be supplied (packs)
s22 [redacted]		
ESTRADIOL estradiol 0.01 mg/day transdermal system	29-Apr-2024	s47 [redacted]

In addition, Sandoz is currently reviewing the Medicine Shortage notification for all strengths of Estradot s22 [redacted]

I trust this information is of use.

Thank you again for your patience and support in this application.

Kind regards,

s22 [redacted]
s22 [redacted]

SANDOZ PTY LTD
Suite 1501, 100 Pacific Highway
North Sydney, NSW 2060
Australia
T s22 [redacted]
M s22 [redacted]
s22 [redacted] @sandoz.com

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From: Section 19A Submissions <Section19ASubmissions@Health.gov.au>

Sent: Wednesday, March 13, 2024 1:19 PM

To: s22 [redacted] @sandoz.com>

Cc: s22 [redacted] @sandoz.com>; s22 [redacted] @sandoz.com>

Subject: Supply enquiry section 19A - estradiol transdermal system products & return to supply dates for ARTG estradiol patch products [SEC=OFFICIAL]

This Message Is From an External Sender

This message came from outside your organization.

Dear s22 [redacted]

I hope you are well.
Can you please confirm if supply via s19A has commenced for the below s19A approved products:
s22 [redacted]
ESTRADIOL estradiol 0.1 mg/day transdermal system
Additionally, we are investigating the supply situation of estradiol patches over the coming months and would like to gauge Sandoz's confidence in the return to supply date of the following products:

Product in shortage	Current published resolution date
s22 [redacted]	
ESTRADOT 100 estradiol 100 microgram transdermal drug delivery system sachet AUST R: 338060	17 May 2024
s22 [redacted]	

Please let me know if you have any questions about the above.
A response by COB Friday 15 March 2024 would be much appreciated.
Kind regards,

s22 [redacted]
s22 [redacted]
s22 [redacted] **– Medicine Shortages Section**
Pharmacovigilance Branch
Medicines Regulation Division | Health Products Regulation Group
Australian Government, Department of Health and Aged Care
T: s22 [redacted] | E: s22 [redacted] @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.
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From: s22
To: s22
Cc: s22 Medicine Shortages
Subject: RE: Medicine shortage notification for Estradot products [SEC=OFFICIAL]
Date: Friday, 1 November 2024 4:38:05 PM
Attachments: image002.png

Hi s22

Thank you for your email, and I'm sorry I missed your call earlier (we are playing phone tag!).

I appreciate you updating the notifications for the two strengths noted below. I continue to urge Sandoz to consider updating the remaining notifications to align as a priority, however happy to discuss further at the meting on Monday.

See you then.

Kind regards
s22

From: s22 @sandoz.com>
Sent: Friday, 1 November 2024 2:27 PM
To: s22 @health.gov.au>
Cc: s @sandoz.com>; s22 @sandoz.com>; s22 @sandoz.com>
Subject: RE: Medicine shortage notification for Estradot products [SEC=OFFICIAL]

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

Dear s22 ,

Thank you for contacting us today with your review and assessment.

Please be assured that Sandoz is committed to meet our obligations in relation to reporting changes to the period of shortage and notifying a realistic timeframe for shortage duration to support patients and health professionals. As you may be aware a call to discuss the global medicines shortage for Estradot s22 range of products is scheduled with TGA and Sandoz for Monday 04/11/2024.

I confirm, medicines shortages notification for ESTRADOT 100 mcg (AUST R 338060) and s22 has been updated today until 30/04/2025 to support Sandoz' application to continue supply of estradiol transdermal products under the section 19A pathway. All other strengths will be updated according to further market assessments and in line with discussions with TGA on Monday to manage community expectations.

Please advise if you require any further information to evaluate and approve Sandoz' current S19 application.

Kind regards
s22

s22
s22

SANDOZ PTY LTD
Suite 1501, 100 Pacific Highway
North Sydney, NSW 2060
AUSTRALIA

Mobile: s22
s22 @sandoz.com

SANDOZ

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---

From: s22 @sandoz.com>
Sent: Friday, 1 November 2024 8:47 AM
To: s22 @sandoz.com>; s22 @sandoz.com>; s22 @sandoz.com>
Subject: Fw: Medicine shortage notification for Estradot products [SEC=OFFICIAL]

From: s22 @health.gov.au>
Sent: Thursday, October 31, 2024 5:00:48 PM
To: s22 @sandoz.com>
Cc: s22 @health.gov.au>; Medicine Shortages <medicine.shortages@health.gov.au>
Subject: Medicine shortage notification for Estradot products [SEC=OFFICIAL]

This Message Is From an External Sender
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Dear s22

Thank you for providing the market assessment data for Estradot transdermal products on 8

October 2024.

My team has collated the data, and the assessment demonstrates there will be **insufficient** supply of registered Estradot products to meet the usual demand, until at least April 2025. For several strengths, there are no planned deliveries of the ARTG stock for the next 6 months.

As per the *Therapeutic Goods Act 1989* (Section 30EFA), sponsors are required to report changes to the period of a shortage within 10 working days beginning on the first day the person knows, or ought reasonably to have known, of the change to that period. Section 30EI of the Act provides *'For the purposes of this Act, there is a shortage of a medicine in Australia at a particular time if, at any time in the 6 months after that particular time, the supply of that medicine in Australia will not, or will not be likely to, meet the demand for the medicine for all of the patients in Australia who take, or who may need to take, the medicine'.*

It is important to consider the next 6 months supply outlook when making changes to reported medicine shortages. Based on the information you provided on 8 October, in response to our market assessment request, there are significant discrepancies between the reported shortage end dates and supply projections over the next 6 months. Considering this, could you please review and update the medicine shortage notifications for Estradot products immediately, to ensure you are meeting your obligations in relation to reporting changes to the period of a shortage.

Additionally, we have heard from patients and clinical groups that the repeated shortage extensions are having a significant impact on continued patient treatment and is impacting the clinician's ability to make informed clinical considerations for their patients. In our experience, notifying a realistic timeframe for shortage duration (guided by the dynamic nature of the supply and demand situation) and erring on the conservative side is received better within the wider community, then repeatedly extending the shortage.

I am aware that during the shortage period of registered Estradot products, Sandoz intend to continue supply of estradiol transdermal products under the section 19A pathway, and I wanted to assure you that we are supportive of this to reduce the impact on Australian patients.

Our aim is to support patients and health professionals during the shortage by providing accurate information about the shortage duration and management actions. This helps with managing community expectations around ongoing availability of the ARTG stock and assists with the TGA's consideration of additional management strategies to alleviate the shortage impact where needed.

We look forward to receiving your updated shortage notifications as a priority.

Kind regards

s22
s22
s22 – **Medicine Shortages Section**
Pharmacovigilance Branch
Medicines Regulation Division | Health Products Regulation Group

Australian Government, Department of Health and Aged Care
T: s22 [redacted] | E: s22 [redacted] @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.

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From: s22
To: s22
Cc: s22 Medicine Shortages
Subject: RE: Medicine shortage notification for Estradot products [SEC=OFFICIAL]
Date: Tuesday, 5 November 2024 10:51:30 AM
Attachments: image002.png

Hi s22

It was great to meet with the Sandoz team yesterday. We really thank Sandoz for the transparent conversation yesterday, and as discussed we are happy to support the ongoing need for section 19A products into 2025.

