PHARMAC
TE PĀTAKA WHAIORANGA

Level 9, 40 Mercer Street, Wellington
PO Box 10254, Wellington 6143, New Zealand
P: +64 4 460 4990 | F: +64 4 460 4995
www.pharmac.govt.nz

2 November 2021

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF SURGICAL IMPLANTS, MEDICAL AND SURGICAL INSTRUMENTS AND POWER TOOLS, AND ASSOCIATED PRODUCTS

Pharmac invites proposals for the supply of Surgical Implants, Medical and Surgical Instruments and Power Tools, and Associated Products in New Zealand.

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

- Schedule 1 sets out the background to the RFP, the range of products included and the types of proposals sought;
- Schedule 2 describes the process that Pharmac expects to follow in relation to the RFP;
- Schedule 3 specifies the information and evidence you need to include in your proposal;
- Schedule 4 and attachments 1, 2, 4 and 5 contain the forms in which you are to provide details of your proposal; and
- Attachment 3 contains the Pharmac standard terms and conditions to list medical devices on the Pharmaceutical Schedule.

All proposals must be submitted to Pharmac via the Government Electronic Tenders Service (**GETS**) no later than **5.00pm, Thursday 16 December 2021**.

If you have any questions about this RFP, please post these via GETS. We encourage suppliers to register with GETS and subscribe to this RFP to ensure they are kept up to date with this process.

We look forward to receiving your proposal.

Yours sincerely

Lisa Williams
Director of Operations

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

1. Products

Pharmac is interested in considering proposals from suppliers of Surgical Implants, Medical and Surgical Instruments and Power Tools, and Associated Products, for purchase by, and use in, New Zealand District Health Board hospitals and their associated community services (**DHB hospitals**). Pharmac recognises that there are health sector changes proposed and that new arrangements in respect of the purchaser would be reflected in any resulting agreements.

For this Surgical Implants, Medical and Surgical Instruments and Power Tools, and Associated Products RFP, the medical devices fall under three groups:

- Surgical Implants;
- Medical and Surgical Instruments and Power Tools; and
- Associated Products, which are consumable and reusable medical devices required for Surgical Implants and Medical and Surgical Instruments to be used.

The Surgical Implants, Medical and Surgical Instruments and Power Tools, and Associated Products, which are in scope and out of scope of this RFP are outlined further in Schedule 1, clause 6 below.

2. RFP background

In 2010, Pharmac was appointed responsibility for the assessment, standardisation, prioritisation, and procurement of medical devices. In August 2012, Cabinet approved an accelerated plan for transitioning this work to Pharmac.

Since then Pharmac has been taking a category-by-category approach to enter into medical device agreements (**National Contracts**) to build a medical devices schedule. As a result of this, medical devices are listed on the Pharmaceutical Schedule and DHB hospitals choose which products they purchase using the terms and conditions that are set out in the Pharmac agreements.

Surgical Implants, Medical and Surgical Instruments and Power Tools, and Associated Products is the latest category of medical devices Pharmac has commenced procurement activity in. The purpose is to establish, non-exclusive National Contracts with suppliers to secure the supply of these medical devices and ensure nationally consistent pricing for the products used by DHB hospitals.

This RFP enables suppliers to submit proposals for both high-volume consumable products, and implantable devices and technical equipment with a long life expectancy. Suppliers that have products listed in the Pharmaceutical Schedule as a result of any previous Pharmac procurement process are unable to submit the same products for consideration in this RFP.

3. Impacts of RFP

Pharmac intends to establish National Contracts with suppliers to secure the supply of Surgical Implants, Medical and Surgical Instruments and Power Tools, and Associated Products purchased by, and used, in DHB hospitals. It is expected that products subject to a National Contract will be listed in Part III of Section H of the Pharmaceutical Schedule. The National Contracts would not be exclusive of other suppliers, and it is likely that multiple suppliers of equivalent Surgical Implants, Medical and Surgical Instruments and Power Tools, and Associated Products will be listed, where appropriate.

There may be some products associated with, but not exclusive to, Surgical Implants, Medical and Surgical Instruments and Power Tools, and Associated Products that are already listed in Part III of Section H of the Pharmaceutical Schedule as the result of previous contracting activity.

4. **Expected outcome of the RFP**

(a) Pharmac intends to establish National Contracts with suppliers to:

(i) list a range of Surgical Implants, Medical and Surgical Instruments and Power Tools, and Associated Products, available for purchase and use in DHB hospitals, in Part III of Section H of the Pharmaceutical Schedule;

(ii) ensure that a range of Surgical Implants, Medical and Surgical Instruments and Power Tools, and Associated Products is accessible to all DHBs under standard contractual terms;

(iii) secure future supply of Surgical Implants, Medical and Surgical Instruments and Power Tools, and Associated Products for DHB hospitals, at competitive prices;

(iv) ensure access to an appropriate level of clinical support, education and training, and associated materials, for relevant DHB hospital health professionals;

(v) ensure access to an appropriate level of technical support for other relevant DHB hospital personnel;

(vi) engage and establish relationships with new and current suppliers of Surgical Implants, Medical and Surgical Instruments and Power Tools, and Associated Products; and

(vii) move commercial arrangements for Surgical Implants, Medical and Surgical Instruments and Power Tools, and Associated Products into a national framework administered by Pharmac, to create better health outcomes for patients within the funding available.

