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20 April 2021

INVITATION FOR REGISTRATION OF INTEREST FOR LISTING AGREEMENTS FOR POINT OF CARE TESTING EQUIPMENT AND ASSOCIATED CONSUMABLES ("INVITATION")

In coordination with PHARMAC, NZ Health Partnerships ("NZHP") has previously released Requests for Proposals ("RFPs") for ranges of medical devices which PHARMAC may list on the Pharmaceutical Schedule. The intent was that PHARMAC listing agreements could be entered in appropriate cases without a further substantive RFP submission from suppliers that participated in the NZHP process.

PHARMAC now invites Registrations of Interest ("ROI") for the supply of Point of Care Testing medical devices from suppliers ("Submitter(s)") for consideration for listing on the Pharmaceutical Schedule.

Please note this includes but is not limited to those suppliers who currently have contracts with or are in contract negotiations with NZHP for Point of Care Testing medical devices. Suppliers that did not submit proposals to the NZHP RFP for these devices are required to provide more extensive information in response to this ROI.

This Invitation for ROIs incorporates the following schedules:

- Schedule 1 sets out the background to the Invitation and description of the ROI sought;
- Schedule 2 describes the process that PHARMAC expects to follow in relation to the Invitation;
- Schedule 3 sets out the information that should be included in or form part of the ROI; and
- Schedule 4 contains the ROI proposal form in which you are to provide details of your submission.

If you wish to submit a ROI in response to the Invitation, please submit via the Government Electronic Tenders Service (GETS) (www.gets.govt.nz) no later than 5.00pm on **25 May 2021.** If you have any questions about this Invitation, please post these on GETS. Responses to all questions will be published on GETS.

PHARMAC looks forward to receiving your ROI.

Yours sincerely

Lisa Williams

Director of Operations

Schedule 1: Background to Invitation and Description of Registration of Interest Sought

1. Background to Invitation

In 2010, Cabinet decided that PHARMAC would assume responsibility for managing the assessment, standardisation, prioritisation and procurement of medical devices for the District Health Boards ("DHBs"). In August 2012, Cabinet approved an accelerated plan for transitioning this work to PHARMAC. Since then PHARMAC has been taking a category-by-category approach to completing national contracting, where medical devices are listed on the Pharmaceutical Schedule and DHBs choose which products they purchase. During the national contracting phase DHBs can still purchase medical devices that are not listed on the Pharmaceutical Schedule.

As PHARMAC moves to the next phase of the medical device programme DHBs would only be able to purchase medical devices listed on the Pharmaceutical Schedule, subject to any pre-approved exceptions. It is important that, prior to moving to the next phase of medical device management, the Pharmaceutical Schedule is as comprehensive a list as possible of the medical devices purchased by DHBs.

PHARMAC and NZHP have previously agreed that where NZHP has run a procurement process for medical devices, and it reflected PHARMAC's approach to national contracting, PHARMAC did not intend on releasing an RFP and would consider listing the medical devices that NZHP had contracted on the Pharmaceutical Schedule.

This ROI is the process that PHARMAC is utilising to commence the transfer of agreements from NZHP to PHARMAC and for suppliers to have their Point of Care Testing medical devices considered for listing on the Pharmaceutical Schedule. PHARMAC intends on running further ROIs for other medical device categories currently managed by NZHP at a later date.

Prior to PHARMAC's move to the next stage of hospital medical device management, PHARMAC encourages suppliers to engage with this opportunity for having their medical devices listed on the Pharmaceutical Schedule.

2. Overview

The purpose of this Invitation is to seek submissions for the supply of Point of Care Testing equipment and associated consumables medical devices by a ROI.

In the event a listing agreement is progressed with a Submitter in accordance with the process set out in this ROI, supply of the medical devices would be contracted, under PHARMAC's standard terms and conditions for listing on the Pharmaceutical Schedule, which are set out in Attachment 2.

Schedule 4 contains the ROI proposal forms in which you are to provide details of your submission.

3. NZHP Suppliers

PHARMAC acknowledges Submitters to this Invitation may currently have a contract with or be in contract negotiations with NZHP for the Medical Devices in scope of this ROI ("NZHP Suppliers"). Any contracts resulting from this ROI process would reflect, at a high level, existing terms and conditions in place between NZHP Suppliers and NZHP to the extent the terms and conditions are acceptable to PHARMAC and DHBs. In particular,

PHARMAC is not intending to renegotiate pricing included in those contracts as a result of this ROI.

