PHARMAC
Pharmaceutical Management Agency

Level 9, 40 Mercer Street, Wellington 6011
PO Box 10-254, Wellington 6143, New Zealand
**Phone 64-4-460-4990**
Fax 64-4-460-4995
Information line **0800 66 00 50**
enquiry@pharmac.govt.nz
www.pharmac.govt.nz

3 May 2018

Dear Supplier

**REQUEST FOR PROPOSALS – SUPPLY OF UROLOGY, OSTOMY AND CONTINENCE PRODUCTS**

PHARMAC invites proposals for the supply of urology, ostomy and continence products to New Zealand DHB hospitals and their associated community settings.

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

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

All proposals must be submitted to PHARMAC via the Government Electronic Tenders Service (**GETS**) (www.gets.govt.nz) no later than 5.00 pm on **15 June 2018**.

If you have any questions about this RFP, please post these on GETS.

We look forward to receiving your proposal.

Yours sincerely

Lisa Williams
Director of Operations

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

1. **Products**

PHARMAC is interested in considering proposals from suppliers of medical devices used in urology, ostomy and continence care (**UOC Products**) for use in DHB hospitals and their associated community settings (**DHB Hospitals**), that includes:

- Single-use consumables
- Defined-life multiple-use consumables
- Enuresis alarms

The full scope of the RFP is outlined in Schedule 1, clause 5(a) below.

2. **RFP background and impact**

PHARMAC is taking a phased approach to its activity in medical devices. The UOC Products category is the latest category of medical devices that PHARMAC has commenced procurement activity in.

PHARMAC intends to establish national listing agreements **(National Contracts)** with suppliers to secure the supply of UOC Products used by DHB Hospitals. It is expected that UOC Products subject to a National Contract will be listed in Section H, Part III of the Pharmaceutical Schedule. The National Contracts would not be exclusive of other suppliers, and it is likely that multiple suppliers of equivalent UOC Products will be listed, where appropriate.

There may be some products associated with, but not exclusive to, UOC Products that are already listed in Part III Section H of the Pharmaceutical Schedule as the result of previous contracting activity. Suppliers who currently have products associated with UOC Products listed in Part III of Section H of the Pharmaceutical Schedule under other categories may submit additional proposals via this RFP that could result in an amendment to their current agreement.

3. **Expected outcome of the RFP**

(a) PHARMAC intends to establish National Contracts with suppliers in the UOC Products category to:

(i) list a range of UOC Products available for use by DHB Hospitals in Part III of Section H of the Pharmaceutical Schedule;

(ii) secure future supply of UOC Products for DHB Hospitals at competitive prices;

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

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

(v) engage and establish relationships with new and current suppliers of UOC Products; and

(vi) move commercial arrangements for UOC Products into a national framework administered by PHARMAC, to create better health outcomes for patients within the funding available to DHB Hospitals.

(b) This RFP is the only process PHARMAC expects to run prior to negotiation with suppliers, to determine whether the UOC Products are contracted for and listed in the Pharmaceutical Schedule. PHARMAC recognises that the use of UOC Products touches a wide group of patients and health professionals therefore, in the event a National Contract is entered into with a supplier as an outcome of this RFP process, and the UOC Products 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 UOC Products;

(ii) it will be discretionary for DHB Hospitals to purchase the UOC Products from the supplier, however where they do, DHB Hospitals will be expected to purchase the UOC Products under the PHARMAC National Contract;

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

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

## 4. Types of proposals sought

(a) PHARMAC is willing to consider the following types of proposals:

(i) proposals for UOC Products as set out in Schedule 1 clause 5(a) of this RFP;

(ii) single pricing option per UOC Product; and

(iii) 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) Proposals must meet all the mandatory information and evidence requirements as set out in Schedule 3.

(c) Proposals may be submitted on the basis that there may be incremental changes or upgrades for the proposed UOC Products during the life of the National Contract, and that if agreed between the parties, the changed or upgraded product would be made available to DHB Hospitals within a reasonable timeframe.

(d) PHARMAC is not willing to consider proposals for cross-category bundles of products.

(e) PHARMAC is not willing to consider out of scope products as set out in Schedule 1, clause 5(b) of this RFP.

