

Schedule 1: Pharmaceutical, background to RFP and types of proposals sought

1. Pharmaceutical

Pharmac - Te Pātaka Whaioranga is interested in considering proposals from suppliers of oestradiol gel.

The intent of this RFP is to secure supply of oestradiol gel and provide an additional presentation of oestradiol for individuals.

2. Background to RFP

Oestradiol is the major female sex hormone. It is used in the management of a range of conditions. We understand most of the funded oestradiol usage in Aotearoa New Zealand is for the management of menopausal symptoms. It is most commonly used in a transdermal patch presentation.

Current Funding

Oestradiol gel is not currently funded in Aotearoa New Zealand. There are currently three forms (patches, tablets and implant) of oestradiol listed on the Pharmaceutical Schedule (see Table 1 for details). Oestradiol patches have a dispensing restriction of up to 2 doses per week applied. There are no other funding restrictions to the supply of the currently funded presentations of oestradiol.

Table 1: Oestradiol listing in Section B and Part II of Section H of the Pharmaceutical Schedule for use in the Community and Te Whatu Ora hospitals.

	Restrictions	Listed in Section B, H or both	Subsidy/ Price (NZ\$)	Per	Fully or Part Subsidised	Brand or Generic Manufacturer
OESTROGENS						
OESTRADIOL						
Tab 1 mg	Both	\$4.12 (\$11.10)	28	Part	Estrofem
Tab 2 mg		Section B	\$4.12 (\$11.10)	28	Part	Estrofem
Patch 50 mcg per 24 hours	No more than 1 patch per week	Section B	\$7.04	4	Fully	Climara
		Both	\$14.50	8	Fully	Estradot
Patch 25 mcg per day	No more than 2 patches per week	Section B	\$9.85	8	Fully	Estradiol TDP Mylan
		Section B	\$13.50	8	Fully	Estraderm MX ¹
		Both	\$14.50	8	Fully	Estradot
Patch 50 mcg per day	No more than 2 patches per week	Section B	\$10.75	8	Fully	Estradiol TDP Mylan
		Section B	\$14.50	8	Fully	Estraderm MX ¹
		Section B	\$10.75	8	Fully	Estradiol Viatrix
		Both	\$14.50	8	Fully	Estradot
Patch 75 mcg per day	No more than 2 patches per week	Section B	\$11.88	8	Fully	Estadiol TDP Mylan
		Section B	\$11.88	8	Fully	Estradiol Viatrix
		Both	\$14.50	8	Fully	Estradot
Patch 100 mcg per day	No more than 2 patches per week	Section B	\$15.50	8	Fully	Estraderm MX ¹
		Section B	\$12.95	8	Fully	Estradiol TDP Mylan
		Section B	\$12.95	8	Fully	Estradiol Viatrix
Implant 50 mg		Section H	-	-	Fully	Any brand
OESTRADIOL VALERATE						
Tab 1 mg		Both	\$12.36	84	Fully	Progynova
Tab 2 mg		Both	\$12.36	84	Fully	Progynova

¹ Extraderm MX is supplied under Section 29 of the Medicines Act.

Over recent years the global demand for oestradiol patches has increased substantially, driven by increasing awareness of the benefits of oestradiol in managing menopausal symptoms. This has outpaced available supply and has led to global supply issues resulting in disrupted treatment and stress for many people requiring oestradiol. From July 2018 to June 2023, the total units of oestradiol patches dispensed has increased annually by 39%. Please see Schedule 3 below for further dispensing information and forecasted usage.

Pae Ora (Healthy Futures) Act 2022

Pharmac - Te Pātaka Whaioranga's role within the health sector is to support all New Zealanders to achieve the shared vision of Pae Ora.

The Pae Ora (Healthy Futures) Act 2022 (the Act) took effect on 1 July 2022. It shapes the reform of the health sector in Aotearoa New Zealand. Achieving Pae Ora means that people and their whānau will live longer in good health, have improved health and quality of life, are part of healthy, inclusive and resilient communities, and live in environments that sustain their wellbeing.