(b) This RFP is the only process Pharmac expects to run prior to negotiation with suppliers, to determine whether their Surgical Implants, Medical and Surgical Instruments and Power Tools, and Associated Products are contracted for and listed in the Pharmaceutical Schedule. In the event a National Contract(s) is entered into with a supplier(s), as an outcome of this RFP process, and the Surgical Implants, Medical and Surgical Instruments and Power Tools, and Associated Products are listed in the Pharmaceutical Schedule:

(i) the listing shall be non-exclusive and will include pricing and details of the Surgical Implants, Medical and Surgical Instruments and Power Tools, and Associated Products;

(ii) it is anticipated that multiple suppliers of Surgical Implants, Medical and Surgical Instruments and Power Tools, and Associated Products may be listed, where appropriate;

(iii) any resultant National Contract will be between the supplier and Pharmac. DHB hospitals will be able to purchase under the National Contract, effective from the listing date, and will not be required to individually approve the National Contract for it to come into effect;

(iv) it will be discretionary for DHB hospitals to purchase Surgical Implants, Medical and Surgical Instruments and Power Tools, and Associated Products from the supplier, however where they do, DHB hospitals will be required to purchase the Surgical Implants, Medical and Surgical Instruments and Power Tools, and Associated Products under the terms and conditions of the Pharmac National Contract.

5. **Types of proposals sought**

Submitting suppliers must submit a proposal for National Contracts for Surgical Implants, Medical and Surgical Instruments and Power Tools, and Associated Products with pricing to be published (and publicly available) on the Pharmaceutical Schedule once a non-exclusive contract is signed by both parties, following consultation and approval.

Proposals must meet all the mandatory information and evidence requirements as set out in Schedule 4 and Attachments 1, 2, 4, and 5.

Proposals for Surgical Implants, Medical and Surgical Instruments and Power Tools, and Associated Products may be submitted on the basis that there may be incremental changes or upgrades for the proposed Surgical Implants, Medical and Surgical Instruments and Power Tools, and Associated Products during the life of the National Contract, and that if agreed between the parties, the changed or upgraded product would be made available to DHB hospitals within a reasonable timeframe.

5.1 **Types of proposals Pharmac is willing to consider**

(a) Pharmac is willing to consider the following types of proposals for listing in the Pharmaceutical Schedule for use in DHB hospitals:

(i) proposals for Surgical Implants, Medical and Surgical Instruments and Power Tools, and Associated Products as set out in Schedule 1, clause 6(a) of this RFP;

(ii) single pricing option per medical device submitted;

(iii) proposals with alternative options to access Surgical Implants, Medical and Surgical Instruments, Power Tools and Associated Products, including outright purchase, lease, rent, rent to buy and supplier provided equipment options; and

(iv) additional pricing options* (in addition to pricing proposals submitted that have no volume/spend commitment)

**Please note that complex additional pricing models that would pose a significant administrative burden to Pharmac or DHB hospitals are unlikely to be progressed.*

5.2 **Types of proposals Pharmac is NOT willing to consider**

(a) Pharmac is not willing to consider proposals for cross-category bundles of products;

(b) Pharmac is not willing to consider out of scope products as set out in Schedule 1, clause 6(b) of this RFP.

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

6. **Scope**

(a) In scope

Pharmac is willing to consider proposals for Surgical Implants, Medical and Surgical Instruments and Power Tools, and Associated Products, for listing in Part III of Section H of the Pharmaceutical Schedule for use by DHB hospitals, and the following products are considered **in scope** of this RFP (examples of Surgical Implants, Medical and Surgical Instruments and Power Tools, and Associated Products have been provided in Attachment 1):

Category	**Sub-categories – including but not limited to**
	• Reconstructive implants o Breast implants o Testicular implants o Urological reconstruction

Surgical Implants	• Surgical stents – **excluding interventional radiology or cardiology modalities**
	• Orthopaedic soft tissue implants
	• Surgical mesh
	• Ocular implants
	  o Intra Ocular Lenses
	  o Corneal implants
	  o Eye prosthesis
	  o Glaucoma drainage devices/aqueous shunts
	• Aural implants
	  o Cochlea implants
	  o BAHA implants
	  o Aural ventilation tubes
	• Implantable Neurostimulators
	  o Spinal cord stimulators
	  o Peripheral nerve stimulators
	  o Intracranial stimulators
	  o Incontinence implantables