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

5. **Scope of UOC Products category**

(a) <u>In scope</u>

PHARMAC is willing to consider proposals for UOC Products for listing in Part III of Section H of the Pharmaceutical Schedule for use by DHB Hospitals; and the following products are considered **'in scope'** of this RFP:

(i) Ostomy systems for intestinal and urinary ostomies;

(ii) Ostomy kits and sets;

(iii) Ostomy sealing and skin care products;

(iv) Ostomy accessories and miscellaneous ostomy products;

(v) Non-surgical wound drainage systems including wound pouches;

(vi) Urinary drainage bags;

(vii) Urinary catheters;

(viii) Urinary catheter sets;

(ix) External urinary drainage devices;

(x) Incontinence pads and pants;

(xi) Paediatric nappies;

(xii) Faecal collection systems;

(xiii) Protective underlays;

(xiv) Continence skin care products;

(xv) Urology and continence accessories and miscellaneous urology and continence products; and

(xvi) Enuresis alarms.

(b) <u>Out of scope</u>

PHARMAC is not willing to consider proposals for any other products for this RFP, including but not limited to the following products as identified as **'out of scope'** for this RFP:

(i) Urology surgical instruments, endoscopes and surgical implants;

(ii) Urology equipment including urodynamic equipment and associated consumables;

(iii) Airway stoma medical devices;

(iv) Toileting aids (eg. bedpans and handheld urinals);

(v) Suction devices to remove internal fluid collections; and

(vi) Skin care products not used as part of UOC care.

## 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 RFPs must be submitted by a single submitter. Submitters may have joint commercial arrangements with other suppliers and these can be combined into a single submission.

   (c) All proposals must be submitted to PHARMAC via GETS no later than 5.00 pm (New Zealand time) on **15 June 2018**. Late proposals will only be considered at PHARMAC's discretion, considering the need for fairness to other suppliers and integrity of the RFP process.

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

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

   (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, as published on PHARMAC's website (www.pharmac.govt.nz), to the extent applicable. Please be aware of the FFC. More information on the FFC can be found at www.pharmac.health.nz/factors-for-consideration.

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

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

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

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

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

(B) technical support, where applicable;

(C) information for patients;

(D) transition support;

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

(A) stock management;

(B) supply chain;

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

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

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

(vii) provision of reference sites, where applicable;

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

(ix) any other matters that the Evaluation Committee considers to be relevant (provided that PHARMAC will notify such matters and allow an opportunity for submitters of proposals to address them).

(d) Each proposal will be evaluated on the basis that the price offered, the expenditure entailed, and any other terms included in the proposal, are the best that the supplier is able to offer. If you do not put forward your best terms you risk having your proposal excluded at the evaluation stage.

(e) PHARMAC is not bound to select the lowest priced proposal or any proposal.

3. **PHARMAC may request further information**

(f) 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.

(g) If PHARMAC requests further information from or about you, it is not obliged to request the same or any other information from or about any other party provided that, in PHARMAC's judgment, this would not be unfair to any other party.

4. **Negotiation**

(a) PHARMAC may negotiate with the submitter(s) of one or more preferred proposals; in the latter case, whether or not the acceptance of either supplier's proposal would exclude acceptance of the other proposal.

(b) Negotiations will proceed on the basis that PHARMAC's standard terms and conditions to list medical devices on the Pharmaceutical Schedule, which are available as a download (Attachment 2) from GETS, will apply.

(c) You **must** complete and submit Attachment 3 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 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 Operating Policies and Procedures.

(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 National Contract; or

(ii) the termination of the RFP process.

## 6. Miscellaneous

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

(i) to make such adjustments to the above RFP process as it considers appropriate, at any time during the process, provided that it notifies suppliers affected by those changes;

(ii) not to accept any proposal;

(iii) to seek clarification of any proposal;

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

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

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

(vii) to terminate this RFP process at any time, by notifying suppliers who submitted proposals, and, following termination, to negotiate with any supplier(s) on whatever terms PHARMAC thinks fit; and

(viii) to re-advertise for proposals.

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

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

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

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

(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 document.

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

(j) PHARMAC will consider your proposal and information exchanged between the parties in any negotiations relating to your proposal, excluding information already in the public domain, to be confidential to us and our employees, legal advisors and other consultants, the Ministry of Health and DHBs ("**Confidential Information"**). However, you acknowledge that it may be necessary or appropriate for PHARMAC to release Confidential Information:

(i) pursuant to the Official Information Act 1982; or

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

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

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

PHARMAC may consult with you before deciding whether to disclose Confidential Information for the purposes described in sub-clauses (i) to (iv) above. You acknowledge, however, that it is for PHARMAC to decide, in its absolute discretion, whether it is necessary or appropriate to disclose information for any of the above purposes, provided that PHARMAC shall act in good faith in disclosing any Confidential Information.

