

## Timeline of decision making on tender supply agreement for oestradiol patches

Timeline for consultation and tender	Dates
Consultation begins (feedback on the Tender items)	July 2023
Any alternative commercial proposals (ACPs) due*	August 2023
Consultation closes	August 2023
Tender Clinical Advisory Committee meets and considers consultation responses	September 2023
Estimated consultation on any ACPs being progressed	September/October 2023
Final Invitation to Tender issued (suppliers to bid)	November 2023
Invitation to Tender closes	December 2023
Tender Clinical Advisory Committee meets to review products	February 2024
Internal Tender Evaluation Committee reviewed bids	March 2024
Board delegates decision to CE	July 2024
Clinical advice sought from Endocrinology Advisory Committee on preferred brand	August 2024
Approval by Acting CE on principal supplier status and brand switch	September 2024
Public Announcement	November 2024
Estradiol TDP Mylan to be listed (subject to Medsafe approval)	1 July 2025
Brand switch takes affect	1 December 2025

\*Option for suppliers to submit a commercial proposal for the medicine as an alternative to tendering which, if accepted, would result in the medicine being removed from the tender process. We did not receive any ACPs in relation to oestradiol patches.

## Summary of Tender Decision for Oestradiol Patches

- Pharmac’s primary goal is to ensure a secure, ongoing supply, to meet the demand for oestradiol patches for people needing hormone replacement therapy (HRT).
- Viatris, the supplier of the Estradiol TDP Mylan brand, was able to provide us with confidence that it could provide the levels of supply that New Zealand needs, both now and into the future.
- By awarding a tender to Viatris for its Estradiol TDP Mylan brand, we can ensure that people will have ongoing, stable access to oestradiol patches.
- Sandoz, the currently contracted supplier of oestradiol patches, has been unable to provide enough stock of its Estradot brand to meet New Zealanders needs.
- This decision will mean that people who are not already taking the Estradiol TDP Mylan brand will need to change to it by the end of 2025.
- We understand that the Estradiol TDP Mylan patch may not be clinically appropriate for some people. There is an ‘Alternative Brand Allowance’, to fund other brands of oestradiol patch for people who cannot, for clinical reasons, use the funded HRT options.
- There have been ongoing supply issues for oestradiol patches over the past four years, which have had significant impacts for people needing HRT.
- Demand for patches has, and continues to, grow rapidly globally.

## Background Information on Tender Decision Oestradiol Patches

### *Oestradiol patches*

Oestradiol patches are indicated for use in menopausal hormone therapy and postmenopausal osteoporosis to replace endogenous oestrogen. They are a form of hormone replacement therapy (HRT)

Oestradiol patches are currently funded on the Pharmaceutical Schedule with restrictions of no more than 2 patches per week.

Approximately 85,000 people used oestradiol patches in 2023/24.

The contracted supplier is Sandoz, for the Estradot brand. However, there have been significant supply issues with this brand since 2020, with the supplier continuing to be unable to meet demand in New Zealand. This brand is currently used by about half the market.

Despite Pharmac funding multiple additional brands, including the Viatris brand (Estradiol TDP Mylan), to help maintain stocks of oestradiol patches in New Zealand,

ongoing global supply issues have resulted in there being periods of low or no supply of patches. This has caused significant ongoing issues for people requiring HRT.

Demand for oestradiol patches has tripled in the past four years, and international suppliers are struggling to keep up with global demand. We have heard about the impacts that supply constraints have had on people's health and wellbeing.

Due to ongoing supply issues, there is a current substantial unmet need for people who require oestradiol patches.

Pharmac recently made a decision to fund oestradiol gel, as an alternative option for people requiring HRT.

### ***Tender for oestradiol patches***

Oestradiol patches were included in the 2023/24 annual tender as part of Pharmac's efforts to secure supply of oestradiol patches that can meet current and future demand.

Tendering for secure supply of oestradiol patches and funding oestradiol gel were part of our strategy to ensure long term continuity of supply and ongoing access for those who need it.

Pharmac uses the annual tender to help keep up with the increasing cost and demand for medicines we already fund, and to secure future supply.

Once a year, we invite suppliers to bid to be the leading suppliers of certain medicines. This means they would have exclusive supply for at least 95% of the funded public market (also known as Principal Supply Status). We publicly consult on all items that are included in the draft tender before finalising the list of items to be tendered. We did not receive any consultation feedback as a result of consultation on oestradiol patches being included in the annual tender.

As a result of the annual tender Viatris, the supplier of Estradiol TDP Mylan, has been conditionally awarded the tender supply agreement for oestradiol patches. This brand is currently used by about 25% of people.

The award is conditional on Estradiol TDP Mylan gaining full regulatory consent from Medsafe by 1 July 2025. This brand currently has provisional consent from Medsafe and is undergoing evaluation for full approval.

If full regulatory consent is obtained, from 1 July 2025 everyone who uses funded oestradiol patches will need to start moving to the Estradiol TDP Mylan brand, if they are not already using this brand. Estradiol TDP Mylan will be the only funded brand of oestradiol patches from 1 December 2025.

Viatris has assured Pharmac that it will be able to meet future demand for oestradiol patches. This decision will help us improve supply of oestradiol patches.

The decision to award the tender to Viatris was made using our Factors for Consideration. The primary driver for the decision to award the tender to Viatris is securing certainty of supply.

Awarding the contract to Viatris will result in consistent supply and avoid the adverse impact of treatment disruption and regular brand switching.

### ***Clinical advice***

We sought clinical advice from our Endocrinology Specialist Advisory Committee to understand whether the Estradiol TDP Mylan brand of patches would meet the health need for people who require oestradiol. The Committee told us that:

- consistent access to the Estradiol TDP Mylan brand of oestradiol patches, and access to other oestradiol presentations, such as [the gel \(funded from 1 November 2024\)](#) or tablet, would meet the health needs of people who require oestradiol.
- stable supply of oestradiol patches would allow more effective treatment monitoring and dose changes, to improve people's experience on treatment.

