PHARMAC
Pharmaceutical Management Agency

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29 April 2016

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF ORTHOPAEDIC IMPLANTS AND ASSOCIATED PRODUCTS

PHARMAC invites proposals for the supply of orthopaedic implants and associated products to DHB hospitals in New Zealand.

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

- Schedule 1 sets out the background to the RFP and the range of products included and types of proposals sought;
- Schedule 2 describes the process that PHARMAC expects to follow in relation to the RFP;
- Schedule 3 specifies the general information you need to include in your proposal; and
- Schedule 4 and attachment 1, specifies the format and product information that you must include as part of your proposal.

All proposals must be submitted to PHARMAC via the Government Electronic Tenders Service (GETS) (www.gets.govt.nz) no later than **5.00 p.m.** on **10 JUNE 2016.**

If you have any questions about this RFP, please post these on GETS or alternatively contact Maree Hodgson (Device Category Manager) by email maree.hodgson@pharmac.govt.nz at PHARMAC.

We look forward to receiving your proposal.

Yours sincerely

Sarah Fitt

Sarah Fitt
Director of Operations

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

1. **Medical Devices**

PHARMAC is interested in considering any proposal from suppliers of **orthopaedic implants and associated products** used in the repair or replacement of bones that have been damaged through injury or disease.

2. **Background to RFP**

The background to this RFP is as follows:

(a) *PHARMAC's involvement with orthopaedic implants*

As a result of initial consultations and sector discussions, and taking into account the 2013 status of national contracts in orthopaedic implants under Health Benefits Limited, PHARMAC focused initial work in orthopaedic implants in the trauma, spine and craniomaxillofacial (CMF) sub-specialties to expand the suite of national contracts in those areas. There were also recently negotiated contracts in place for hip and knee implants with two rights of renewal through to April 2017 that offered savings to DHBs.

As PHARMAC has progressed work with the trauma, spine and CMF sub-categories several issues have become clear:

- there is a degree of overlap of both products and suppliers in many of the orthopaedic implant sub-category areas;
- CMF implant procedures are primarily undertaken by maxillofacial and plastic surgeons and although they are used in bone replacement/augmentation and generally have the same supplier network, these also require clinical input from areas other than orthopaedic specialists;
- multiple agency involvement within the various sub-categories has led to a degree of sector confusion;
- usage data is reported inconsistently;
- scope of the orthopaedic implant category needs to consider the inclusion of associated instruments and consumables essential for the use of the implants; and
- with current hip and knee contracts due to expire in April 2017 and many other areas without contracts it is timely to look at the entire category.

(b) *Reasons for running the RFP*

PHARMAC has been asked to take a greater role in medical devices. Orthopaedic implants make up a large proportion of the medical device market and the need for intervention with orthopaedic implants, with our ageing population and other health and activity factors, is growing.

In order to resolve some of the issues outlined in 2 (a) above, PHARMAC proposes to enter into national contracts for all orthopaedic implants currently used in New Zealand. This should provide clarity for suppliers, health professionals and other stakeholders involved with the supply, distribution and purchase of orthopaedic implants as well as simplify the contractual arrangements for all parties.

As a result of this RFP process, we expect to enter into national contracts for all orthopaedic implants and associated products by the end of April 2017. This timeframe should allow sufficient time for the expiry of any non-PHARMAC contracts (eg hip and

knee implants) and allow smooth transition to any new national contracts with PHARMAC.

(c) *Impact of RFP on current national contracts*

As part of its work, to date, PHARMAC has entered into one agreement relating to spine, trauma and CMF products with Stryker. Current listing arrangements with PHARMAC for orthopaedic implants or associated products would not be affected by this RFP unless superseded by a further arrangement with the supplier in question. This RFP does not offer any exclusivity for the supply of orthopaedic implants or associated products in DHB hospitals.

Suppliers who currently have their orthopaedic implants listed in Part III of Section H of the Pharmaceutical Schedule may choose to submit additional proposals via the RFP to amend their current agreement, to extend their product ranges or submit an entirely new proposal for consideration.

