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6 March 2023

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF VARIOUS PHARMACEUTICALS

Pharmac invites proposals for the supply of various pharmaceuticals in the New Zealand subsidised community and hospital markets as set out in Schedule 1 of this document.

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**. **NZST** on **6 April 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 proposals.

Yours sincerely

Lisa Williams
Director of Operations

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

1. Definitions

For the purpose of this RFP, the following definitions shall apply:

Aggregated Proposal means a proposal for more than one formulation and strength of the same chemical entity, which Pharmac is to consider accepting in the aggregate. You may not aggregate across different chemical entities in your proposal.

Chemical Entity means any pharmaceutical that contains, and is described generically according to, the relevant active ingredient specified in Schedule 1.

Pharmaceutical means each individual form and strength within a chemical entity.

2. Pharmaceutical

Pharmac is interested in considering any proposal from suppliers of the pharmaceuticals below in the **community** and **hospital markets**:

- Heparinised saline – inj 10 iu per ml, 5 ml ampoule
- Heparin sodium – inj 1,000 iu per ml, 5 ml ampoule
- Morphine – oral liq 1 mg per ml
- Morphine – oral liq 2 mg per ml
- Morphine – oral liq 5 mg per ml
- Morphine – oral liq 10 mg per ml
- Povidone-iodine with ethanol – soln 10% with ethanol 70%

Pharmac is interested in considering any proposal from suppliers of the pharmaceuticals below in the **hospital market only**:

- Chlorhexidine with cetrimide – irrigation soln 0.015% with cetrimide 0.15%, 50 ml or less ampoule
- Hydrogen peroxide – soln 3% (10 vol)
- Povidone-iodine – soln 5%

Pharmac is interested in considering any proposal from suppliers of the pharmaceutical below in the **community market only**:

- Midazolam – presentations suitable for buccal and/or intranasal use, variety of strengths

The intention of this RFP is to secure long-term supply of the pharmaceuticals stated above to ensure continuity of supply for New Zealanders.

3. Background to RFP and Pharmaceutical Specifics

Pfizer has notified of its decision to cease manufacturing from its Perth, Australia site, and to no longer supply a number of pharmaceuticals manufactured at that site to the New Zealand market.

All the pharmaceuticals in scope of this RFP are being sourced as direct replacements for currently funded Pfizer products (as outlined below), except for midazolam and morphine for which we are willing to consider proposals for similar clinically suitable chemicals and presentations.

Midazolam

The scope for midazolam products has been widened to include any presentation that is suitable for buccal and/or intranasal use (e.g. plastic ampoule, pre-filled syringe, nasal spray etc). The incumbent Pfizer midazolam product is a plastic ampoule, this presentation allows midazolam to be administered at home buccally, or intranasally, for the treatment of prolonged or recurrent seizures (glass ampoules cannot be administered in this way due to risk of injury from broken glass).

Our clinical advice is that ongoing supply of a buccal/nasal midazolam product is necessary, and that there is a range of dosing used and therefore a range of strengths may need to be considered to ensure the health needs continues to be met. Internationally, other presentations of buccal and intranasal midazolam are available.

To improve the likelihood of securing a suitable replacement product, the scope of this RFP has been expanded to include additional presentations, including plastic ampoules, pre-filled syringes, nasal sprays etc. Suppliers may submit proposals for any strengths of midazolam they have available, but Pharmac's preference would be any or a combination of the following strengths: 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg (total unit strength). Through this RFP, Pharmac reserves the right to award one or all strengths of midazolam.

Hospital supply of midazolam is out of scope of this RFP as plastic ampoules are not currently funded in Section H, and the midazolam ampoules listed in Section H of the Pharmaceutical Schedule currently have Principal Supply Status until mid 2024.