Medical and Surgical Instruments and Power Tools	• Surgical microscopes
	• Power tools
	• Implant site preparation and tissue debridement devices including but not limited to:
	  o pulse lavage devices
	  o ultrasonic devices
	• Body tissue harvesting devices including but not limited to:
	  o dermatomes
	  o bone harvesting morselizers
	• Prostate seeding instruments
	• Medical examination instruments not already listed as the result of a previous Pharmac process
	• Surgical instruments not already listed as the result of a previous Pharmac process

Associated Products: consumable and reusable medical devices required for implants and Instruments to be used	• Accessories, spare parts and consumables associated with surgical implants and/or instruments. • Surgical headlamps • Surgical Tourniquets • Any product submitted that Pharmac considers to be in scope for this RFP on evaluation of submissions.

(b) Out of scope

The following products are considered **out of scope** for this RFP;

(i) Any Surgical Implants, Medical and Surgical Instruments and Power Tools, and Associated Products, submitted by a supplier, that the supplier has currently listed under a Pharmac agreement, or has previously requested to have them delisted;

(ii) Contraceptive implants; and

(iii) Any medical devices submitted by a supplier that Pharmac does not consider to be in scope of this process but may not have been explicitly noted as out of scope.

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) All proposals must be submitted by a single submitter. Submitters may have joint commercial arrangements with other suppliers, and these can be combined into a single submission.

(c) All proposals must be submitted to Pharmac via GETS no later than **5.00pm** (New Zealand time) on **Thursday 16 December 2021.** Late proposals will only be considered at Pharmac's discretion, considering the need for fairness to other suppliers and integrity of the RFP process.

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

(e) If you have any enquiries about this RFP, you should submit them via GETS.

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 (**FFC**) that form part of Pharmac's current Operating Policies and Procedures (**OPPs**), as published on Pharmac's website, to the extent applicable. Please be aware of the FFC.

(c) The information considered during the evaluation process will be at the discretion of the Evaluation Committee however it will include:

(i) information and evidence provided by you in accordance with Schedules 3 and 4, and Attachments 1, 2, 4, and 5 of this RFP;

(ii) your ability to legally supply the proposed products to New Zealand DHB hospitals;

(iii) your ability to provide the appropriate level of product management and support, including but not limited to:

(A) clinical training and education in the use and handling of products;

(B) training and support in equipment cleaning and maintenance (where applicable);

(C) technical support, where applicable;

(D) information for patients, where applicable;

(E) supply chain to support sustainable provision of products; and

(F) transition support;

(iv) your ability to ensure continuity of supply to DHB hospitals including but not limited to:

(A) stock management;

(B) supply chain;

(C) identification and management of key risks to continuity of supply;

(v) DHB hospital usage and financial impact, where applicable;

(vi) other major markets for the proposed products, where applicable;

(vii) provision of reference sites, where applicable;

(viii) any advice received from relevant clinicians and/or DHB hospital staff; and

(ix) any other matters 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).

(d) 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.

(e) Pharmac is not bound to select any proposal.

3. Pharmac may request further information

(a) Pharmac may request such further information as it considers necessary from or about you for the purposes of clarifying or evaluating your proposal, including (but not limited to) detailed information about your company structure, credit status and any other relevant company information.

(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 judgment, this would not be unfair to any other party.

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) Negotiations will proceed on the basis that Pharmac's standard terms and conditions to list medical devices on the Pharmaceutical Schedule, which are available as a download (Attachment 3) from GETS, will apply.

(c) You **MUST** complete and submit Attachment 4 of this RFP as part of your proposal by declaring that you have read and understood Pharmac's standard terms and conditions for the supply of medical devices, and where you disagree with any of the standard terms and conditions, include comments about the terms and conditions you would seek to amend during any negotiation.

(d) Pharmac expects your proposal to be the best you can offer, however, Pharmac does not exclude the possibility that the final price agreed will be different from the price put forward in your proposal, as a result of the impact that other negotiated terms may have on price.

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

(f) If Pharmac and the supplier(s) are unable to reach a provisional National Contract 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 National Contract will be conditional on consultation with DHB hospitals and other interested parties, to the extent Pharmac considers consultation to be necessary or appropriate, and on Pharmac 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 National Contract and responses to consultation will be considered by Pharmac's Board (or by the Board's delegate acting under delegated authority) in accordance with the FFC in Pharmac's then current OPPs.

(d) If the Board (or its delegate) does not approve the provisional National Contract, then Pharmac may initiate negotiations for a provisional National Contract 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 negotiated National Contract(s); 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 it notifies suppliers affected by those changes;

(ii) not to accept any proposal;

(iii) to seek clarification of any proposal;

(iv) to meet with any supplier in relation to its proposal;

(v) to enter into an agreement or arrangement that differs in material respects from that envisaged in this RFP letter;

(vi) to suspend this RFP process. For example, if during the RFP process (and before a provisional National Contract is entered into) it becomes apparent to Pharmac that further consultation is appropriate or required we may suspend the RFP process in order to consult. In this situation we may ask you to adapt and resubmit your proposal, in light of consultation, or alternatively we may request that new proposals be submitted;

(vii) 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; and

(viii) to re-advertise for proposals.

