PHARMAC
Pharmaceutical Management Agency

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21 June 2018

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF PRODUCTS USED IN THE INFUSION OF FLUIDS INTO THE BODY

PHARMAC invites proposals for the supply of products used in the infusion of fluids into the body in New Zealand 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 specifies the information and evidence you need to include in your proposal;
- Schedule 4 and Attachments 01, 02, 03, 04, 06 and 07 contain the forms on which you are to provide the details of your proposal; and
- Attachment 05 contains the PHARMAC standard terms and conditions to list medical devices on the Pharmaceutical Schedule

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 **17 August 2018**.

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

We look forward to receiving your proposal.

Yours sincerely

Lisa Williams
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 products used in the infusion of fluids (including blood transfusion) **into** the body **(Infusion Medical Devices)**, falling under two groups:

- **Non-Dedicated & Consumable Infusion Devices; and**
- **Equipment and Associated Devices**

Full scope of the Infusion Medical Devices is outlined further in Schedule 1, clause 4 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 Infusion Medical Devices.

(c) *Impact of RFP*

PHARMAC intends to establish national listing agreements (**National Contracts**) with suppliers to secure supply of Infusion Medical Devices used in DHB hospitals and their associated community services (**DHB Hospitals**). It is expected that Infusion Medical Devices subject to a National Contract would be listed in Part III of Section H of the Pharmaceutical Schedule. National Contracts would not be exclusive of other suppliers, and it is possible that multiple suppliers of equivalent Infusion Medical Devices would be listed, where appropriate.

PHARMAC recognises there would need to be enough flexibility and options within a standard contractual framework for the Equipment and Associated Devices group to enable DHBs to transition to the PHARMAC National Contracts without being disadvantaged or causing unnecessary disruptions, and to have access to the level of support they are currently receiving should they wish to continue with it.

3. Expected outcome of the RFP

3.1 PHARMAC intends to establish National Contracts with suppliers in the category of Infusion Medical Devices to:

(a) list a range of Infusion Medical Devices available for use in DHB Hospitals in Section H, Part III of the Pharmaceutical Schedule;

(b) secure future supply of Infusion Medical Devices for DHB Hospitals at competitive prices;

(c) secure a range of options for DHB Hospitals to access Equipment and Associated Devices, including outright purchase, lease, rent, rent to buy and supplier provided equipment options[1];

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

(e) ensure access to an appropriate level of technical support, education and training for other relevant DHB Hospital personnel, including but not limited to, clinical engineers;

(f) engage and establish relationships with new and current suppliers of Infusion Medical Devices; and

(g) move commercial arrangements for Infusion Medical Devices into a national framework administered by PHARMAC to create better health outcomes for patients within the funding available in DHB Hospitals.

3.2 This RFP is the only process PHARMAC expects to run prior to negotiation with suppliers, to determine whether the Infusion Medical Devices are contracted for and listed in the Pharmaceutical Schedule. PHARMAC recognises that the use of medical devices touches a wide group of health professionals. Therefore, in the event a National Contract is entered into with a supplier as an outcome of this RFP process, and the Infusion Medical Devices are listed in Part III of Section H of the Pharmaceutical Schedule:

(a) the listing shall be non-exclusive and would include pricing and details of the Infusion Medical Devices;

(b) it would be discretionary for DHB Hospitals to purchase the Infusion Medical Devices from the supplier, however where they do, DHB Hospitals would be expected to purchase these Infusion Medical Devices under the PHARMAC agreement;

(c) it is anticipated that multiple suppliers of Infusion Medical Devices would be listed, where appropriate;

(d) any resultant National Contracts would be between the supplier and PHARMAC. DHBs would be able to purchase under the PHARMAC listing agreement, effective from the listing date, and would not be required to individually approve the agreement for it to come into effect;

[1] In the context of this RFP, supplier provided equipment means when the DHB Hospital purchases an agreed number of consumables or pays a different agreed price for consumables, in return for the supplier providing the associated piece of equipment at no charge to the DHB Hospital.

(e) there may be alternative options for procuring Equipment and Associated Devices, such as various loan options, that are included in the National Contract which may not be described in Part III of Section H of the Pharmaceutical Schedule.