Specialist Advisory Committee Advice for midazolam

Pharmac sought clinical advice on midazolam from the Neurological Advisory Committee. In summary, the Committee advised that the discontinuation of the plastic ampoules would result in an unmet health need, and that glass ampoules are not a suitable alternative. The Committee also highlighted that it is important to have a range of strengths of midazolam available, or at least a product from which a range of concentrations can easily be calculated. The Committee considered that the currently funded dose strengths (inj 1 mg per ml, 5 ml and inj 5 mg per ml, 3 ml) are suitable, and it is important to maintain the lower strength especially for paediatric dosing.

Morphine

The currently funded morphine product is morphine hydrochloride, however through this RFP suppliers may submit proposals for any morphine salts of the oral liquid form.

Current funding

All the products in scope of this RFP are currently supplied by Pfizer and are listed in either Section B or Part II of Section H, or both, of the Pharmaceutical Schedule for use in either the community or Te Whatu Ora hospitals, or both.

The current restrictions on certain pharmaceuticals are listed below and these would remain as a result of this RFP. The tables below outline the current funding for each pharmaceutical.

No confidential rebates currently apply to these listings.

Table 1: Various pharmaceutical listings 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
Analgesics					
MORPHNE HYDROCHLORIDE Oral liquid 1 mg per ml	Only on a controlled drug form. No patient co-payment payable. Safety medicine: prescriber may determine dispensing frequency.	11.98	200 ml	✓	**RA-Morph**
MORPHINE HYDROCHLORIDE Oral liquid 2 mg per ml	Only on a controlled drug form. No patient co-payment payable. Safety medicine: prescriber may determine dispensing frequency.	16.24	200 ml	✓	**RA-Morph**
MORPHINE HYDROCHLORIDE Oral liquid 5 mg per ml	Only on a controlled drug form. No patient co-payment payable. Safety medicine: prescriber may determine dispensing frequency.	19.44	200 ml	✓	**RA-Morph**
MORPHINE HYDROCHLORIDE Oral liquid 10 mg per ml	Only on a controlled drug form. No patient co-payment payable. Safety medicine: prescriber may determine dispensing frequency.	27.74	200 ml	✓	**RA-Morph**
Antithrombotic Agent					
HEPARIN SODIUM Inj 1,000 iu per ml, 5 ml ampoule		86.11	50	✓	**Pfizer**
HEPARINISED SALINE Inj 10 iu per ml, 5 ml ampoule		65.48	50	✓	**Pfizer**
Minor Skin Infections					
POVIDONE-IODINE WITH ETHANOL Soln 10% with ethanol 70%	……	1.63 (7.78)	100 ml	✓	**Pfizer**

Table 2: Various pharmaceutical listings in Part II of Section H of the Pharmaceutical Schedule for us in Te Whatu Ora hospitals only

	Subsidy/ Price (NZ$)	Per	Fully Subsidised	Brand or Generic Manufacturer
Anti-infective preparations				
HYDROGEN PEROXIDE Soln 3% (10 vol)				**Any brand**
Antiseptics and Disinfectants				
CHLORHEXIDINE WITH CETRIMIDE Irrigation soln 0.015% with cetrimide 0.15%, 30 ml ampoule	29.76	30	✓	**Pfizer**
POVIDONE-IODINE Soln 5%				**Any brand**

Table 3: Midazolam listing in Section B of the Pharmaceutical Schedule for use in the Community only.

		Subsidy/ Price (NZ$)	Per	Fully Subsidised	Brand or Generic Manufacturer
Sedatives and Hypnotics					
MIDAZOLAM Inj 1 mg per ml, 5 ml plastic ampoule	On a PSO for status epilepticus use only. PSO must be endorsed for status epilepticus use only.	17.28	10	✓	**Pfizer**
MIDAZOLAM Inj 5 mg per ml, 3 ml plastic ampoule	On a PSO for status epilepticus use only. PSO must be endorsed for status epilepticus use only.	13.09	5	✓	**Pfizer**

Reasons for running the RFP

Pharmac wishes to secure supply of the pharmaceuticals set out in this RFP, to ensure there is no disruption for people who use these funded medicines. Pharmac's strong preference is to secure supply of pharmaceuticals that have or will have Medsafe approval.

