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

16 July 2018

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF PATIENT WARMING AND COOLING PRODUCTS

PHARMAC invites proposals for the supply of Patient Warming and Cooling Products in New Zealand DHB Hospitals.

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

- Schedule 1 sets out the background to the RFP, 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 details of your proposal; and
- Attachment 2 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 pm on **Friday 24 August 2018**.

If you have any questions about this RFP, you should submit them to Alyssa Currie 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: Background to RFP and types of proposals sought

1. Products

PHARMAC is interested in considering proposals from suppliers of Patient Warming and Cooling Products. For the purposes of this RFP, Patient Warming and Cooling Products means medical devices that are used to regulate or support the regulation of a patients' core body temperature.

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. Patient Warming and Cooling Products 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 supply of Patient Warming and Cooling Products used by DHB Hospitals. It is expected that Patient Warming and Cooling Products 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 Patient Warming and Cooling Products would be listed, where appropriate.

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.

3. Expected outcome of the RFP

(a) PHARMAC intends to establish National Contracts with suppliers in the category of Patient Warming and Cooling Products to:

(i) list a range of Patient Warming and Cooling Products available for use in DHB Hospitals in Part III of Section H of the Pharmaceutical Schedule;

(ii) secure future supply of Patient Warming and Cooling Products for DHB Hospitals at competitive prices;

(iii) secure a range of options for DHB Hospitals to access Patient Warming and Cooling Equipment, including outright purchase and supplier provided equipment options[1];

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

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

[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 additional charge to the DHB Hospital.

(vi) engage and establish relationships with new and current suppliers of Patient Warming and Cooling Products; and

(vii) move commercial arrangements for Patient Warming and Cooling 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 Patient Warming and Cooling Products are contracted for and listed in the Pharmaceutical Schedule. Therefore, in the event a National Contract is entered into with a supplier and the Patient Warming and Cooling 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 Patient Warming and Cooling Products;

(ii) it will be discretionary for DHB Hospitals to purchase the Patient Warming and Cooling Products from the supplier, however where they do, DHB Hospitals will be expected to procure these Patient Warming and Cooling Products under the PHARMAC National Contract;

(iii) it is anticipated that multiple suppliers of Patient Warming and Cooling Products would be listed, where appropriate;

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

(v) there may be alternative options for procuring Patient Warming and Cooling Equipment, such as outright purchase and supplier provided equipment, that are included in the National Contract that are not described in Part III of Section H of the Pharmaceutical Schedule; and

(vi) it will be at the DHB Hospital's discretion as to which procurement option they wish to use within the National Contract and will be decided by them in discussion with the supplier.

4. Types of proposals sought

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

(i) proposals for Patient Warming and Cooling Products as set out in Schedule 1, clause 5(a) of this RFP;

(ii) single pricing option per Patient Warming and Cooling Products; 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) Suppliers wishing to submit proposals MUST submit proposals for the supply of Patient Warming and Cooling Products to DHB Hospitals with pricing to be published on the Pharmaceutical Schedule (no volume/spend commitment).

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

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

(e) PHARMAC is not willing to consider proposals for cross-category bundles of products (eg. bundling Patient Warming and Cooling Products with VTE prevention products where pricing and/or terms in one category is dependent on usage in the other).

(f) 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 Patient Warming and Cooling Products

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

PHARMAC is willing to consider proposals for Patient Warming and Cooling 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) Forced air warming and cooling equipment and consumables:
- Systems;
- Blankets;
- Garments;
- Connecting hoses;
- Procedure packs; and
- Accessories.

(ii) Blood and fluid warming and cooling equipment and consumables:
- Systems;
- Administration sets;
- Irrigation sets;
- Blankets;
- Garments; and
- Accessories.

(iii) Conductive warming and cooling equipment:
- Systems;
- Connecting cables;
- Batteries;
- Blankets;
- Mattresses;
- Garments; and
- Accessories.

(iv) Neonatal warming systems:
- Infant radiant warmers;

- Systems;
- Batteries;
- Connecting cables;
- Blankets;
- Mattresses; and
- Accessories.

(v) Warming cabinets:
- Blanket warmers;
- Fluid warmers; and
- Combination warmers.

(vi) Chemically activated warming blankets;

(vii) Thermal insulating blankets and garments;

(viii) Accessories:
- Mounting accessories;
- Poles; and
- Other accessories.

(ix) Miscellaneous equipment:
- Spare parts;
- Cleaning tools;
- Servicing equipment; and
- Other miscellaneous equipment.

(b) Out of scope

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

(i) Heater-cooler devices used with heart-lung machines;

(ii) Hot and cold packs;

(iii) Hot water bottles;

(iv) Hydrocollators;

(v) Incubators;

(vi) Medical refrigerators; and

(vii) Temperature monitors

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 which can be combined into a single proposal.

(c) All proposals must be submitted to PHARMAC via GETS no later than 4.00pm (New Zealand time) on **Friday 24 August 2018**. Late proposals will only be considered at PHARMAC's discretion, taking into account the needs 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).