We discussed the importance of having longer MSN's published on our database, to help patients and clinicians plan ongoing treatment. I thank Sandoz for agreeing to update the notifications, and I would appreciate if you could please update the remaining Estradot notifications as a priority today, given the confirmation that supply of ARTG products will continue to be intermittent for most of 2025. As noted yesterday, longer shortage periods on our database not only helps our team with assessment of section 19A applications, but could also assist the main department in terms of PBS considerations for submissions Sandoz has made for the section 19A products.

s22 . It's important that notifications align with the information that was shared with us yesterday, in line with reporting requirements.

Happy to chat if needed.

Kind regards
s22

From: s22 @sandoz.com>
Sent: Friday, 1 November 2024 2:27 PM
To: s22 @health.gov.au>
Cc: s22 @sandoz.com>; s22 @sandoz.com>; s22 @sandoz.com>
Subject: RE: Medicine shortage notification for Estradot products [SEC=OFFICIAL]

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

Dear s22

Thank you for contacting us today with your review and assessment.

Please be assured that Sandoz is committed to meet our obligations in relation to

reporting changes to the period of shortage and notifying a realistic timeframe for shortage duration to support patients and health professionals. As you may be aware a call to discuss the global medicines shortage for Estradot s22 range of products is scheduled with TGA and Sandoz for Monday 04/11/2024.

I confirm, medicines shortages notification for ESTRADOT 100 mcg (AUST R 338060) and s22 has been updated today until 30/04/2025 to support Sandoz' application to continue supply of estradiol transdermal products under the section 19A pathway. All other strengths will be updated according to further market assessments and in line with discussions with TGA on Monday to manage community expectations.

Please advise if you require any further information to evaluate and approve Sandoz' current S19 application.

Kind regards
s22

s22
s22

SANDOZ PTY LTD
Suite 1501, 100 Pacific Highway
North Sydney, NSW 2060
AUSTRALIA

Mobile: s22
s22 @sandoz.com

SANDOZ

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From: s22 @sandoz.com>
Sent: Friday, 1 November 2024 8:47 AM
To: s22 @sandoz.com>; s22 @sandoz.com>; s22 @sandoz.com>
Subject: Fw: Medicine shortage notification for Estradot products [SEC=OFFICIAL]

From: s22 @health.gov.au>
Sent: Thursday, October 31, 2024 5:00:48 PM
To: s22 @sandoz.com>
Cc: s22 @health.gov.au>; Medicine Shortages <medicine.shortages@health.gov.au>

Subject: Medicine shortage notification for Estradot products [SEC=OFFICIAL]

This Message Is From an External Sender
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Dear s22

Thank you for providing the market assessment data for Estradot transdermal products on 8 October 2024.

My team has collated the data, and the assessment demonstrates there will be **insufficient** supply of registered Estradot products to meet the usual demand, until at least April 2025. For several strengths, there are no planned deliveries of the ARTG stock for the next 6 months.

As per the *Therapeutic Goods Act 1989* (Section 30EFA), sponsors are required to report changes to the period of a shortage within 10 working days beginning on the first day the person knows, or ought reasonably to have known, of the change to that period. Section 30EI of the Act provides *'For the purposes of this Act, there is a shortage of a medicine in Australia at a particular time if, at any time in the 6 months after that particular time, the supply of that medicine in Australia will not, or will not be likely to, meet the demand for the medicine for all of the patients in Australia who take, or who may need to take, the medicine'.*

It is important to consider the next 6 months supply outlook when making changes to reported medicine shortages. Based on the information you provided on 8 October, in response to our market assessment request, there are significant discrepancies between the reported shortage end dates and supply projections over the next 6 months. Considering this, could you please review and update the medicine shortage notifications for Estradot products immediately, to ensure you are meeting your obligations in relation to reporting changes to the period of a shortage.

Additionally, we have heard from patients and clinical groups that the repeated shortage extensions are having a significant impact on continued patient treatment and is impacting the clinician's ability to make informed clinical considerations for their patients. In our experience, notifying a realistic timeframe for shortage duration (guided by the dynamic nature of the supply and demand situation) and erring on the conservative side is received better within the wider community, then repeatedly extending the shortage.

I am aware that during the shortage period of registered Estradot products, Sandoz intend to continue supply of estradiol transdermal products under the section 19A pathway, and I wanted to assure you that we are supportive of this to reduce the impact on Australian patients.

Our aim is to support patients and health professionals during the shortage by providing accurate information about the shortage duration and management actions. This helps with managing community expectations around ongoing availability of the ARTG stock and assists with the TGA's consideration of additional management strategies to alleviate the shortage impact where

needed.

We look forward to receiving your updated shortage notifications as a priority.

Kind regards

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

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From: s22
To: s22
Cc: s22 ; Medicine Shortages
Subject: RE: Medicine shortage notification for Estradot products [SEC=OFFICIAL]
Date: Tuesday, 5 November 2024 5:21:53 PM
Attachments: image001.jpg
image002.png

Hi s22
Many thanks for your continued support and managing the reporting of MSNs for Estradot and s22 .
As discussed, Sandoz has updated MSN for Estradot today and is in the process of updating MSN for s22 , which your department should receive today/tomorrow.
Please reach out directly if any clarification is required.
Many thanks
s22

From: s22 @health.gov.au>
Sent: Tuesday, 5 November 2024 10:52 AM
To: s22 @sandoz.com>
Cc: s22 @sandoz.com>; s22 @sandoz.com>; s22 @sandoz.com>; s22 @health.gov.au>; Medicine Shortages <medicine.shortages@health.gov.au>
Subject: RE: Medicine shortage notification for Estradot products [SEC=OFFICIAL]

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Hi s22
It was great to meet with the Sandoz team yesterday. We really thank Sandoz for the transparent conversation yesterday, and as discussed we are happy to support the ongoing need for section 19A products into 2025.
We discussed the importance of having longer MSN's published on our database, to help patients and clinicians plan ongoing treatment. I thank Sandoz for agreeing to update the notifications, and I would appreciate if you could please update the remaining Estradot notifications as a priority today, given the confirmation that supply of ARTG products will continue to be intermittent for most of 2025. As noted yesterday, longer shortage periods on our database not only helps our team with assessment of section 19A applications, but could also assist the main department in terms of PBS considerations for submissions Sandoz has made for the section 19A products.
We also discussed Sandoz submitting 'anticipated' notifications for the remaining s22 It's important that notifications align with the information that was shared with us yesterday, in line with reporting requirements.
Happy to chat if needed.
Kind regards
s22

From: s22 @sandoz.com>
Sent: Friday, 1 November 2024 2:27 PM
To: s22 @health.gov.au>
Cc: s22 @sandoz.com>; s22 @sandoz.com>; s22

s22 [redacted] @sandoz.com>

Subject: RE: Medicine shortage notification for Estradot products [SEC=OFFICIAL]

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Dear s22 [redacted],

Thank you for contacting us today with your review and assessment.

Please be assured that Sandoz is committed to meet our obligations in relation to reporting changes to the period of shortage and notifying a realistic timeframe for shortage duration to support patients and health professionals. As you may be aware a call to discuss the global medicines shortage for Estradot s22 [redacted] range of products is scheduled with TGA and Sandoz for Monday 04/11/2024.