As a government health entity, Pharmac - Te Pātaka Whaioranga is to give effect to the principles of te Tiriti o Waitangi (as set out in [section 6](#) of the Act) and be guided by the health sector principles (as set out in [section 7](#) of the Act), including equity, engagement, and the promotion of health and wellbeing.

This RFP includes sections for suppliers to outline how they can support Pharmac - Te Pātaka Whaioranga and the broader health system to give effect to the principles of te Tiriti o Waitangi, that is, tino rangatiratanga (self-determination), ōritetanga (equity), whakamaru (active protection), kōwhiringa (options), and pātuitanga (partnership).

We are aware that there are various cultural views of menopause. This can influence whether people seek support from health services in relation to menopause. For example, prior to colonisation, Māori women's reproductive journey was celebrated and enthusiastically spoken about in stories of creation, prayer, war rituals, song and in daily lives and interactions. In Te Ao Māori, menopause is regularly seen as a natural developmental stage of life¹. It is therefore important that the implementation support resulting from this RFP is culturally appropriate and recognises the different ways menopause may be viewed.

Patents

Pharmac - Te Pātaka Whaioranga makes no representation as to the patent status and descriptions of any oestradiol gel presentation forms, including but not limited to in relation to method(s) of manufacture, and it is the responsibility of the supplier to ensure its product does not infringe any third-party intellectual property rights. Pharmac - Te Pātaka Whaioranga accepts no liability for any patent infringement that might occur as a result of this RFP process or Pharmac – Te Pātaka Whaioranga's acceptance of any proposal, including infringement of process patents.

Specialist Advisory Committee advice

Pharmac - Te Pātaka Whaioranga has sought clinical advice regarding oestradiol patches and appropriate alternatives. The relevant records of the most recent clinical advice are linked below:

¹ <https://www.tandfonline.com/doi/full/10.1080/07399332.2021.1923717>

- Endocrinology Advisory Committee – [May 2023](#)
- Reproductive and Sexual Health Advisory Committee – [May 2023](#)

Reasons for running the RFP

Pharmac - Te Pātaka Whaioranga is aware of multiple oestradiol gel products available in the New Zealand private market under Section 29 of the Medicines Act 1981 and approved by regulatory bodies overseas. In light of this competition, the purpose of this RFP is to:

- secure ongoing supply of an alternative presentation of oestradiol to alleviate supply pressures for oestradiol patches.
- provide people with a greater range of funded oestradiol presentations.

Any proposals progressed for consideration for funding would be assessed using Pharmac's decision-making framework as outlined in its [OPPs](#) with reference to the [Factors for Consideration](#) and in line with [Te Pātaka Whaioranga – Pharmac's Te Tiriti policy](#).

Intended outcome of the RFP

Principal Supply Status

Through this RFP, Pharmac - Te Pātaka Whaioranga intends to award the successful supplier Principal Supply Status (PSS) for oestradiol gel.

The awarding of PSS means that the successful supplier's brand would be the principal funded brand of oestradiol in New Zealand. The supplier would be guaranteed at least 95% of the funded oestradiol gel market.

Brands of oestradiol gel other than the PSS brand could be funded for use in up to 5% of the funded market, using the alternative brand allowance outlined below. PSS includes both the community and hospital markets.

The PSS period would be **3 years** with an optional PSS extension period of **1 year** should the successful supplier obtain Medsafe approval for its oestradiol gel within the original 3 year PSS period. Exercising the extension period would be by mutual agreement between Pharmac - Te Pātaka Whaioranga and the successful supplier.

Alternative Brand Allowance

Typically, the 5% alternative brand allowance (ABA) would be for individuals with unique clinical circumstances who need an alternative brand of treatment funded. Pharmac - Te Pātaka Whaioranga retains its discretion as to who could access funding for an alternative brand and how funded access to it would be enabled. Funded access to an ABA brand could be by a listing on the Pharmaceutical Schedule or by Pharmac - Te Pātaka Whaioranga's [Exceptional Circumstances framework](#).