(f) it will be at the DHB Hospitals discretion as to which procurement options they wish to use within the National Contract and will be decided by them in discussion with the supplier.

As noted in Schedule 2 clause 2 (b) of this RFP, PHARMAC may at its sole discretion evaluate proposals for supply of 'Non-Dedicated and Consumable Infusion Devices' and proposals for supply of 'Equipment and Associated Devices' on a different timetable from one another.

4. Scope of Infusion Devices Category

4.1 The following products are considered "**in scope**" for this RFP:

Non-Dedicated and Consumable Infusion Devices*

(a) Intravenous and arterial cannulas and catheters and accessories;

(b) Other vascular devices and access aids eg intravenous or arterial administration ports and associated needles, intraosseous needles, ports, drivers and injection guns, arm boards, vascular access lights, intravenous and arterial catheter and needle positioning aids;

(c) Intravenous and arterial tubing and administration sets and related products;

(d) Intravenous and arterial infusion bags and containers and related products;

*Note this **excludes** products which are prefilled with infusion fluids/medicine.*

(e) Non-Dedicated infusion accessories eg IV poles, IV pole clamps or mounts, docking stations, lock boxes, external battery packs, brackets, adaptors (such as syringe adaptors), carry bags.

(f) Blood administration and transfusion medical devices;

(g) Needleless intravenous injection and withdrawal systems;

(h) Devices used in the infusion of hazardous substances such as chemotherapy including **closed system transfer devices.** NIOSH[2] defines a closed system drug transfer device as 'a drug transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drug or vapour concentrations outside of the system'.

(i) Consumable non-powered infusion pumps-such as ambulatory elasotomeric infusion pumps and associated sets.

[2] The National Institute for Occupational Safety and Health (NIOSH)

**Further detail of in-scope Non-Dedicated and Consumable Infusion Devices can be found in Attachment 01.*

Equipment and Associated Devices

(j) Powered infusion pumps (both mains powered and/or battery powered), ie devices used to pump fluids such as medications, saline solution, blood, total parenteral nutrition (TPN) solutions into a patient in a controlled manner via a variety of administration routes (eg arterial, intravenous, epidural, subcutaneous). For example:

- Volumetric pumps
- Syringe infusion pumps (Syringe drivers);
- Ambulatory syringe drivers;
- Patient controlled analgesia (PCA) infusion pumps;
- Smart pumps.

(k) Infusion pump components/spare parts.

(l) Accessories which are designed specifically for use in conjunctions with a particular brand of infusion pump (Dedicated Accessories) eg IV poles, IV pole clamps or mounts, docking stations, lock boxes, external battery packs, brackets, adaptors (such as syringe adaptors), casters, carry bags.

(m) Consumables which are designed specifically for use in conjunctions with a particular brand of infusion pump (Dedicated Consumables) eg intravenous and arterial tubing and administration sets and related products.

4.2 The following products are identified as "**out of scope**" for this RFP, and PHARMAC is not such products via this RFP:

(a) Enteral nutrition pumps and associated devices– pumps intended to be used only to deliver liquid nutrients and medications to a patient's digestive tract;

(b) Hemodialysis infusion or syringe pumps, dedicated consumables, components and accessories as outlined in the 26 February 2018 **Haemodialysis Equipment and Products RFP**;

(c) Peritoneal Dialysis infusion pumps, dedicated consumables, components and accessories;

(d) Insulin specific infusion pumps;

(e) Ophthalmic infusion pumps;

(f) Phlebotomy devices;

(g) Waste containment and removal products/services; and

(h) Patient monitoring products such as pressure cuffs.

4.3 Miscellaneous medical devices used in the infusion of fluids into the body which are not identified in this RFP as either:

(a) 'in scope' as outlined in clause 4.1 of this Schedule 1; or

(b) 'out of scope' as clause in section 4.2 of this Schedule 1,

will only be considered through this process at PHARMAC's discretion.