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 supply of the pharmaceuticals set out in this RFP, to ensure that the health needs of people who use these medicines can continue to be met with minimal disruption. Successful suppliers would be awarded Principal Supply Status (PSS) for the pharmaceutical, with a 3 month transition period from the date of listing. The award of PSS means that the successful supplier's brand of pharmaceutical would be the main funded brand of that pharmaceutical in New Zealand and would be guaranteed at least 95% of the funded pharmaceutical market included within the scope of this RFP.

Each successful supplier would be awarded PSS for their pharmaceutical that would last for 3 years from the point of listing, with the potential for an optional 12-month extension on mutual agreement available to the successful supplier(s), providing that PSS does not extend beyond 1 July 2028 (including the 12 month extension, if activated).

One of the intended outcomes for running this RFP is to consider if removing the part charge on povidone-iodine with ethanol would be possible.

As a result of this RFP, Pharmac could award multiple contracts to more than one supplier for across the range of chemical entities and presentations in scope. . Pharmac reserves the right to award any or all of the pharmaceuticals listed in scope of this RFP.

4. Types of proposals sought for various pharmaceuticals to be listed in Section B and Part II of Section H of the Pharmaceuticals Schedule for use in the Community and Te Whatu Ora hospitals.

The pharmaceuticals in this section are:

- Heparinised saline inj 10 iu per ml, 5 ml ampoule
- Heparin sodium inj 1,000 iu per ml, 5 ml ampoule
- Morphine - oral liquid 1 mg per ml
- Morphine – oral liquid 2 mg per ml
- Morphine – oral liquid 5 mg per ml
- Morphine – oral liquid 10 mg per ml
- Povidone-iodine with ethanol soln 10% with ethanol 70%

a) Suppliers wishing to submit proposals in this section (section 4) MUST submit proposals for community and hospital supply of one or more pharmaceuticals in this section (Section 4).

b) Proposals MUST include a period of PSS for each pharmaceutical 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 12-month extension providing that PSS does not extend beyond 1 July 2028 (including the 12 month extension, if activated).

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

   i) Proposals for individual pharmaceuticals.

   ii) Proposals that include multiple presentations within a chemical entity (Aggregated Proposals, see definitions).

   iii) Submitters of Aggregated Proposals within a chemical MUST also submit individual proposals for each presentation capable of being accepted on its own.

   iv) 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 the ability to obtain those consents within a timeframe acceptable to Pharmac. For example, you may be required to demonstrate you have the dossier for that brand of pharmaceutical ready to submit to Medsafe within one month of such a request being made by Pharmac.

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

vi) Proposals made on the assumption that the current funding restrictions for each pharmaceutical would remain.

vii) Pharmac's preference is for transparent pricing without a rebate, however a proposal that includes a flat (e.g. per unit) rebate would be considered.

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

i) Proposals that include pharmaceuticals other than those listed in scope of this RFP.

ii) Proposals that include PSS for some but not all pharmaceuticals included in the proposal.

iii) Proposals that involve listing a pharmaceutical with a partial subsidy.

iv) In the case of chemicals that are listed in both Section B and Section H of the Pharmaceutical Schedule, proposals that would result in one supplier supplying in community and a different supplier in hospitals.

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) other than the flat rebate structure noted in paragraph (c)(vii) above; 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.

vii) Bundling, or combining pricing across the different chemical entities (i.e. not an aggregated proposal) in scope is prohibited.

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

5. Types of proposals sought for various pharmaceutical listings in Part II of Section H of the Pharmaceutical Schedule for use in Te Whatu Ora hospitals only.

The pharmaceuticals in this section are:

- Chlorhexidine with cetrimide irrigation soln 0.015% with cetrimide 0.15%, 50 ml or less ampoule
- Hydrogen peroxide soln 3% (10 vol)
- Povidone-iodine soln 5%

a) Suppliers wishing to submit proposals in this section (Section 5) MUST submit proposals for hospital supply for one or more pharmaceuticals in this section (Section 5).

b) Proposals MUST include a period of PSS for each pharmaceutical 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 12-month extension providing that PSS does not extend beyond 1 July 2028 (including the 12 month extension, if activated).