(b) You must not initiate or engage in any communication with other suppliers in relation to the RFP, whether before or after submission of any proposal(s), until such time as a provisional National Contract is accepted by Pharmac's Board (or its delegate).

(c) You must not at any time initiate any communication with Pharmac, the Ministry of Health (including its operation unit Medsafe), the Minister of Health (or any Associate Ministers) or DHBs, or advisors to Pharmac, with a view to influencing the outcome of this RFP process.

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

(e) You must limit the information provided to that which is requested in Schedule 3 and 4 and Attachments 1, 2 4 and 5, and provide it succinctly and clearly. Please do not provide brochures or additional information (e.g. PEHNZ forms and presentations) unless specifically requested to do so in this RFP document.

(f) Proposals are submitted in reliance on your own knowledge, skill, and independent advice, and not in reliance on any representations made by Pharmac.

(g) 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 contained in this RFP document.

(h) 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 Surgical Implants, Medical and Surgical Instruments and Power Tools, and Associated Products by Pharmac's apparent acceptance, and instead a separate agreement needs to be negotiated.

(i) Pharmac is not liable in any way whatsoever 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.

(j) It is possible that more than one supplier may be awarded a National Contract as a result of this RFP. Nothing in this RFP prevents Pharmac from entering into agreements with other suppliers in respect of Surgical Implants, Medical and Surgical Instruments and Power Tools, and Associated Products or restricts the terms that may be agreed with any other supplier.

(k) Pharmac will consider your proposal and information exchanged between the parties 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 and DHBs (**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; or

(ii) in the course of consultation on a provisional National Contract entered into with a supplier; or

(iii) in publicly notifying any approval by the Pharmac Board (or its delegate) of that National Contract; or

(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 purposes described in sub-clauses (i) to (iv) above. You acknowledge, however, that it is for Pharmac to decide, in 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 Pharmac internal Evaluation Committee evaluating proposals from **January 2022**;

(ii) negotiating with submitter(s) of one or more preferred proposals from **April 2022;**

(iii) consulting on provisional National Contracts from **2nd quarter 2022**; and

(iv) Pharmac's Board, (or its delegate), considering any provisional National Contracts from **May 2022** at the earliest.

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

(b) Under this indicative timetable, the earliest that changes to the Pharmaceutical Schedule could be implemented is **1 July 2022**.

8. Governing Law

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

Schedule 3: Information and evidence to be included in your proposal

Please include the following information and evidence in your proposal. Proposals that do not include mandatory information and evidence will only be considered at Pharmac's discretion, considering the need for fairness to other suppliers and integrity of the RFP process.

Document	Evidence / Information
Attachment 1: **Surgical Implants, Medical and Surgical Instruments and Power Tools, and Associated Products Proposed Product List**	You **must** complete all fields in Attachment 1 for each proposed product. If you consider a field not applicable you must state "NA".
WAND (for products classified as Medical Devices by Medsafe)	You **must** be able to legally supply your proposed products to New Zealand DHB hospitals as evidenced by WAND number. Please **do not** provide WAND documents. Where WAND is not applicable to a proposed product you **must** state the reason why it is not applicable.
International compliance	You **must** provide evidence of international compliance certification. Either by providing the searchable Australian Register of Therapeutic Goods (ARTG) Identifier or applicable certificate. The name of the certifying body and certificate number must be included in Attachment 1 for each proposed product, and you **must** attach a copy of all relevant certificates.
GS1 (GTIN) and UNSPSC	It is desirable that you provide GTIN and UNSPSC codes for each proposed product at the time of submitting your proposal. Please note that Pharmac's standard terms and conditions require provision of GTIN numbers, if requested by Pharmac or a DHB, within six months of the request.
DHB usage data	If you are currently supplying a proposed product to any DHB hospital, you **must** provide combined volume and cost information for all DHB hospitals for the period 1 November 2020 – 31 October 2021, for all proposed products submitted, by line item, in **Attachment 1**. You **must** also include any sales to DHB hospitals via logistics providers.
Non-DHB reference sites	If you **are not** currently supplying a proposed product to any DHB hospital, you **must** provide three clinical reference sites for that product. It is desirable that the clinical reference sites you provide use the proposed products in similar clinical settings as DHB hospitals would use them.
Attachment 2: **Financial analysis of your proposal**	If any of your proposed products are currently supplied to DHB hospitals (contracted and non-contracted) you **must** provide a detailed financial impact analysis of your proposal for each DHB based on recent usage; to be **attached** as an Excel spreadsheet. A preferred format is included in Attachment 2 (Example 1). You may provide your financial analysis in an alternative format provided it is a pivotable excel format and includes the following for each DHB and each proposed product: (a) the product description, brand, manufacturer and your supplier product code (as proposed in Attachment 1); (b) your current (as of 1 November 2021) price offered to each DHB; (c) your proposed price (as proposed in Attachment 1); (d) DHB hospital sales volume (including via logistics providers) for: • 1 November 2018 – 31 October 2019 (desirable for infrequently purchased products)