ROIs submitted by NZHP Suppliers will be assessed by PHARMAC on the following basis:

(a) Reviewing the applicable information in a ROI proposal, which is relevant to NZHP Suppliers as stated in Schedule 3 and Schedule 4a.

(b) In the event a PHARMAC listing agreement is progressed with a NZHP Supplier in accordance with the process set out in this ROI, it shall:

(i) supersede and extinguish all prior agreements and understandings between the NZHP Supplier and any District Health Board (or agent of a District Health Board, including any contract in place or being negotiated with NZHP) regarding supply of the Medical Devices to DHB hospitals; and

(ii) not be subject to a defined term and shall continue in force until amended by agreement or terminated on reasonable notice; and

(iii) not be exclusive. DHB's would continue to be able to purchase Medical Devices from suppliers which are not currently listed on the Pharmaceutical Schedule, until such time as PHARMAC progresses to the next phase of medical devices management. At which point and subject to any pre-approved exceptions, DHB hospitals would only be able to purchase medical devices listed in the Pharmaceutical Schedule.

4. **Other Suppliers**

PHARMAC acknowledges Submitters to this Invitation may not currently be under a contract or in contract negotiations with NZHP (including suppliers whose proposals for medical devices were not progressed with NZHP) (“Other Suppliers”). ROI’s submitted by Other Suppliers will be assessed by PHARMAC on the following basis:

(a) Assessing the applicable information in a ROI, which is relevant to Other Suppliers as stated in Schedule 3 and Schedule 4b.

(b) In the event a PHARMAC listing agreement is progressed with an Other Supplier in accordance with the process set out in this ROI, it shall:

(i) supersede and extinguish all prior agreements and understandings between the Other Supplier and any District Health Board (or agent of a District Health Board, including any contract in place or being negotiated with NZHP) regarding supply of the Medical Devices to DHB hospitals; and

(ii) not be subject to a defined term and shall continue in force until amended by agreement or terminated on reasonable notice; and

(iii) not be exclusive. DHB hospitals would continue to be able to purchase Medical Devices from suppliers which are not currently listed on the Pharmaceutical Schedule, until such time as PHARMAC progresses to the next phase of medical devices management. At which point and

subject to any pre-approved exceptions, DHB hospitals would only be able to purchase medical devices listed in the Pharmaceutical Schedule.

5. **ROI Outcome**

The ROI will be assessed by PHARMAC and as a result of that assessment each Submitter will be notified whether its ROI has been accepted or not (Schedule 2, paragraph 3).

In the event an ROI is accepted by PHARMAC, PHARMAC will notify the Submitter whether it:

(a) meets the NZHP Supplier category criteria and will proceed to contract negotiations with PHARMAC; or

(b) meets the Other Supplier category criteria and the proposal will undergo evaluation in accordance with Schedule 2, clause 3.

For the avoidance of doubt, if a Submitter does not meet the NZHP Supplier category criteria then the Submitter would be in the Other Supplier category and will be required to provide all information in accordance with Schedule 4b. If a Submitter is unsure whether they are a NZHP Supplier or Other Supplier please submit a question through GETS.

Schedule 2: Invitation Process

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

1. **Submission**

   (a) ROIs must be submitted via GETS no later than **5.00pm** on **Tuesday 25 May 2021**. ROIs submitted after this time will only be considered at PHARMAC's discretion, considering the need for fairness to other suppliers and the integrity of the Invitation process.

   (b) All ROIs and any questions arising out of this Invitation must be submitted to PHARMAC via GETS. Responses to all enquiries will be published on GETS.

   (c) Joint ROIs submitted to PHARMAC by one or more Submitters will be considered, provided the ROI provides full details of each Submitter and only one Submitter is identified as the point of contact with PHARMAC in relation to the ROI.

2. **Scope**

   (a) In scope

   The scope of this RFP is Point of Care Testing Equipment, Associated Consumables and Services (Scope). Point-of-care tests (POCTs) are diagnostic tests conducted by non-laboratory trained staff (e.g. physicians and their assistants) near to or at the site of patient care, and are used in many primary care settings worldwide. The goal of POCT is to provide accurate, reliable, fast and cost-effective information about the patient's condition. As a result this is a test that can be used for diagnosis, monitoring or prognosis and may be acted upon resulting in medical intervention on a patient.