I confirm, medicines shortages notification for ESTRADOT 100 mcg (AUST R 338060) and s22 [redacted] has been updated today until 30/04/2025 to support Sandoz' application to continue supply of estradiol transdermal products under the section 19A pathway. All other strengths will be updated according to further market assessments and in line with discussions with TGA on Monday to manage community expectations.

Please advise if you require any further information to evaluate and approve Sandoz' current S19 application.

Kind regards

s22 [redacted]
s22 [redacted]
SANDOZ PTY LTD
Suite 1501, 100 Pacific Highway
North Sydney, NSW 2060
AUSTRALIA
Mobile: s22 [redacted]
s22 [redacted] @sandoz.com

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---

From: s22 [redacted] @sandoz.com>

Sent: Friday, 1 November 2024 8:47 AM

To: s22 [redacted] @sandoz.com>; s22 [redacted] @sandoz.com>; s22 [redacted] @sandoz.com>

Subject: Fw: Medicine shortage notification for Estradot products [SEC=OFFICIAL]

From: s22 [redacted] @health.gov.au>

Sent: Thursday, October 31, 2024 5:00:48 PM

To: s22 [redacted] @sandoz.com>

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

Subject: Medicine shortage notification for Estradot products [SEC=OFFICIAL]

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Dear s22

Thank you for providing the market assessment data for Estradot transdermal products on 8 October 2024.

My team has collated the data, and the assessment demonstrates there will be **insufficient** supply of registered Estradot products to meet the usual demand, until at least April 2025. For several strengths, there are no planned deliveries of the ARTG stock for the next 6 months.

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It is important to consider the next 6 months supply outlook when making changes to reported medicine shortages. Based on the information you provided on 8 October, in response to our market assessment request, there are significant discrepancies between the reported shortage end dates and supply projections over the next 6 months. Considering this, could you please review and update the medicine shortage notifications for Estradot products immediately, to ensure you are meeting your obligations in relation to reporting changes to the period of a shortage.

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I am aware that during the shortage period of registered Estradot products, Sandoz intend to continue supply of estradiol transdermal products under the section 19A pathway, and I wanted to assure you that we are supportive of this to reduce the impact on Australian patients.

Our aim is to support patients and health professionals during the shortage by providing accurate information about the shortage duration and management actions. This helps with managing community expectations around ongoing availability of the ARTG stock and assists with the TGA's consideration of additional management strategies to alleviate the shortage impact where needed.

We look forward to receiving your updated shortage notifications as a priority.

Kind regards

s22

edicine 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

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Therapeutic Goods Administration | eBusiness Services

Medicine Shortage Notification

Notification ID: MS-2023-NT-01565-1
Submission ID: MS-2024-00136-1
Client Reference: ESTRADOT 100

Notifier

Notifier

Sponsor Name:	Sandoz Pty Ltd
Sponsor Address:	100 Pacific Highway North Sydney NSW 2060
Australian telephone number for public contact purposes:	1800 726 369
Medical information email for public contact purposes:	medical.information@sandoz.com
Primary Contact	
Name:	s22 [redacted]
Phone Number:	s22 [redacted]
Email Address:	s22 [redacted]@sandoz.com
Secondary Contact	
Name:	s22 [redacted]
Phone Number:	s22 [redacted]
Email Address:	s22 [redacted]@sandoz.com

ARTG Entry

ARTG Entry

ARTG number of the product that has a supply disruption:

ARTG ID	ARTG Name	Active Ingredient	Strength	Dosage Form
338060	ESTRADOT 100 estradiol 100 microgram transdermal drug delivery system sachet	estradiol	1.56mg	Drug delivery system, transdermal

ATC Descriptor:	Genito urinary system and sex hormones
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:	8765H
Do you have a designated sponsor representative within your organisation who is a point of contact on PBS matters?	No

Details

Details

When was the shortage known to the sponsor?	13/12/2023
Nature of the shortage:	Anticipated
Shortage reason:	Manufacturing

Manufacturing site problem:	s47 [redacted]	
Shortage reason - further information:		Document 22
Estimated period supply will be affected at wholesaler points:	**From:** **To:**	26/01/2024 17/05/2024
Availability:	Available	
TGA publication date:	15/12/2023	
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?	Yes	
Estimated normal demand volumes for Australia:	s47 [redacted]	
Estimated percentage share of the Australian market:	s47 [redacted]	
Estimated current stock at sponsor / manufacturing level in Australia:	s47 [redacted]	
Estimated current stock at wholesaler / distributor level in Australia:	s47 [redacted]	
What is meant by 1 unit in this context:	Pack of 8 pouches	

Impact

Are there therapeutic alternatives on the Australian market?	Yes
What is the status of substitute options for this product in Australia?	Exact Therapeutic Alternatives
Are they available in adequate supplies to meet demand?	Unknown at this time
Provide details:	
Do any specific population groups use this product?	No
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 Pharmacists	15-Dec-2023
Letter to Wholesalers	15-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
Working to expedite next shipment	13-Dec-2023

Further comments on management actions:

Supporting Information

Supporting data will be:

Sponsor website where medicine shortage information is available:

Document 22

Therapeutic Goods Administration | eBusiness Services

Medicine Shortage Notification

Notification ID: MS-2023-NT-01565-1
Submission ID: MS-2024-00136-1
Client Reference: ESTRADOT 100

Notifier

Notifier

Sponsor Name:	Sandoz Pty Ltd
Sponsor Address:	100 Pacific Highway North Sydney NSW 2060
Australian telephone number for public contact purposes:	1800 726 369
Medical information email for public contact purposes:	medical.information@sandoz.com
Primary Contact	
Name:	s22 [redacted]
Phone Number:	s22 [redacted]
Email Address:	s22 [redacted]@sandoz.com
Secondary Contact	
Name:	s22 [redacted]
Phone Number:	s22 [redacted]
Email Address:	s22 [redacted]@sandoz.com

ARTG Entry

ARTG Entry

ARTG number of the product that has a supply disruption:

ARTG ID	ARTG Name	Active Ingredient	Strength	Dosage Form
338060	ESTRADOT 100 estradiol 100 microgram transdermal drug delivery system sachet	estradiol	1.56mg	Drug delivery system, transdermal

ATC Descriptor:	Genito urinary system and sex hormones
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:	8765H
Do you have a designated sponsor representative within your organisation who is a point of contact on PBS matters?	No

Details

Details

When was the shortage known to the sponsor?	13/12/2023
Nature of the shortage:	Current
Shortage reason:	Manufacturing

Manufacturing site problem:	s47 [redacted]	
Shortage reason - further information:		Document 23
Estimated period supply will be affected at wholesaler points:	**From:** **To:**	17/01/2024 17/05/2024
Availability:	Limited Availability	
TGA publication date:	15/12/2023	
Is this shortage related to other medicines within the same Therapeutic class?	No	
Is this shortage specific to Australia?	Yes	
Estimated normal demand volumes for Australia:	s47 [redacted]	
Estimated percentage share of the Australian market:	s47 [redacted]	
Estimated current stock at sponsor / manufacturing level in Australia:	s47 [redacted]	
Estimated current stock at wholesaler / distributor level in Australia:	s47 [redacted]	
What is meant by 1 unit in this context:	Pack of 8 pouches	

Impact

Are there therapeutic alternatives on the Australian market?	Yes
What is the status of substitute options for this product in Australia?	Exact Therapeutic Alternatives
Are they available in adequate supplies to meet demand?	Unknown at this time
Provide details:	
Do any specific population groups use this product?	No
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 Pharmacists	15-Dec-2023
Letter to Wholesalers	15-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
Working to expedite next shipment	13-Dec-2023