Document	Evidence / Information
	• 1 November 2019 – 31 October 2020 (desirable for infrequently purchased products) • 1 November 2020 – 31 October 2021 (**mandatory for all products**) (e) projected annual cost to each DHB at their current price • current price (b) x DHB sales volume (1 November 2020 – 31 October 2021) (f) projected annual cost to each DHB at proposed price • proposed price (c) x DHB sales volume (1 November 2020 – 31 October 2021) (g) projected financial impact for each DHB of your proposal *projected annual cost at proposed price (f) – projected annual cost at current price (e)* Where you have supplied products to a DHB hospital under an alternative procurement model (eg rent/lease option, free on consumable commitment) you need to provide those details by DHB hospital, with outline of model and terms – including but not limited to any expiry/completion date for provision of the products and/or transfer of ownership.
Attachment 4: **Acceptance of Pharmac's standard terms and conditions**	You **must** complete, sign and date the declaration set out in Attachment 4. You **must** indicate whether you agree or disagree with Pharmac's standard terms and conditions for medical devices for your proposed Surgical Implants, Medical and Surgical Instruments and Power Tools, and Associated Products. If you do not agree with any of Pharmac's standard terms and conditions for medical devices for your proposed products you **must** provide detailed comment, including the clause reference and any proposed changes or alternative clauses and justification, in Table 1 of Attachment 4. If you would like Pharmac to consider any other terms and conditions that are not included in Pharmac's standard terms and conditions, you **must** provide details and justification in Table 2 of Attachment 4.
Attachment 5: **Document and information checklist**	You **must** complete the document and information checklist set out in Attachment 5. You **must** note any additional attachments not specifically listed in the box provided in Attachment 5.
Schedule 4: **Proposal form**	You **must** complete all sections of Schedule 4. Note, suppliers that have submitted information to Pharmac, as referenced in section 4, within the last 12 months, do not need to provide this information again, provided the information is still accurate in the context of this RFP. Please note the process this information was submitted under. If you consider a section to be not applicable, you **must** state "NA". The response you provide in each section **must** be comprehensive and relevant to the information that has been requested, and you **must** include relevant attachments.

Schedule 4: Proposal form

An electronic version of this form is available on GETS, GETS RFP reference number: **25017697**. You should expand the boxes, as necessary.

[*Supplier to insert date*]

Director of Operations
Pharmac
c/- Sam Bright
Procurement Manager

By electronic transfer using GETS

Dear Sir/Madam

Proposal for the supply of Surgical Implants, Medical and Surgical Instruments and Power Tools, and Associated Products

In response to your request for proposals (**RFP**) dated **2 November 2021** we put forward the following proposal in respect of Surgical Implants, Medical and Surgical Instruments and Power Tools, and Associated Products.

Please refer to Schedule 3 for information and evidence to be included in your proposal. You must also include information as outlined Attachments 1,2, 4 and 5 as part of your proposal.

Set out below is further information in support of our proposal.

1. Company details	
Full legal entity name as stated at Companies Office or equivalent international register.	
Address	
Phone	
Email	
2. Contact person(s) for this RFP	
Name, Position	
Phone	
Mobile	
Email	

3. Executive summary	
Proposal summary Include: • overview of products and services • benefits to DHB hospitals of this proposal • why Pharmac should accept this proposal	**Maximum 500 words**

4. Information about our company, contracts, and markets. Suppliers that have submitted this information to Pharmac in previous RFPs, where the information is still directly applicable and will remain the same for this RFP, can progress to no.5	
Company information	
(a) Type of entity (legal status) E.g., a New Zealand registered limited liability company	
(b) Does your organisation identify as being a Māori business? 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 our 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]* *In line with this policy, Pharmac is committed to understand and support what roles Māori businesses play in our supply chain. You can add any further comment on how your company supports economic and social outcomes for Māori in question 10(c) below.*