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

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

   iii) Proposals made on the assumption that the current funding restrictions for each pharmaceutical would remain.

   iv) Pharmac's preference is for transparent pricing without a rebate, however a proposal that includes a flat discount (e.g. per unit) would be considered.

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

   i) Proposals that include pharmaceuticals other than those listed in scope of this RFP.

   ii) Proposals that include community supply of one or more of the pharmaceuticals in this section (Section 5).

   iii) Proposals that include PSS for some but not all pharmaceuticals included in your proposal.

   iv) Proposals that involve listing a pharmaceutical 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.

   vii) Bundling, or combining pricing across the different pharmaceuticals in scope is not allowed.

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

6. Type of proposals sought for listing in Section B of the Pharmaceutical Schedule for use in the community only.

The pharmaceuticals in this section are:

- Midazolam presentations suitable for buccal and/or intranasal use (eg plastic ampoule, pre-filled syringes, nasal spray etc), in the following strengths: 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg (total unit strength).

a) Suppliers wishing to submit proposals in this section (Section 6) MUST submit proposals for community supply of at least one presentation of midazolam.

b) Proposals MUST include a period of PSS for each pharmaceutical 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 12-month extension providing that PSS does not extend beyond 1 July 2028 (including the 12-month extension, if activated).

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

    i) Proposals for individual pharmaceuticals

    ii) Proposals that include multiple presentations within midazolam (Aggregated Proposals, see definitions)

    iii) Aggregated Proposals within a chemical entity MUST also submit individual bids for each presentation capable of being accepted on its own.

    iv) 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 the ability to obtain those consents within a timeframe acceptable to Pharmac. For example, you may be required to demonstrate you have the dossier for that brand of pharmaceutical ready to submit to Medsafe within one month of such a request being made by Pharmac.

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

    vi) Proposals for midazolam must be suitable for intranasal and buccal use, however, the registration of the product is not required to be specifically for intranasal or buccal use.

    vii) Proposals made on the assumption that the current funding restrictions for each pharmaceutical would remain.

    viii) Pharmac reserves the right to award any or all of the pharmaceutical presentations listed in scope of this RFP

    ix) Pharmac's preference is for transparent pricing without a rebate, however a proposal that includes a flat discount (e.g. per unit) would be considered.

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

i) Proposals that include pharmaceuticals other than those listed in scope of this RFP.

ii) Proposals that include hospital supply of one or more of the presentations of midazolam in this section (Section 6).

iii) Proposals that include PSS for some but not all pharmaceuticals included in your proposal.

iv) Proposals that involve listing a pharmaceutical 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.

vii) Bundling, or combining pricing across the different pharmaceuticals in scope is not allowed.

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

Please note that suppliers can submit proposals for any or all of the pharmaceuticals in the different sections (sections 4-6 of Schedule 1). There is no requirement for suppliers to provide proposals for a pharmaceutical in every section (section 4-6 of Schedule 1).

7. Samples

Suppliers should provide Pharmac with labelling and images of the products in their proposal. Samples of the product(s) should be provided upon request from 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. Samples delivered to Pharmac are at the respondent's cost.

8. Supplier Code of Conduct

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.

9. Patents

Pharmac makes no representation as to the patent status of any of the various pharmaceuticals, 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. (NZST) on **6 April 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) Please ensure that your proposal includes all information included in the Proposal Form.

(d) You cannot withdraw your proposals, once submitted, while the RFP process is continuing.

(e) In preparing your proposal you acknowledge and agree that in submitting your proposal you rely on your own knowledge, skill, and independent advice or assessment of the market size for the various pharmaceuticals listed in scope of this RFP and Pharmac is to have no liability in that regard.

(f) If you have any questions about this RFP, please submit these via GETS. The close date for questions on GETS will be 5.00 p.m. (NZST) 24 March 2023.

2. Evaluation

(a) Following the deadline for submitting proposals an Evaluation Committee comprising 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.

