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Pharmaceutical Management Agency

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Dear Supplier

REQUEST FOR PROPOSALS – supply of medical thermometer products

PHARMAC invites proposals for the supply of Medical Thermometer Products to DHB hospitals in New Zealand ("DHBs").

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

- Schedule 1 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 specifies the information a Supplier needs to include with its proposals; and
- Schedule 4 specifies the product details, specifications and pricing a Supplier needs to include with its proposals.

If you wish to submit a proposal, you must submit it to PHARMAC via the Government Electronic Tenders Services (GETS) no later than **5.00 p.m.** on **Wednesday, 23 March 2016**

If you have any questions about this RFP, please contact Ryan Graves (Device Category Manager) by email ryan.graves@pharmac.govt.nz at PHARMAC.

We look forward to receiving your proposal.

Yours sincerely

Sarah Fitt

Sarah Fitt
Director of Operations

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 Medical Thermometers and associated products used to measure patient body temperature as described in Schedule 4.

2. Background to RFP

In 2010, Cabinet decided that PHARMAC would assume responsibility for managing the assessment, standardisation, prioritisation and procurement of medical devices for the District Health Boards. In August 2012, Cabinet approved an accelerated plan for transitioning this work to PHARMAC. The goal of this decision is to help achieve national consistency in managing medical devices, improve transparency of decision-making and improve the cost-effectiveness of public spending to generate savings for re-investment into health.

PHARMAC sought feedback from stakeholders in May 2013 on a number of identified medical device categories to commence initial procurement work to generate benefits for the District Health Boards. The medical thermometer products category is one of the categories identified.

PHARMAC recognises that the use of medical devices touches a wide group of health professionals; therefore, during the initial procurement phase District Health Board hospitals will be permitted to purchase Medical Thermometer Products outside of the Pharmaceutical Schedule, however, they will be encouraged to utilise the Schedule as there will be benefits in choosing medical devices from nationally negotiated agreements.

PHARMAC intends to establish listing agreements with suppliers to gain the best price for Medical Thermometer Products that are required for use in the District Health Board hospitals. It is expected that medical devices subject to a listing agreement will be listed in the Schedule. It is also anticipated that multiple suppliers of equivalent products will be listed, where appropriate.

3. Types of Proposal Sought

PHARMAC is willing to consider proposals for the supply of Medical Thermometer Products that may lead to a National Contract agreement and listing on the Pharmaceutical Schedule.

Schedule 3 specifies the information required from the Supplier that needs to be included with the proposal.

Schedule 4 provides specific details regarding the Medical Thermometer Products, and information regarding the requirement to complete a spreadsheet of details, product specifications and pricing relating to the Medical Thermometer Products.

For the avoidance of doubt this RFP is the only process PHARMAC expects to run prior to negotiation with Suppliers, in order to determine whether the Medical Thermometer Products are contracted and listed in the Pharmaceutical Schedule.

In the event a listing agreement is entered into with a Supplier and the Medical Thermometer Products are listed in the Pharmaceutical Schedule:

(a) the listing shall be non-exclusive and will include pricing and details of the Medical Thermometer Products;

(b) it will be discretionary for District Health Board hospitals to purchase the Medical Thermometer Products from the nominated Submitter in particular, however where they do, DHBs will be expected to purchase under the national agreement;

(c) PHARMAC will consider options with the Submitter including volume based discount arrangements, rebates and arrangements that guarantee listing in the Pharmaceutical Schedule for a set period of time;

(d) PHARMAC may offer listing protection in the Pharmaceutical Schedule for a period of up to 3 years, meaning that PHARMAC will not enter any other arrangement with effect in that period that would result in the removal of the protected product from the Schedule; and

(e) any resultant listing agreement will be between the Submitter and PHARMAC. DHBs will be able to purchase under the PHARMAC listing agreement, and will not be required to individually approve the agreement for it to come into effect.

Schedule 2: RFP process

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

1. **Submission**

   (a) Proposals must be submitted to PHARMAC via the Government Electronic Tenders Services (GETS).