5. Types of proposals sought

5.1 All Infusion Medical Devices

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

(b) Suppliers wishing to submit proposal MUST only submit products once either as a 'Non-Dedicated and Consumable Infusion Devices' product (via Attachment 01) or as an 'Equipment and Associated Devices' product (via Attachment 02).

(c) Proposals must meet all the mandatory information and evidence requirements as set out in Schedule 4 and Attachments 01, 02, 03, 04, 06, 07.

(d) Proposals may be submitted on the basis that there may be incremental changes or upgrades for the proposed Infusion Medical Devices 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.

(e) PHARMAC is not willing to consider 'out of scope' products as set out in clause 4.2 of this Schedule 1.

5.2 Non-Dedicated and Consumable Infusion Devices

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

- proposals for Non-Dedicated and Consumable Infusion Devices as set out in Schedule 1 clause 4.1 (a) to (i) of this RFP;
- single pricing option per product (PHARMAC's preferred pricing option for Non-Dedicated and Consumable Infusion Devices); and
- additional pricing options.

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

(b) PHARMAC is **not** willing to consider the following types of proposals:

- Proposals for cross-category bundles of products;
- Proposals which include medicines;

- Proposals which bundle Non-Dedicated and Consumable Infusion Devices and Equipment and Associated Devices;

- Proposals which bundle Non-Dedicated and Consumable Infusion Devices across subcategories of Non-Dedicated and Consumable Infusion Devices (as identified by different tabs (worksheets) in Attachment 01 of this RFP.

5.3 **Equipment and Associated Devices**

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

- proposals for Equipment and Associated Devices as set out in Schedule 1 clause 4.1 (k) to (m) of this RFP;

- single pricing option per product; and

- additional pricing options.

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

(b) PHARMAC is **not** willing to consider the following types of proposals:

- Proposals for cross-category bundles of products;

- Proposals which include medicines;

- Proposals which bundle Non-Dedicated and Consumable Infusion Devices and Equipment and Associated Devices.

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) Proposals must be submitted to PHARMAC via GETS no later than **4.00 p.m**. (New Zealand time) on **17 August 2018**. Late proposals will only be considered at PHARMAC's discretion, considering the need for fairness to other suppliers and 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) At PHARMAC's sole discretion PHARMAC may evaluate proposals for supply of **'**Non-Dedicated and Consumable Infusion Devices**'** and proposals for supply of **'**Equipment and Associated Devices**'** on a different timetable from one another.

   (c) 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.

   (d) 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 greatest weight by the Evaluation Committee but all FFC are important.

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

(i) Information and/or evidence provided by you in accordance with Schedule 4 and Attachments 01, 02, 03, 04, 06, 07 of this RFP;

(ii) your ability to meet PHARMAC's Standard Terms and Conditions (as set out in Schedule 4 and Attachments 05 and 06 of this RFP);

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

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

(B) technical training and support (where applicable);

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

(D) transition support.

(iv) information and evidence of your understanding and 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 risk to continuity of supply; and

(D) recall and product safety management.

(v) DHB Hospital usage data and financial impact (where applicable);

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

(vii) provision of reference sites and referees where applicable;

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

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

(f) 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.

(g) 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 (Attachment 05) from GETS, will apply.

(c) You **MUST** complete and submit Attachment 06 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 and/or examples about the terms and conditions you would seek to discuss during any negotiation.

(d) 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.

(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 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 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 a negotiated agreement; or

(ii) the termination of the RFP process.

6. **Miscellaneous**

(a) PHARMAC reserves the right, having regard to probity principles:

(i) to make such adjustments to the above RFP process as it considers appropriate, at any time during the process, provided that 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;

(viii) to re-advertise for proposals.

(b) PHARMAC may consult or seek clinical, technical and/or operational advice from PTAC, its relevant sub-committee, relevant clinicians and/or DHB Hospital staff at any stage of the RFP process. PHARMAC will notify you if this 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 submitting their proposal(s), until such time as a provisional National Contract 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 operation unit Medsafe), the Minister of Health (or any Associate Ministers) or District Health Boards, 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 Schedule 4 and Attachments 01, 02, 03, 04, 06, 07, 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.