(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 the 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 any of the pharmaceuticals in this RFP 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) Pharmac may request further information 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 that 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 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 counter-offers 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 delegate's decision to accept a negotiated agreement; or

(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 to accept any proposals.

(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.

(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 advisory committee at any stage of this 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. Pharmac may exclude your proposal if you do not comply with any of the terms in this RFP.

(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 any of the pharmaceuticals in this RFP 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 **April 2023**

(ii) negotiating with respondents of one or more preferred proposals in **April – May 2023**

(iii) consulting on a provisional agreement(s) from **May 2023** onwards

(iv) Pharmac's Board, or the Board's delegate, considering the provisional agreement(s) from **June 2023** onwards

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 **July 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 jurisdiction in all matters relating to this RFP.

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Schedule 3: Current listing and market information

The following information relates to the estimated subsidised market size of the various pharmaceuticals in scope of this procurement.

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 the various pharmaceuticals 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 not obliged to notify you in the event of any changes to the figures in the spreadsheet attached.

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

Pharmaceuticals set out in Section 4 (Community and Hospital) of Schedule 1

Chemical	Presentation	Community expenditure 2022 FYR	Community usage 2022 FYR (units)	Hospital expenditure 2022 FYR	Hospital usage 2022 FYR (units)	Patients Total 2022 (community only)	Chronic patients* 2022 (community only)
Heparinised saline	Inj 10 iu per ml, 5ml ampoule	$87,976.04	77,555	$142,919.67	108,300	72	12
Heparin sodium	Inj 1,000 iu per ml, 5 ml ampoule	$1,283,082.74	1,025,939	$494,188.82	388,250	520	327
Morphine hydrochloride	Oral liq 1 mg per ml	$479,984.41	10,344,442	$26,790.61	565,600	16,303	2,787

Morphine hydrochloride	Oral liq 2 mg per ml	$22,041.97	271,437	$5,694.13	68,800	214	45
Morphine hydrochloride	Oral liq 5 mg per ml	$44,687.57	459,721	$5,271.44	52,400	854	133
Morphine hydrochloride	Oral liq 10 mg per ml	$45,385.36	327,213	$3,419.57	23,800	538	64
Povidone-iodine with ethanol	Soln 10% with ethanol 70%	$4,927.68	302,300	$16,989.00	215,500	18	0

** Chronic Patient: means a patient is flagged as 'chronic' if they received dispensing of the chemical over 150 days or more during FYR2022 AND had 3 or more dispensing of the same.*

Pharmaceuticals set out in Section 5 (Hospital Only) of Schedule 1

Chemical	**Presentation**	**Community expenditure 2022 FYR**	**Community usage 2022 FYR (units)**	**Hospital expenditure 2022 FYR**	**Hospital usage 2022 FYR**	**Patients Total 2022 (community only)**	**Chronic patients 2022 (community only)**
Chlorhexidine with cetrimide	Irrigation soln 0.015% with cetrimide 0.15%, 30 ml ampoule			$151,294.25	150,660		
Hydrogen peroxide	Soln 3% (10 vol)			$35,294.27	10,540		
Povidone-iodine	Soln 5%			$52,708.77	695,100		

Pharmaceuticals set out in Section 6 (Community Only) of Schedule 1

Chemical	Presentation	Community expenditure 2022 FYR	Community usage 2022 FYR (units)	Hospital expenditure 2022 FYR**	Hospital usage 2022 FYR**	Patients Total 2022 (community only)	Chronic patients 2022 (community only)
Midazolam	Inj 1 mg per ml, 5 ml ampoule	$55,101.28	35,020	$9,753.82	6,183	476	6
Midazolam	Inj 5 mg per ml, 3 ml ampoule	$1,033,166.09	419,823	$4,720.05	1,860	16,978	2,489

******** *Please note that the expenditure and usage for midazolam products in the hospital market are used through the 5% Alternative Brand Allowance for the currently funded midazolam glass ampoules in the hospital market.*

Schedule 4: Proposal form

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

[***Supplier to insert date***]

Director of Operations
C/- Sam Bright
Pharmac

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

Tēnā koutou, **Proposal for the supply of various pharmaceuticals**

Set out below is further information in support of our proposal in respect of [***insert pharmaceutical name(s)***].

