PHARMAC
TE PĀTAKA WHAIORANGA

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Thursday 24 November

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF NON-INJECTABLE TESTOSTERONE PRODUCTS

Pharmac invites proposals for the supply of non-injectable testosterone in the New Zealand subsidised community and hospital markets.

This request for proposals (**RFP**) letter incorporates the following schedules:

- Schedule 1 specifies the pharmaceuticals for which Pharmac is requesting proposals and sets out the background to the RFP and the types of proposals sought.
- Schedule 2 describes the process that Pharmac expects to follow in relation to the RFP.
- Schedule 3 sets out information about the estimated size of the current subsidised market for the pharmaceuticals.
- Schedule 4 contains the RFP form in which you are to provide details of your proposal.

If you wish to submit a proposal, you must submit it to Pharmac via the Government Electronic Tenders Service (GETS) (www.gets.govt.nz) no later than 4.00 p.m. on Thursday 19 January 2023.

If you have any questions about this RFP, please post these on GETS or alternatively contact Pharmac by email at **procurement@pharmac.govt.nz**. Responses to all questions will be published on GETS.

We look forward to receiving your proposal.

Yours sincerely,

Lisa Williams
Director of Operations

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

1. Pharmaceutical

   Pharmac is interested in considering proposals from suppliers of one or more non-injectable presentation forms of testosterone, namely:

   - capsules/tablets; and/or
   - gel/cream; and/or
   - patches.

   The intention of this RFP is to have a variety of non-injectable presentation forms available for patients. Through this RFP, we would look to list one of either a capsule or tablet and one of either a gel or a cream. Principal Supply Status would apply to the listed form only.

2. Background to RFP:

   Testosterone is an androgen medicine that is approved in New Zealand for replacement in primary and secondary male hypogonadal disorders and masculinisation in transgender therapy. Pharmac is interested in entering into an agreement with supplier(s) to secure ongoing supply of non-injectable presentation form(s) of testosterone.

   Current funding

   There are currently three testosterone presentation forms (injections, capsules, and patches) listed on the Pharmaceutical Schedule (see Table 1 below for details). Prior to 1 November 2021 all were funded without funding restrictions.

   The Andriol Testocaps brand of testosterone undecanoate cap 40 mg has recently been discontinued, with stock expected to have been exhausted at a wholesaler/distributor level in August 2022. Pharmac sourced an alternative brand of testosterone undecanoate cap 40 mg (Steril-Gene) to continue to meet the health need of people using testosterone capsules. Steril-Gene is not Medsafe-approved and is currently supplied in accordance with section 29 of the Medicines Act 1981.

   Funding for testosterone undecanoate cap 40 mg is currently restricted to people who had been dispensed testosterone undecanoate cap 40 mg prior to 1 November 2021. This restriction was put in place due to the supply issues of the discontinuation. All proposals should be made on the basis that no restrictions would apply (including proposals for capsules/tablets).

   No confidential rebates currently apply to testosterone listings in the Pharmaceutical Schedule.

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

		Subsidy/ Price (NZ$)	Per	Fully Subsidised	Brand or Generic Manufacturer
Androgen Agonists and Antagonists					
TESTOSTERONE Patch 5 mg per day	……	90.00	30	✓	**Androderm**
TESTOSTERONE CIPIONATE Inj 100 mg per ml, 10 ml vial	……[1]	393.00	1	✓	**Taro-Testosterone**
TESTOSTERONE ESTERS Inj 250 mg per ml, 1 ml		12.98	1	✓	**Sustanon Ampoules**
TESTOSTERONE UNDECANOATE Cap 40 mg	***Subsidy by endorsement.*** Subsidised for patients who were taking testosterone undecanoate cap 40 mg prior to 1 November 2021 and the prescription is endorsed accordingly. Pharmacists may annotate the prescription as endorsed where there exists a record of prior dispensing of testosterone undecanoate cap 40 mg in the preceding 12 months. ……	21.00	60	✓	**Andriol Testocaps**
		35.00	100	✓	**Steril-Gene**
Inj 250 mg per ml, 4 ml vial	……	86.00	1	✓	**Reandron 1000**

Depo-testosterone is listed on the schedule at $85.00 per 1 injection and is currently out of stock until November 2022. Taro testosterone is currently being supplied under Section 29 through a stock guarantee with Pharmac to cover the current out of stock of the Depo-testosterone brand.