   (b) Proposals must be submitted no later than 5.00 p.m. (New Zealand time) on **Wednesday, 23 March 2016**. Late proposals will only be considered at PHARMAC's discretion.

   (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 contact Ryan Graves, (ryan.graves@pharmac.govt.nz) or submit questions through GETS (www.gets.govt.nz).

2. **Evaluation**

   (a) Following the deadline for submission, any proposals will be assessed by PHARMAC and PHARMAC will determine, at its sole discretion but in light of probity principles, whether to seek a National Contract in relation to the Medical Thermometer Products.

   (b) PHARMAC will evaluate proposals in light of its 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 it will be guided by the decision mechanism set out in PHARMAC's then current Operating Policies and Procedures (OPPs), as published on PHARMAC's website (www.pharmac.govt.nz), to the extent applicable. The information to be taken into account in applying the decision mechanism will include, in particular:

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

      (ii) information provided by you in accordance with Schedule 3 of this document.

   (c) 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.

   (d) 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):

(i) product samples, in which case you must supply the requested sample within 10 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) Following evaluation PHARMAC may negotiate with the submitter of proposals.

(b) Negotiations will proceed on the basis that PHARMAC's standard terms and conditions for supply of medical devices, which are available on request from PHARMAC, 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 provisional agreement(s) 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 the decision mechanism in PHARMAC's then current OPPs.

(d) The RFP process will be complete once PHARMAC has notified suppliers of either:

(i) the Board's or its delegate's decisions regarding the Medical Thermometer Products it will include on the Pharmaceutical Schedule; or

(ii) the termination of the RFP process.

6. **Miscellaneous**

(a) PHARMAC reserves the right:

(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 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;

(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; and

(vii) 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 their 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's directors or officers, the Ministry of Health (including its operating unit Medsafe), the Minister of Health (or any Associate Ministers) or District Health Boards 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) Proposals are submitted in reliance on your own knowledge, skill, and independent advice, and not in reliance on any representations made by PHARMAC.

(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 contained 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 Medical Thermometer Products by PHARMAC's apparent acceptance and instead a separate agreement needs to be negotiated.

(h) 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.

(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 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.

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) evaluating proposals in March - April 2016;

(ii) negotiating with submitter(s) of preferred proposal(s) in April - May 2016;

(iii) consulting on provisional agreement(s) in May - June 2016;

(iv) PHARMAC's Board, or the Board's delegate, considering provisional agreement(s) in or after June - July 2016,

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

(b) Under this indicative timetable, the earliest that changes to the Pharmaceutical Schedule could be implemented is 1 June 2016.

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

(A spreadsheet containing information on the Submitter's Medical Thermometer Products, specifications and pricing also requires completion and submitting. See separately attached GETS document for this spreadsheet).

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

(a) full legal name of Supplier;

(b) contact person;

(c) contact details (including but not limited to physical address, telephone and email addresses);

(d) confirmation that the Medical Thermometer Products meet the relevant standards and regulatory requirements for its intended use, and provide evidence of registration in one of the following foreign jurisdictions (Europe, the United States, Canada or Australia) with pre-market approval processes and/or evidence of a third party conformity assessment demonstrating the product complies with the International Medical Device Regulators Forum (IMDRF) Essential Principles for Safety and Performance. All products would require WAND notification before being considered.

(e) details of the Medical Thermometer Products and any associated services available that are applicable to the key features of your proposal;

(f) services provided for maintenance and calibration; please detail service agreements including, but not limited to:

- frequency of calibration and maintenance
- performed by DHB clinical engineers on-site, or off-site service centre
- replacement / repair policies
- cost of respective services, including within the warranty period and following the expiry of the warranty period
- specialist equipment or manuals required
- training of DHB clinical engineers

(g) indicative pricing (GST exclusive), including any related conditions or proposed terms affecting cost for PHARMAC;

(h) alternative pricing models; PHARMAC is aware that a range of price models have been offered to DHBs in the past to cover a combination of thermometer equipment, consumables and / or servicing. Please include details of your current pricing model(s), and which DHBs have accessed the pricing model(s) in the period 1 January 2015 to 31 December 2015.