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	[*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*

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.	
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, previous supply performance, and ability to ensure continuity of supply of the proposal items (s)	
(e) Information about our quality assurance processes:	
(f) 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.	
(g) 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 group of pharmaceuticals or chemical entities)	
(a) Chemical name	
(b) Brand name	
(c) Form	*[e.g. capsule, ampoule]*
(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 group of pharmaceuticals or chemical entities)	
(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 (duplicate this table for more than one group of pharmaceuticals or chemical entities)	
(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 provide evidence of the submission, the status of the regulatory approval application.	*[N/A if product is approved by Medsafe]*
(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(s), including other countries where the product is widely in use; any additional information about our, or our suppliers existing supply commitments.	
(d) 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.

Pricing for pharmaceuticals set out in Section 4 of Schedule 1

Combined Individual proposals (combined refers to the combined community and hospital market, not a combination of forms and strengths**)**

You may submit a proposal for the combined community/hospital market

Please insert more rows if necessary

Item – (Chemical Entity, Form and Strength)	**Unit (Pack Size)**	**Listing amount (Price/Pack)**	**Brand name**	**Lead Time** (time in months or weeks from 1) Pharmac notification that the response has been accepted without any further consultation or decisions pending to; 2) product being in the NZ supply chain)	**Alternative Pricing Mechanism** (see schedule 1 section 4 for allowed rebates or similar)

Combined Aggregated proposals
You may submit a Proposal that includes both an Aggregated Proposal and a Combined Community/Hospital Proposals, provided that you comply with the terms stated in Schedule 1 of this RFP.

Aggregated proposals may be submitted within a chemical entity only.

Item – (Chemical Entity, Form and Strength)	**Unit (Pack Size)**	**Listing amount (Price/Pack)**	**Brand name**	**Lead Time** (time in months or weeks from 1) Pharmac notification that the response has been	**Alternative Pricing Mechanism** (see schedule 1 section 4

				accepted without any further consultation or decisions pending to; 2) product being in the NZ supply chain)	for allowed rebates or similar)

Pricing for pharmaceuticals set out in Section 5 of Schedule 1					
Individual proposals – Hospital Supply You may submit a proposal for hospital supply Please insert more rows if necessary					
Item – (Chemical Entity, Form and Strength)	**Unit (Pack Size)**	**Listing amount (Price/Pack)**	**Brand name**	**Lead Time** (time in months or weeks from 1) Pharmac notification that the response has been accepted without any further consultation or decisions pending to; 2) product being in the NZ supply chain)	**Alternative Pricing Mechanism** (see schedule 1 section 4 for allowed rebates or similar)

Pricing for pharmaceuticals set out in Section 6 of Schedule 1					
Individual proposals – Community Supply You may submit a proposal for the community market Please insert more rows if necessary					
Item – (Chemical Entity, Form and Strength)	**Unit (Pack Size)**	**Listing amount (Price/Pack)**	**Brand name**	**Lead Time** (time in months or weeks from 1) Pharmac notification that the response has been	**Alternative Pricing Mechanism** (see schedule 1 section 4

				accepted without any further consultation or decisions pending to; 2) product being in the NZ supply chain)	for allowed rebates or similar)
Aggregated Proposal You may submit a Proposal that includes both an Aggregated Proposal and an Individual Community Proposals, provided that you comply with the terms stated in Schedule 1 of this RFP. ***Aggregated proposals may be submitted within a chemical entity only.***					
Item – (Chemical Entity, Form and Strength)	**Unit (Pack Size)**	**Listing amount (Price/Pack)**	**Brand name**	**Lead Time** (time in months or weeks from 1) Pharmac notification that the response has been accepted without any further consultation or decisions pending to; 2) product being in the NZ supply chain)	**Alternative Pricing Mechanism** (see schedule 1 section 4 for allowed rebates or similar)