Pharmacology and Therapeutics Advisory Committee (PTAC) and Advisory Committee Advice

Pharmac has sought clinical advice on non-injectable testosterone treatments on several occasions. The relevant minutes to the most recent clinical advice are linked below:

- PTAC – 19 & 20 May 2022
- Endocrinology Advisory Committee – 8 August 2022

Please note that at the time of issue of this RFP the Endocrinology Advisory Committee meeting minutes for 8 August 2022 were not yet finalised. These will be published on the Endocrinology Advisory Committee page (linked above) as soon as possible.

Reasons for running the RFP

[1] For testosterone esters, the table shows the listing in Section B of the Pharmaceutical Schedule. However, for Part II of Section H of the Pharmaceutical Schedule the presentation and strength are: Inj testosterone decanoate 100 mg, testosterone isocarproate 60 mg, testosterone phenylpropionate 60 mg and testosterone propionate 30 mg per ml, 1 ml ampoule.

Pharmac is aware that there are several non-injectable testosterone products currently approved by Medsafe, undergoing Medsafe evaluation, or approved by regulatory bodies overseas. As a result of this potential competition, the purpose of this RFP is to:

- secure long-term supply of suitable non-injectable testosterone presentation form(s) to meet the health needs and aspirations of New Zealanders. Our preference is to secure supply of testosterone presentation form(s) that have, or would gain, Medsafe consent.

- manage expenditure on funded non-injectable testosterone products.

Any proposals progressed for consideration for funding would be assessed using Pharmac's decision-making framework as outlined in its Operating Policies and Procedures (OPPs) with reference to the Factors for Consideration.

Intended outcome of the RFP

Through this RFP, Pharmac intends to secure an appropriate range of non-injectable testosterone presentation forms, to ensure there is sufficient variety to meet the health needs and aspirations of patients. Successful suppliers would be awarded Principal Supply Status (PSS) for their presentation form, with a 3 month transition period from the date of listing. The award of PSS means that the successful supplier's brand of non-injectable testosterone would be the main funded brand of that presentation form (ie for the gel/cream market only, or the capsule/tablet market only) in New Zealand and would be guaranteed at least 95% of the funded testosterone presentation form included within the scope of this RFP.

Each successful supplier would be awarded PSS for their presentation form(s) that would last for 3 years from the point of listing. There would be the potential for a 12-month extension on mutual agreement available to the successful supplier(s).

As a result of this RFP, Pharmac could award contracts to more than one supplier for differing presentation forms.

Funding scenarios

- All three presentation forms are listed (capsules/tablets, gel/cream, patches)
- Only capsules/tablets and gel/cream are listed
- Only capsules/tablets and patches are listed
- Only gel/cream and patches are listed
- Only one presentation is listed

Where capsules/tablets and gel/cream are specified please note that Pharmac would only fund one presentation form (i.e., a capsule or a tablet but not both). PSS would apply to the listed form only.

Suppliers can provide different pricing for each funding scenario mentioned above. Question 11 in the response form below gives a supplier the opportunity to change its proposed pricing depending on the funding scenario.

Pharmac notes that the markets for other presentation forms of testosterone may be impacted by funding changes resulting from proposals progressed through this RFP. For the avoidance of doubt, any proposed changes resulting from this RFP would be issued

for consultation under section 70 of the Pae Ora (Healthy Futures) Act 2022 before any decisions are made.

3. Types of proposals sought

a) Suppliers wishing to submit proposals MUST submit proposals for community and hospital supply of one or more non-injectable testosterone presentation forms.

b) Proposals MUST include a period of Principal Supply Status (PSS) for each non-injectable testosterone presentation form included in the proposal, with an alternative brand allowance of 5%, following a transition period of 3 months , for a period of approximately 3 years from the date of listing with an optional 1-year extension.

c) Pharmac is willing to consider the following types of proposals:

i) Proposals that include multiple strengths of testosterone capsules/tablets.

ii) Proposals that include multiple strengths of testosterone patches.

iii) Proposals that include multiple strengths of testosterone gels/cream.

iv) Proposals that include supply of more than one non-injectable presentation forms MUST also submit individual proposals for each testosterone presentation form capable of being accepted on its own.