Additionally, our Tender Clinical Advisory Committee considered the suitability aspects of the Estradiol TDP Mylan patch. The Committee is made up of expert pharmacists, doctors and nurses. They considered the packaging, adhesiveness, size and presentation of the Estradiol TDP Mylan patches to be acceptable.

### ***Changing brands of oestradiol patches***

We are aware of adverse experiences for many people due to supply issues with oestradiol patches, frequent brand changes and inconsistent treatment access. People have reported a lack of clinical effect from different brands, and we are aware there is an overall preference for the Estradot brand.

Paradoxically, we note that there have been negative reports relative to Estradot for the Estradiol Sandoz brand listed in April 2024. We understand the Estradiol Sandoz brand is manufactured in the same plant and in the exact same way as Estradot, however with different packaging.

We understand that the Estradiol TDP Mylan patch may not be clinically appropriate for some people. The tender agreement allows for an 'Alternative Brand Allowance', which can be used to fund other brands of oestradiol patch for people for whom the Estradiol TDP Mylan brand of patches, and other funded options (eg oestradiol gel), is not clinically appropriate.

We will be seeking clinical advice to inform how we can best implement this option and will provide information about the process closer to the time of the brand change.

We know changing brands of oestradiol patches can be difficult for people. We have a number of implementation activities planned to assist and support people with the change.

# Hon David Seymour

MP for Epsom

Deputy Prime Minister (from 31 May 2025)

Minister for Regulation

Associate Minister of Education (Partnership Schools)

Associate Minister of Finance

Associate Minister of Health (Pharmac)



29 November 2024

Hon Paula Bennett  
Pharmac Board Chair  
[boardchair@pharmac.govt.nz](mailto:boardchair@pharmac.govt.nz)

Dear Paula

I am concerned about the process and response to Pharmac's recent decision to change the funded brand of oestradiol patches from Estradot to Estradiol TDP Mylan.

This decision has resulted in significant concern from those who will be impacted by this change.

I am seeking assurances from Pharmac that patient voice and experiences were diffidently accounted for within the decision-making process. I have set clear expectations for Pharmac's engagement with patients, and for Pharmac to ensure that it considers patient voice in making each decision.

I would appreciate it if Pharmac could provide me with information on:

- the consultation process undertaken for this decision and what engagement was had with patient groups
- how those voices were incorporated into decision making
- how we are now addressing the concerns raised about the impact of the change to patients.

I expect this request to be treated as a matter of priority. My office is available to answer questions, should you have them.

Regards

A handwritten signature in blue ink, appearing to read 'David Seymour'.

Hon David Seymour  
**Associate Minister of Health**

29 November 2024

Hon David Seymour  
Associate Minister of Health  
Parliament

Dear Minister Seymour

Thank you for your request for more information about Pharmac's decision to move to one funded brand of oestradiol patches – the Mylan patch supplied by Viatris.

The Board have asked Pharmac these questions. Please find below Pharmac's response to your questions.

You asked about the consultation process undertaken for this decision and what engagement was had with patient groups. You also asked how those voices were incorporated into decision-making.

As part of Pharmac's 2023/24 annual tender process, the following consultation documents were published on Pharmac's website and feedback was invited.

- [Consultation on proposed 2023/24 Invitation to Tender: For consumers](#)
- [Consultation on proposed 2023/24 Invitation to Tender: For healthcare professionals](#)
- [Consultation on proposed 2023/24 Invitation to Tender: For industry.](#)

In addition to the annual tender process, at various points while responding to the ongoing supply issues with oestradiol, Pharmac also heard directly from consumers, health professionals and others, about the impact of the shortages. Pharmac have regularly engaged with Dr Linda Dear who represents Menodoctor (a menopause clinic) and has a large consumer following.

Consumers have written to Pharmac about the adverse experiences they have had due to the ongoing supply issues with oestradiol patches, including the impact of frequent brand changes, inconsistent access and the performance of different brands. In the past year Pharmac has received hundreds of pieces of correspondence from consumers and health professionals.

This correspondence, along with the clinical advice we received, informed Pharmac's decision-making about how best to improve the supply of oestradiol patches.

Because of the high public interest in this treatment, on reflection, Pharmac should have had a more robust consultation for the decision to change the funded brand of oestradiol patches.

The tender consultation in this instance was not sufficient. Pharmac's focus was centred on ensuring supply, that they moved at a pace and as such have not consulted as they should have. Pharmac have taken these concerns on board and will look to improve their consultation processes and will be reporting back to the Board.

Pharmac apologises to you as our Minister, but more importantly, to the distress and anxiety this is causing some people We can and will, do better.

You asked how we are now addressing the concerns raised about the impact of the change to patients.

Pharmac understands the Mylan brand of patch or other funded alternatives might not be clinically suitable for everyone. Pharmac's supply agreement with Viartis allows for Pharmac to fund other brands of patches for people who cannot use the Mylan patch or other funded options. Pharmac are actively working to put in place a process for accessing other brands if needed, including Estradot.

Pharmac are still working out the details of this. As information is confirmed, Pharmac will share this publicly and work with media and advocacy groups to ensure this information reaches those who are impacted.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Paula Bennett', with a stylized flourish at the end.