(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. Please be aware of the FFC. More information on the FFC can be found at www.pharmac.health.nz/factors-for-consideration.

(c) The requirement for PHARMAC to pursue its statutory objective means that particular emphasis will be given to those aspects of proposals which demonstrate "health outcomes", and those aspects of proposals which demonstrate the impact on the "funding provided" for pharmaceuticals. Those FFC which relate directly to these aspects will be given 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 and evidence provided by you in accordance with Schedules 3 and 4 of this RFP and Attachments 1,3, 4 and 5;

(ii) your ability to 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) training and education in equipment cleaning and maintenance (where applicable);

(C) technical support for clinical engineers (where applicable);

(D) information for patients (where applicable);

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

(F) equipment tracking, maintenance and repair (where applicable); and

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

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

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

3. PHARMAC may request further information

(a) PHARMAC may request such further information as it considers necessary from or about you for the purposes of clarifying or evaluating your proposal, including (but not limited to) detailed information about your company structure, credit status and any other relevant company information.

(b) If PHARMAC request 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 judgement, 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 be excluded 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) on GETS, will apply. Category specific terms, including terms for equipment, would be negotiated with successful submitter(s).

(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. Where you disagree with any of the standard terms and conditions, you must 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, due to 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 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) 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 you and/or they submit a 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, the Ministry of Health (including its operating unit Medsafe), the Minister of Health (or any Associate Ministers) or DHBs, or advisors to PHARMAC, with a view to influencing the outcome of this RFP process.

(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 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 (Product Evaluation

Health NZ) forms and presentations) unless specifically requested to do so in the 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 Patient Warming and Cooling Products 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 Patient Warming and Cooling Products or restrict 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 from September 2018;

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

(iii) consulting on any provisional National Contracts from January 2019; and

(iv) PHARMAC's Board, or the Board's delegate, considering any provisional National Contracts from February 2019,

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 February 2019.

8. Governing Law

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

Schedule 3: Information 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 maintaining the integrity of the RFP process.

Document	**Evidence / Information**
Attachment 1: **Patient Warming and Cooling Products spreadsheet**	You **must** complete all fields in Attachment 1 for each proposed product. If you consider a field not applicable you must state "N/A".
WAND	You **must** be able to legally support 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.
International compliance	You **must** provide evidence of international compliance certification. 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 Patient Warming and Cooling Products at 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 Patient Warming and Cooling Products to any DHB Hospital, you **must** provide combined volume and cost information for all DHB Hospitals for the period 1 July 2017 to 30 June 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 supply a proposed Patient Warming and Cooling Products 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 Patient Warming and Cooling Products in similar clinical settings as DHB Hospitals would use them.
Attachment 3:	You **must** complete, sign and date the declaration set out in Attachment 3.

Acceptance of PHARMAC's standard terms and conditions	You **must** indicate whether you agree or disagree with PHARMAC's standard terms and conditions for medical devices for your proposed products. If you do not agree with any of PHARMAC's standard terms and conditions for medical device for your proposed products you **must** provide detailed comment, including any proposed alternative clauses and justification, in Table 1 of Attachment 3. 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: **Document and information checklist**	You **must** complete the document and information checklist set out in Attachment 4. You **must** note any additional attachments not specifically listed in the box provided in Attachment 4.
Attachment 5: **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 using the format in Attachment 5.
Schedule 4: **Proposal 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 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/- Alyssa Currie
Device Category Manager

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

Dear Sir/Madam

Proposal for the supply of Patient Warming and Cooling Products

In response to your request for proposals (**RFP**) dated 16 July 2018, we put forward the following proposal in respect of Patient Warming and Cooling Products.

Please refer to Schedule 3 for information and evidence to be included in your proposal. You must also include information as outlined in 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	
New Zealand Business Number	
Address	
Phone	
Email	
Facsimile	
(b) Contact person (s) for this RFP	
Name, Position	
Phone	
Mobile	
Email	
(c) Liaison person(s) for DHB Hospitals and PHARMAC	
Name, position	
Phone	
Facsimile	
Email	
Detail training and experience	
(d) Customer Support and General Enquiries	
Customer Service Hours (NZST)	

Phone	
Facsimile	
Email	
(e) Details of proposed Contract Manager	
Name, position	
Phone	
Email	

(f) Executive summary	
Proposal summary Include: • overview of products and services • benefits to DHB Hospitals of this proposal • why PHARMAC should accept this proposal	**Maximum 500 words**

(g) Information about our company, contracts and markets	
Company information	
Type of entity (legal status) Eg, a New Zealand registered limited liability company	
City and country of residence of our company	
Information about company size, structure and annual turnover Include sales/product support staff relevant to this RFP. **Attach** Organisational Chart, please include name of attached document in the response column	
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)	
Established locations within New Zealand Include function of each location (eg. head office, warehouse). For suppliers not currently based in New Zealand include information on whether you intend to establish local representation in New Zealand and how you would manage the needs of DHB Hospitals from your current location.	