v) 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 New Zealand (including Ministry of Health market approval). In these circumstances, suppliers may be required to show your ability to obtain those consents within a time frame acceptable to Pharmac. For example, you may be required to demonstrate you have the dossier for that brand of testosterone presentation form ready to submit to Medsafe within one month of such a request being made by Pharmac.

vi) In addition to the above, Pharmac is willing to list the product on the Pharmaceutical Schedule ahead of registration depending on availability, clinical need, and supply lead times of the product.

vii) Proposals made on the assumption that no funding restriction would apply (including proposals for capsules/tablets)

viii) Generally, Pharmac’s preference is for transparent pricing without a rebate, however a proposal that include a flat discount (eg per unit) would be considered.

ix) Bundle proposals for multiple presentation forms of non-injectable testosterone may be made.

d) Pharmac is not willing to consider the following types of proposals:

   i) Proposals that do not include at least one strength of a non-injectable testosterone presentation form.

   ii) Proposals that include Principal Supply for some but not all strengths of the non-injectable testosterone presentation form included in the proposal.

   iii) Proposals that include pharmaceuticals other than non-injectable testosterone presentation forms.

   iv) Proposals that involve listing the non-injectable testosterone presentation forms with a partial subsidy.

   v) Proposals that involve listing foreign currency exchange rate clauses or prices linked to any index.

   vi) Proposals that include expenditure caps, or other expenditure risk-sharing mechanism (including volume base tiered pricing); two-part pricing arrangements, whereby Pharmac may make an up-front payment (in addition to an ongoing subsidy) in return for the listing of a pharmaceutical on specific term.

e) Subject to the above, Pharmac is open to considering any other types of proposals you may wish to put forward.

4. Samples

a) Suppliers should provide Pharmac with labelling and images of the products in their proposal. Samples of the product(s) should be provided upon request by Pharmac (and, if supply is intended to be in a different presentation, form, or strength from the provided samples, information about the differences must be supplied) within a reasonable timeframe of such a request.

5. Supplier Code of Conduct

a) The New Zealand Government is committed to sustainable and inclusive government procurement and have outlined the expectations of all suppliers in the Supplier Code of Conduct. Pharmac expects suppliers to meet or exceed the minimum standards set out in the Supplier Code of Conduct.

6. Patents

a) Pharmac makes no representation as to the patent status of any non-injectable testosterone 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 accepts no liability for any patent infringement that might occur because of this RFP process or Pharmac's acceptance of a proposal, including infringement of process patents.

Schedule 2: RFP process.

Pharmac expects to follow the process set out below in the sequence indicated.

1. Submission

    a) You may submit more than one proposal. Each proposal will be considered as a separate proposal.

    b) Proposals must be submitted to Pharmac via the Government Electronic Tenders Service (GETS) no later than **4:00 p.m. (New Zealand time) on Thursday 19 January 2023**. Late proposals will only be considered at Pharmac's discretion, considering the need for fairness to other suppliers and integrity of the RFP process.

    c) You cannot withdraw your proposal, once submitted, while the RFP process is continuing.

    d) In preparing your proposal you acknowledge and agree that in submitting your proposal you will rely on your own knowledge, skill, and independent advice or assessment of the market size for non-injectable testosterone and Pharmac is to have no liability in that regard.

    e) If you have any questions about this RFP, please submit these via GETS.

2. Evaluation

    a) Following the deadline for submitting proposals an Evaluation Committee comprising of Pharmac staff will evaluate each proposal to select its preferred proposal(s).

    b) The Evaluation Committee will evaluate proposals considering Pharmac's statutory objective which is "to secure for eligible people in need of pharmaceuticals, the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided". In doing so the Evaluation Committee will be guided by the Factors for Consideration that form part of Pharmac's then current Operating Policies and Procedures (OPPs), as published on Pharmac's website (www.pharmac.govt.nz), to the extent applicable.

    c) The requirement for Pharmac to pursue its statutory objective means that particular emphasis will be given to those aspects of proposals which demonstrate "health outcomes", and those aspects of proposals which demonstrate the impact on the "funding provided" for pharmaceuticals. Those Factors which relate directly to these aspects will be given the greatest weight by the Evaluation Committee, but all Factors are important, especially suitability due to the variety of presentations in scope. Additional consideration would be given to issues impacting priority populations, and issues relating to equity.