Hon Paula Bennett  
**Chair, Pharmac Board**



**MEMORANDUM FOR CONSIDERATION BY DIRECTOR, PHARMACEUTICALS  
UNDER DELEGATED AUTHORITY**

**To:** Chief Executive

**From:** Acting Director, Pharmaceuticals

**Date:** August 2024

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**TENDER FOR PRINCIPAL SUPPLY STATUS IN THE COMMUNITY AND HEALTH  
NEW ZEALAND - TE WHATU ORA HOSPITALS FOR OESTRADIOL**

**Recommendations**

It is recommended that having regard to the Factors for Consideration set out in Pharmac's - Te Pātaka Whaioranga Operating Policies and Procedures you exercise your delegated authority and:

**resolve** to conditionally\* accept the tender from Viatris Limited for its brand to be the principal supply brand of the Community Pharmaceutical oestradiol patch 25 mcg per day, patch 50 mcg per day, patch 75 mcg per day and patch 100 mcg per day from 1 December 2025 until 30 June 2027;

*\*Acceptance is conditional on Viatris gaining full Medsafe consent prior to the list date of 1 July 2025*

**resolve** to amend the price and subsidy of Viatris Limited's brand of oestradiol patch 50 mcg per day, patch 75 mcg per day and patch 100 mcg per day in the Hormone Preparations - Systemic Excluding Contraceptive Hormones therapeutic group in Section B of the Pharmaceutical Schedule from 1 July 2025 as follows:

<b>Chemical and presentation</b>	<b>Brand (Supplier)</b>	<b>Pack Size</b>	<b>Current price and subsidy (ex-man., ex. GST)</b>	<b>New Price and subsidy (ex-man., ex. GST)</b>
Oestradiol patch 25 mcg per day	Estradiol TDP Mylan (Viatis)	8	\$9.85	\$8.89
Oestradiol patch 50 mcg per day	Estradiol TDP Mylan (Viatis)	8	\$10.75	\$9.26
Oestradiol patch 75 mcg per day	Estradiol TDP Mylan (Viatis)	8	\$11.88	\$10.33
Oestradiol patch 100 mcg per day	Estradiol TDP Mylan (Viatis)	8	\$12.95	\$10.59

**resolve** to delist the following products from Section B of the Pharmaceutical Schedule on 1 December 2025:



Chemical and presentation	Supplier	Brand
Oestradiol patch 25 mcg per day	Sandoz	Estradot
Oestradiol patch 25 mcg per day	Juno	Estraderm MX
Oestradiol patch 25 mcg per day	Well Med	Lyllana
Oestradiol patch 50 mcg per day	Sandoz	Estradot
Oestradiol patch 50 mcg per day	Viatrix	Estradiol Viatrix
Oestradiol patch 50 mcg per day	Juno	Estraderm MX
Oestradiol patch 50 mcg per day	Sandoz	Estradiol Sandoz
Oestradiol patch 50 mcg per day	Well Med	Lyllana
Oestradiol patch 75 mcg per day	Sandoz	Estradot
Oestradiol patch 75 mcg per day	Viatrix	Estradiol Viatrix
Oestradiol patch 75 mcg per day	Sandoz	Estradiol Sandoz
Oestradiol patch 75 mcg per day	Well Med	Lyllana
Oestradiol patch 100 mcg per day	Sandoz	Estradot
Oestradiol patch 100 mcg per day	Juno	Estraderm MX
Oestradiol patch 100 mcg per day	Viatrix	Estradiol Viatrix
Oestradiol patch 100 mcg per day	Well Med	Lyllana
Oestradiol patch 100 mcg per day	Sandoz	Estradiol Sandoz

**resolve** to conditionally\* accept the tender from Viatrix Limited for its brand to be the principal supply brand of the Hospital Pharmaceutical oestradiol oestradiol patch 25 mcg per day, patch 50 mcg per day, patch 75 mcg per day and patch 100 mcg per day with a DV Limit of 5%, from 1 December 2025 until 30 June 2027;

*\*Acceptance is conditional on Viatrix gaining full Medsafe consent prior to the list date of 1 July 2025*

**resolve** to list Viatrix Limited's brand of oestradiol oestradiol patch 25 mcg per day, patch 50 mcg per day, patch 75 mcg per day and patch 100 mcg per day in the Hormone Preparations - Systemic Excluding Contraceptive Hormones therapeutic group in Part II of Section H of the Pharmaceutical Schedule from 1 July 2025 as follows:

Chemical and presentation	Brand (Supplier)	Pack Size	Current price and subsidy <sup>1</sup> (ex-man., ex. GST)	New Price and subsidy (ex-man., ex. GST)
Oestradiol patch 25 mcg per day	Estradiol TDP Mylan (Viatrix)	8	\$14.50	\$8.89

Oestradiol patch 50 mcg per day	Estradiol TDP Mylan (Viatriis)	8	\$14.50	\$9.26
Oestradiol patch 75 mcg per day	Estradiol TDP Mylan (Viatriis)	8	\$14.50	\$10.33
Oestradiol patch 100 mcg per day	Estradiol TDP Mylan (Viatriis)	8	\$14.50	\$10.59

<sup>1</sup> Refers to the price and subsidy of Sandoz brand.

**resolve** to delist the following products from Part II of Section H of the Pharmaceutical Schedule on 1 December 2025:

Chemical and presentation	Supplier	Brand
Oestradiol patch 25 mcg per day	Sandoz	Estradot
Oestradiol patch 25 mcg per day	Juno	Lyllana
Oestradiol patch 50 mcg per day	Sandoz	Estradot
Oestradiol patch 50 mcg per day	Juno	Lyllana
Oestradiol patch 75 mcg per day	Sandoz	Estradot
Oestradiol patch 75 mcg per day	Juno	Lyllana
Oestradiol patch 100 mcg per day	Sandoz	Estradot
Oestradiol patch 75 mcg per day	Juno	Lyllana

s 9(2)(b)(ii)

**resolve** to approve [letter](#) for the conditional award to Viatriis for oestradiol patches.

**resolve** to list on 1 December 2025 and delist on 1 March 2026 in the Various therapeutic group in Section B of the Pharmaceutical Schedule the following brand switch fee:

Chemical and presentation	Brand	Pack Size	Proposed subsidy and price (ex-man., ex. GST)
Pharmacy Services, Brand switch fee (BSF)	BSF Estradiol TDP Mylan	1 fee	\$4.50
May only be claimed once per patient			

**resolve** to add a note to the following presentations of chemical name as listed in Section B of the Pharmaceutical Schedule from 1 December 2025 until 28 February 2026 as follows (changes in bold):

OESTRADIOL

Oestradiol patch 25 mcg per day	<b>Brand Switch Fee payable</b>	\$8.85	8	√ <u>Estradiol TDP Mylan</u>
Oestradiol patch 50 mcg per day	<b>Brand Switch Fee payable</b>	\$10.75	8	√ <u>Estradiol TDP Mylan</u>
Oestradiol patch 75 mcg per day	<b>Brand Switch Fee payable</b>	\$11.88	8	√ <u>Estradiol TDP Mylan</u>
Oestradiol patch 100 mcg per day	<b>Brand Switch Fee payable</b>	\$12.95	8	√ <u>Estradiol TDP Mylan</u>

Proactively Released

## Why proposal should be considered by the Acting Chief Executive under Delegated Authority

The proposal outlined in this decision paper has an estimated Financial Impact (NPV) of more than \$10,000,000. Decision-making for this proposal was delegated to the Chief Executive by the Board at its meeting on 26 July 2024.

The Financial Impact (NPV) is calculated on the basis of the net present value of the proposed subsidy (ex-manufacturer exclusive of GST) over five years at a discount rate of 8% to be paid by the funder for the product(s) and the forecast demand, taking into account any effect of the change/decision on that demand, versus the status quo.

### Executive Summary

- It is proposed to conditionally award Viatris' brand of oestradiol patch 25 mcg per day, patch 50 mcg per day, patch 75 mcg per day and patch 100 mcg per day (oestradiol patches), Principal Supply Status in the community and in Health New Zealand (NZ) hospitals until 30 June 2027. This award is conditional subject to Viatris gaining full Medsafe consent for its brand of oestradiol patches.
- Acceptance of this proposal would result in a brand change for some users of oestradiol patches. However, some people will already be using Viatris' brand of oestradiol patches due to the significant supply issues for this product over the last few years. There is currently a number of brands listed on the schedule in an attempt to mitigate the impact of this supply issue.
- s 9(2)(ba)(i), s 9(2)(b)(ii) [REDACTED]
- Viatris have outlined that their US manufacturing plant has the capacity to meet the required levels of supply for New Zealand and would supply a harmonised pack with the US, which would provide significant continuity of supply benefits. Viatris have confirmed if successfully awarded the tender, it would be able to meet the estimated required volumes for the New Zealand market.
- Due to ongoing supply issues, there is a current substantial unmet need for people who require oestradiol patches. Based on the supply outlook provided by Viatris, we consider acceptance of this proposal would meet this need by providing a consistent supply option and avoiding the adverse impact of treatment disruption and regular brand switching.
- Note that there is a consumer preference for the incumbent brand Estradot and there has been reports of adverse experience for people required to change between different brands due to supply issues. On balance Pharmac staff consider that this proposal is the best approach to meet the health need of people who require oestradiol patches and support continuity of supply. Clinical advice has highlighted that adequate supply of oestradiol patches and an alternative oestradiol gel option would meet the health needs of people who require oestradiol.
- Viatris oestradiol patches products currently hold provisional consent from Medsafe. Viatris have applied for provisional consent to full Medsafe consent pathway. s 9(2)(ba)(i) [REDACTED]

- Awarding this tender to Viatris' brand of oestradiol patches would result in an estimated reduction to the community pharmaceutical expenditure of \$ 9.6 million (3-year NPV, 8%) and an estimated reduction in hospital pharmaceutical expenditure of \$ 1,000 (3 year NPV, 8%) over the tender period. This would result in an estimated saving of \$ 9.6 million to the Combined Pharmaceutical Budget (CPB) over the tender period ending 30 June 2027 (\$19 million 5-year NPV 8%).
- This recommendation is based on the ongoing supply issues with the incumbent brand and Viatris' ability to supply the market. <sup>s 9(2)(b)(ii)</sup> [REDACTED] we consider that continuity of supply to be the key consideration and justification for this award and not savings to the CPB.
- We consider it appropriate to apply a Brand Switch Fee (BSF) as oestradiol is used on a long-term basis by the majority of patients, the last brand change in this market was in 2016. Pharmac staff also consider that there would be a reasonable level of counselling required from Pharmacists to explain the sole supply brand and ensure appropriate application instructions are communicated. It is estimated that a BSF would cost Health NZ \$380,000. The criteria for a BSF are met and we have been in touch with Health NZ to let them know. Should Health NZ be unsupportive of the BSF we would be sure to propose removing this via a future decision paper. Staff note that if a BSF is not supported we would need to consider additional implementation activities to support patients and pharmacists.

### **Summary of impact for populations with highest health need**

As no changes are proposed to the supply or listing of oestradiol patches, nor their availability we do not see any further impacts on populations with highest health need at this time.