Further comments on management actions:

Supporting Information

Supporting data will be:	
Sponsor website where medicine shortage information is available:	

Therapeutic Goods Administration | eBusiness Services

Medicine Shortage Notification

Notification ID: MS-2023-NT-01565-1
Submission ID: MS-2024-01135-1
Client Reference: ESTRADOT 100

Notifier

Notifier

Sponsor Name:	Sandoz Pty Ltd
Sponsor Address:	100 Pacific Highway North Sydney NSW 2060
Australian telephone number for public contact purposes:	1800 726 369
Medical information email for public contact purposes:	medical.information@sandoz.com
Primary Contact	
Name:	s22 [redacted]
Phone Number:	s22 [redacted]
Email Address:	s22 [redacted]@sandoz.com
Secondary Contact	
Name:	s22 [redacted]
Phone Number:	s22 [redacted]
Email Address:	s22 [redacted]@sandoz.com

ARTG Entry

ARTG Entry

ARTG number of the product that has a supply disruption:

ARTG ID	ARTG Name	Active Ingredient	Strength	Dosage Form
338060	ESTRADOT 100 estradiol 100 microgram transdermal drug delivery system sachet	estradiol	1.56mg	Drug delivery system, transdermal

ATC Descriptor:	Genito urinary system and sex hormones
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:	8765H
Do you have a designated sponsor representative within your organisation who is a point of contact on PBS matters?	No

Details

Details

When was the shortage known to the sponsor?	13/12/2023
Nature of the shortage:	Current
Shortage reason:	Manufacturing

Manufacturing site problem:	s47 [redacted]	
Shortage reason - further information:		Document 24
Estimated period supply will be affected at wholesaler points:	**From:** **To:**	17/01/2024 15/07/2024
Availability:	Limited Availability	
TGA publication date:	15/12/2023	
Is this shortage related to other medicines within the same Therapeutic class?	No	
Is this shortage specific to Australia?	Yes	
Estimated normal demand volumes for Australia:	s47 [redacted]	
Estimated percentage share of the Australian market:	s47 [redacted]	
Estimated current stock at sponsor / manufacturing level in Australia:	s47 [redacted]	
Estimated current stock at wholesaler / distributor level in Australia:	s47 [redacted]	
What is meant by 1 unit in this context:	Pack of 8 pouches	

Impact

Are there therapeutic alternatives on the Australian market?	Yes
What is the status of substitute options for this product in Australia?	Exact Therapeutic Alternatives
Are they available in adequate supplies to meet demand?	Unknown at this time
Provide details:	
Do any specific population groups use this product?	No
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 Pharmacists	15-Dec-2023
Letter to Wholesalers	15-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
Working to expedite next shipment	13-Dec-2023

Further comments on management actions:

Supporting Information

Supporting data will be:	
Sponsor website where medicine shortage information is available:	

Therapeutic Goods Administration | eBusiness Services

Medicine Shortage Notification

Notification ID: MS-2023-NT-01565-1
Submission ID: MS-2024-02915-1
Client Reference: ESTRADOT 100

Notifier

Notifier

Sponsor Name:	Sandoz Pty Ltd
Sponsor Address:	100 Pacific Highway North Sydney NSW 2060
Australian telephone number for public contact purposes:	1800 726 369
Medical information email for public contact purposes:	medical.information@sandoz.com
Primary Contact	
Name:	s22 [redacted]
Phone Number:	s22 [redacted]
Email Address:	s22 [redacted]@sandoz.com
Secondary Contact	
Name:	s22 [redacted]
Phone Number:	s22 [redacted]
Email Address:	s22 [redacted]@sandoz.com

ARTG Entry

ARTG Entry

ARTG number of the product that has a supply disruption:

ARTG ID	ARTG Name	Active Ingredient	Strength	Dosage Form
338060	ESTRADOT 100 estradiol 100 microgram transdermal drug delivery system sachet	estradiol	1.56mg	Drug delivery system, transdermal

ATC Descriptor:	Genito urinary system and sex hormones
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:	8765H
Do you have a designated sponsor representative within your organisation who is a point of contact on PBS matters?	No

Details

Details

When was the shortage known to the sponsor?	13/12/2023
Nature of the shortage:	Current
Shortage reason:	Manufacturing

Manufacturing site problem:	s47 [redacted]	
Shortage reason - further information:		Document 25
Estimated period supply will be affected at wholesaler points:	**From:** **To:**	17/01/2024 15/09/2024
Availability:	Limited Availability	
TGA publication date:	15/12/2023	
Is this shortage related to other medicines within the same Therapeutic class?	No	
Is this shortage specific to Australia?	Yes	
Estimated normal demand volumes for Australia:	s47 [redacted]	
Estimated percentage share of the Australian market:	s47 [redacted]	
Estimated current stock at sponsor / manufacturing level in Australia:	s47 [redacted]	
Estimated current stock at wholesaler / distributor level in Australia:	s47 [redacted]	
What is meant by 1 unit in this context:	Pack of 8 pouches	

Impact

Are there therapeutic alternatives on the Australian market?	Yes
What is the status of substitute options for this product in Australia?	Exact Therapeutic Alternatives
Are they available in adequate supplies to meet demand?	Unknown at this time
Provide details:	
Do any specific population groups use this product?	No
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 Pharmacists	15-Dec-2023
Letter to Wholesalers	15-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
Working to expedite next shipment	13-Dec-2023

Further comments on management actions:

Supporting Information

Supporting data will be:	
Sponsor website where medicine shortage information is available:	

Therapeutic Goods Administration | eBusiness Services

Medicine Shortage Notification

Notification ID: MS-2023-NT-01565-1
Submission ID: MS-2024-03494-1
Client Reference: ESTRADOT 100

Notifier

Notifier

Sponsor Name:	Sandoz Pty Ltd
Sponsor Address:	100 Pacific Highway North Sydney NSW 2060
Australian telephone number for public contact purposes:	1800 726 369
Medical information email for public contact purposes:	medical.information@sandoz.com
Primary Contact	
Name:	s22 [redacted]
Phone Number:	s22 [redacted]
Email Address:	s22 [redacted] @sandoz.com
Secondary Contact	
Name:	s22 [redacted]
Phone Number:	s22 [redacted]
Email Address:	s22 [redacted] @sandoz.com

ARTG Entry

ARTG Entry

ARTG number of the product that has a supply disruption:

ARTG ID	ARTG Name	Active Ingredient	Strength	Dosage Form
338060	ESTRADOT 100 estradiol 100 microgram transdermal drug delivery system sachet	estradiol	1.56mg	Drug delivery system, transdermal

ATC Descriptor:	Genito urinary system and sex hormones
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:	8765H
Do you have a designated sponsor representative within your organisation who is a point of contact on PBS matters?	No

Details

Details

When was the shortage known to the sponsor?	13/12/2023
Nature of the shortage:	Current
Shortage reason:	Manufacturing