    d) The information to be considered in applying the Factors by the Evaluation Committee will be at its discretion, however it will include:

i) Information provided by you in accordance with Schedule 4 of this RFP, including information provided under clause 3 below.

ii) Any advice from Pharmacology and Therapeutic Advisory Committee (PTAC), or relevant specialist advisory committee, any relevant professional organisation or healthcare professionals. This may include specific clinical advice regarding relative risks and benefits of non-injectable testosterone products following the closing of this RFP.

iii) Any other matter or information that the Evaluation Committee considers to be relevant (provided that Pharmac will notify such matters and allow an opportunity for submitters of proposals to address them) having regard to probity principles.

e) Each proposal will be evaluated on the basis that the price offered, the expenditure entailed, and any other terms included in the proposal, are the best that the supplier is able to offer. If you do not put forward your best terms you risk having your proposal excluded at the evaluation stage.

f) Pharmac is not bound to select the lowest priced proposal(s) or any proposal.

3. Pharmac may request further information.

a) If it considers necessary from or about you for the purposes of clarifying or evaluating your proposal, including (but not limited to):

i) Detailed information about your company structure, credit status and any other relevant company information.

ii) Any other additional information about your pharmaceuticals.

b) If Pharmac requests further information from or about you, it is not obliged to request the same or any other information from or about any other party, provided that in Pharmac's judgement this would not be unfair to any other party.

Please note the Pharmac may seek advice from PTAC, or relevant specialist advisory committee, any relevant professional organisations or health care professionals about your product including evaluation of any product samples.

4. Negotiation

a) Pharmac may negotiate with the submitter(s) of one or more preferred proposals, in the latter case whether or not the acceptance of either supplier's proposal would exclude acceptance of the other proposal.

b) Negotiation will proceed on the basis that Pharmac's standard terms and conditions for supply of pharmaceuticals, which are included as an attachment to this RFP.

c) Given that Pharmac expects your proposal to be the best you can offer, Pharmac does not intend to initiate negotiation with you on Price. However, Pharmac does not exclude the possibility that the final price agreed will be

different from the price put forward in your proposal, because of the impact that other negotiated terms may have on price.

d) Pharmac may negotiate and enter into a provisional agreement with a preferred supplier(s) on whatever special terms, in addition to Pharmac's standard terms and conditions, Pharmac considers appropriate.

e) If Pharmac and the supplier(s) are unable to reach a provisional agreement within what Pharmac considers to be a reasonable time, Pharmac may terminate those negotiations and negotiate with a different supplier(s).

5. Consultation and approval

a) Any provisional agreement will be conditional on consultation with suppliers and other interested parties, to the extent Pharmac considers consultation to be necessary or appropriate, and on Board approval (or approval by the Board's delegate acting under delegated authority).

b) Pharmac will not consider any counteroffers received during consultation.

c) The provisional agreement and responses to consultation will be considered by Pharmac's Board (or by the Board's delegate acting under delegated authority) in accordance with Pharmac's decision-making framework as outlined in its OPPs with reference to the Factors for Consideration.

d) If the Board or its delegate does not approve the provisional agreement, then Pharmac may initiate negotiations for a provisional agreement with any other supplier(s).

e) The RFP process will be complete once Pharmac has notified suppliers of either

i) The Board's or its delegates decision to accept a negotiated agreement

ii) The termination of the RFP process.

6. Miscellaneous

a) Pharmac reserves the right, having regard to probity principles:

i) To make such adjustments to the above RFP process as it considers appropriate at any time during the process, provided that Pharmac notifies suppliers affected by those changes.

ii) Not accept any proposal.

iii) To meet with any supplier in relation to its proposal.

iv) To enter into an agreement or arrangement that differs in material respects from that envisaged in this RFP letter.

v) To suspend this RFP process. For example, if during the RFP process (and before a provisional agreement is entered into) it becomes apparent to Pharmac that further consultation is appropriate or required, we may suspend the RFP process to consult. In this situation, we may ask you to adapt and resubmit your proposal considering consultation, or alternatively we may request that a new proposal be submitted.

vi) To terminate this RFP process at any time, by notifying suppliers who submitted proposals, and, following termination, to negotiate with any supplier(s) on whatever terms Pharmac thinks fit.