<b>TENDER SUMMARY</b>				
<b>Formulation – Pack size</b>	Current subsidy <sup>1</sup>	Proposed subsidy	Proposed unit subsidy	Price difference
Oestradiol tdds 25 mcg per day - 8Patch	\$14.50	\$8.89	\$1.11	39% decrease
Oestradiol tdds 50 mcg per day - 8Patch	\$14.50	\$9.26	\$1.16	36% decrease
Oestradiol tdds 75 mcg per day - 8Patch	\$14.50	\$10.33	\$1.29	29% decrease
Oestradiol tdds 100 mcg per day - 8Patch	\$14.50	\$10.59	\$1.32	27% decrease
	<b>YE 30 June 2024</b>	<b>YE 30 June 2025</b>	<b>YE 30 June 2026</b>	<b>YE 30 June 2027</b>
<b>Number of patients</b>	84,000	97,155	116,329	129,467
<b>Number of Māori or Pacific Peoples (PP)</b>	Māori: 6,900 PP: 1,600	Māori: 8,000 PP: 1,800	Māori: 9,600 PP: 2,200	Māori: 10,700 PP: 2,400
<b>Market data</b>	<b>YE 30 June 2024</b>	<b>YE 30 June 2025</b>	<b>YE 30 June 2026</b>	<b>YE 30 June 2027</b>
<b>*Expenditure (gross)</b>	\$6,940,000	\$11,730,000	\$14,780,000	\$16,450,000
<b>CPB – Community Impact</b>	\$0	\$0	(\$5,090,000)	(\$5,660,000)
<b>CPB – Health NZ hospitals Impact</b>	\$0	\$0	(\$354)	(\$354)
<b>Total CPB impact (NPV)</b>	(\$9,600,000)			
*Estimated community and hospital expenditure by accepting this proposal				
Please note all NPVs calculated are with an 8% discount rate over the 2023/24 ITT principal supply period ending on 30 June 2027.				
<sup>1</sup> Refers to the price and subsidy of Sandoz's brand.				

<b>MARKET DYNAMICS - COMMUNITY</b>						
patch 25 mcg per day	Scripts in FYE 2023		Gross Drug Cost in FYE 2023		Estimated Patients in FYE 2023 (Chronic)	
	47,085		\$762,853		28,672 (2,347)	
	1-year change	5-year change	1-year change	5-year change	1-year change	5-year change
	50 %	403 %	57 %	404 %	85 %	606 %
patch 50 mcg per day	Scripts in FYE 2023		Gross Drug Cost in FYE 2023		Estimated Patients in FYE 2023 (Chronic)	
	73,517		\$1,377,104		39,918 (4,758)	
	1-year change	5-year change	1-year change	5-year change	1-year change	5-year change
	73 %	528 %	78 %	515 %	117 %	776 %
patch 75 mcg per day	Scripts in FYE 2023		Gross Drug Cost in FYE 2023		Estimated Patients in FYE 2023 (Chronic)	
	21,003		\$435,342		10,637 (3,460)	
	1-year change	5-year change	1-year change	5-year change	1-year change	5-year change
	97 %	1345 %	99 %	1274 %	138 %	1474 %
patch 100 mcg per day	Scripts in FYE 2023		Gross Drug Cost in FYE 2023		Estimated Patients in FYE 2023 (Chronic)	

	31,039		\$520,289		22,130 (2,239)
	<b>1-year change</b>	<b>5-year change</b>	<b>1-year change</b>	<b>5-year change</b>	<b>1-year change</b>
	136 %	662 %	103 %	495 %	246 %
					1445%
<b>MARKET DYNAMICS - HOSPITAL</b>					
Health New Zealand hospitals currently spend approximately \$0 per year on Oestradiol tdds 25 mcg per day.					
Health New Zealand hospitals currently spend approximately \$400 per year on Oestradiol tdds 50 mcg per day.					
Health New Zealand hospitals currently spend approximately \$0 per year on Oestradiol tdds 75 mcg per day.					
Health New Zealand hospitals currently spend approximately \$500 per year on Oestradiol tdds 100 mcg per day.					

Proactively Released



## Background

Oestradiol patches are indicated for use in menopausal hormone therapy (MHT) and postmenopausal osteoporosis to replace endogenous oestrogen. Oestradiol patches are currently listed on the Pharmaceutical Schedule with restrictions of no more than 2 patches per week. The contracted supplier is Sandoz, however, there have been significant supply issues with this product since 2020, resulting in the listing of multiple different brands.

Oestradiol patches were included in the draft 2023/24 ITT. Tender Clinical Advisory Committee (TCAC) reviewed the draft list and considered this item appropriate to include in the tender. The draft 2023/24 was released in July for public consultation. No consultation responses were received in relation to oestradiol patches.

Note separate to this proposal Pharmac is proposing to fund an oestradiol gel treatment option, as a result of an [RFP](#) dated 5 April 2024. [Consultation closed on this proposal](#) on 15 August 2024 and a final decision on this proposal is anticipated in September 2024. If approved an oestradiol gel alternative would be available from 1 November 2024.

Upon release on the final 2023/24 ITT, <sup>s 9(2)(j), s 9(2)(b)</sup> <sup>(ii)</sup> bid for each strength of oestradiol patches. TCAC then reviewed Viatris Limited's product. In [March 2024](#) Pharmac's internal Tender Evaluation Committee (TEC) evaluated the tender bids in light of Pharmac's statutory objective, with the outcome of recommending this tender award. A summary of the minutes is provided below, where the TEC:

- provisionally recommended <sup>s 9(2)(b)(ii)</sup> Viatris for oestradiol patches subject to full Medsafe approval
- The TCAC considered there to be no clinical reason for not awarding a tender for all strengths of oestradiol patches.
- noted that Viatris was helping to supply the oestradiol market due to the ongoing supply issue.
- was not aware of any outstanding supply issues that would prevent the award of the tender for oestradiol patches to Viatris.
- considered the Viatris <sup>s 9(2)(b)(ii)</sup>
- Viatris has agreed to additional buffer stock given the ongoing supply issue and understands that the award is based on full Medsafe approval.

## Proposal

This proposal is to award Viatris Limited's oestradiol patches Principal Supply Status (PSS) in the community and Health NZ hospitals with a 5% alternative brand allowance. If approved, this proposal would not result in a change to the eligibility criteria for oestradiol patches. This recommendation is primarily intended to resolve the ongoing supply issue for the funded oestradiol market. It is also noted that Viatris' <sup>s 9(2)(b)(ii)</sup> of all tender bids received.