4. Information about our company, contracts, and markets. Suppliers that have submitted this information to Pharmac in previous RFPs, where the information is still directly applicable and will remain the same for this RFP, can progress to no.5	
Within these definitions, does your organisation identify as a Māori business? This information will inform Pharmac's supplier's database and will be reported to NZGPP, subject to any concerns you identify (see (c)).	
(c) For some of its procurement Pharmac is required to report to NZGPP on whether an organisation identifies as a Māori business as part of new progressive procurement reporting requirements. Please indicate either 'Yes' or 'No' as to whether you agree to Pharmac reporting on your organisation's status as a Māori business. If you indicate 'No', please provide reasons for our consideration.	*[Yes / No]*
(d) City and country of residence of your company e.g. Sydney, Australia	
(e) Information about company size, structure, and annual turnover Include sales/product support staff relevant to this RFP. **Attach** Organisational Chart.	
(f) Total number of New Zealand based staff Include FTE for each section (eg.5 FTE sale/product support, 4 FTE logistics, 3 FTE corporate and administration). Please also indicate, of those staff, how many would be involved in supporting the proposed Surgical Implants, Medical and Surgical Instruments and Power Tools, and Associated Products	
(g) Established locations within New Zealand Include function of each location (e.g. head office, warehouse).	
(h) If you are currently not based in New Zealand: Do you intend to establish a company location(s) here?	

4. Information about our company, contracts, and markets. Suppliers that have submitted this information to Pharmac in previous RFPs, where the information is still directly applicable and will remain the same for this RFP, can progress to no.5	
How would you manage the needs of your New Zealand DHB hospital customers from where you are located? N/A if New Zealand based	
(i) Company ownership State ownership (e.g. public ownership) Include: • If your organisation is controlled by an overseas entity; • if your organisation is part of a group of entities owned by a 'parent' company - please outline your relationship with these companies • names and percentage shareholdings of the major shareholders and directors	
(j) Evidence of financial stability and ability to cover financial liabilities **Attach** supporting evidence (e.g. annual financial report, Companies Register financial statement, insurance certificate, bank letter).	
Contracts and markets	
(k) Current contracts and standing agreements in place with DHB hospitals or organisations acting on their behalf Include all DHB contracts, not just those relevant to this RFP. For each provide: • parties to the agreement • contract reference number • type of agreement (national/regional/DHB specific) • range of products covered • expiry date • other relevant information (e.g. now standing agreement after contract expiry) Can be provided as an attachment, note name of attachment in response column.	
(l) Products not included	

4. Information about our company, contracts, and markets. Suppliers that have submitted this information to Pharmac in previous RFPs, where the information is still directly applicable and will remain the same for this RFP, can progress to no.5	
Include any Surgical Implants, Medical and Surgical Instruments and Power Tools, and Associated Products you currently supply to DHB hospitals (contracted or not contracted) that you have not included in this proposal and the reason for this. Please identify: • If this is due to manufacture discontinuation and when the expected discontinuation date is; • If superseding products have been proposed in your proposal instead; • If there is a change of distribution arrangement pending; • If already on a Pharmac agreement with you	
(a) Healthcare customers in New Zealand Include DHB hospital and private healthcare organisations you currently supply with the Surgical Implants, Medical and Surgical Instruments and Power Tools, and Associated Products and other Medical Devices (please give a short summary for these, including type of Medical Devices supplied)	
(b) Information on other major markets for proposed product ranges. For each product range include: • type of market (e.g. private hospital, public hospital) • any contracts held • annual volume • any other relevant information	***NB.*** *Only required for product ranges that New Zealand DHB hospitals are <u>not</u> currently purchasing.*
(c) Information about clinical reference sites Provide information about each reference site included in Attachment 1 including the location and relevant clinical settings in which the product is used (e.g. inpatient care, outpatient clinics, home use).	***NB.*** *Only required for product ranges that New Zealand DHB hospitals are <u>not</u> currently purchasing.*
(d) Other relevant company and market information	

5. Information about our ability to manage and support our proposed Surgical Implants, Medical and Surgical Instruments and Power Tools, and Associated Products		
Training and Education		
(a) Training and education Include an overview of the training and education that would be regularly provided to DHB hospitals for the proposed products including: • frequency • location • format • content • staff groups (e.g. hospital, community) • other relevant information		
(b) Training and education materials Include training and education materials that would be provided to DHB hospitals purchasing the proposed products.	For DHB hospital staff	For patients (if applicable)
(c) Product support staff information about the staff that would be involved in supporting the proposed products (including those staff providing clinical training and support). Include: • technical skills; • experience; • qualifications; and • other role responsibilities (e.g. if they are responsible for supporting other Device Categories etc)		
DHB Transition		
(d) Experience transitioning DHB hospitals or other similar facility to your Surgical Implants, Medical and Surgical Instruments and Power Tools, and Associated Products Please outline: • extent of transition (e.g. switching multiple consumable device product ranges within the Surgical Implants, Medical and Surgical Instruments and Power Tools, and Associated Products for DHB hospital use); • when transition occurred; • extra resources utilised (e.g. whether international product/transition specialist were called on for a period);		

5. Information about our ability to manage and support our proposed Surgical Implants, Medical and Surgical Instruments and Power Tools, and Associated Products	
(e) Transition support Include an outline of the support that would be provided to DHB hospitals transitioning to the proposed products. **Attach** a detailed transition plan setting out the transition steps, roles and responsibilities and timeframes. Note name of attachment in response column.	
(f) Entering National Contracts Please outline if you foresee any challenges for your company to move to a National Contract. Are there solutions to these challenges which you would like Pharmac to consider?	
Customer Support	
(g) Customer support hours Include: • standard support hours (NZ time) for customer support and orders; and • any 24/7 troubleshooting support relevant to the proposed products or specific products if applicable;	
(h) Complaints management processes Include overview of key roles and responsibilities for investigation and response, and escalation and continuous quality improvement processes.	
(i) Other relevant information about ability to support the proposed products.	

