PHARMAC
Pharmaceutical Management Agency

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03 November 2017

Dear Supplier

**REQUEST FOR PROPOSALS – SUPPLY OF NEEDLES AND SYRINGES (INCLUDING SOME SPECIALTY PRODUCTS)**

PHARMAC invites proposals for the supply of Needles and Syringes in New Zealand District Health Board (**DHB**) Hospitals.

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

- Schedule 1 specifies the medical devices for which PHARMAC is requesting proposals and sets out the background to the RFP and the types of proposals sought;
- Schedule 2 describes the process that PHARMAC expects to follow in relation to the RFP;
- Schedule 3 contains the RFP form in which you are to provide details of your proposal;
- Schedule 4 contains the RFP form in which you are to provide details of your acceptance of PHARMAC Standard Terms and Conditions for Medical Devices Part 1-7; and
- Schedule 5 contains the RFP form with the checklist of documents to be submitted with your proposal;

and the following attachments:

- Attachment 1: Product list in which you provide detailed information about all proposed Needle and Syringe products; and
- Attachment 2: PHARMAC Standard Terms and Conditions for Medical Devices (Parts 1-7).

If you wish to submit a proposal, you must submit it to PHARMAC via the Government Electronic Tenders Service (**GETS**) (www.gets.govt.nz) no later than **4.00 p.m**. on **14 December 2017**.

If you have any questions about this RFP, you should submit them to Jeremy Price via GETS. We encourage suppliers to register with GETS and subscribe to this RFP.

We look forward to receiving your proposal.

Yours sincerely

Sarah Fitt

Sarah Fitt
Director of Operations



A1071633

## 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 needles and syringes (as outlined in Schedule 1, clause 4 (a) below).

2. **Background to RFP**

(a) *PHARMAC's role in Medical Devices*

In 2010, Cabinet decided that PHARMAC would assume responsibility for managing the assessment, standardisation, prioritisation and procurement of medical devices for the DHBs. In August 2012, Cabinet approved an accelerated plan for transitioning this work to PHARMAC.

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.

(b) *Reasons for running the RFP*

PHARMAC is taking a phased approach to its activity in medical devices. Following consultation feedback received in September 2016, PHARMAC has decided to expand its medical devices scope to include 11 new categories, one of which is needles and syringes.

(c) *Impact of RFP*

PHARMAC intends to establish national listing agreements (**National Contracts**) with suppliers to secure supply of needles and syringes used in DHB hospitals. It is expected that needles and syringes subject to a listing agreement will be listed in Part III of Section H of the Pharmaceutical Schedule. Listing agreements would not be exclusive of other suppliers, and it is possible that multiple suppliers of equivalent needles and syringes will be listed, where appropriate.

3. **Expected outcome of the RFP**

(a) As a result of this RFP, PHARMAC expects to:

(i) list a range of needles and syringes available for use in DHB hospitals in Section H, Part III of the Pharmaceutical Schedule;

(ii) secure future supply of needles and syringes for DHB hospitals at competitive prices;

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

(iv) engage and establish relationships with new and current suppliers of needles and syringes; and

(v) move commercial arrangements for needles and syringes into a national framework administered by PHARMAC to create better health outcomes for patients within the funding available in DHB Hospitals.

(b) PHARMAC recognises that the use of medical devices touches a wide group of health professionals. Therefore, in the event an agreement is entered into with a supplier as an outcome of this RFP process and the needles and syringes are listed in Part III of Section H of the Pharmaceutical Schedule:

(i) the listing shall be non-exclusive and will include pricing and details of the needles and syringes;

(ii) it will be discretionary for DHB Hospitals to purchase the needles and syringes from the supplier, however where they do, DHB Hospitals will be expected to purchase these needles and syringes under the PHARMAC agreement;

(iii) it is anticipated that multiple suppliers of needles and syringes will be listed, where appropriate; and

(iv) any resultant listing agreement(s) will be between the supplier and PHARMAC. DHBs will be able to purchase under the PHARMAC listing agreement, effective from the listing date, and will not be required to individually approve the agreement for it to come into effect.