Manufacturing site problem:	s47 [redacted]	
Shortage reason - further information:		Document 26
Estimated period supply will be affected at wholesaler points:	**From:** **To:**	17/01/2024 28/10/2024
Availability:	Unavailable	
TGA publication date:	15/12/2023	
Is this shortage related to other medicines within the same Therapeutic class?	No	
Is this shortage specific to Australia?	Yes	
Estimated normal demand volumes for Australia:	s47 [redacted]	
Estimated percentage share of the Australian market:	s47 [redacted]	
Estimated current stock at sponsor / manufacturing level in Australia:	s47 [redacted]	
Estimated current stock at wholesaler / distributor level in Australia:	s47 [redacted]	
What is meant by 1 unit in this context:	Pack of 8 pouches	

Impact

Are there therapeutic alternatives on the Australian market?	Yes
What is the status of substitute options for this product in Australia?	Exact Therapeutic Alternatives
Are they available in adequate supplies to meet demand?	Unknown at this time
Provide details:	
Do any specific population groups use this product?	No
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 Pharmacists	15-Dec-2023
Letter to Wholesalers	15-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
Working to expedite next shipment	13-Dec-2023

Further comments on management actions:

Supporting Information

Supporting data will be:	
Sponsor website where medicine shortage information is available:	

Therapeutic Goods Administration | eBusiness Services

Medicine Shortage Notification

Notification ID: MS-2023-NT-01565-1
Submission ID: MS-2024-03624-1
Client Reference: ESTRADOT 100

Notifier

Notifier

Sponsor Name:	Sandoz Pty Ltd
Sponsor Address:	100 Pacific Highway North Sydney NSW 2060
Australian telephone number for public contact purposes:	1800 726 369
Medical information email for public contact purposes:	medical.information@sandoz.com
Primary Contact	
Name:	s22 [redacted]
Phone Number:	s22 [redacted]
Email Address:	s22 [redacted]@sandoz.com
Secondary Contact	
Name:	s22 [redacted]
Phone Number:	s22 [redacted]
Email Address:	s22 [redacted]@sandoz.com

ARTG Entry

ARTG Entry

ARTG number of the product that has a supply disruption:

ARTG ID	ARTG Name	Active Ingredient	Strength	Dosage Form
338060	ESTRADOT 100 estradiol 100 microgram transdermal drug delivery system sachet	estradiol	1.56mg	Drug delivery system, transdermal

ATC Descriptor:	Genito urinary system and sex hormones
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:	8765H
Do you have a designated sponsor representative within your organisation who is a point of contact on PBS matters?	No

Details

Details

When was the shortage known to the sponsor?	13/12/2023
Nature of the shortage:	Current
Shortage reason:	Manufacturing

Manufacturing site problem:	s47 [redacted]	
Shortage reason - further information:		Document 27
Estimated period supply will be affected at wholesaler points:	**From:** **To:**	17/01/2024 28/10/2024
Availability:	Limited Availability	
TGA publication date:	15/12/2023	
Is this shortage related to other medicines within the same Therapeutic class?	No	
Is this shortage specific to Australia?	Yes	
Estimated normal demand volumes for Australia:	s47 [redacted]	
Estimated percentage share of the Australian market:	s47 [redacted]	
Estimated current stock at sponsor / manufacturing level in Australia:	s47 [redacted]	
Estimated current stock at wholesaler / distributor level in Australia:	s47 [redacted]	
What is meant by 1 unit in this context:	Pack of 8 pouches	

Impact

Are there therapeutic alternatives on the Australian market?	Yes
What is the status of substitute options for this product in Australia?	Exact Therapeutic Alternatives
Are they available in adequate supplies to meet demand?	Unknown at this time
Provide details:	
Do any specific population groups use this product?	No
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 Pharmacists	15-Dec-2023
Letter to Wholesalers	15-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
Working to expedite next shipment	13-Dec-2023

Further comments on management actions:

Supporting Information

Supporting data will be:	
Sponsor website where medicine shortage information is available:	

Therapeutic Goods Administration | eBusiness Services

Medicine Shortage Notification

Notification ID: MS-2023-NT-01565-1
Submission ID: MS-2024-04548-1
Client Reference: ESTRADOT 100

Notifier

Notifier

Sponsor Name:	Sandoz Pty Ltd
Sponsor Address:	100 Pacific Highway North Sydney NSW 2060
Australian telephone number for public contact purposes:	1800 726 369
Medical information email for public contact purposes:	medical.information@sandoz.com
Primary Contact	
Name:	s22 [redacted]
Phone Number:	s22 [redacted]
Email Address:	s22 [redacted]@sandoz.com
Secondary Contact	
Name:	s22 [redacted]
Phone Number:	s22 [redacted]
Email Address:	s22 [redacted]@sandoz.com

ARTG Entry

ARTG Entry

ARTG number of the product that has a supply disruption:

ARTG ID	ARTG Name	Active Ingredient	Strength	Dosage Form
338060	ESTRADOT 100 estradiol 100 microgram transdermal drug delivery system sachet	estradiol	1.56mg	Drug delivery system, transdermal

ATC Descriptor:	Genito urinary system and sex hormones
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:	8765H
Do you have a designated sponsor representative within your organisation who is a point of contact on PBS matters?	No

Details

Details

When was the shortage known to the sponsor?	13/12/2023
Nature of the shortage:	Current
Shortage reason:	Manufacturing

Manufacturing site problem:	s47 [redacted]	
Shortage reason - further information:		Document
Estimated period supply will be affected at wholesaler points:	**From:** **To:**	17/01/2024 20/01/2025
Availability:	Limited Availability	
TGA publication date:	15/12/2023	
Is this shortage related to other medicines within the same Therapeutic class?	No	
Is this shortage specific to Australia?	Yes	
Estimated normal demand volumes for Australia:	s47 [redacted]	
Estimated percentage share of the Australian market:	s47 [redacted]	
Estimated current stock at sponsor / manufacturing level in Australia:	s47 [redacted]	
Estimated current stock at wholesaler / distributor level in Australia:	s47 [redacted]	
What is meant by 1 unit in this context:	Pack of 8 pouches	

Impact

Are there therapeutic alternatives on the Australian market?	Yes
What is the status of substitute options for this product in Australia?	Exact Therapeutic Alternatives
Are they available in adequate supplies to meet demand?	Unknown at this time
Provide details:	
Do any specific population groups use this product?	No
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 Pharmacists	15-Dec-2023
Letter to Wholesalers	15-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
Working to expedite next shipment	13-Dec-2023

Further comments on management actions:

Supporting Information

Supporting data will be:	
Sponsor website where medicine shortage information is available:	

Therapeutic Goods Administration | eBusiness Services

Medicine Shortage Notification

Notification ID: MS-2023-NT-01565-1
Submission ID: MS-2024-04699-1
Client Reference: ESTRADOT 100

Notifier

Notifier

Sponsor Name:	Sandoz Pty Ltd
Sponsor Address:	100 Pacific Highway North Sydney NSW 2060
Australian telephone number for public contact purposes:	1800 726 369
Medical information email for public contact purposes:	medical.information@sandoz.com
Primary Contact	
Name:	s22 [redacted]
Phone Number:	s22 [redacted]
Email Address:	s22 [redacted]@sandoz.com
Secondary Contact	
Name:	s22 [redacted]
Phone Number:	s22 [redacted]
Email Address:	s22 [redacted]@sandoz.com

ARTG Entry

ARTG Entry

ARTG number of the product that has a supply disruption:

ARTG ID	ARTG Name	Active Ingredient	Strength	Dosage Form
338060	ESTRADOT 100 estradiol 100 microgram transdermal drug delivery system sachet	estradiol	1.56mg	Drug delivery system, transdermal