3. Expected outcome of the RFP

(a) As a result of this RFP, we expect to:

(i) list a range of orthopaedic implants and associated products available for use in New Zealand in Part III of Section H of the Pharmaceutical Schedule;

(ii) secure future supply of orthopaedic implants and associated products for DHB hospitals at competitive prices;

(iii) ensure a clinically appropriate range of orthopaedic implants and associated products is available to DHBs and patients;

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

(v) engage and establish relationships with new and current suppliers of orthopaedic implants and associated products; and

(vi) move orthopaedic commercial arrangements into a national framework administered by PHARMAC to create better health outcomes for patients within the funding available in DHB hospitals.

4. Types of proposals sought

(a) PHARMAC is willing to consider the following types of proposals for listing in Part III of Section H of the Pharmaceutical Schedule for use in DHB hospitals:

(i) proposals that involve orthopaedic implants as described in clause 1 above; and/or

(ii) proposals that involve associated products, which includes:

(A) external fixation for bone repairs;
(B) bone graft materials;
(C) cement for use with orthopaedic implantation;

(D) cement mixing bowls and accessories for use of cement;
(E) provision of loan sets and consignment stock associated with submitted product ranges;
(F) haemostatic agents; and
(G) drill bits, reamers, saw blades, burrs and any power tool consumables used in association with the implants.

(b) PHARMAC is also willing to consider:

(i) proposals that include volume based discount arrangements (e.g. volume based tiered pricing) provided tiers, if any, are:

(A) limited to a maximum of three, including the published price in Part III of Section H of the Pharmaceutical Schedule;

(B) structured as follows:
1) Price for no level of commitment;
2) Price for 40% commitment;
3) Price for 80% commitment;

(C) based on commitment levels being applied against individual sub-specialties as follows:
1) Hips;
2) Knees;
3) Trauma;
4) Spine;
5) CMF;
6) Hands and wrists;
7) Foot and ankle;
8) Shoulders and elbows; and

(D) based on commitment levels to be determined by volume of usage at a DHB hospital level.

(c) Clinical education or support services.

(d) PHARMAC is **not** willing to consider proposals for any other products, including but not limited to the following ranges:

(A) Soft tissue implants;
(B) Soft tissue fixation devices; and
(C) Antibiotic powders for use with orthopaedic cement.

(e) PHARMAC is **not** willing to consider proposals for the supply of power tools and navigational systems outside access to their use being available as part of a commitment level to consumables as per 4 (b).

(f) Proposals must meet all the mandatory requirements as set out in the responses column of product information requirements in Schedule 3.

(g) Proposals should be submitted on the basis that there may be incremental changes or upgrades for the proposed orthopaedic implants and associated products during the life of the contract, and that if agreed between PHARMAC and

the successful supplier, the changed or upgraded product would be made available to DHBs within a reasonable timeframe.

(h) Under the New Zealand Public Health and Disability Act 2000, as well as under DHBs' Operational Policy Framework, DHBs are required to comply with the Pharmaceutical Schedule as determined by PHARMAC.

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 to PHARMAC via GETS no later than 5pm (New Zealand time) on **10 June 2016.** Late proposals will only be considered at PHARMAC's discretion, taking into account the need for fairness to other suppliers and integrity of the RFP process.

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

(d) If you have any enquiries about this RFP you should submit them on GETS or alternatively contact Maree Hodgson (maree.hodgson@pharmac.govt.nz).

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 in light of 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 from 1 July 2016 will 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. Please note that the FFC reflect a change in the way in which PHARMAC makes decisions, replacing PHARMAC's existing Decision Criteria from 1 July. Please be aware of the FFC. More information on the FFC can be found at www.pharmac.health.nz/factors-for-consideration.

(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 for Consideration which relate directly to these aspects will be given the greatest weight by the Evaluation Committee but all FFC are important.