(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 Infusion Medical Devices 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 National Contract as a result of this RFP. Nothing in this RFP prevents PHARMAC from entering into agreements with other suppliers in respect of Infusion Medical Devices 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 National Contract entered into with a supplier; or

(iii) in publicly notifying any approval by the PHARMAC Board 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 Evaluation Committee evaluating proposals in September/October 2018;

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

(iii) consulting on a provisional National Contract from February 2019;

(iv) PHARMAC's Board, or the Board's delegate, considering this provisional National Contract in or after March 2019;

(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) As noted in clause 2 (b) of this Schedule, PHARMAC may evaluate proposals for supply of 'Non-Dedicated and Consumable Infusion Devices' and proposals for supply of 'Equipment and Associated Devices' on a different timetable from one another. The anticipated timetable outlined in clause 7(a) would be the approximate timeframe for the first evaluation process.

(c) Under this indicative timetable, the earliest that changes to the Pharmaceutical Schedule could be implemented is May 2019.

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, taking into account the need for fairness to other suppliers and integrity of the RFP process.

Document	Evidence / Information
2018-06-21 Schedule 4 Proposal response Form	You **must** complete all sections of Schedule 4. If you consider a section to be not applicable, you **must** state "N/A". The response you provide in each section **must** be concise and relevant to the information that has been requested, and you **must** include relevant attachments.
Attachment 01 (excel) Non-Dedicated and Consumable Infusion Devices List	You **must** complete all fields in Attachment 01 for each proposed product. If you consider a field not applicable you must state "N/A". Please ensure your products have been submitted under the appropriate worksheet tab.
Attachment 02 (excel) Equipment and Associated Device List	You **must** complete all fields in Attachment 02 for each proposed product. If you consider a field not applicable you must state "N/A".
WAND	You **must** be able to legally supply your proposed products to New Zealand DHB Hospitals as evidenced by WAND registration 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 in the applicable are of Attachment 01 and/or 02.
International compliance	You **must** provide evidence of international compliance certification. The name of the certifying body(ies) and certificate number(s) must be included in Attachment 01 and/or 02 for each proposed product. you **must** attach a copy of the relevant certificates for each product/product range as applicable. If you have international compliance certification from multiple international regulatory bodies for a product/product range please submit one with others available on request.
GS1 (GTIN) and UNSPSC	It is desirable that you provide GTIN and UNSPSC codes for each proposed Infusion Medical Device 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 Infusion Medical Devices to any DHB Hospital, you **must** provide combined volume and cost information for all DHB Hospitals for the period 1 June 2017 to 31 May 2018 for all line items submitted in **Attachment 01 and/or 02**. You **must** also include any sales to DHB Hospitals via logistics providers.
Non-DHB reference sites	If you **are not** currently supplying a proposed Infusion Medical Device to any DHB Hospital, you **must** provide three clinical reference sites for that product range. It is desirable that the clinical reference sites you provide use the proposed Infusion Medical Device in similar clinical settings as DHB Hospitals would use them.

Document	Evidence / Information
Attachment 03 (excel) Financial Analysis for Non-Dedicated and Consumable Infusion Devices	If you are currently supplying a proposed Non-Dedicated and Consumable Infusion Devices to any DHB Hospital, you **must** provide combined volume and cost information for each DHB Hospital for the period 1 June 2017 to 31 May 2018 for all line items submitted in **Attachment 01**. You **must** also include any sales to DHB Hospitals via logistics providers (with logistic provider sales also separated by DHB);
Attachment 04 (excel) Financial analysis for Equipment and Associated Devices	All suppliers proposing to supply equipment must provide: Information on the total costs of ownership for any equipment (Powered Infusion Pumps, and Other Reusable Infusion Equipment). If you are currently supplying Equipment and Associated Devices to any DHB Hospital, you **must** provide: • combined volume and cost information for all DHB Hospitals for the period 1 June 2017 to 31 May 2018 for all line items submitted in Attachment 02 as Parts, Accessories and Dedicated Consumables. You **must** also include any sales to DHB Hospitals via logistics providers (with logistic provider sales also separated by DHB); • combined volume and cost information for all DHB Hospitals for the five preceding years (for the period 1 June 2013 to 31 May 2018) for all line items submitted in Attachment 02 as Equipment (Powered Infusion Pumps, Non-powered Equipment other Miscellaneous Equipment). You **must** also include any sales to DHB Hospitals via logistics providers (with logistic provider sales also separated by DHB);
Attachment 06 (word) Acceptance of PHARMAC's standard terms and conditions	You **must** complete, sign and date the declaration set out in Attachment 06. You **must** indicate whether you agree or disagree with PHARMAC's standard terms and conditions for medical devices for your proposed products.
Attachment 07 (word): Document and information checklist	You **must** complete the document and information checklist set out in Attachment 07. You **must** note any additional attachments not specifically listed in the box provided in Attachment 07 and note the name of the documents.