## 7. Anticipated timetable

(a) Following receipt of proposals, PHARMAC anticipates:

(i) the PHARMAC internal Evaluation Committee evaluating proposals from June 2018;

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

(iii) consulting on any provisional National Contracts from August 2018; and

(iv) PHARMAC's Board, or the Board's delegate, considering any provisional National Contracts from September 2018.

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 October 2018.

## 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 |
|---|---|
| **Attachment 1:**<br>**UOC Products spreadsheet** | You **must** complete all fields in Attachment 1 for each proposed product. If you consider a field not applicable you must state "NA". |
| 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.<br>Where WAND is not applicable to a proposed product you **must** state the reason why it is not applicable. |
| International compliance | You **must** provide evidence of international compliance certification.<br>The name of the certifying body and certificate number must be included in Attachment 1 for each proposed product and you **must** attach a copy of all relevant certificates. |
| GS1 (GTIN) and UNSPSC | It is desirable that you provide GTIN and UNSPSC codes for each proposed UOC Product at the time of submitting your proposal.<br>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 UOC Product to any DHB Hospital, you **must** provide combined volume and cost information for all DHB Hospitals for the period 1 April 2017 to 31 March 2018 for all line items submitted in **Attachment 1**. You **must** also include any sales to DHB Hospitals via logistics providers. |
| Non-DHB reference sites | If you **are not** currently supplying a proposed UOC Product to any DHB Hospital, you **must** provide three clinical reference sites for that product. It is desirable that the clinical reference sites you provide use the proposed UOC Products in similar clinical settings as DHB Hospitals would use them. |
| **Attachment 3:**<br>**Acceptance of PHARMAC's standard terms and conditions** | You **must** complete, sign and date the declaration set out in Attachment 3.<br>You **must** indicate whether you agree or disagree with PHARMAC's standard terms and conditions for medical devices for your proposed products. |

| Document | Evidence / Information |
|---|---|
| | If you do not agree with any of PHARMAC's standard terms and conditions for medical devices for your proposed products you **must** provide detailed comment, including any proposed alternative clauses and justification, in Table 1 of Attachment 3.<br><br>If you would like PHARMAC to consider any other terms and conditions that are not included in PHARMAC's standard terms and conditions, you **must** provide details and justification in Table 2 of Attachment 3. |
| **Attachment 4:**<br><br>**Document and information checklist** | You **must** complete the document and information checklist set out in Attachment 4.<br><br>You **must** note any additional attachments not specifically listed in the box provided in Attachment 4. |
| **Attachment 5:**<br><br>**Financial analysis of your proposal** | If any of your proposed products are currently supplied to DHB Hospitals (contracted and non-contracted) you **must** provide a detailed financial impact analysis of your proposal for each DHB based on recent usage; to be **attached** as an Excel spreadsheet.<br><br>A preferred format is included in Attachment 5. You may provide your financial analysis in an alternative format provided it includes the following for each DHB and each proposed product:<br><br>(a) the product description, code and brand;<br><br>(b) your current (as at May 2018) price offered to each DHB;<br><br>(c) your proposed price (as included in Attachment 1);<br><br>(d) DHB Hospital sales volume (including via logistics providers) for 1 April 2017 to 31 March 2018<br><br>(e) projected annual cost to each DHB at current price<br><br>*current price (b) x DHB sales volume (d)*<br><br>(f) projected annual cost to each DHB at proposed price<br><br>*proposed price (c) x DHB sales volume (d)*<br><br>(g) projected financial impact for each DHB of your proposal<br><br>*projected annual cost at proposed price (f) – projected annual cost at current price (e)* |
| **Schedule 4:**<br><br>**Proposal form** | You **must** complete all sections of Schedule 4. If you consider a section to be not applicable, you **must** state "NA".<br><br>The response you provide in each section **must** be comprehensive and relevant to the information that has been requested, and you **must** include relevant attachments. |

## Schedule 4: Proposal form

An electronic version of this form is available on 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/- Denise Mundy
Senior Device Category Manager

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

Dear Sir/Madam

**Proposal for the supply of Urology, Ostomy & Continence Products**

In response to your request for proposals (**RFP**) dated 3 May 2018 we put forward the following proposal in respect of Urology, Ostomy and Continence Products.