vii) To readvertise for proposals.

b) Pharmac may consult or seek clinical advice from PTAC or relevant specialist advisory committee at any stage of the RFP process. Pharmac will notify you if the clinical advice results in any changes to the terms of the RFP.

c) You must not initiate or engage in any communication with other suppliers in relation to this RFP, whether before or after submitting their proposal(s), until such time as a provisional agreement is accepted by Pharmac's Board or the Board's delegate.

d) You must not initiate or engage in any communication with Pharmac, the Ministry of Health (including its operating unit Medsafe), the Minister of Health (or any Associate Ministers), Te Whatu Ora, Te Aka Whai Ora or any of their officers or directors, or advisors to Pharmac with a view to influencing the outcome of this RFP process. Failure to comply with this clause will entitle Pharmac, in its sole discretion, to disqualify you from this RFP process.

e) You must pay your own costs for preparing and submitting your proposal.

f) Your submission of a proposal will be taken as acceptance of the terms contained in this RFP letter. Pharmac may exclude your proposal if you do not comply with any of the terms in this RFP letter.

g) This is an RFP and not a tender. Your proposal is not an offer capable of being converted into a contract for the supply of non-injectable testosterone pharmaceutical(s) by Pharmac's apparent acceptance and instead a separate agreement needs to be negotiated.

h) Pharmac is not liable in any way for any direct or indirect loss (including loss of profit), damage or cost of any kind incurred by you or any other person in relation to this RFP.

i) Pharmac will consider your proposal and information exchanged between us in any negotiations relating to your proposal, excluding information already in the public domain, to be confidential to us and our employees, legal advisors and other consultants, the Ministry of Health, Te Whatu Ora, and Te Aka Whai Ora (confidential information). However, you acknowledge that it may be necessary or appropriate for Pharmac to release confidential information:

i) Pursuant to the Official Information Act 1982.

ii) During consultation on a provisional agreement with a supplier.

iii) In publicly notifying any approval by the Pharmac Board of that agreement.

iv) Otherwise, pursuant to Pharmac's public law or any other legal obligations.

Pharmac may consult with you before deciding whether to disclose confidential information for the purpose described in sub-clauses (i) to (iv) above. You acknowledge, however, that it is for Pharmac to decide, at its absolute discretion, whether it is necessary or appropriate to disclose information for any of the above purposes, provided that Pharmac shall act in good faith in disclosing any confidential information.

7. Anticipated timetable

a) Following receipt of proposals, Pharmac anticipates:

i) The Evaluation Committee evaluating proposals in February 2023.

ii) Seeking clinical advice (if necessary) in March 2023.

iii) Negotiating with submitter(s) of one or more preferred proposals in April-May 2023.

iv) Consulting on a provisional agreement in May 2023.

v) Pharmac's Board, or the Board's delegate, considering this provisional agreement in or after June 2023.

Provided that the above time frames are only approximate and may be extended, without notice being required from Pharmac, if any stages of the RFP process take longer than anticipated.

b) Under this indicative timetable, the earliest that changes to the Pharmaceutical Schedule could be implemented is 1 June 2023.

c) Please note that if a proposal for principal supply is accepted, the date of implementation may be later to allow for an orderly transition to any principal supply arrangement.

8. Governing Law

This RFP is governed by New Zealand law, and the New Zealand courts have exclusive jurisdiction in all matters relating to this RFP.

Schedule 3: Current listing and market information

The following information relates to the estimated subsidised market size of testosterone products in the Sex Hormones Non-Contraceptive section of the Hormone Preparations – Systemic excluding Contraceptive Hormones group under the current restrictions.

The information is approximate and indicative only. Pharmac makes no representation as to the accuracy of this information or as to the level of sales or likely sales of testosterone and, while Pharmac has taken all reasonable care in preparing the information set out below, it accepts no liability for any errors or omissions in the information. Pharmac is no obliged to notify you in the event of any change to the figures below.

The tables below show the volume, expenditure, and patient numbers for the currently funded testosterone products.