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/- Chloë Dimock
Device Category Manager

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

Dear Sir/Madam

Proposal for the supply of Infusion Medical Devices

In response to your request for proposals (**RFP**) dated **21 June 2018** we put forward the following proposal in respect of Infusion Medical Devices.

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

1. Company Details	
Full legal trading name in New Zealand	
New Zealand Business Number	
Address	
Phone	
Email address	
Facsimile	
2. Contact person (s) for this RFP	
Name - Position	
Phone	
Mobile	
Email address	

3. Proposal executive summary	
Include: • overview of products and services • value/benefits to DHB Hospitals of this proposal • why PHARMAC should accept this proposal	Non-Dedicated and Consumable Infusion Devices **[Maximum 500 words]** Equipment and Associated Devices **[Maximum 500 words]**

4. Information about our company, contracts and market	
Company Information	
(a) Type of entity (legal status): e.g. a New Zealand registered limited liability company	
(b) information about our company size, structure and annual turnover Include sales/product staff relevant to this RFP also identifying the overall scope of their role in the company. **Attach** organisational chart, please include name of attached document in the response column	
(c) City and country of residence of our company e.g. Sydney, Australia	
(d) 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)	
(e) Established locations within New Zealand Include function of each location (eg. head office, warehouse).	
(f) If you are currently not based in New Zealand: **Do you intend to establish a company location(s) here?** **How would you manage the needs of your New Zealand DHB Hospital customers from where you are located?** N/A if New Zealand based	
(g) Company ownership State ownership (eg. 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	
(h) Evidence of financial stability and ability to cover financial liabilities Include: • how you would cover your financial liabilities in the event of a major failure to supply (eg. Insurance which covers product recall) • information about your financial stability (eg. annual turnover,	

guarantor companies) **Attach** supporting evidence (eg. annual financial report, Companies Register financial statement, insurance certificate, bank letter), please list names of attached documents in the response column.	
New Zealand Contracts and Markets	
(i) Current healthcare customers in New Zealand Include DHB Hospital and private healthcare organisations.	
(j) 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/scope of products covered • expiry date • other relevant information (eg. now standing agreement after contract expiry) Can be provided as an attachment, note name of attachment in response column.	
(k) If not a current supplier of Infusion Medical Devices to New Zealand DHB Hospitals do you have experience in supplying other Medical Devices to New Zealand hospitals (public or private)? Please detail • what Medical Devices you have supplied; • any contracts and standing agreements in place with DHB Hospitals	

Other information	
(l) Other relevant company and market information PHARMAC should consider when evaluating our proposal Please provide a succinct summary [preferably <500 words]	Non-Dedicated and Consumable Infusion Devices Equipment and Associated Devices

5. Company information in relation to Infusion Devices and our compliance with regulations and standards			
Company knowledge and experience with supplying Infusion Medical Devices			
(a) New Zealand knowledge and experience with the Infusion Medical Devices proposed Please provide a succinct summary of your Infusion Medical Device supply experience in New Zealand.	Non-Dedicated and Consumable Infusion Devices Equipment and Associated Devices		
(b) Information on other major markets for proposed Infusion Medical Devices product ranges. For each product range include: • International markets product ranges are sold into; • type of markets (eg. private hospital, public hospital in Australia) • any contracts held • annual revenue • any other relevant information eg supply performance	Non-Dedicated and Consumable Infusion Devices Equipment and Associated Devices		
Company compliance with regulations and standards			
(c) New Zealand Medical Device regulation	Are all proposed products notified on the Web Assisted Notification of Devices	If No (and WAND is applicable), when will all proposed products be	Does your company comply with the Medsafe regulated guidelines and codes related