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

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

| **(a) Company details** | |
|---|---|
| Full legal trading name in New Zealand | |
| Address | |
| Phone | |
| Email | |
| Facsimile | |
| **(b) Contact person (s) for this RFP** | |
| Name, Position | |
| Phone | |
| Mobile | |
| Email | |

| (c) Executive summary | |
|---|---|
| Proposal summary<br>Include:<br>• overview of products and services<br>• benefits to DHB Hospitals of this proposal<br>• why PHARMAC should accept this proposal | **Maximum 500 words** |

| (d) Information about our company, contracts and markets | |
|---|---|
| **Company information** | |
| Type of entity (legal status)<br>Eg, a New Zealand registered limited liability company | |
| City and country of residence of our company | |
| Information about company size, structure and annual turnover<br>Include sales/product support staff relevant to this RFP.<br>**Attach** Organisational Chart. | |
| Total number of New Zealand based staff<br>Include FTE for each section (eg. 5 FTE sale/product support, 4 FTE logistics, 3 FTE corporate and administration) | |
| Established locations within New Zealand<br>Include function of each location (eg. head office, warehouse). | |
| Company ownership<br>State ownership (eg. public ownership)<br>Include:<br>• any parent companies and relationships<br>• names and percentage shareholdings of the major shareholders and directors | |

| | |
|---|---|
| Evidence of financial stability and ability to cover financial liabilities<br><br>Include:<br>• how you would cover your financial liabilities in the event of a major failure to supply (eg. a recall)<br>• information about your financial stability (eg. annual turnover, guarantor companies)<br><br>**Attach** supporting evidence (eg. annual financial report, Companies Register financial statement, insurance certificate, bank letter). | |
| **Contracts and markets** | |
| Current contracts and standing agreements in place with DHB Hospitals or organisations acting on their behalf<br><br>Include all DHB contracts, not just those relevant to this RFP.<br><br>For each provide:<br>• parties to the agreement<br>• contract reference number<br>• type of agreement (national/regional/DHB specific)<br>• range of products covered<br>• expiry date<br>• other relevant information (eg. now standing agreement after contract expiry)<br><br>Can be provided as an attachment, note name of attachment in response column. | |
| Products not included<br><br>Include any UOC Products currently supplied to DHB Hospitals (contracted or not contracted) that are not included in this proposal and the reason for this. | |
| Healthcare customers in New Zealand<br><br>Include DHB Hospital and private healthcare organisations. | |
| Information on other major markets for proposed product ranges.<br><br>For each product range include:<br>• type of market (eg. private hospital, public hospital)<br>• any contracts held | ***NB.*** *Only required for product ranges that New Zealand DHB Hospitals are not currently purchasing.* |

| | |
|---|---|
| • annual revenue<br>• any other relevant information | |
| Information about clinical reference sites<br><br>Provide information about each reference site included in Attachment 1 including the location and relevant clinical settings in which the product is used (eg. inpatient care, outpatient clinics, home use). | ***NB.*** *Only required for product ranges that New Zealand DHB Hospitals are <u>not</u> currently purchasing.* |
| Other relevant company and market information | |

| **(e) Information about our ability to manage and support our proposed products** | | |
|---|---|---|
| Customer support hours<br><br>Include:<br>• standard support hours (NZ time) for customer support and orders<br>• any 24/7 troubleshooting support relevant to the proposed products | | |
| Product support staff<br><br>Include information about technical skills, experience and qualifications of the staff that would be involved in supporting the proposed products (including those providing training and education). | | |
| Training and education<br><br>Include an overview of the training and education that would be regularly provided to DHB Hospitals for the proposed products including:<br>• frequency<br>• location<br>• format<br>• content<br>• staff groups (eg. hospital, community)<br>• other relevant information | | |
| Training and education materials<br><br>Include training and education materials that would be provided to DHB Hospitals purchasing the proposed products. | For DHB Hospital staff | For patients |
| | | |