(d) The information to be taken into account in applying the decision mechanism by the Evaluation Committee will be at its discretion, however it will include:

(i) information provided by you in accordance with Schedules 3 and 4 of this RFP;

(ii) product information requirements as set out in Schedule 3 of this RFP;

(iii) ability to provide the appropriate level of clinical support needed for these products, including but not limited to:

(A) training and education in the use and handling of products;
(B) in-theatre support for clinical teams;
(C) supply chain to support sustainable provision of the goods;

(iv) provision of DHB usage data where applicable and reference sites;

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

(vi) 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).

(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 or 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):

(i) product samples, in which case you must supply the requested sample within 20 business days of PHARMAC's request; and

(ii) 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 suppliers 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 for supply of medical devices, which are available from GETS, will apply.

(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, as a result 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 being 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 the factors for consideration in PHARMAC's then current OPPs.

(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(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 agreement 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 submitting your proposal(s), until such time as a provisional agreement is accepted by PHARMAC's Board or the Board's delegate.

(c) You must not at any time initiate any communication with PHARMAC, the Ministry of Health (including its operating 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 provide it succinctly and clearly.

(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 it does 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 orthopaedic implants 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 contract as a result of this RFP. Nothing in this RFP prevents PHARMAC from entering into agreements with other suppliers in respect of orthopaedic implants 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 agreement entered into with a supplier; or

(iii) in publicly notifying any approval by the PHARMAC Board of that agreement; or

(iv) otherwise pursuant to PHARMAC's public law or any other legal obligations.

(l) 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

Following receipt of proposals, PHARMAC anticipates:

(a) the Evaluation Committee evaluating proposals from13 June – July 2016;

(b) negotiating with submitter(s) of one or more preferred proposals in August – September 2016;

(c) consulting on provisional agreement(s) from October 2016;

(d) PHARMAC's Board, or the Board's delegate, considering provisional agreements for approval in or after November 2016; and

(e) orthopaedic implants and associated products being listed as agreements are approved, and that all agreements would be finalised for 1 April 2017 listing,

provided that the above timeframes are only approximate and may be extended, without notice being required from PHARMAC, if any stages of the RFP process take longer than anticipated.

8. Governing Law

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

Schedule 3: Information to be included in your proposal

1. The following information should be included in or form part of your proposal:

(a) details of all sizes of your orthopaedic implants and associated products currently available as set out in Attachment 1;

(b) information on current usage and expenditure of your orthopaedic implants and associated products as specified in Attachment 1;

(c) information on usage and expenditure by DHB Hospital;

(d) information about management and technical skills of your staff;

(e) describe your current supply arrangements, supply volumes and relevant supply terms in other major markets including recent tenders awarded (in New Zealand and/or other countries);

(f) describe proposed distribution and supply arrangements for your orthopaedic implants and associated products (this includes any information regarding freight or delivery costs to DHBs);

(g) explain your current or proposed complaints management processes, including ability to recall stock, refund or credit for damaged or faulty goods;

(h) evidence of:

(i) how you envisage working with PHARMAC and other key stakeholders;

(ii) availability of a comprehensive training, ongoing education and product and customer support package.

2. Product Information requirements

(a) Please confirm your ability to meet the following requirements and provide documented evidence where required:

Requirement	Evidence requirement is met	Response
All products must be WAND registered	WAND registration number must be provided as per the format in Attachment 1.	Mandatory
International compliance	Evidence of international compliance certificates must be provided.	Mandatory
DHB current usage data	Provide usage and current pricing information by DHB for the period 1 April 2015 – 31 March 2016 for all line items submitted.	Mandatory
Current contract status	Provide information on active DHB hospital contracts with expiry date.	Mandatory
Impact analysis of your proposal	Provide financial impact analysis of your proposal for DHBs based on	Mandatory where DHBs

Requirement	Evidence requirement is met	Response
	current usage patterns.	are currently using your products