## Factors for Consideration

This paper sets out Pharmac's staff's assessment of the proposal using the Factors for Consideration in the [Operating Policies and Procedures](#). The Decision Maker is not bound to accept Pharmac's staff's assessment of the proposal under the [Factors for Consideration](#) and may attribute different significance to each of the Factors from that attributed by Pharmac's staff.

All Factors have been considered during the assessment of this proposal, however, only Factors where Pharmac staff consider there to be a change from status quo have been outlined below.



## Suitability

### Clinical advice

#### Tender Clinical Advisory Committee

In February 2024, Pharmac staff sought advice from members of the Tender Clinical Advisory Committee (TCAC) over clinical considerations relating to the Tender. The complete minutes are available [here](#); however, the advice received specifically relating to Viatrix Limited's oestradiol patches tender bids is summarised as follows:

- Considered the physical characteristics of Estradiol in an eight patch pack to be appropriate;
- The pack size, packaging and labelling of these products to be appropriate.
- TCAC noted the patches stuck and could be identified on the skin.
- TCAC noted that the American spelling of oestradiol (estradiol) was on the packaging and the packaging made reference to the milligram per patch (eg 0.025mg per patch) compared with the incumbent Estradot brand which references microgram per patch (eg 25mcg per patch). The Committee considered that consumers might interpret microgram per patch as a lower strength than milligram per patch, and that clear communication on the equivalence of the Estradiol brand with the incumbent brand Estradot would need to be provided in the result of a brand change.
- The Committee noted that patch adhesion is an important factor to consider and that the product appeared to have good adhesion on the skin.
- The Committee considered that there were no clinical issues with different suppliers for different strengths but considered it would be preferable to have the same brand funded across all strengths of oestradiol.

#### Endocrinology Advisory Committee

Pharmac staff sought [additional clinical advice](#) from the Endocrinology Advisory Committee to understand if there would be an unmet need if Viatrix's Mylan brand would be the sole oestradiol patch brand available. The committee provided the following information:

- Noted having an oral, patch and gel oestradiol treatment option would be suitable for most indications and having two transdermal options where oral oestrogen is contraindicated would support patient preference.
- Noted the importance of a consistent and secure supply was critical to meet the needs of people who require oestradiol, combined with three different presentations being available.

- One member noted that they had received feedback from patients that felt the Mylan [now known as Viatriis] brand didn't provide the same dose of estrogen as Estradot. The member considered that most individuals requiring transdermal oestradiol for MHT are have significant menopausal symptoms pretreatment and are sensitive to any dosage changes.
- Noted inconsistent supply and regularly changing between brands does not allow appropriate dose titration if required for a specific brand.
- Considered there should not be a significant difference between brands of patches and it was unclear why people reported any differences.
- One member noted positive feedback for Viatriis's Mylan brand for paediatric use due to the slightly smaller size and ease to cut to size and leave the remaining patch in the plastic sleeve.
- Noted the importance of the proposed brand being available in equivalent strengths and having a matrix formulation to allow dose titration for people who require lower doses, such as paediatric patients. Staff note the Mylan brand is a matrix patch formulation.
- Considered whether there would be value in a dual supply market to ensure adequate supply.
- One member considered there was risk in having sole supply of an oestradiol patch and considered while an oestradiol gel alternative would be available there will be woman who have a preference of a patch over a gel and may not want to use a gel alternative if they experience inadequate clinical effect or intolerable side effects with the Mylan brand.

The concerns raised about the different brands have been considered and are factored into the implementation plan for oestradiol patches.

#### **Advisor Conflicts of Interest**

No relevant conflicts of interest have been declared by any of the clinical advisors who contributed to the above advice.

#### **Impact of brand-change**

Note that over the last four years there have been six brands sources for short term supply and listed on the Schedule.

Staff are aware of adverse experiences for many people due to supply issues with oestradiol patches, frequent brand changes and inconsistent treatment access. People have reported a lack of clinical effect from different brands, and we are aware there is an overall preference for the Estradot brand. Paradoxically, we note that there have been negative reports relative to Estradot for the Estradiol Sandoz brand listed in April 2024. We understand the Estradiol Sandoz brand is manufactured in the same plant and in the exact same way as Estradot, however with different packaging for the US market.

Staff consider brand preference and adverse experience related to different brands is likely exacerbated by the supply issue itself and inconsistent access to patches and the frequent switching of different brands. We consider different brands may have different application instructions, may have been dispensed in a different strength than prescribed (lower strength and additional cost or higher strength requiring cutting of a patch, or multiple strengths) and received by a patient in a stressful and/or frustrating environment. We consider that due to inconsistent supply there has likely been limited

opportunity for an individual to trial a specific brand for an appropriate period and for a prescriber to monitor and dose adjust as required.

Clinical advice has indicated the health need would likely be met with adequate supply of Viatrix' Mylan brand patches and an oestradiol gel alternative. Staff note an alternate option to manage this market could be via a dual supply arrangement which would require a separate procurement process (considered further below). On balance staff recommend proceeding with this proposal noting the 5% ABA could be utilised if required for an exceptional group unable to respond to the Mylan patch brand or an oestradiol gel alternative.