   The following products are considered **in scope** of this ROI:

   (i) POCT Blood Glucose Meters
   (ii) POCT Lactate Meters
   (iii) POCT Blood Ketone Meters
   (iv) POCT Urinalysis Analysers; e.g. bHCG, acetoacetate (ketones)
   (v) POCT Blood Gas Analysers
   (vi) POCT Haemoglobin Meters
   (vii) POCT Hb1Ac Analysers
   (viii) POCT D-Dimer Analysers
   (ix) POCT Haematology Analysers
   (x) POCT Viscoelastic coagulation analysers
   (xi) POCT Platelet Function Analysers
   (xii) POCT INR Meters
   (xiii) POCT APTT Meters
   (xiv) POCT Transcutaneous Bilirubin meters
   (xv) POCT multianalyte analysers

   Consumables for each POCT equipment are considered **in scope**.

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

Only products that meet the POCT definition set out in section 2(a) above will be considered. Any POCT products not included in section 2(a) are considered to be **out of Scope** for this RFP.

For the avoidance of doubt, any medical device currently listed in the Pharmaceutical Schedule is considered out of scope.

3. **ROI Assessment**

(a) Following the deadline for submission in accordance with clause 1 above, any ROIs will be assessed by PHARMAC and PHARMAC will determine whether to accept an ROI from a Submitter in relation to any of the medical devices.

(b) PHARMAC will assess ROIs 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 PHARMAC will be guided by the Factors for Consideration ("Factors") that form part of PHARMAC's then current Operating Policies and Procedures ("OPPs"), as published on PHARMAC's website (www.pharmac.govt.nz), to the extent applicable. More information on the Factors 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 ROIs which demonstrate "health outcomes", and those aspects of proposals which demonstrate the impact on the "funding provided" for pharmaceuticals. Those Factors which relate directly to these aspects will be given the greatest weight by PHARMAC, but all Factors are important.

(d) The information to be taken into account in applying the Factors by PHARMAC will be at its discretion, however it will include:

(i) demonstration of experience and knowledge within the healthcare sector;

(ii) ability to provide a range of medical devices as set out in Schedule 4 and that are appropriate for use;

(iii) quality of Medical devices, as specified in Schedule 3;

(iv) ability to supply the Medical devices, as specified in Schedule 3; and

(v) information provided by you in accordance with Schedule 3 of this ROI.

(e) PHARMAC may accept any number of ROIs for the Medical devices.

(f) PHARMAC may consult with interested parties to the extent PHARMAC considers consultation to be necessary or appropriate at any stage.

4. **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.

(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.

5. Negotiation

(a) In the event contractual negotiations commence with one or more Submitters following the assessment of ROI's, PHARMAC may negotiate with the Submitter(s) of one or more ROI's, in the latter case whether or not the acceptance of either Submitter's ROI would exclude acceptance of the other ROI.

(b) Negotiations will proceed on the basis that PHARMAC's standard terms and conditions for supply of Medical devices, will apply, these are available as Attachment 2. Where a Submitter has a contract with NZHP, PHARMAC intends to reflect at a high level the existing contract terms and conditions, including price, rather than renegotiating them, to the extent the terms and conditions are acceptable to PHARMAC and DHBs. PHARMAC acknowledges that there may be some drafting or style differences and these details would be discussed with Submitters.

(c) For Other Suppliers, PHARMAC expects your ROI to be the best you can offer and 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 ROI, as a result of the impact that other negotiated terms may have on price.

(d) PHARMAC may negotiate and enter into a provisional agreement with a preferred Submitter(s) on whatever special terms, in addition to PHARMAC's standard terms and conditions, PHARMAC considers appropriate.

(e) If PHARMAC and the Submitters(s) are unable to reach a provisional agreement within what PHARMAC considers to be a reasonable time, PHARMAC may terminate those negotiations and negotiate with a different Submitter(s).

6. Consultation and approval

(a) In the event contractual negotiations commence with one or more Submitters following the assessment of ROI's, which results in a provisional agreement, any provisional agreement will be conditional on consultation with suppliers and other interested parties, to the extent PHARMAC considers consultation to be necessary or appropriate, and on Board approval (or approval by the Board's delegate acting under delegated authority).