(i) confirmation that any parties who will be supplying the Medical Thermometer Products have a business continuity plan(s) with a brief summary of the plan(s);

(j) information relating to continuity of supply of Medical Thermometer Products in New Zealand. This should include information on 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;

(k) 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);

(l) describe proposed distribution and supply arrangements for the Products (this includes any information regarding freight or delivery costs to DHBs);

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

(n) demonstration of experience and knowledge within the healthcare sector, and specifically with District Health Board hospitals;

(o) Evidence of:

- how the Supplier envisages working with PHARMAC and other key stakeholders;
- availability of training, education and product support;
- the Supplier's organisational infrastructure, including legal status;
- an indication of pricing as appropriate for provision of the Medical Thermometer Products;
- a copy of registration in one of the following foreign jurisdictions: Europe, the United States, Canada, Australia. For example, if product is registered in Australia, a copy of the Australian Register of Therapeutic Goods (ARTG) certificate; and
- a copy of the WAND notification registration;

(p) proposals/suggestions about devices and any associated services not expressly identified in the RFP that PHARMAC may wish to consider;

(q) the Submitter's own rationale for why it considers PHARMAC should accept your proposal;

(r) any particular information that the Submitter considers PHARMAC should take into account when assessing your proposal; and

(s) a declaration of any conflicts of interest that the Supplier or an associated person or organisation may have that could affect or compromise the Supplier or PHARMAC in relation to this RFP process or performance under any listing agreement if successful.

Schedule 4: Medical Thermometer Product Details, Specifications and Pricing

PHARMAC invites suppliers of Medical Thermometer Products to submit its range of products as applicable to the Medical Thermometer Products categories set out below. Medical Thermometer Products listed on the Pharmaceutical Schedule would be accessible by the District Health Board hospitals.

In Scope for the Medical Thermometer Products Category:

The **principle purpose of the product will be to measure patient body temperature** or is used to take periodic or continuous body temperature measurements.

A full list of product details required, specifications and pricing, and in-scope descriptions, are listed in the attached spreadsheet under the following subcategories:

- Electronic medical thermometer
    - Oral
    - Axilla
    - Rectal
- Infrared thermometers
    - Ear / Tympanic
    - Temporal artery
    - Skin
- Patient temperature strips or dots
    - Oral
    - Axilla
    - Skin
- Thermometer probes
    - Oesophageal
    - Rectal
    - Nasopharyngeal
- Fibre-optic medical thermometer
    - Patient monitoring temperature probes
- Patient temperature continuous or trend monitors
    - Temperature monitoring system
    - Digestive tract capsule thermometer
- Medical thermometer probe or tip covers
    - Oral
    - Axilla
    - Rectal
    - Ear / Tympanic
    - Skin
- Medical thermometer accessories
    - Carrying cases or covers
    - Medical thermometer racks / bases / stands
- Miscellaneous equipment
    - Calibration equipment
    - Maintenance equipment
    - Repair equipment

- Spare parts
- Service manuals
- Specialised batteries

Out of Scope Medical Thermometer Products Categories:

- Multifunctional devices with built-in thermometry where the primary function is not body temperature monitoring
- Multifunctional probes which have primary functions other than temperature monitoring such as a pulmonary artery catheter (e.g. Swan-Ganz catheter).
- Temperature Management Systems which **control and monitor** a patient's temperature.
- Mercury-containing thermometers (being phased out as New Zealand is a signatory on the Minamata Convention on Mercury, 2013).
- Environment monitoring thermometers (e.g. thermometers measuring incubator, fridge, or room temperatures).

We are not specifically seeking proposals for products in these areas as part of this RFP process, but may consider them at a later date.

Schedule of Medical Thermometer Products Categories Spreadsheet

A Schedule of Medical Thermometer Products Categories spreadsheet is separately attached on GETS and **must be completed and submitted** as part of the Submitter's response.

When completing the spreadsheet, please ensure the instructions below are followed:

- Please do not alter the spreadsheet format.
- In the submission please list all models, versions or sizes in the range of products on a separate line.
- All prices to be submitted in $NZ
- Please submit the spreadsheet in an excel format document (not pdf).