ATC Descriptor:	Genito urinary system and sex hormones
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:	8765H
Do you have a designated sponsor representative within your organisation who is a point of contact on PBS matters?	No

Details

Details

When was the shortage known to the sponsor?	13/12/2023
Nature of the shortage:	Current
Shortage reason:	Manufacturing

Manufacturing site problem:	s47 [redacted]	
Shortage reason - further information:		Document
Estimated period supply will be affected at wholesaler points:	**From:** **To:**	17/01/2024 30/04/2025
Availability:	Unavailable	
TGA publication date:	15/12/2023	
Is this shortage related to other medicines within the same Therapeutic class?	No	
Is this shortage specific to Australia?	Yes	
Estimated normal demand volumes for Australia:	s47 [redacted]	
Estimated percentage share of the Australian market:	s47 [redacted]	
Estimated current stock at sponsor / manufacturing level in Australia:	s47 [redacted]	
Estimated current stock at wholesaler / distributor level in Australia:	s47 [redacted]	
What is meant by 1 unit in this context:	Pack of 8 pouches	

Impact

Are there therapeutic alternatives on the Australian market?	Yes
What is the status of substitute options for this product in Australia?	Exact Therapeutic Alternatives
Are they available in adequate supplies to meet demand?	Unknown at this time
Provide details:	
Do any specific population groups use this product?	No
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 Pharmacists	15-Dec-2023
Letter to Wholesalers	15-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
Working to expedite next shipment	13-Dec-2023

Further comments on management actions:

Supporting Information

Supporting data will be:	
Sponsor website where medicine shortage information is available:	

Therapeutic Goods Administration | eBusiness Services

Medicine Shortage Notification

Notification ID: MS-2023-NT-01565-1
Submission ID: MS-2024-04732-1
Client Reference: ESTRADOT 100

Notifier

Notifier

Sponsor Name:	Sandoz Pty Ltd
Sponsor Address:	100 Pacific Highway North Sydney NSW 2060
Australian telephone number for public contact purposes:	1800 726 369
Medical information email for public contact purposes:	medical.information@sandoz.com
Primary Contact	
Name:	s22 [redacted]
Phone Number:	s22 [redacted]
Email Address:	s22 [redacted] @sandoz.com
Secondary Contact	
Name:	s22 [redacted]
Phone Number:	s22 [redacted]
Email Address:	s22 [redacted] @sandoz.com

ARTG Entry

ARTG Entry

ARTG number of the product that has a supply disruption:

ARTG ID	ARTG Name	Active Ingredient	Strength	Dosage Form
338060	ESTRADOT 100 estradiol 100 microgram transdermal drug delivery system sachet	estradiol	1.56mg	Drug delivery system, transdermal

ATC Descriptor:	Genito urinary system and sex hormones
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:	8765H
Do you have a designated sponsor representative within your organisation who is a point of contact on PBS matters?	No

Details

Details

When was the shortage known to the sponsor?	13/12/2023
Nature of the shortage:	Current
Shortage reason:	Manufacturing

Manufacturing site problem:	s47 [redacted]	
Shortage reason - further information:		Document
Estimated period supply will be affected at wholesaler points:	**From:** **To:**	17/01/2024 31/12/2025
Availability:	Unavailable	
TGA publication date:	15/12/2023	
Is this shortage related to other medicines within the same Therapeutic class?	No	
Is this shortage specific to Australia?	Yes	
Estimated normal demand volumes for Australia:	s47 [redacted]	
Estimated percentage share of the Australian market:	s47 [redacted]	
Estimated current stock at sponsor / manufacturing level in Australia:	s47 [redacted]	
Estimated current stock at wholesaler / distributor level in Australia:	s47 [redacted]	
What is meant by 1 unit in this context:	Pack of 8 pouches	

Impact

Are there therapeutic alternatives on the Australian market?	Yes
What is the status of substitute options for this product in Australia?	Exact Therapeutic Alternatives
Are they available in adequate supplies to meet demand?	Unknown at this time
Provide details:	
Do any specific population groups use this product?	No
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 Pharmacists	15-Dec-2023
Letter to Wholesalers	15-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
Working to expedite next shipment	13-Dec-2023

Further comments on management actions:

Supporting Information

Supporting data will be:	
Sponsor website where medicine shortage information is available:	

Therapeutic Goods Administration | eBusiness Services

Medicine Shortage Notification

Notification ID: MS-2023-NT-01565-1
Submission ID: MS-2024-04732-1
Client Reference: ESTRADOT 100

Notifier

Notifier

Sponsor Name:	Sandoz Pty Ltd
Sponsor Address:	100 Pacific Highway North Sydney NSW 2060
Australian telephone number for public contact purposes:	1800 726 369
Medical information email for public contact purposes:	medical.information@sandoz.com
Primary Contact	
Name:	s22 [redacted]
Phone Number:	s22 [redacted]
Email Address:	s22 [redacted] @sandoz.com
Secondary Contact	
Name:	s22 [redacted]
Phone Number:	s22 [redacted]
Email Address:	s22 [redacted] @sandoz.com

ARTG Entry

ARTG Entry

ARTG number of the product that has a supply disruption:

ARTG ID	ARTG Name	Active Ingredient	Strength	Dosage Form
338060	ESTRADOT 100 estradiol 100 microgram transdermal drug delivery system sachet	estradiol	1.56mg	Drug delivery system, transdermal

ATC Descriptor:	Genito urinary system and sex hormones
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:	8765H
Do you have a designated sponsor representative within your organisation who is a point of contact on PBS matters?	No

Details

Details

When was the shortage known to the sponsor?	13/12/2023
Nature of the shortage:	Current
Shortage reason:	Manufacturing

Manufacturing site problem:	s47 [redacted]	
Shortage reason - further information:		Document
Estimated period supply will be affected at wholesaler points:	**From:** **To:**	17/01/2024 31/12/2025
Availability:	Limited Availability	
TGA publication date:	15/12/2023	
Is this shortage related to other medicines within the same Therapeutic class?	No	
Is this shortage specific to Australia?	Yes	
Estimated normal demand volumes for Australia:	s47 [redacted]	
Estimated percentage share of the Australian market:	s47 [redacted]	
Estimated current stock at sponsor / manufacturing level in Australia:	s47 [redacted]	
Estimated current stock at wholesaler / distributor level in Australia:	s47 [redacted]	
What is meant by 1 unit in this context:	Pack of 8 pouches	

Impact

Are there therapeutic alternatives on the Australian market?	Yes
What is the status of substitute options for this product in Australia?	Exact Therapeutic Alternatives
Are they available in adequate supplies to meet demand?	Unknown at this time
Provide details:	
Do any specific population groups use this product?	No
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 Pharmacists	15-Dec-2023
Letter to Wholesalers	15-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
Working to expedite next shipment	13-Dec-2023

Further comments on management actions:

Supporting Information

Supporting data will be:	
Sponsor website where medicine shortage information is available:	

Therapeutic Goods Administration | eBusiness Services

Medicine Shortage Notification

Notification ID: MS-2023-NT-01565-1
Submission ID: MS-2024-04765-1
Client Reference: ESTRADOT 100