Eligibility Criteria

We would be looking to list oestradiol gel on the Pharmaceutical Schedule without any funding or dispensing restrictions.

3. Types of proposals sought

Pharmac - Te Pātaka Whaioranga is willing to consider the following types of proposals:

- (a) Suppliers **MUST** submit proposals for community and hospital supply of oestradiol gel.
- (b) Proposals **MUST** include a period of PSS for oestradiol gel with an alternative brand allowance of 5% for a period of 3 years from the date of listing with an optional 1-year extension should the successful supplier obtain Medsafe approval for its oestradiol gel within the original 3 year PSS period.
- (c) Proposals **MUST** be made on the assumption that no funding or dispensing restrictions would apply.
- (d) Proposals **MUST** include an anticipated lead time.
- (e) Pharmac is willing to consider the following types of proposals:
 - (i) Proposals that include pharmaceuticals that have not yet gained all necessary consents. Consents mean all consents, permits, licences and authorisations, whether statutory or otherwise, required for the supply of the pharmaceutical in Aotearoa New Zealand (including Ministry of Health-Manatū Hauora market approval). In these circumstances, suppliers may be required to show your ability to obtain those consents within a time frame acceptable to Pharmac - Te Pātaka Whaioranga. For example, you may be required to demonstrate you have the dossier ready to submit to Medsafe within one month of such a request being made by Pharmac - Te Pātaka Whaioranga.
 - (ii) In addition to the above, Pharmac - Te Pātaka Whaioranga is willing to consider listing the product on the Pharmaceutical Schedule ahead of full Medsafe approval depending on availability, clinical need, and supply lead times of the product.
 - (iii) Generally, Pharmac - Te Pātaka Whaioranga's preference is for transparent pricing without a rebate, however a proposal that include a flat discount (eg per unit) would be considered.
- (f) Suppliers **MUST** include information outlining the support that would be provided to implement the proposal, particularly any culturally appropriate initiatives that would contribute to equitable access and outcomes for Māori, Pacific peoples, tāngata whaikaha - disabled people and other populations experiencing health inequities.

Pharmac - Te Pātaka Whaioranga is **NOT** willing to consider the following types of proposals (out of scope)

- (a) Proposals involving pharmaceuticals or related products other than oestradiol gel. For the avoidance of doubt, proposals must not include other presentations of oestradiol such as creams, patches, tablets, or implants.
- (b) Proposals where the supplier expects to be exempt from gaining all necessary consents.

- (c) Proposals that involve foreign currency exchange rate clauses or prices linked to any index.
- (d) Proposals that involve an end date for rebates.
- (e) Two-part pricing arrangements, whereby Pharmac - Te Pātaka Whaioranga may make an up-front payment (in addition to any ongoing subsidy) in return for the listing of a pharmaceutical on specific terms.
- (f) Proposals that include a 'hard or soft cap', where a rebate exists over a certain level of expenditure or volume used.

Subject to the above, Pharmac - Te Pātaka Whaioranga is open to considering any other types of proposals you may wish to put forward.

Labelling, images and samples

Suppliers **MUST** provide Pharmac - Te Pātaka Whaioranga with detailed labelling and images of the products and packaging as part of their proposal.

FOUR physical samples of all pharmaceuticals included should be provided **within three weeks of this RFP closing**. If supply is intended to be in a different presentation, form and strength from the provided samples, information about the differences must be supplied.

Samples delivered to Pharmac - Te Pātaka Whaioranga are at the respondent's cost.

Supplier Code of Conduct

The New Zealand Government is committed to sustainable and inclusive government procurement and the [Supplier Code of Conduct](#) outlines the Government's expectations of suppliers in this respect. Pharmac - Te Pātaka Whaioranga expects suppliers to meet or exceed the minimum standards set out in the Supplier Code of Conduct.