*RFP and dual market*

Pharmac have considered whether a separate procurement process for a dual oestradiol patch market would be appropriate. We consider that a dual market scenario would be difficult to implement in a way that supports continuity of supply. <sup>s 9(2)(j), s 9(2)(b)(ii)</sup>

[Redacted content]

*Utilising the ABA*

Pharmac staff consider that this tender proposal could be supported by utilising the 5% ABA for those people for whom the Viatrix brand of patches is not clinically appropriate. A Special Authority, or other mechanism ie via our Exceptional Circumstances Framework, may be appropriate to allow for use of an alternate brand for a small patient group unable to benefit from the Mylan brand and an oestradiol gel alternative. However, further clinical advice would be required to understand criteria either via a Special Authority or via our Exceptional Circumstances Framework for people unable to use the proposed brand. The table below highlights the impact to the costs and savings of this decision if an alternate brand was made available under the tender agreement with the 5% ABA. <sup>s 9(2)(b)(ii), s 9(2)(j)</sup>

[Redacted content]

Alternate brand utilisation (ABU) scenario*# s 9(2)(b)(ii), s 9(2)(j)	NPV - 3 year	NPV - 5 year
[Redacted content]		

# ABU scenarios >5% capture the cost of the Estradot brand and brand compensation as outlined in the 2023/24 Invitation to Tender contract terms

*Additional considerations*

We note the following considerations in relation to the potential patient impact or impact to Health NZ hospitals as a result of this proposal:

- The TCAC considered that Viatris’ brand of oestradiol patches was appropriate Principal Supply Status in the community and Health NZ hospitals.
- Viatris is currently supplying the market to help mitigate the supply issue from Sandoz product.
- Viatris is considered to have a good continuity of supply reputation and has indicated that it will be able to meet the forecasted demand for this product. Viatris have agreed in a signed letter to hold 2 months additional stock prior to the start date to support the transition.
- Clinical advice received indicates that an additional treatment presentation (gel) and consistent supply of a brand would address the current unmet need.

This decision would meet the [criteria](#) for a brand switch fee:

- Change to a sole supply agreement with a large patient group affected.
- Oestradiol is used on a long-term basis by the majority of patients
- There hasn’t been a brand change in this market in the past seven years.
- Pharmac Staff consider that there will be a reasonable level of counselling required from Pharmacists to explain the sole supply brand has changed and to ensure appropriate application instructions are communicated, noting differences between many brands.
- Pharmacists are likely well placed to support the implementation of this decision and ensure effective and appropriate use of the Mylan brand.
- Although, there are likely to be patients already familiar with the Viatris Mylan product, we note for many, interaction with the Mylan brand has been inconsistent.
- The estimated cost of a BSF will be \$380,000.
- Considering the cost of this BSF to Health NZ Pharmac Staff have emailed Health NZ Pharmacy services to confirm support with implementing a BSF for this proposal. At this stage staff have not had a response from Health NZ however we do not anticipate any major issues and will continue to engage with Health NZ as we approach the list date for this proposal. Should Health NZ be unsupportive of the BSF we would be sure to propose removing this via a future

decision paper. Staff note that is a BSF is not supported we would need to consider additional implementation activities to support patients and pharmacists.



## Costs and Savings

### Tender bids summary

The table below summarises the estimated NPV savings, registration status, and the expected date of price change for the best bids received from <sup>s 9(2)(b)(ii)</sup> [redacted]

s 9(2)(b)(ii), s 9(2)(j)

[Redacted table content]

### Cost and savings to Pharmaceutical expenditure

Viatrix's tender price for oestradiol patches would result in an estimated reduction to the community pharmaceutical expenditure of \$ 9.6 million and an estimated reduction in hospital pharmaceutical expenditure of \$ 1,000 over the tender period. This would result in an estimated saving of \$ 9.6 million (NPV, 8%) to the Combined Pharmaceutical Budget (CPB) over the tender period ending 30 June 2027. Note that the estimated savings from awarding Viatrix's tender bid is estimated relative to the forecasted



expenditure of the oestradiol patch market. The forecasted expenditure for the oestradiol patch market captures the current Sandoz pricing for their brand Estradot.

Note that due to supply issues there have been a number of brands listed on the schedule which have different pricing than the Sandoz Estradot brand. In the 2024 calendar year the average per patch price subsidised by Pharmac was less than the price per patch of the Estradot brand (\$1.64 vs \$1.81). Assuming this average patch price would continue for forecasted usage in the status quo, the estimated savings of this decision would be \$7.1 million over the tender period.

### **Health related costs and savings to the family, whānau and wider community**

We note that people and whanau navigating supply issues with oestradiol patches incur costs to travel between pharmacies for stock and or new prescriptions where a different strength is required due to an out of stock. We consider this proposal would alleviate these costs by improving continuity of supply and providing consistency for individuals prescribed a given dose of oestradiol patches.

### **Costs and savings to the rest of the health system**

As highlighted above, supply issues for oestradiol patches incurs individual patient time but additionally there is significant time and cost incurred by the health system to manage. Namely, pharmacists to counsel and organise new prescriptions when required or prescribers having to issue new prescriptions to help a patient to maintain treatment with alternate available strengths.



### **Health need**

### **Availability and suitability of existing medicines, medical devices and treatments**

Pharmac funds multiple oestradiol containing tablet presentations (oestradiol valerate (fully funded), oestradiol (part subsidised), oestradiol and norethisterone acetate (part subsidised)). However, clinical advice has outlined that transdermal oestradiol is preferred by clinicians and consumers due to safety concerns with oral oestradiol, in particular for people with an age over 45 years, increased BMI, VTE risk or any concern around liver dysfunction.

We note that Pharmac is undertaking a procurement process to secure supply and fund an oestradiol gel. This is intended to provide an additional transdermal oestradiol treatment option and to support supply issues with oestradiol patches.

### **Health need of the person**

We consider there to be an unmet need due to the current supply issues for the incumbent brand of oestradiol patches. Previous advice from the [Endocrinology Advisory Committee](#) have outlined the significant amount of stress and frustration for people accessing oestradiol patches due to ongoing supply issues. Members noted not being able to have a prescription dispensed consistently due to supply issues particularly disadvantages people in paid or volunteer work, who have transport issues, who have limited flexibility in childcare or who live in rural areas.