Notifier

Notifier

Sponsor Name:	Sandoz Pty Ltd
Sponsor Address:	100 Pacific Highway North Sydney NSW 2060
Australian telephone number for public contact purposes:	1800 726 369
Medical information email for public contact purposes:	medical.information@sandoz.com
Primary Contact	
Name:	s22 [redacted]
Phone Number:	s22 [redacted]
Email Address:	s22 [redacted]@sandoz.com
Secondary Contact	
Name:	s22 [redacted]
Phone Number:	s22 [redacted]
Email Address:	s22 [redacted]@sandoz.com

ARTG Entry

ARTG Entry

ARTG number of the product that has a supply disruption:

ARTG ID	ARTG Name	Active Ingredient	Strength	Dosage Form
338060	ESTRADOT 100 estradiol 100 microgram transdermal drug delivery system sachet	estradiol	1.56mg	Drug delivery system, transdermal

ATC Descriptor:	Genito urinary system and sex hormones
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:	8765H
Do you have a designated sponsor representative within your organisation who is a point of contact on PBS matters?	No

Details

Details

When was the shortage known to the sponsor?	13/12/2023
Nature of the shortage:	Current
Shortage reason:	Manufacturing

Manufacturing site problem:	s47 [redacted]	
Shortage reason - further information:		Document
Estimated period supply will be affected at wholesaler points:	**From:** **To:**	17/01/2024 31/12/2025
Availability:	Unavailable	
TGA publication date:	15/12/2023	
Is this shortage related to other medicines within the same Therapeutic class?	No	
Is this shortage specific to Australia?	Yes	
Estimated normal demand volumes for Australia:	s47 [redacted]	
Estimated percentage share of the Australian market:	s47 [redacted]	
Estimated current stock at sponsor / manufacturing level in Australia:	s47 [redacted]	
Estimated current stock at wholesaler / distributor level in Australia:	s47 [redacted]	
What is meant by 1 unit in this context:	Pack of 8 pouches	

Impact

Are there therapeutic alternatives on the Australian market?	Yes
What is the status of substitute options for this product in Australia?	Exact Therapeutic Alternatives
Are they available in adequate supplies to meet demand?	Unknown at this time
Provide details:	
Do any specific population groups use this product?	No
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 Pharmacists	15-Dec-2023
Letter to Wholesalers	15-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
Working to expedite next shipment	13-Dec-2023

Further comments on management actions:

Supporting Information

Supporting data will be:	
Sponsor website where medicine shortage information is available:	

Therapeutic Goods Administration | eBusiness Services

Medicine Shortage Notification

Notification ID: MS-2023-NT-01565-1
Submission ID: MS-2025-00161-1
Client Reference: ESTRADOT 100

Notifier

Notifier

Sponsor Name:	Sandoz Pty Ltd
Sponsor Address:	100 Pacific Highway North Sydney NSW 2060
Australian telephone number for public contact purposes:	1800 726 369
Medical information email for public contact purposes:	medical.information@sandoz.com
Primary Contact	
Name:	s22 [redacted]
Phone Number:	s22 [redacted]
Email Address:	s22 [redacted]@sandoz.com
Secondary Contact	
Name:	
Phone Number:	
Email Address:	

ARTG Entry

ARTG Entry

ARTG number of the product that has a supply disruption:

ARTG ID	ARTG Name	Active Ingredient	Strength	Dosage Form
338060	ESTRADOT 100 estradiol 100 microgram transdermal drug delivery system sachet	estradiol	1.56mg	Drug delivery system, transdermal

ATC Descriptor:	Genito urinary system and sex hormones
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:	8765H
Do you have a designated sponsor representative within your organisation who is a point of contact on PBS matters?	No

Details

Details

When was the shortage known to the sponsor?	13/12/2023
Nature of the shortage:	Current
Shortage reason:	Manufacturing

Manufacturing site problem:	s47 [redacted]	
Shortage reason - further information:		Document
Estimated period supply will be affected at wholesaler points:	**From:** **To:**	17/01/2024 31/12/2025
Availability:	Limited Availability	
TGA publication date:	15/12/2023	
Is this shortage related to other medicines within the same Therapeutic class?	No	
Is this shortage specific to Australia?	Yes	
Estimated normal demand volumes for Australia:	s47 [redacted]	
Estimated percentage share of the Australian market:	s47 [redacted]	
Estimated current stock at sponsor / manufacturing level in Australia:	s47 [redacted]	
Estimated current stock at wholesaler / distributor level in Australia:	s47 [redacted]	
What is meant by 1 unit in this context:	Pack of 8 pouches	

Impact

Are there therapeutic alternatives on the Australian market?	Yes
What is the status of substitute options for this product in Australia?	Exact Therapeutic Alternatives
Are they available in adequate supplies to meet demand?	Unknown at this time
Provide details:	
Do any specific population groups use this product?	No
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 Pharmacists	15-Dec-2023
Letter to Wholesalers	15-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
Working to expedite next shipment	13-Dec-2023

Further comments on management actions:

Supporting Information

Supporting data will be:	
Sponsor website where medicine shortage information is available:	

Therapeutic Goods Administration | eBusiness Services

Medicine Shortage Notification

Notification ID: MS-2023-NT-01565-1
Submission ID: MS-2025-01350-1
Client Reference: ESTRADOT 100

Notifier

Notifier

Sponsor Name:	Sandoz Pty Ltd
Sponsor Address:	100 Pacific Highway North Sydney NSW 2060
Australian telephone number for public contact purposes:	1800 726 369
Medical information email for public contact purposes:	medical.information@sandoz.com
Primary Contact	
Name:	s22 [redacted]
Phone Number:	s22 [redacted]
Email Address:	s22 [redacted] @sandoz.com
Secondary Contact	
Name:	s22 [redacted]
Phone Number:	s22 [redacted]
Email Address:	s22 [redacted] @sandoz.com

ARTG Entry

ARTG Entry

ARTG number of the product that has a supply disruption:

ARTG ID	ARTG Name	Active Ingredient	Strength	Dosage Form
338060	ESTRADOT 100 estradiol 100 microgram transdermal drug delivery system sachet	estradiol	1.56mg	Drug delivery system, transdermal

ATC Descriptor:	Genito urinary system and sex hormones
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:	8765H
Do you have a designated sponsor representative within your organisation who is a point of contact on PBS matters?	No

Details

Details

When was the shortage known to the sponsor?	13/12/2023
Nature of the shortage:	Current
Shortage reason:	Manufacturing

Manufacturing site problem:	s47 [redacted]	
Shortage reason - further information:		Document
Estimated period supply will be affected at wholesaler points:	**From:** **To:**	17/01/2024 31/12/2025
Availability:	Unavailable	
TGA publication date:	15/12/2023	
Is this shortage related to other medicines within the same Therapeutic class?	No	
Is this shortage specific to Australia?	Yes	
Estimated normal demand volumes for Australia:	s47 [redacted]	
Estimated percentage share of the Australian market:	s47 [redacted]	
Estimated current stock at sponsor / manufacturing level in Australia:	s47 [redacted]	
Estimated current stock at wholesaler / distributor level in Australia:	s47 [redacted]	
What is meant by 1 unit in this context:	Pack of 8 pouches	

Impact

Are there therapeutic alternatives on the Australian market?	Yes
What is the status of substitute options for this product in Australia?	Exact Therapeutic Alternatives
Are they available in adequate supplies to meet demand?	Unknown at this time
Provide details:	
Do any specific population groups use this product?	No
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 Pharmacists	15-Dec-2023
Letter to Wholesalers	15-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
Working to expedite next shipment	13-Dec-2023

Further comments on management actions:

Supporting Information

Supporting data will be:	
Sponsor website where medicine shortage information is available:	

From: Section 19A Submissions
To: s22 [redacted]
Subject: FW: Section 19A Application - s22 [redacted]) [SEC=OFFICIAL]
Date: Monday, 26 August 2024 10:46:51 AM
Attachments: image001.jpg
image003.png
image004.gif

FYI

s2 [redacted]

From: s22 [redacted] @sandoz.com>
Sent: Friday, August 16, 2024 5:20 PM
To: Section 19A Submissions <Section19ASubmissions@Health.gov.au>
Cc: s22 [redacted] @sandoz.com>
Subject: RE: Section 19A Application - s22 [redacted] [SEC=OFFICIAL]

Dear s2 [redacted]

Thank you for your email.