Table 1 – Volume data

				Usage (units dispensed) financial year ending 30 June 2022				
Chemical Name	**Presentation**	**Unit of measure**	**Pack size**	**2017/18**	**2018/19**	**2019/20**	**2020/21**	**2021/22**
Testosterone	Patch 5 mg per day	Patch	30	57,000	70,000	76,000	78,000	83,485
Testosterone cipionate	Inj 100 mg per ml, 10 ml vial	Injection	1	2,000	2,000	2,000	3,000	1,347
Testosterone esters	Inj 250 mg per ml, 1 ml	Injection	1	14,000	13,000	14,000	15,000	20,075
Testosterone undecanoate	Cap 40 mg	Capsules	60	452,000	537,000	543,000	602,000	583,308
Testosterone undecanoate	Inj 250 mg per ml, 4 ml vial	Injection	1	12,000	12,000	13,000	14,000	15,097

Please note:

- Usage is combined for community and hospital.
- Testosterone undecanoate cap 40 mg was restricted to continuing patients only from 1 November 2021.

Table 2 – Gross expenditure data

				Usage (units dispensed) financial year ending 30 June 2022				
Chemical Name	**Presentation**	**Unit of measure**	**Pack size**	**2017/18**	**2018/19**	**2019/20**	**2020/21**	**2021/2022**
Testosterone	Patch 5 mg per day	Patch	30	$153,005	$200,282	$226,542	$232,878	$250,450
Testosterone cipionate	Inj 100 mg per ml, 10 ml vial	Injection	1	$114,447	$127,146	$144,513	$224,369	$114,495
Testosterone esters	Inj 250 mg per ml, 1ml	Injection	1	$174,623	$171,404	$174,806	$198,185	$260,672
Testosterone undecanoate	Cap 40 mg	Capsule	60	$125,342	$180,637	$188,772	$209,762	$204,240
Testosterone undecanoate	Inj 250 mg per ml, 4 ml vial	Injection	1	$988,054	$1,050,834	$1,138,382	$1,217,158	$1,298,000

Table 3 – Patient data

				Patient number financial year ending 30 June 2022				
Chemical Name	**Presentation**	**Unit of measure**	**Pack size**	**2017/18**	**2018/19**	**2019/20**	**2020/21**	**2021/2022**
Testosterone	Patch 5 mg per day	Patch	30	623	734	725	687	735
Testosterone cypionate	Inj 100 mg per ml, 10 ml vial	Injection	1	274	317	382	555	465
Testosterone esters	Inj 250 mg per ml, 1ml	Injection	1	1,087	1,027	1,059	1,184	1,647
Testosterone undecanoate	Cap 40 mg	Capsule	60	670	707	735	813	764
Testosterone undeconate	Inj 250 mg per ml, 4 ml vial	Injection	1	3,028	3,229	3,464	3,720	4,006

Table 4 – Māori patient numbers

	Usage (units dispensed) financial year ending 30 June 2022					
Patient Numbers last 12 months (source, Qlik) Chemical and presentations	**2019**		**2020**		**2021**	
	Māori	**% of Total**	**Māori**	**% of Total**	**Māori**	**% of Total**
Testosterone patch	60	8%	50	7%	50	7%
Testosterone cypionate inj	30	8%	40	7%	40	9%
Testosterone esters inj	110	10%	130	11%	140	9%
Testosterone undecanoate cap	70	10%	70	9%	80	10%
Testosterone undecanoate inj	310	9%	360	10%	390	10%
Total	**580**	**9%**	**650**	**9%**	**700**	**9%**

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Schedule 4: Proposal form

An editable version of this form is available on the GETS listing for this RFP.

[*Supplier to insert date*]

Lisa Williams, Director of Operations
C/- Sophie Iles
Pharmac

By electronic transfer using GETS (www.gets.govt.nz)

Tēnā koutou,

Proposal for the supply of non-injectable testosterone presentation form.