Supply chain arrangements you would have in place to support NZ market requirements	Information relating to continuity of supply of products in New Zealand. This should include information on:
	• distribution arrangements and stockholding in New Zealand;
	• minimum order size;
	• delivery frequency and lead times for:
	  ○ a stable demand situation;
	  ○ in the event of supply disruptions; and
	  ○ when there is an unexpected surge in demand for your product.
	Please include any specific measures you will take to secure stock for New Zealand from international production.
		Mandatory

Consignment stock arrangements you would have in place to support NZ market requirements	1. Describe your current consignment stock management system including but not limited to; • risk and liability arrangements; • responsibility for stock management; and • auditing arrangements. 2. Provide information relating to current arrangements with DHBs in regard to consignment products and associated instruments, and cost of consignment held at each DHB, as per schedule 4, table 1 if you are currently providing this service. **OR where not currently providing this service** Provide information relating to your ability to support consignment products and associated instruments if a DHB hospital required that service.	Mandatory
Change management process	Detailed plan to support DHBs during any product swap out. Provide details of the process you would follow to support a DHB if they were interested in changing to your product range, including but not limited to: • establishing	Mandatory

Requirement	Evidence requirement is met	Response
	requirements; • timelines for change; • forecasting to meet increased demands; and • training & education provided.	
Gs1 status	Provide GTIN codes for items.	Desirable
UNSPSC	Provide UNSPSC codes for items.	Desirable
Does the manufacturer operate a waste reduction policy? Is there a recycling process for their products in New Zealand?	Please give details.	Desirable

NB Mandatory response requirements: Where provision of a response to a requirement is indicated as mandatory in the above table a response to that requirement must be submitted, otherwise the proposal will not be able to be considered.

Schedule 4: Proposal form

An electronic version of this form is available on PHARMAC's website at www.pharmac.govt.nz and on GETS (www.gets.govt.nz). You should expand the boxes as necessary.

[*Supplier to insert date*]

Director of Operations
PHARMAC
C/- Maree Hodgson
Device Category Manager

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

Dear Sir/Madam

Proposal for the supply of orthopaedic implants and associated products

In response to your request for proposals (**RFP**) dated 29 April 2016 we put forward the following proposal in respect of orthopaedic implants and associated products.

You must also include information as outlined in Schedule 3 and Attachment 1 (Excel document) as part of your proposal.

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

(a) Our contact details:

Full legal trading name in NZ	
Key Contact person	
Address	
Phone	
Facsimile	
Email address	

(b) Key features of our proposal and associated services available:

(c) Information relating to pricing ($NZ, GST exclusive), including any related conditions or proposed terms affecting cost for DHBs (e.g. reference price protection, risk sharing mechanisms, etc.):

(d) Evidence of market approval and any other required consents:

WAND registration details supplied against line items in Attachment 1	[yes/no]
TGA/FDA/CE details supplied against line items in Attachment 1	[yes/no]

(e) Information about our ability to ensure the continuity of supply of the medical devices:

(f) Information about our previous supply performance and relevant expertise including our overseas market (nb: site references show which products are supplied to these sites, and referees are available to contact):

(g) Proposals/suggestions (e.g. pricing, risk sharing arrangements, etc) regarding the medical device not expressly identified in this RFP that we would like PHARMAC to consider as part of our proposal:

(h) Reasons why PHARMAC should accept our proposal:

(i) Additional information that PHARMAC should consider when evaluating our proposal:

(j) Consignment stock information for current service provision, if applicable:

Table 1

DHB	DHB hospital/locations where stock is held	Description of each consignment set held	Number of each set held	Current value of each set held	New value of each set held based on proposal	Annual spend on replenishment of each consignment set per DHB 1 April 2015 – 31 March 2016	Storage provisions provided with sets (trolleys, shelving etc)	Weight of individual trays in Kilograms (Kg)	Stocktake process and timings (staff involved)	Requirements review process and staff positions involved – DHB signing authority	Date requirements were last reviewed
[DHB name in full]											