Company ownership State ownership (eg. public ownership) Include: • any parent companies and relationships • names and percentage shareholdings of the major shareholders and directors	
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. a 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).	
Contracts and markets	
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 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.	
Products not included	

Include any Patient Warming and Cooling Products currently supplied to DHB Hospitals (contracted or not contracted) that are not included in this proposal and the reason for this.	
Information on other major markets for proposed product ranges For each product range include: • type of market (eg. private hospital, public hospital) • any contracts held • annual revenue • any other relevant information	***NB.*** *Only required for product ranges that New Zealand DHB Hospitals are <u>not</u> currently purchasing.*
Information about clinical reference sites Provide information about each reference site included in Attachment 1 including the location and relevant clinical settings in which the product is used (e.g. 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	

(h) Information about our ability to manage and support our proposed products	
Customer support hours Include: • standard support hours (NZ time) for customer support and orders • any 24/7 troubleshooting support relevant to the proposed products	
Product support staff 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 Include an overview of the training and education 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	
Training and education materials Include training and education materials that would be provided to DHB Hospitals purchasing the proposed products. Include details of any other educational/developmental sponsorship your company provides for DHB Hospital staff associated with Patient Warming and Cooling Products (eg. conference packages, conference fees, travel and accommodation expenses). Include whether it is paid in full or partially subsidised by your company.	
Transition support Include an outline of the support that would be provided to DHB Hospitals transitioning to the proposed products. **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 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.	

(i) Information about our proposed distribution and supply arrangements and ability to ensure continuity of supply to DHB Hospitals	
Stock Management	
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.		
Consignment stock Include an outline of whether your company is offering any consignment stock and how you intend to manage this, including: • risk and liability • responsibility for management • auditing arrangements		
Warehouse location(s) within New Zealand Include if warehouse owned by company or owned by a logistics provider.		
Recall management 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 Include exclusivity, expiry date, termination notice period.	***NB.*** *Not required if you are the manufacturer and distributor of all proposed products.*	
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 • timeframes		
Potential supply issues and response to unexpected increase in demand		
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.		

Response to unexpected increase in demand Include: • any access to alternative international supply and timeframes • communication with DHB Hospitals • communication with PHARMAC • how stock is prioritised • other relevant information	

(j) Information about our compliance with regulations and standards			
Quality Management System(s) certification for your company **If Yes, <u>attach</u> evidence** Include relevant section(s) of standard where certification is not for full standard.	ISO 9001 [Yes/No]	ISO 13485 [Yes/No]	Other [specify]
Quality Management Systems(s) certification for manufacturer(s) **If Yes, <u>attach</u> evidence** Include: • manufacturer's name • relevant section(s) of standard where certification is not for full standard	ISO 9001	ISO 13485	Other
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. **<u>Attach</u>** evidence of compliance where available.	Standard	Compliance	Evidence
Permit to supply the products 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.	

(k) Pricing and financial analysis of our proposal	
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 5).	***NB.*** *Only required if the proposed products are currently supplied to DHB Hospitals*
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.	
Pricing information	

Include any information related to pricing provided in Attachment 1, including any related conditions or proposed terms.	
Additional charges Include any charges not included in pricing provided in Attachment 1 and associated conditions.	

(I) Information about Patient Warming and Cooling equipment	
Equipment details Include: • details of key operational and safety features including alarms, controls, lock-out, indicators and displays • details of electrical and non-electrical safety features • compatibility with New Zealand power supply and power points for mains operated equipment • delivery lead time • product support, training and education Details should be specific for each different type of Patient Warming and Cooling equipment included in the proposal.	***NB.*** *Only required if the proposed products include equipment*
Loan equipment options Include: • details of contingencies in place for peaks in demand • assumptions used to estimate fleet size • delivery and retrieval timeframe(s) • delivery, receipt and pre-use procedures • details of risk and liability during key exchange activity points • details of any consignment arrangements • management and operational arrangements including information tracking • respective supplier and DHB responsibilities for fleet management • details of any termination terms and conditions • any differences between current arrangements with DHB Hospitals and proposed arrangements	

Details should be specific for each different type of equipment included in the proposal.	
Warranties, servicing and calibration Include: • frequency of calibration and maintenance • details relating to preventive servicing, corrective maintenance and repairs, including whether this is performed by supplier, DHB clinical engineers on-site, or at off-site service centre • details of replacement and repairs policy • overview of warranty coverage, including warranty for repairs and spare parts • cost for all services within the warranty period and following expiry of warranty period • whether replacement loan equipment is providing while maintenance and repairs is undertaken • duration and availability of maintenance, servicing and calibration services after date of delivery • duration and availability of spare parts after date of delivery • training of DHB staff (eg, clinical engineers) Details should be specific for each different type of equipment included in the proposal.	
Operating manuals Include an overview of the content of operating manuals, instructions and guides for use by clinical and technical personnel. **Do not** include copies of full equipment operating or service manuals.	

(m) Other relevant information

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. Also refer to Attachment 3.	
Working with key stakeholders Include information about how you envisage working with PHARMAC and other key stakeholders.	
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 that you do not believe is already covered	