6. Information about our compliance with regulations and standards			
(a) New Zealand regulation	Are all proposed products notified on the Medsafe Web Assisted Notification of Devices 'WAND'	If No (and WAND is applicable or registration as a medicine is required), what is the timeframe all products are	Does your company comply with the Medsafe regulated guidelines and codes related to supply of

6. Information about our compliance with regulations and standards			
	Database or registered as a medicine as applicable?	expected to meet regulatory requirements?	Medical Devices in New Zealand. e.g. New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods
	[Yes/No]		[Yes/No]
(b) Quality Management System(s) certification for your company **If yes, attach evidence** Include relevant section(s) of standard where certification is not for full standard.	ISO 9001 [Yes/No]	ISO 13485 [Yes/No]	Other [specify]
(c) Quality Management Systems(s) certification for manufacturer(s) **If yes, attach evidence** Include: • manufacturer's name • relevant section(s) of standard where certification is not for full standard	ISO 9001	ISO 13485	Other
(d) Other relevant standards for the proposed products List any other standards that are relevant to the proposed products including but not limited to: **AS/NZ standards (e.g. AS/NZS3551, AS/NZS 4187, AS/NZS 4815**) • ISO standards • IEC standards Describe the extent of compliance with the listed standard and the product range the standard applies to. **Attach** evidence of compliance where available.	Standard	Compliance	Evidence
(e) Right to supply to New Zealand DHB hospitals Include: • a statement confirming that you have all the necessary rights and permits to supply the products and associated services to New Zealand DHB hospitals.			

6. Information about our compliance with regulations and standards	
• information about process and expected timeframe for obtaining the necessary rights and permits to supply any products and associated services to New Zealand DHB hospitals that you don't currently hold the rights to. Note: Permits and rights include, but are not limited to, distribution rights and New Zealand legislative requirements for specific types of products.	

7. Information about our proposed distribution and supply arrangements and ability to ensure continuity of supply to DHB hospitals		
Supply Chain & Stock Management		
(a) Company role in supply chain	Manufacturer [Yes/No]	Distributor [Yes/No]
(b) Distribution agreement(s) overview Include exclusivity, expiry date, termination notice period.	***NB.*** *Not required if you are the manufacturer and distributor of all proposed products.*	
(c) Stock holding within New Zealand Include any relevant information about how you would set and manage your stock levels in New Zealand for the proposed products.		
(d) Warehouse location(s) within New Zealand Include if warehouse owned by your company or owned by a logistics provider.		
(e) Consignment stock Outline if your company is offering any consignment stock and how it intends to manage this. Include information on risk and liability requirements, responsibility for management, assignment and invoicing requirements, auditing arrangements etc.		
(f) Outline how your company manages its Surgical Implants, Medical and Surgical Instruments and Power Tools, and Associated Products inventory and forecasting		
(g) Please outline how your company would manage a recall of its Surgical Implants, Medical and Surgical Instruments and Power Tools, and Associated Products		

7. Information about our proposed distribution and supply arrangements and ability to ensure continuity of supply to DHB hospitals	
(h) Manufacture to delivery Explain your supply chain from start of manufacture to delivery to DHB hospitals or DHB hospital nominated locations (e.g. service satellite clinic), include: • steps • who is involved (e.g. international freight carrier, warehousing, logistic providers, New Zealand freight providers) • timeframes for each step Please note any differences in your supply chain for different product ranges	
Potential supply issues and response to unexpected increase in demand	
(i) Key supply continuity risks and mitigations For each product range include the key risks to continuity of supply to DHB hospitals and the steps that will be taken to mitigate these risks.	
(j) Response to unexpected increase in demand Include: • any access to alternative international supply and timeframes • communication with DHB hospitals • communication with Pharmac • how stock is prioritised • other relevant information	
(k) Please provide any further details you would like Pharmac to know about your company's experience and capabilities in relation to continuity of supply of the proposed medical devices Please provide a succinct summary [preferably <500 words]	
8. Pricing and financial analysis of our proposal	
(a) Financial impact Include overview of how proposed pricing compares to that currently offered to DHB hospitals. **Attach** detail in Excel format. (Preferred format is included in Attachment 2; alternative formats may be submitted provided the detail set out in Schedule 3 is included).	***NB.*** *Only required if the proposed products are currently supplied to DHB hospitals*