	‘WAND’ Medsafe Database?	WAND notified?	to supply of Medical Device in New Zealand. eg New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods
	[Yes/No]	[eg All products would be WAND Notified no later than 30 November 2018]	[Yes/No]
(d) Quality Management System(s) certification for your company **If Yes, attach evidence**, please list names of attached documents in the response column Include relevant section(s) of standard where certification is not for full standard.	ISO 9001 [Yes/No]	ISO 13485 [Yes/No]	Other [specify]
(e) Quality Management Systems(s) certification for manufacturer(s) **If Yes, attach evidence**, please list names of attached documents in the response column Include: • manufacturer’s name • relevant section(s) of standard where certification is not for full standard	ISO 9001 [Yes/No]	ISO 13485 [Yes/No]	Other [specify]
(f) 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 • 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, please list names of attached documents in the response column.	Standard	Compliance	Evidence

NB: for suppliers of Infusion Pumps please provide the information related to Infusion Pump standards in the relevant section of the 'Infusion Pump' Tab of **Attachment 02.**			
(g) 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, or • information about process and expected timeframe for obtaining the necessary rights and permits to supply the products and associated services to New Zealand DHB Hospitals. The relevant permits and rights may vary between products. Permits and rights include, but are not limited to, distribution rights and New Zealand legislative requirements for specific types of products.			
(h) Please provide any further details you would like PHARMAC to know about your company's experience and capabilities in relation to the Infusion Medical Devices your company is proposing to supply. Please provide a succinct summary [preferably <500 words]	Non-Dedicated and Consumable Infusion Devices Equipment and Associated Devices		

6. Information about our proposed distribution and supply arrangements including our ability to ensure continuity of supply to DHB Hospitals:	
Stock Management	
(a) 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. *[eg we have at least 3 months' worth of stock at any one time based on historic and forecasted sales]*		
(b) Warehousing in New Zealand Please outline warehousing locations within New Zealand. Include if warehouse owned by company or owned by a logistics provider.		
(c) Consignment stock Outline if your company is offering any consignment stock; and how it intends to manage this: risk and liability, responsibility for management, auditing arrangements etc		
(d) Outline how your company manages its Infusion Medical Devices Inventory and Forecasting		
(e) Please outline how your company would manage a recall of its Infusion Medical Devices. **NB:** for suppliers of Infusion Pumps please provide the information related to Infusion Pump recalls in the relevant section of the 'Infusion Pump' Tab of **Attachment 02**.		
Supply Chain		
(f) Are you the Manufacturer and Distributor of your proposed Infusion Medical Devices?	Manufacturer	Distributor
	[Yes/No]	[Yes/No]
(g) If you are the Distributor and not the Manufacturer- please outline the distribution agreements you have including exclusivity and expiry dates.	***NB.*** *Not required if you are the manufacturer and distributor of all proposed products.*	

(h) Manufacture to delivery For each product range, from start of manufacture to delivery to DHB Hospitals or DHB Hospital nominated locations (eg. home delivery), include: • steps • who is involved (eg international freight carrier, warehousing, logistic providers, New Zealand freight providers) • timeframes for each step **NB:** for suppliers of Infusion Pumps please provide the information related to Infusion Pump manufacture to delivery in the relevant section of the 'Infusion Pump' Tab of **Attachment 02.**	
Unexpected Increase in demand / potential out of stock situations	
(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 in which these could be mobilised/available for use in NZ DHBs • communication with DHB Hospitals • communication with PHARMAC • how stock is prioritised • other relevant information	
Other supply chain, experience	
(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 Infusion Medical Devices. Please provide a succinct summary [preferably <500 words]	Non-Dedicated and Consumable Infusion Devices Equipment and Associated Devices