(b) PHARMAC will not consider any counter-offers received during consultation.

(c) The provisional agreement and responses to consultation will be considered by PHARMAC's Board (or by the Board's delegate acting under delegated authority) in accordance with PHARMAC's decision-making framework as outlined in its OPPs with reference to the Factors for Consideration.

(d) If the Board or its delegate does not approve the provisional agreement, then PHARMAC may initiate negotiations for a provisional agreement with any other Submitter(s).

7. ROI Process Completion

The ROI 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 Invitation process.

8. **Miscellaneous**

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

(i) to make such adjustments to the above Invitation 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 ROI;

(ii) to seek clarification of any ROI;

(iii) to meet with any Submitter in relation to its ROI;

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

(v) to suspend or cancel this Invitation process. For example, if during the Invitation process it becomes apparent to PHARMAC that further consultation is appropriate or required PHARMAC may suspend the process in order to consult. In this situation we may ask Submitters to adapt and resubmit its ROI in light of consultation, or alternatively PHARMAC may request that new ROIs be submitted;

(vi) to terminate this Invitation process at any time, by notifying Submitters who submitted ROIs; and

(vii) to re-advertise for ROIs.

(b) The Submitter must not initiate or engage in any communication with other Submitters in relation to the ROI, whether before or after submitting its ROI.

(c) The Submitter must not at any time initiate any communication with PHARMAC's Board members or staff, the Ministry of Health (including its operating unit Medsafe), the Minister of Health (or any Associate Ministers) or District Health Boards, with a view to influencing the outcome of this Invitation process.

(d) The Submitter must pay its own costs for preparing and submitting the ROI.

(e) ROIs are submitted in reliance on the Submitters own knowledge, skill, and independent advice, and not in reliance on any representations made by PHARMAC.

(f) The submission of an ROI as part of this Invitation process will be taken as acceptance of the terms contained in this Invitation. PHARMAC may exclude the Submitter's ROI if it does not comply with any of the terms contained in this Invitation.

(g) This is an Invitation for ROI and not a tender. The Invitation is not an offer capable of being converted into a listing agreement by PHARMAC's apparent acceptance.

(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 the Submitter or any other person in relation to this Invitation.

(i) PHARMAC will consider the Invitation process and information exchanged between the parties in any negotiations relating to the ROI, excluding information already in the public domain, to be confidential to it and its employees, legal advisors and other consultants, the Ministry of Health and DHBs (**Confidential Information**). However, the Submitter acknowledges that it may be necessary or appropriate for PHARMAC to release Confidential Information:

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

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

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

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

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

9. Anticipated timetable

(a) PHARMAC anticipates the following timeframes for this ROI:

(i) Invitation questions close –14 May 2021

(ii) Invitation closed for ROI – 25 May 2021

(iii) NZHP Suppliers notified of evaluation process outcome – May 2021 onwards

(iv) Other Suppliers notified of evaluation process outcome – June 2021 onwards

(v) PHARMAC's Board, or the Board's delegate, considering any provisional agreement – June 2021 onwards

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

10. Governing Law

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

Schedule 3: Information to be included in the Registration of Interest

NZHP Suppliers

The following information should be included in or form part of the ROI as set out in Schedule 4a and Attachment 1:

(a) full legal name of Submitter and proposed supplier (if different);

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

(c) completion of a spreadsheet containing information on the Submitter's medical devices and specifications and pricing. Please refer to GETS for access to the template for this spreadsheet; and

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

Other Suppliers

The following information should be included in or form part of the ROI as set out in Schedule 4, Attachments 1, 3, 4 and 5:

(a) full legal name of Submitter and proposed supplier (if different);

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

(c) detailed logistic and supply chain summary for the medical devices;

(d) details of the medical devices, any associated services available and key features of the medical devices;

(e) completion of a spreadsheet containing information on the Submitter's medical devices and specifications and pricing. Please refer to GETS for access to the template for this spreadsheet;

(f) information on current usage of the medical devices by individual DHBs;

(g) any overseas markets (including site referees);

(h) demonstration of experience and knowledge within the healthcare sector, with DHBs or experience in overseas markets;

(i) evidence of:

(i) how the Submitter envisages working with PHARMAC and other key stakeholders;

(ii) availability of training, education and product support;

(iii) the Submitter's organisational infrastructure, including legal status;

(j) the Submitter's own rationale for why it considers PHARMAC should accept its ROI;

(k) any particular information that the Submitter considers PHARMAC should take into account when assessing the ROI;

(l) a declaration of any conflicts of interest that the Submitter or an associated person or organisation may have that could affect or compromise the Submitter or PHARMAC in relation to the Submitter's participation in this Invitation process or performance under any listing agreement if successful; and

(m) any waste reduction policy and recycling process for the medical devices in New Zealand.