## 4. Scope of the Needles, and Syringes

**In-Scope**

(a) PHARMAC is willing to consider proposals which include one or more of the following needles and syringes or related products (**Needles and Syringes**) for listing in Part III of Section H of the Pharmaceutical Schedule for use by DHB Hospitals (in-scope products):

(i) allergy testing needles;

(ii) biopsy or diagnostic procedure needles and syringes not associated with Interventional Radiology procedures as outlined in the 22 September 2017 Interventional Radiology RFP;

(iii) conventional needles and syringes, including (but not limited to):

- hypodermic needles (including 'safety' needles);
- hypodermic syringes (including, luer-lock, luer-slip, catheter tip, eccentric tip syringes, colour coded and 'safety' syringes);
- hypodermic syringes with fixed needles;
- tuberculin syringes with or without fixed needles;
- glass syringes;
- needle caps or protection devices/accessories;

(iv) diabetes management needle and syringe products including:

- lancets,
- insulin needles; and
- insulin syringes;

*Please note currently there are a number of diabetes management needle and syringe products listed under PHARMAC listing agreements for use in DHB Hospitals (Part III Section H of the Pharmaceutical Schedule) AND in the community (Section B of the Pharmaceutical Schedule). However, for the purposes of this RFP PHARMAC intends to contract for supply of diabetes management needle and syringe products in DHB hospitals ONLY. The current listings in Part III of Section H will continue to be listed following this RFP unless superseded or amended by this process.*

(v) high pressure syringes;

(vi) syringes used for suction and irrigation purposes including bulb syringes and ear syringes;

(vii) mixing and withdrawal products, including (but not limited to) items such as:

- admixture (mixing) needles;
- blunt fill needles;
- filter needles and straws; and
- vented needles & air inlet needles;

(viii) anaesthesia speciality needles and syringes, including (but not limited to) items such as:

- epidural needles;
- loss of resistance syringes;
- spinal needles (Lumbar puncture needles);
- spinal aspiration needles;
- retrobulbar needles;
- peripheral nerve block needles; and
- ultrasound and nerve stimulation needles.

(ix) thoracentesis, paracentesis and pericardiocentesis needles and syringes not submitted via other PHARMAC procurement processes such as the Interventional Cardiology registration of interest (**ROI**) or Interventional Radiology RFP.

(b) Miscellaneous needle and syringe products not identified as 'in scope' as outlined in section (a) above or 'out of scope' as defined in section (c) below will be considered through this process at PHARMAC's discretion.

**Out of Scope**

(c) PHARMAC is not willing to consider proposals for any other products under this RFP.

Products defined as out of scope have either been subject to a previous PHARMAC procurement process or it is PHARMAC's intention to include these products in an alternative competitive process.

Out of scope products include but are not limited to the following products (out of scope products):

(i) dental products, including (but not limited to) items such as:

- dental syringes, needles or syringes with needles;
- medical cartridge syringes;
- medical air syringes;
- dental impression material syringes;
- dental impression material syringe accessories; and
- dental syringe accessory kits;

(ii) dialysis products, including (but not limited to) items such as:

- fistula needles;
- haemodialysis unit single needle controllers;
- haemodialysis unit single needle pump sets; and
- haemodialysis infusion or syringe pumps;

(iii) enteral feeding products, such as enteral/oral syringes;

(iv) gastroenterology equipment products, including (but not limited to) items such as:

- endoscopic aspiration or biopsy needles;
- endoscopic haemostatic balloons or needles or tubes or accessories;
- endoscopic insufflation needles; and
- endoscopic needles or punches, jejunostomy catheter and needle sets endoscopy equipment;

(v) infusion and transfusion products, including (but not limited to) items such as:

- bag and vial access devices;
- intraosseous needles;
- (intraosseous) vascular access drivers/ injection guns;
- vascular access devices such as IV cannula, arterial cannula, central and PICC lines;
- butterfly/ scalp vein needles/ winged infusion sets;
- Huber needles;
- intravenous or arterial tubing, needleless injection ports or stopcocks or manifolds;
- needleless injection manifold kits;
- needleless intravenous injection syringe sets or injection cannulae;
- needleless vial or bag withdrawal cannulas or adapters or decanters;
- ventricular cannulas or needles;
- vial access devices;
- intravenous syringe infusion pumps;
- syringe actuators for an injector; and
- needleless intravenous injection syringe sets or injection cannulae;

(vi) any items used in an Interventional Radiology setting as outlined in the 22 September 2017 Interventional Radiology RFP, these may include (but is not limited to) items such as:

- angiography introducer needles;
- biopsy needles, biopsy guns, and needle guides used in Interventional Radiology procedures;
- breast localisation needles;
- diagnostic procedure needles;
- medical radiological needle or syringe or vial dippers;
- minimally invasive breast biopsy needle guides;
- platinum titanium gold isotope needles;
- radiology procedural needles;
- brachytherapy catheters, syringes, inserters or applicators;
- cardiovascular angiographic injectors and syringes;
- medical radiological syringe or vial shield or holders or carriers; and
- fine needle aspiration (cytology needles);