7. Information about our ability to manage and support our proposed products Training an Education, and DHB Transition		
Training an Education		
(a) Training and education support Include an overview of the training and education support that would be regularly provided to DHB Hospitals for the proposed products including: • frequency • location • format • content • staff groups (eg. hospital, community) • other relevant information **NB:** for suppliers of Infusion Pumps please provide the information related to Infusion Pump training, education and support in the relevant section of the 'Infusion Pump' Tab of **Attachment 02**.		
(b) Training and education materials Outline training and education materials that would be provided to DHB Hospitals purchasing the proposed products. **NB:** for suppliers of Infusion Pumps please provide the information related to Infusion Pump training, education and support in the relevant section of the 'Infusion Pump' Tab of **Attachment 02**.	For DHB Hospital staff	For patients and carers
(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 (eg if they are responsible for supporting other major Device Categories etc) **NB:** for suppliers of Infusion Pumps please provide the information related to Infusion Pump product support staff in the relevant section of the 'Infusion Pump' Tab of **Attachment 02.**	
(d) Other educational/developmental sponsorship your company provides for DHB Hospital staff associated with Infusion Medical Devices Eg conference packages-conference fee, travel and accommodation expenses. Include whether it is paid for in-full or discounted by your company.	
DHB Transition	
(e) Experience transitioning DHB Hospitals to your Infusion Medical Devices Please outline: • extent of transition (eg switching multiple product ranges within a category for majority of DHB use, or one product range for portion of DHBs hospital use); • when transition occurred; • extra resources utilised (eg whether international product/transition specialist were called on for a period); **NB:** for suppliers of Infusion Pumps please provide the information related to Infusion Pump DHB Transition experience in the relevant section of the 'Infusion Pump' Tab of **Attachment 02.**	
(f) Transition support Include an outline of the support that would be provided to DHB Hospitals transitioning to the proposed products. **NB:** for suppliers of Infusion Pumps please provide the information related to Infusion Pump DHB Transition in the relevant section of the 'Infusion Pump' Tab of **Attachment 02.**	

Attach a detailed transition plan setting out the transition steps, roles and responsibilities and timeframes. Note name of attachment in response column.	
Customer Support	
(g) Customer support hours Include: • standard support hours (NZ time) for customer support and orders • any 24/7 troubleshooting support relevant to the proposed products- if no 24/7 support is intended to be provided please provide the rationale for this. **NB:** for suppliers of Infusion Pumps please provide the information related to Infusion Pump customer support in the relevant section of the 'Infusion Pump' Tab of **Attachment 02.**	
(h) Complaints management processes Include overview of key roles and responsibilities for investigation and response, and escalation and continuous quality improvement processes.	
(l) Please identify whether your company provides support for DHB Hospital funded community use of proposed Infusion Medical Devices and what this support entails. **NB:** for suppliers of Infusion Pumps please provide the information related to Infusion Pump community supported use in the relevant section of the 'Infusion Pump' Tab of **Attachment 02**.	
(i) Please provide any further details you would like PHARMAC to know to about Infusion Medical Device support your company provides.	

8. Pricing, and Financial information	
Pricing information	
(a) Financial impact Include: • overview of how proposed pricing compares to that currently offered to DHB Hospitals • justification for any price increases for DHB Hospitals as a result of the proposal Attach detail in Excel format (format is included in Attachment 03 (excel) Financial Analysis for Non-Dedicated & Consumable Infusion Devices and/or Attachment 04 (excel) Financial analysis for Equipment and Associated Device List).	
(b) Pricing information Include any information related to pricing provided in Attachment 01 and/or 02, 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. **NB:** 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 01, 02, 03 or 04 and associated conditions. **NB:** for suppliers of Equipment please provide the information	

related to total cost of ownership in an 'equipment' Tab of **Attachment 04**.	
Continuity of care	
(e) 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. Eg. ACC, palliative care providers.	
(f) Working with key stakeholders Include information about how you envisage working with PHARMAC and other key stakeholders.	

9. Other relevant information	
(a) 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.	
(b) Other information Include any other information that you would like PHARMAC to consider when evaluating this proposal. Please consider any relevant information under PHARMAC's Factors for Consideration decision making framework	