7. Information about our proposed distribution and supply arrangements and ability to ensure continuity of supply to DHB hospitals	
(b) Pricing information Include any information related to pricing provided in Attachment 1, including any related conditions or proposed terms.	
(c) Alternative pricing models Include: • details of any alternative pricing models and associated qualification requirements • details of any DHB hospitals currently accessing the alternative pricing models Any alternative pricing models must have financial analysis **attached** in Excel format. Please note that complex additional pricing models that would pose a significant administrative burden to Pharmac or DHB hospitals are unlikely to be progressed.	
(d) Additional charges Include any charges not included in pricing provided in Attachment 1 and associated conditions.	
(e) Additional options Include any additional proposals or suggestions not expressly identified in this RFP that you would like Pharmac to consider as part of this proposal.	
(f) Please outline how your proposal supports equal opportunity for value across DHB hospitals?	

9. Information about equipment

(a) Equipment details

Provide information relating to proposed terms for supplying equipment to DHBs in addition to details provided in Attachment 1, including the range of procurement options being proposed (e.g. outright purchase, rent, loan, lease, rent-to-buy).

In a separate **attachment**, include, for each procurement option:

- the applicable equipment product codes
- delivery, receipt, installation, and acceptance procedures
- details of risk and liability during key exchange activity points
- details of any consignment/tracking arrangements
- details of any termination terms and conditions
- any differences between current arrangements with DHB hospitals and proposed arrangements and how you would support DHB hospitals moving to your new proposed national supply arrangement
- product support, training, and education not already detailed in section 5
- charge for any non-purchase options, if any (e.g. monthly rental charge, free of charge loan)
- equipment management responsibilities, risk, and ownership requirements for any non-purchase options
- change to purchase/non-purchase options currently in place (e.g. currently provide rental option but have not proposed to provide this option)

Please name the attachment and note the name of the attachment in the adjacent box as well as in the checklist in Attachment 5.

Where you have non-purchase equipment options currently in place with any DHB hospital please include the financial analysis, by DHB hospital, of any proposed non-purchase options in **Attachment 2**.

Proposed pricing for outright purchase options is to be outlined in **Attachment 1.**

NB. *Only required if the proposed products include equipment*

9. Information about equipment	
(b) Warranties, servicing, and calibration Provide information relating to warranty, servicing, and calibration terms for proposed equipment, in addition to details provide in Attachment 1. Include: • details of replacement and repairs policy • overview of warranty coverage, including warranty terms for repairs and spare parts • cost for all maintenance and calibration services within the warranty period and following expiry of warranty period (e.g. hourly labour rate for repairs outside of warranty, maintenance servicing costs per device per year, any freight charges or travel and accommodation costs) • training of DHB staff (e.g. clinical engineers), and any associated costs • any differences between current arrangements with DHB hospitals and proposed arrangements If the detail varies according to the type of equipment or procurement option, please note this here and include the relevant information with the attachment in the Equipment details section above.	
(c) Operating and maintenance manuals Include an overview of the content of operating manuals, instructions, and guides for use by clinical and technical personnel. **Do not** include copies of full equipment operating or maintenance manuals.	

10. Other relevant information	
(a) Continuity of care Include information about willingness and ability to provide a congruent range of products to healthcare providers funded by non-DHB entities, to enable continuity of patient care. e.g. ACC	
(b) Working with key stakeholders Include information about how you envisage working with Pharmac and other key stakeholders.	
(c) Other information Please state any other information you would like Pharmac to consider when evaluating this proposal. • How does your Organisation support social, economic, and environmental outcomes beyond supply of Pharmaceuticals (see New Zealand Government Procurement Broader Outcomes). Please also outline how your organisation: • supports New Zealand businesses, including Māori, Pasifika and regional businesses, as well as social enterprises if relevant (such as noting the Māori Pasifika and regional businesses within your supply chain) • supports improving conditions for New Zealand workers and support workforce diversity. You may also add any further comment on how your company supports economic and social outcomes for Māori	

10. Other relevant information	
(d) Supplier Code of Conduct Any relevant information that demonstrates how you would meet the government expectations outlined in the Supplier Code of Conduct.	
(e) Factors for Consideration Any additional information PHARMAC should consider under its Factors for Consideration Framework:	

11. Environmental Sustainability				
Does your Organisation have an environmental/sustainability policy?	Yes		No	
Does your Organisation have a sustainability report?	Yes		No	
If yes to either of the two above questions, please attach or link:				
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 Invitation*			
Has your Organisation received any environmental/sustainability award(s)?	Yes		No	
If yes, provide details:				
Has your Organisation received any environmental fine/prosecution(s)?	Yes		No	
If yes, provide details:				
Has your Organisation received any environmental audit(s) or does it comply with a recognised standard?	Yes		No	
If yes, provide details:				