Set out below is further information in support of our proposal. You may expand the boxes below to suit the content of your response, please remove any guidance in [*square brackets*]

1. Our Contact Details	
Trading name:	*[insert the name that you do business under]*
Full legal name (if different):	*[if applicable]*
Physical address:	*[if more than one office – put the address of your head office]*
Business website:	*[URL address]*
Type of entity (legal status):	*[sole trader / partnership / limited liability company / other please specify]*
Registration number:	*[if your organisation has a registration number insert it here e.g. NZBN number]*

Does our organisation identify as Māori owned? Pharmac is committed to the Government's progressive procurement approach to increase the diversity of government suppliers and achieve broader economic and social outcomes with a specific focus on Māori businesses. As part of this approach, Pharmac is committed to gaining a better understanding of how our agency can support the economic and social outcomes for Māori through this procurement. One aspect is understanding what roles Māori businesses have in the pharmaceutical supply chain and how we can support Māori businesses in those roles. Pharmac is therefore gathering information from organisations as to whether they identify as a Māori business. A Māori business for Government procurement purposes is: • One that has at least 50% Māori ownership, or • A Māori Authority as defined by Inland Revenue.	[*Yes / No]* *As part of adopting a progressive procurement policy. Pharmac are committed to understand and support what roles Māori businesses play in our supply chain.* *You may also add any further comment on how your company supports economic and social outcomes for Māori*

2. Our Point of Contact	
Contact person:	*[i.e., who communications relating to the attached bid(s) should be made to]*
Position:	
Phone number:	
Mobile number:	
Email address:	

3. Information About Our Organisation	
(a) Information about our Organisation structure:	*[you may embed organisational charts or similar]*
(b) Information about our management and technical skills:	
(c) Information about our financial resources:	

(d) Information about our, or our supplier's, existing supply commitments, including other markets supplied:	
(e) Information about our, or our supplier's, previous supply performance, and ability to ensure continuity of supply of the proposal items (s)	
(f) Information about our quality assurance processes:	
(g) 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, please outline • How your organisation meets or exceed the expectations set out in the Supplier Code of Conduct.	
(h) How our Organisation supports social, economic, cultural, and environmental outcomes beyond supply of Pharmaceuticals (see New Zealand Government Procurement Broader Outcomes). How our organisation: • Supports New Zealand businesses, including Māori, Pasifika, and regional businesses, as well as social enterprises (if relevant) • Supports improving conditions for New Zealand workers and support workforce diversity	

4. Details of pharmaceutical presentation (duplicate this table for more than one presentation)	
(a) Chemical name	
(b) Brand name	
(c) Form	*[e.g. capsule/tablet, patch, gel/cream]*
(d) Strengths	*[e.g. mg per ml]*
(e) Pack size	
(f) Packaging type	

(g) Shelf life	*[include months from date of manufacture, months after opened (if relevant) and temperature to be stored at]*
(h) Labelling and images	*[please embed into your response form or upload to GETS separate to response forms]* *Minimum specification requirements for images:* • *On a plain background (preferably white)* • *Minimal shadows and good lighting* • *The product should take up 80% of the photo*

5. Details of pharmaceutical manufacture (duplicate this table for more than one presentation)	
(a) Name and address of manufacturer/s of the pharmaceutical (including API manufacturer, manufacture of final dose form, packaging etc)	
(b) Details of pharmaceutical manufacturing sites and their registration with Medsafe or other international regulatory body	*[e.g. TGA, FDA, MHRA]*
(c) Batch size/s	
(d) Lead time (time from notification of award to product being available to supply the New Zealand market)	
(e) Approximate manufacture time	
(f) Approximate time for shipping	

6. Evidence of market approval and any other required consents	
(a) Evidence for market approval and any other required consents, include date of market approval.	*[please attach a copy of Medsafe Gazette notice, either by embedding the document here, or uploading a clearly titled document to GETS alongside this form]*
(b) For any proposal products without market approval, but where the dossier has been submitted to Medsafe, please	*[N/A if product is approved by Medsafe]*

provide evidence of the submission, the status of the regulatory approval application.	
(c) For any proposal products without market approval and where the dossier has not been submitted to Medsafe, please provide details of the planned submission date and anticipated timeframes to achieve registration.	*[N/A if product is approved by Medsafe]*
(d) Insert the details of any other consents required for the proposed presentation and any further details that are relevant to assessing the likelihood and timing of your brand gaining all the necessary consents.	*[N/A if product is approved by Medsafe]*
(e) Please confirm that you will supply physical sample of the proposed presentation, to be provided within 10 business days of Pharmac's request.	*[whether or not Pharmac requires a sample will be determined upon initial evaluation of your proposal, please wait to hear from us]*