(vii) laboratory equipment products, these may include (including but not limited to) items such as:

- blood collection sets which may include needles and/or syringes but also include products such as evacuated blood collection tubes;
- blood gas analysis syringe kits / blood gas syringes;
- pipetting syringes; and
- syringe adaptors or holders;

(viii) obstetrics and gynaecology products, including (but not limited to) items such as:

- amniocentesis needles w/wo introducers;
- amniocentesis trays and kits; and
- polocky needles- cervix;

(ix) ophthalmology products, including (but not limited to) items such as:

- needles or cystomes for ophthalmic surgery; and
- ophthalmic needle irrigating or aspirating tips;

(x) suture needles;

(xi) theatre equipment, including (but not limited to) items such as:

- needle counters;
- needle trays or holders; and
- surgical robotic needle drivers; and

(xii) waste removal products, including (but not limited to) items such as:

- needle removal devices; and
- sharps bins.

## 5. **Types of proposals sought**

(a) Suppliers wishing to submit proposals **MUST** submit proposals for the supply of Needle and Syringes to DHB Hospitals with pricing to be published on the Pharmaceutical Schedule (no volume/spend commitment).

(b) PHARMAC is willing to consider proposals which include alternative pricing options.

*Please note pricing model options which are complex and would pose significant administrative burden on DHB Hospitals are unlikely to be progressed. Price bundling across medical device categories and sub categories (as identified by defined tabs in the spreadsheet accompanying this RFP ie Attachment 1) will not be accepted.*

(c) Proposals **MUST** meet all the mandatory requirements as set out in the responses column of product information requirements in Schedule 5

(d) Proposals may be submitted on the basis that there may be incremental changes or upgrades for the proposed Needles and Syringes 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.

(e) Suppliers **MUST** complete Schedules 3, 4 and 5 and Attachment 1 and provide all requested supporting documents. Proposals that do not include the completed Schedules, Attachment 1 or requested supporting documents, or do not conform to all instructions provided in the RFP, may be excluded from consideration.

(f) PHARMAC is not willing to consider proposals for products outside the scope of this RFP.

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

## 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 supplier. Submitters may have joint commercial arrangements with other suppliers and these can be combined into a single proposal.

   (c) All Proposals must be submitted to PHARMAC via GETS no later than **4:00 p.m**. (New Zealand time) on **14 December 2017.** Late proposals will only be considered at PHARMAC's discretion, taking into account the need for fairness to other suppliers and maintaining the 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 (www.gets.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) (if any).

   (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 form part of PHARMAC's current Operating Policies and Procedures (**OPPs**), as published on PHARMAC's website (www.pharmac.govt.nz), to the extent applicable. 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 FFC which relate directly to these aspects will be given the greatest weight by the Evaluation Committee but all FFC are important.

   (d) The information considered during the evaluation process will be at the discretion of the Evaluation Committee. However, it will include:

      (i) information provided by you in accordance with Schedule 3, 4 and 5 of this RFP and Attachment 1.

(ii) evidence provided by you in accordance with the requirements set out in Schedule 3 of this RFP;

(iii) information on your ability to meet PHARMAC's Standard Terms and Conditions (as set out in Schedule 4 and Attachment 2);

(iv) information on your ability to provide the appropriate level of product support, including but not limited to:

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

(B) information for patients (where applicable); and

(C) supply chain to support sustainable provision of products;

(v) DHB usage data and, where applicable, reference sites;

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

(vii) any information received from reference sites and referees; and

(viii) any other information that the Evaluation Committee considers to be relevant, having regard to probity principles.

(e) Each proposal will be evaluated on the basis that the price offered, the expenditure entailed, and any other terms included in the proposal, are the best that the supplier is able to offer. If you do not put forward your best terms and/or do not provide all mandatory information in the requested format, 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) 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 for supply of Medical Devices, which are available as a download (see Attachment Two) on GETS, will apply.

(c) You **MUST** complete and submit Schedule 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) Given that PHARMAC expects your proposal to be the best you can offer, PHARMAC does not intend to initiate negotiations 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.

(e) PHARMAC may negotiate and enter into a provisional agreement(s) 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 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(s) 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(s) 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 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) PHARMAC may consult or seek clinical advice from PTAC or its relevant sub-committee at any stage of the RFP process. PHARMAC will notify you if the clinical advice results in any changes to the terms of the RFP.