Schedule 4a

Proposal form – NZHP Suppliers

An electronic version of this form is available on PHARMAC's website at www.pharmac.govt.nz and on GETS (www.gets.govt.nz). You should expand the boxes as necessary.

[***Supplier to insert date***]

Director of Operations
C/- Sam Bright
PHARMAC
Level 9
40 Mercer Street
Wellington 6011
New Zealand

Dear Sir

Proposal for the supply of Point of Care Testing Equipment and Associated Consumables

In response to your request for invitation (**ROI**) dated 20 April 2021, we put forward the following proposal in respect of Point of Care Testing Equipment and Associated Consumables.

Please refer to Schedule 3 for information and evidence to be included in your proposal. You must include information as outlined in Attachment 1 as part of your response.

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	

Schedule 4b

Proposal form – Other Suppliers

An electronic version of this form is available on PHARMAC's website at www.pharmac.govt.nz and on GETS (www.gets.govt.nz). You should expand the boxes as necessary.

[***Supplier to insert date***]

Director of Operations
C/- Sam Bright
PHARMAC
Level 9
40 Mercer Street
Wellington 6011
New Zealand

Dear Sir,

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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 ROI	
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) Any conflicts of interest	

(h) 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**

(i) 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 (either embed document in this response form, or upload separately to GETS).	
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). Either embed document in this response form, or upload separately to GETS.	
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.	
Information on other major markets for proposed product ranges.	***NB.*** *Only required for product ranges that New Zealand DHB Hospitals are not currently purchasing.*

For each product range include: • type of market (eg. private hospital, public hospital) • any contracts held • annual revenue • any other relevant information	
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 (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	
Information on any other POCT equipment or consumables Provide information on any POCT products that you currently supply to DHBs that are not included in the scope of this ROI (include brand and DHBs purchasing)	

(j) 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 any of the categories Products (eg. conference packages, conference fees, travel and accommodation expenses). Include whether it is paid in full or partially subsidised by your company.	For DHB Hospital staff	For patients
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.		

(k) 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.		
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.		
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	

(I) 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. Any product specific standards should be included in Attachment 1 **<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.	

(m) 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 increased 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.	

(n) Information about Equipment	
Equipment information Include: • details of contingencies in place for peaks in demand for loan equipment • 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 equipment tracking • respective supplier and DHB responsibilities for fleet management • details of any termination terms and conditions • end of life disposal • product support, training and education • 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 and can be included in a separate spreadsheet.	
Warranties and maintenance Include: • 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 provided while maintenance and repairs are undertaken • training of DHB staff	

Details should be specific for each category and different type of equipment included in the proposal and can be included in a separate spreadsheet	
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.	

(o) Information about Analysers	
Analyser information Include: • details of contingencies in place for peaks in demand for loan equipment • 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 equipment tracking • respective supplier and DHB responsibilities for fleet management • details of any termination terms and conditions • end of life disposal • product support, training and education • 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 and can be included in a separate spreadsheet.	
Warranties and maintenance Include: • 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 an extended warranty can be purchased, details of extended warranty and associated costs • whether replacement loan equipment is provided while maintenance and repairs are undertaken • training of DHB staff • does the warranty differ from the warranty currently in place with DHBs Details should be specific for each category and different type of equipment included in the proposal and can be included in a separate spreadsheet	
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.	
Any other information relevant to this proposal	

(p) Other relevant information	
Additional options Include any additional proposals or suggestions not expressly identified in this ROI that you would like PHARMAC to consider as part of this proposal. Also refer to Attachment 3.	
Sustainability and waste reduction policies and initiatives Please provide details of any waste reduction policies and initiatives currently in place for each product.	

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.	