7. Context surrounding proposed product and capability to support the product(s)	
(a) Key features of our proposal	
(b) Confirmation that there are no intellectual property barriers (including patent barriers) to our supply of this product for the proposed indications in New Zealand, with additional information if required:	
(c) Information about our ability to ensure the continuity of supply of the pharmaceutical, including other countries where the product is widely in use:	
(d) Information about our previous supply performance, existing supply commitments and relevant expertise:	
(e) Information relating to the education support plan for the introduction of your treatment(s), including information regarding compounding (if relevant) and stability data once compounded; training for clinicians regarding administration; information regarding the launch of your pharmaceutical in other jurisdictions; and any relevant information relating to the	*[you can attach supporting information (clinician support materials or similar) either by embedding the document here, or uploading a clearly titled document to GETS alongside this form]*

management of potential risks around misuse of the specific testosterone product.	
(f) How our Organisation would support improving access and responsible use of these medicines (e.g., services and resources that would be offered). • In the context of a strained health system, for groups experiencing health disparities in New Zealand, specifically Māori and Pacific peoples (but also those living in high socioeconomic deprivation, those living rurally, those who've been refugees, and those with disabilities), how would you support implementation of your proposal to ensure that access to treatment is equitable and contributes to equitable outcomes.	
(g) Reasons why Pharmac should accept our proposal.	
(h) Any additional information Pharmac should consider under its Factors for Consideration Framework.	

8. Labour and human rights	
(a) Visibility over our supply chain? Please select one of the below options and explain why you have selected this option: **High:** we have mapped the full supply chain for key products and services used by our organisation and have identified key suppliers at all levels of your supply chain. **Moderate**: we have identified major suppliers and have partially or fully mapped the supply chains for key products and services of our supply chain. **Developing**: we have identified major suppliers. We have very limited or no visibility of our supply chains for key products and services of our supply chain. **Other**: summary of the current status of our supply chain visibility	

(b) Our organisation has a policy or policies in place to deal with modern slavery and worker exploitation	Yes		No	
(c) Our organisation has systems to monitor compliance with these policies?	Yes		No	
(d) If you said yes to either of the two above questions, please attach or link. If the answer is no, please provide information on what your organisation is doing, or plans to do, to manage modern slavery and worker exploitation risk.				
(e) Our organisation performs due diligence screening of all prospective suppliers to assess the risk of modern slavery or other human rights harms that may occur in its operations and supply chains	Yes		No	
(f) If yes, please describe how your organisation performs its due diligence for modern slavery and worker exploitation concerns. If no, does your organisation plan to introduce measures to screen prospective suppliers from modern slavery and worker exploitation in future?				
(g) Our organisation complies with recognised standards	Yes		No	
(h) If yes, please identify the standard and outline the degree to which your organisation complies.				

9. Environmental Sustainability				
(i) Our Organisation has an environmental/sustainability policy?	Yes		No	
(j) Our Organisation has a sustainability report?	Yes		No	
(k) If yes to either of the two above questions, please attach or link:				

(l) How does your Organisation contribute to environmental sustainability?	*Please describe the measures you take to contribute to environmental sustainability – in general and specifically in relation to this RFT*			
(m) Our Organisation has received environmental/sustainability award(s)	Yes		No	
(n) If yes, provide details:				
(o) Our Organisation has received environmental fine/prosecution(s)	Yes		No	
(p) If yes, provide details:				
(q) Our Organisation has received environmental audit(s), or complies with a recognised standard?	Yes		No	
(r) If yes, provide details:				

10. Pricing and Terms of Supply	
As outlined in the RFP, you are required to submit prices for each presentation you are intending to supply for. All prices must be in New Zealand dollars and exclusive of GST.	
Individual market price	**Only one presentation is listed**
Gel/Cream	*Proposal price*
Transdermal patches	*Proposal price*
Capsules/Tablets	*Proposal price*

11. Funding scenarios				
	All three presentations are listed	**Only transdermal patches and caps/tabs listed**	**Only gel/cream and caps/tabs listed**	**Only gel/cream and transdermal patches listed**
Combined Market Price for Gel/Cream	*Proposal price*		*Proposal price*	*Proposal price*
Combined Market Price for capsules/tablets	*Proposal price*	*Proposal price*	*Proposal price*	
Combine Market Price for transdermal patches	*Proposal price*	*Proposal price*		*Proposal price*

Signed for and on behalf of **<insert name of supplier>** by

_____
<Insert name>
<Insert designation>