I can confirm that we have access to order s22 [redacted]. Sandoz also has access to cover any future supply gaps of ESTRADOT for the AU market using ESTRAMON, provided that there is still an approved and valid S19A application in place.

s22 [redacted].

Finally, please see below the information about future orders of the US products and an updated SOH at sponsor & wholesaler details as per requested.

SKU	Product	Current stock levels at the sponsor/manufacturing level (as at 16/8/2024)	Current stock levels at the wholesaler/distributor level (as at 15/8/2024)	Dates of expected deliveries (importations) for the next 6 months and quantities expected for each order
s22 [redacted]				
44073880	s47 [redacted]			

USA Product	Current stock levels at the **sponsor** level **(as at 16/8/2024)**	Current stock levels at the **wholesaler/distributor (as at 15/8/2024)**	Dates of orders **for the duration of the approval (until 31 October 2024)** and quantities expected for each order	Other comments
s22 [redacted]				

If there are any further questions or further information you require, please do not hesitate to contact me.

Thank you for your support in our application and I hope you have a wonderful weekend ahead.

Kind regards,

s22 [redacted]

SANDOZ PTY LTD
Suite 1501, 100 Pacific Highway
North Sydney, NSW 2060
Australia

T s22 [redacted]
M s22 [redacted]
s22 [redacted] @sandoz.com

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From: Section 19A Submissions <Section19ASubmissions@Health.gov.au>
Sent: Wednesday, August 14, 2024 4:59 PM
To: s22 [redacted] @sandoz.com>
Cc: s22 [redacted] @sandoz.com>
Subject: RE: Section 19A Application - s22 [redacted]) [SEC=OFFICIAL]

This Message Is From an External Sender
This message came from outside your organization.

Dear s22 [redacted]

Thank you for your email. I am responding on behalf of s22 [redacted]

Your s19A application for s22 [redacted] has been assigned to assessor and they are working to expedite it within their capacity & alongside other competing priorities.

s22 [redacted]

Additionally, in reference to the below table provided by Sandoz last month, can you please confirm that the information about **future orders** of the US products remains applicable? And if you are able to provide updated SOH at sponsor & wholesaler details also – that would be much appreciated.

USA Product	Current stock levels at the **sponsor** level (as of 17 July 2024)	Current stock levels at the **wholesaler/distributor** level (as of 17 July 2024)	Dates of orders **for the duration of the approval (until 31 October 2024)** and quantities expected for each order	Other comments
s22 [redacted]				

Kind regards,

s2

s22 – Medicine Shortages Section
Pharmacovigilance Branch
Medicines Regulation Division | Health Products Regulation Group
Australian Government, Department of Health and Aged Care
T: s22 |
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: s @sandoz.com>
Sent: Wednesday, August 14, 2024 2:11 PM
To: Section 19A Submissions <Section19ASubmissions@Health.gov.au>
Cc: s22 @sandoz.com>
Subject: RE: Section 19A Application - s22

Dear s22

I hope you are well.

Would you be able to provide any updates or feedback in regards to the application below?

We are looking into the shipment of goods and also looking at printing our over labels to be able to ensure an efficient process to provide access of the product to the market. Therefore your advice in regards to the application would be greatly appreciated.

Thank you again for your support in this request and our application and should you require any further information, please do not hesitate to contact me.

Kind regards,

s22

SANDOZ PTY LTD
Suite 1501, 100 Pacific Highway
North Sydney, NSW 2060
Australia

T s22
M s22
s22 @sandoz.com

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From: s
Sent: Monday, August 5, 2024 3:15 PM
To: Section 19A Submissions <Section19ASubmissions@Health.gov.au>
Cc: s22 @sandoz.com>
Subject: RE: Section 19A Application - s22 2 of 2)

(Part 2 of 2 emails)

Dear s22

Please find attached the s22 as per requested for your review.

Kind regards,

s22

SANDOZ PTY LTD
Suite 1501, 100 Pacific Highway
North Sydney, NSW 2060
Australia

T s22
M s22
s22 @sandoz.com

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From: s22 [redacted]
Sent: Monday, August 5, 2024 3:13 PM
To: Section 19A Submissions <Section19ASubmissions@Health.gov.au>
Cc: s22 [redacted] @sandoz.com>
Subject: RE: Section 19A Application - s22 [redacted]) (1 of 2)

(Part 1 of 2 emails)

Dear s22 [redacted]

Thank you for your email.

Please find the attachments (from Attachment 6-20) as per the request below.

Due to the size of the files, I will separately send through the s22 [redacted] as per the request below.

Should you require any further information in regards to the application, please let me know.

Thanks and kind regards,

s22 [redacted]

SANDOZ PTY LTD
Suite 1501, 100 Pacific Highway
North Sydney, NSW 2060
Australia

T s22 [redacted]
M s22 [redacted]
s22 [redacted] @sandoz.com

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From: Section 19A Submissions <Section19ASubmissions@Health.gov.au>
Sent: Monday, August 5, 2024 2:43 PM
To: s22 [redacted] @sandoz.com>
Cc: s22 [redacted] @sandoz.com>
Subject: RE: Section 19A Application - s22 [redacted] [SEC=OFFICIAL]

This Message Is From an External Sender
This message came from outside your organization.

Dear s22 [redacted]

Thank you for your section 19A application for s22 [redacted].

Can you please send us the documents required for the application individually? I am aware that there are many documents, however it will be difficult to assess the application and for the delegate to review if all the information is contained within one document.

There is no need to resend the medicine shortage notifications as separate documents.

Can you also please ensure that if the product cartons contain s22 [redacted], that there are copies of these documents also.

Sorry for any inconvenience.

Kind regards

s22 [redacted]
Medicine Shortages Section
Pharmacovigilance Branch

Phone s22 [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

Document

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: s22 [redacted] @sandoz.com>
Sent: Wednesday, July 31, 2024 4:00 PM
To: Section 19A Submissions <Section19ASubmissions@Health.gov.au>
Cc: s22 [redacted] @sandoz.com>
Subject: Section 19A Application s22 [redacted]

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

Dear Section 19A Team,

Please find attached Section 19A application for s22 [redacted] .
Should you require any further information, please do not hesitate to contact me
Thank you in advance for your support in this application.
Kind regards,
s22 [redacted]

SANDOZ PTY LTD
Suite 1501, 100 Pacific Highway
North Sydney, NSW 2060
Australia
T s22 [redacted]
M s22 [redacted]
s22 [redacted] @sandoz.com

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