(c) You must not initiate or engage in any communication with other suppliers in relation to the RFP, whether before or after you and/or they submit a proposal(s), until such time as a provisional agreement is accepted by PHARMAC's Board or the Board's delegate.

(d) 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 other Associate Ministers) , DHBs, or advisors to PHARMAC with a view to influencing the outcome of this RFP process.

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

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

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

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

(i) 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 Needles and Syringes by PHARMAC's apparent acceptance and instead a separate agreement needs to be negotiated.

(j) 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.

(k) 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 Needle or Syringe Products or restricts the terms that may be agreed with any other supplier.

(l) 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.

(m) 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 Evaluation Committee evaluating proposals in January - February 2018;

(ii) negotiating with submitter(s) of one or more preferred proposals from March/ April 2018;

(iii) consulting on a provisional agreement(s) from April/May 2018; and

(iv) PHARMAC's Board, or the Board's delegate, considering provisional agreement(s) for approval in or after May 2018.

(b) For the avoidance of doubt, the timeframes set out in (a) above are only approximate and may be extended, without notice being required from PHARMAC, if any stages of the RFP process take longer than anticipated.

(c) Under this indicative timetable, the earliest that changes to the Pharmaceutical Schedule could be implemented is 1 July 2018.

**Schedule 3: 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
C/- Jeremy Price, Chloë Dimock
PHARMAC

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

Dear Sir/Madam

**Proposal for the supply of Needles and Syringes**

In response to your request for proposals (**RFP**) dated **3 November 2017** we put forward the following proposal in respect of Needles and Syringes;

***[Please refer to Schedule 3-5 for information and evidence to be included in your proposal. You must also include information as outlined in Attachment 1 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 New Zealand | |
| Key contact person(s) | |
| Address | |
| Phone | |
| Mobile | |
| Facsimile | |
| Email address | |

(b) Key features of our proposal, associated services available and reasons why PHARMAC should accept our proposal:

(c) Information relating to pricing ($NZ, GST exclusive) as outlined in Attachment 1, including any related conditions or proposed terms:

- Any proposed Needle and Syringe Products that do not include a price will not be considered by PHARMAC (unless noted as provided at no cost to the DHB)

(d) Statement of understanding of the New Zealand legislative requirements for proposed Needle and Syringe products:

- All proposed Needle and Syringe Products **MUST** be WAND registered at the time of submission for this RFP. WAND registration number must be provided for all Needle and Syringe Products in Attachment 1. *Please do not provide WAND documents*

More information on Medical Device Legislation in New Zealand can be found on the Medsafe website here

(e) Evidence of international compliance (eg ARTG, CE Mark) and standards which our products comply with (for example ISO standards):

Please attach copies of international compliance certificates and include identification number in Attachment 1.

(f) Information about current contracts we have in place with DHB Hospitals, in addition to the information included in Attachment 1:

Please include the following in your response:

- Expiry dates
- Additional cost and volume data/information
- Other relevant information about current contracts in place with DHB Hospitals
- In scope Needle and Syringe Products currently provided to DHB Hospitals that are not included in proposal, and reason for this.
- For products that are not single use outline where applicable current service agreements, warranties etc.

(g) Financial analysis of our proposal:

Please include the following in your response:

- An overview of how pricing compares to that currently offered to DHB Hospitals
- Impact analysis (Attachment 1)

(h) Information about our proposed distribution and supply arrangements including our ability to ensure continuity of supply to DHB Hospitals:

Please include the following in your response:

- Whether you are a manufacturer or distributor of the proposed Needle and Syringe products
- Terms of any distribution agreements, if you are not the manufacturer, for example the duration and exclusivity of the distribution agreement
- Details of distribution and stock-holding in New Zealand
- Delivery frequency and lead in times, including under stable demand situations, in the event of supply disruptions, and when there is an unexpected surge in demand
- Specific measures to secure stock for New Zealand from international production, including information about agreements in place with other parties in supply chain and notice periods required for any changes
- Any freight and delivery costs to DHB Hospitals
- Minimum shelf life of products
- Other relevant supply chain arrangements

(i) Information about our other major markets and previous supply performance (applicable **ONLY** for products **NOT** currently supplied to DHB hospitals):

Please include the following in your response:

- Private New Zealand hospital market(s)
- International hospital markets (public or private)
- Recent tenders awarded
- please provide **THREE** clinical reference sites where proposed products are used in similar ways and settings to DHB hospitals, with sales volumes for 1 October 2016 to 30 September 2017.
- please provide a supply chain reference

*State 'Not Applicable' if all proposed products are already provided to DHB hospitals*