Additionally, clinical advice from the [Endocrinology Advisory Committee in August 2022](#) highlighted there are a small number of people for whom the current patches do not



provide sufficient transdermal oestrogen dosing, who would benefit from funded access to a greater number of patches. These include people who experience the patches losing therapeutic effect sooner and a requirement to replace the patch every two to three days and less commonly due to patch adherence issues.

Additionally, clinical advice above and [subsequent clinical advice](#) has outlined that there are groups who require more than a 100mcg patch dose twice weekly, such as people undergoing gender affirming therapy. Pharmac has received [a funding application](#) reflecting this.

Staff plan to explore the impact of removing or amending the patch restriction at a later date, when supply issues have resolved.



### Health benefit

Staff consider that adequate supply of oestradiol patches would provide a health benefit for people who require oestradiol patches currently experiencing treatment disruption due to ongoing supply issues.

## Other Considerations

### Supply risks

#### *Current Supply Situation*

Oestradiol patches are currently supplied by Sandoz under the terms of the 2015/16 [Invitation to Tender](#).

There have been long standing supply issues with oestradiol patches since 2020 which presented in a significant way in mid-2022. The initial issue was in the context of [Covid 19](#) as well as increased demand in the market. <sup>s 9(2)(ba)(i), s 9(2)(b)(ii)</sup>

<sup>s 9(2)(b)(ii), s 9(2)(ba)(i)</sup> In each year since 2020 there have been out of stock events for each strength of oestradiol patch.

When seeking alternative options to fulfil market need, several suppliers were contacted. Viatris (then known as Mylan) was one of the [first suppliers](#) to work with Pharmac to get stock into the market in 2020. Viatris stock was initially listed in late 2020. Some strengths were delisted in 2022 before being relisted and supplied continuously since 2022. Other suppliers that were listed prior to 2022 were [Bayer](#) (supplying Climara) and [Juno](#) (supplying Estraderm Mx).

Supply constraints have been particularly challenging in 2024 with significant periods of out of stock and patient impact. Sandoz has been supplying its registered Estradot brand as well as US stock which is provisionally registered. <sup>s 9(2)(b)(ii), s 9(2)(ba)(i)</sup>

A further supplier [WellMed](#) has also been assisting with supply the market for fixed volumes of stock to supply the market from the end of 2024 through to early 2025. Wellmed's product will initially be supplied under section 29 of the Medicines Act 1981, however is seeking provisional registration for its product.

This patient group has experienced instability of supply for an extended period of time. As Pharmac has tried to meet market demand, the patient experience has been of multiple different brands. It would be of benefit to the patient population to have regular supply with a consistent brand.

#### *Viatrix supply considerations*

Viatrix have contributed significantly to stock volume coming into New Zealand. This is at a lower price point than the incumbent. Viatrix have planned deliveries for the rest of 2024. The volumes and delivery dates have been reliable and consistent and Viatrix are proactive to bring [extra stock](#) that can be moved from other markets.

We note that Viatrix has managed to supply significant volumes to New Zealand, which have been secured 'off-shelf' with their US manufacturer. <sup>s 9(2)(b)(ii)</sup>

s 9(2)(j), s 9(2)(b)(ii)

#### **Broader outcomes through Procurement**

Consideration of the Broader Outcomes through Procurement has been undertaken during the evaluation process of this proposal. The information considered in relation to Viatrix to is summarised [here](#).

#### **Comments from Interested Parties**

Section 70(a) of the Pae Ora (Healthy Futures) Act 2022 (the Act) requires Pharmac to consult, when it considers appropriate to do so.

Accordingly, a consultation letter was circulated in July 2023, to all suppliers and other parties that, in the view of Pharmac, may be affected by the recommendations contained in this paper. These responses were considered by the Tender Clinical Advisor Committee their views were included in the October 2023 decision paper to release the 2023/24 Invitation to Tender.

No concerns specific to this proposal were raised during consultation. Advice on tender bids has been sought from members of the Tender Clinical Advisor Committee and is discussed above.

### **Legal advisors' view**

Legal input was sought to support the drafting of the conditional award letter that accompanies this paper. No further input has been sought in relation to this proposal.

### **Implementation**

Section 70(b) Pae Ora (Healthy Futures) Act 2022 requires Pharmac to take measures to inform the public, groups and individuals of Pharmac's decisions concerning the Pharmaceutical Schedule. Accordingly, if the Director, Pharmaceuticals adopts the recommendations contained in this paper Pharmac staff would undertake the following activities:

- Notify Viatris and other pharmaceutical suppliers that might be affected by this proposal.
- Contract Manager working closely with the incumbent supplier (Sandoz) and incoming supplier (Viatris) to support a transition.
- Inform the Schedule Analyst.
- Notify health professionals, pharmacists and the public through the Pharmaceutical Schedule Update

In order to assist with the proposed change in brand, we plan to undertake the following implementation activities:

- An implementation plan will be developed and will include the following activities:
  - Communications to stakeholders, health professionals and the public.
    - Primary care prescribers update
    - Community Pharmacists email subscription.
    - Health NZ Chief Pharmacists update
    - Stakeholder emails (eg regulatory bodies, professional bodies, Māori health providers, patient advocacy groups).
    - Include information on the website to note key dates and outline changes.
  - Education
    - Liaise with Viatris re supplier resources in particular around application of the patches.

- Make targeted brand-change patient information leaflets available on the website to download.
- Education for healthcare professionals.
- Consumer education and cultural understanding around menopause planned for Dec 2024 (Rerere korero and other channels) together with information about funded oestrogen presentations.
- Engage with Healthify and/or other providers for educational resources, FAQs, and to link with supplier resources.

### **Attachments**

Attachment One: Summary of Pharmaceutical Report

Attachment Two: Relevant Tender Evaluation Committee Meeting and Tender Clinical Advisory Committee Meeting minutes