| | |
|---|---|
| Transition support<br><br>Include an outline of the support that would be provided to DHB Hospitals transitioning to the proposed products.<br><br>**Attach** a detailed transition plan setting out the transition steps, roles and responsibilities and timeframes. Note name of attachment in response column. | |
| Complaints management processes<br><br>Include overview of key roles and responsibilities for investigation and response, and escalation and continuous quality improvement processes. | |
| Other relevant information about ability to support the proposed products. | |

| **(f) Information about our compliance with regulations and standards** | | | |
|---|---|---|---|
| Quality Management System(s) certification for your company<br><br>**If Yes, attach evidence**<br><br>Include relevant section(s) of standard where certification is not for full standard. | ISO 9001<br>[Yes/No] | ISO 13485<br>[Yes/No] | Other<br>[specify] |
| Quality Management Systems(s) certification for manufacturer(s)<br><br>**If Yes, attach evidence**<br><br>Include:<br>• manufacturer's name<br>• relevant section(s) of standard where certification is not for full standard | ISO 9001 | ISO 13485 | Other |
| Other relevant standards for the proposed products<br><br>List any other standards that are relevant to the proposed products including but not limited to:<br>• AS/NZ standards<br>• ISO standards<br>• IEC standards | Standard | Compliance | Evidence |

| | | | |
|---|---|---|---|
| Describe the extent of compliance with the listed standard and the product range the standard applies to.<br><br>**Attach** evidence of compliance where available. | | | |
| Permit to supply the products to New Zealand DHB Hospitals<br><br>Include:<br><br>• 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<br>• 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. | | | |

| **(g) Information about our proposed distribution and supply arrangements and ability to ensure continuity of supply to DHB Hospitals** | | |
|---|---|---|
| **Stock Management** | | |
| Minimum shelf life on delivery<br><br>Include for each product range the minimum shelf life on delivery to a DHB Hospital. | | |
| Stock holding within New Zealand<br><br>Include any relevant information about how you would set and manage your stock levels in New Zealand for the proposed products. | | |
| Warehouse location(s) within New Zealand<br><br>Include if warehouse owned by company or owned by a logistics provider. | | |
| Recall management<br><br>Include how a major recall of a proposed product(s) would be managed. | | |
| **Supply Chain** | | |
| Company role in supply chain | Manufacturer | Distributor |
| | [Yes/No] | [Yes/No] |

| | |
|---|---|
| Distribution agreement(s) overview<br><br>Include exclusivity, expiry date, termination notice period. | ***NB.*** *Not required if you are the manufacturer and distributor of all proposed products.* |
| Manufacture to delivery<br><br>For each product range, from start of manufacture to delivery to DHB Hospitals or DHB Hospital nominated locations (eg. home delivery), include:<br>• steps<br>• who is involved<br>• timeframes | |
| **Potential supply issues and response to unexpected increase in demand** | |
| Key supply continuity risks and mitigations<br><br>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. | |
| Response to unexpected increase in demand<br><br>Include:<br>• any access to alternative international supply and timeframes<br>• communication with DHB Hospitals<br>• communication with PHARMAC<br>• how stock is prioritised<br>• other relevant information | |

| **(h) Financial analysis of our proposal** | |
|---|---|
| Financial impact<br><br>Include overview of how proposed pricing compares to that currently offered to DHB Hospitals.<br><br>**Attach** detail in Excel format.<br><br>(preferred format is included in Attachment 5; alternative formats may be submitted provided the detail set out in Schedule 3 is included). | ***NB.*** *Only required if the proposed products are currently supplied to DHB Hospitals* |

| (i) Other relevant information | |
|---|---|
| Pricing information<br>Include any information related to pricing provided in Attachment 1, including any related conditions or proposed terms. | |
| Additional charges<br>Include any charges not included in pricing provided in Attachment 1 and associated conditions. | |
| Enuresis alarm information<br>Include for any alarms proposed in Attachment 1:<br>• Maintenance requirements and responsibilities (if serviceable)<br>• Any other relevant information<br>**Attach** product specifications | |
| Additional options<br>Include any additional proposals or suggestions not expressly identified in this RFP that you would like PHARMAC to consider as part of this proposal.<br>Also refer to Attachment 3. | |
| Continuity of care<br>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.<br>Eg. ACC, palliative care providers. | |
| Working with key stakeholders<br>Include information about how you envisage working with PHARMAC and other key stakeholders. | |

| Other information<br>Include any other information that you would like PHARMAC to consider when evaluating this proposal. | |
|---|---|