(j) Information about our organisation:

Please include the following in your response:

- Organisational structure
- Information on ability to manage liability in event of a major product recall or failure to supply
- Management, technical skills, experience and qualifications of staff in relation to the proposed Needle and Syringe products
- Customer support hours for troubleshooting and advice
- Other relevant information about your organisation

(k) Information about our financial resources:

Please include the following in your response:

- information about your ability to manage liability in event of a major product recall or failure to supply event as described in Part 6 of PHARMAC standard terms and conditions (Attachment 2) for the supply of medical devices

(l) Information about our Quality Management Systems including our current complaints management process and our ability to recall stock, refund or credit for damaged or faulty goods:

Please include the following in your response:

- Information about conformance to ISO 9000 Quality management or ISO 1345:2016 Medical devices quality management systems
- Attach evidence where available

(m) Our understanding of DHB educational requirements and our experience in providing training and product support for the devices submitted.

Please include the following in your response:

- information on the type of training and education you would provide for DHBs for your Needle and Syringe products
- information on the instructions and guides for your Needle and Syringe products (as applicable) proposed for clinical personnel
- information on your educational team including their qualifications and the number of personnel
- Information about our instructions and/or educational resources for patients (where applicable)

*Please do not include copies of full manuals or advertising pamphlets*

(n) Information about our ability to support DHB transition to our products. Please include the following in your response:

- Overview of transition support with detailed transition plan specific to your Needle and Syringe products attached

(o) Information about our current (and/or proposed) consignment stock management system: (if applicable):

Please include the following in your response:

- Risk and liability arrangements
- Responsibility for stock management
- Auditing arrangements
- Other relevant consignment stock management information

*State 'Not Applicable' if you do not offer consignment for the submitted products*

(p) Information about how you envisage working with PHARMAC and other key stakeholders:

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

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

Please consider any relevant information under PHARMAC's Factors for Consideration decision making framework

**Schedule 4: Acceptance of PHARMAC's Standard Terms and Conditions for Medical Devices Part 1-7**

An electronic version of this form is available on GETS or on PHARMAC's website.

Note: Parts 1-7 are standard terms and conditions. Parts 8 and 9 and all Schedules contain terms and conditions specific to the individual supplier and its contracted devices and have not been attached. Where reference is made in Parts 1-7, to Part 8, Part 9 and the Schedules, the required detail will be negotiated with the successful supplier.

**Proposal for the supply of needle and syringe products**

**[Company name]** declares the following:

I have read and understood the proposed PHARMAC Standard Terms and Conditions for Medical Devices Parts 1-7 (Attachment 2) and **agree/disagree** with the terms and conditions of contract.

I have provided detailed comment about all terms and conditions we do not agree with in the table below:

Signature(s):

Name:

Position:

Date:

Additional rows can be added to the table as required

| Clause Number | Comments |
|---|---|
| | |
| | |
| | |
| | |
| | |
| | |
| | |

**Schedule 5: Checklist of documents to be submitted with your proposal**

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

| Requirement | Evidence / Information | Response | Attached to submission (Y/N) |
|---|---|---|---|
| **Schedule 3:** Proposal form | • Contact details<br>• Key feature of proposal<br>• Pricing information<br>• Statement of understanding of New Zealand legislative requirements<br>• Evidence of international compliance and standards your products meet<br>• Information about current arrangements with DHBs<br>• Financial analysis<br>• Distribution and supply arrangements<br>• Other major supply markets<br>• Information about your organisation<br>• Information about your financial resources<br>• Information about your Quality Management Systems<br>• Information about DHB educational requirements<br>• Transition support and plan<br>• Information about consignment stock<br>• Information on how you would work with PHARMAC and other key stakeholders<br>• Proposal/suggestions you would like PHARMAC to consider<br>• Additional information PHARMAC should consider | Mandatory | |
| **Schedule 4:** Acceptance of PHARMAC Terms and Conditions | • Complete highlighted sections and Table if applicable | Mandatory | |
| **Schedule 5:** Check list | • Complete attached to submission column | Mandatory | |
| **Attachment 1**: Product and pricing spreadsheet<br>DHB hospital usage<br>Financial impact analysis | • Provide product details as requested<br>• DHB volume and cost details<br>• Financial impact analysis details (final tab in Attachment 1)<br><br>Please note: All proposed Needle and Syringe Products **MUST** be WAND registered at the time of submission for this RFP. | Mandatory | |
| Alternative pricing model attachments | Please label any related attachments as - Alternative Pricing Model #1, #2 etc | Optional | |