PHARMAC
Pharmaceutical Management Agency

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22 September 2017

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF INTERVENTIONAL RADIOLOGY CONSUMABLE PRODUCTS

PHARMAC invites proposals for the supply of Interventional Radiology (**IR**) Consumable Products (**IR Consumable Products**) to New Zealand District Health Board (**DHB**) Hospitals.

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

- 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 and 4 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 p.m. on **30 October 2017**.

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

We look forward to receiving your proposal.

Yours sincerely

Sarah Fitt
Director of Operations

Schedule 1: Background to RFP and types of proposals sought

1. Background to RFP

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

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

Under the New Zealand Public Health and Disability Act 2000, as well as under DHBs' Operational Policy Framework, DHBs are required to comply with the Pharmaceutical Schedule as determined by PHARMAC.

(b) *Reasons for running the RFP*

PHARMAC is taking a phased approach to its activity in medical devices.

Following consultation feedback received in September 2016, PHARMAC decided to expand its medical devices scope to include establishing national contracts for IR Consumable Products.

(c) *Impact of RFP*

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

There may be some products associated with, but not exclusive to, IR that were listed in Part III Section H of the Pharmaceutical Schedule as the result of the registration of interest for Interventional Cardiology products. Suppliers who currently have products in the scope of this RFP for which they hold a contract for Interventional Cardiology (being listed in Part III of Section H of the Pharmaceutical Schedule) may choose to submit additional proposals for those products for consideration via this RFP to amend their current agreement for these products or to extend their product ranges.

2. Expected outcome of the RFP

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

(i) secure and list a range of IR Consumable Products available for use by DHB Hospitals in Section H, Part III of the Pharmaceutical Schedule;

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

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

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

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

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

(b) For the avoidance of doubt this RFP is the only process PHARMAC expects to run prior to negotiation with suppliers, to determine whether the IR Consumable 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 IR Consumable 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 IR Consumable Products;

(ii) it will be discretionary for DHB Hospitals to procure the IR Consumable Products from the supplier, however where they do, DHB Hospitals will be expected to procure these IR Consumable Products under the National Contract;

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

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

(c) For the avoidance of doubt, under the New Zealand Public Health and Disability Act 2000, as well as under DHBs' Operational Policy Framework, DHBs are required to act in accordance with the Pharmaceutical Schedule.

3. Scope of IR Consumable Products category

For the purposes of this RFP, Interventional Radiology (IR) Consumable Products means consumable medical devices used for minimally invasive, endovascular and percutaneous, image guided, diagnostic and treatment procedures.

(a) PHARMAC is willing to consider proposals which include one or more of the following IR Consumable Products for listing in Part III of Section H of the Pharmaceutical Schedule for use by DHB Hospitals (in-scope products):

(i) Catheters used in IR procedures
(ii) Catheters - others
- Specialty catheters
- Catheter repair kit
- Catheter securing device
- Insertion/access sets

(iii) Introducer sheaths used in IR procedures
- Access kits

(iv) Guide wires used in IR procedures
(v) Peripherally inserted stents/grafts
- Insertion sets
- Stent retrievers

(vi) IR Needles
(vii) Thrombectomy/flow diversion devices
(viii) Endarterectomy devices
- Dissectors
- Other retrieval devices

(ix) Embolization agents
(x) IVC filters
(xi) Ablation therapy
- Probes
- Catheters

(xii) Accessories & miscellaneous items (ONLY if used in IR procedures)
- Other access/procedure kits/packs
- Vascular closure devices
- Radial artery wrist splints

(b) PHARMAC is not willing to consider proposals for any other products under this RFP, including but not limited to the following products (out of scope products):

(i) any items **not** used in an Interventional Radiology setting;
(ii) imaging equipment
(iii) contrast media;
(iv) general radiology equipment e.g. positioning boards, sandbags, x-ray markers;
(v) endoscopy equipment;
(vi) ablation systems/generators and other hardware associated with IR procedures.

4. Types of proposals sought

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

(b) PHARMAC is willing to consider proposals which include alternative pricing options. If a supplier offers tiered pricing, prices should be based on:

- Tier 1: No level of commitment (published price);
- Tier 2: 40% commitment (maybe confidential); and
- Tier 3: 70% commitment (maybe confidential),

where commitment levels are determined by volume of usage at a DHB Hospital.

(c) Proposals may be submitted on the basis that there may be incremental changes or upgrades for the proposed IR Consumable 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 DHBs within a reasonable timeframe.

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

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

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

Schedule 2: RFP process

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

1. **Submission**

   (a) You may submit more than one proposal. Each proposal will be considered as a separate proposal.

   (b) All proposals must be submitted on the documentation provided. Do not alter the forms in any way.

   (c) All proposals must be submitted by a single Submitter or point of contact. Submitters may have joint commercial arrangements with other suppliers which can be combined into a single proposal.

   (d) All proposals must be submitted to PHARMAC via GETS no later than 5.00 p.m. (New Zealand time) on **30 October 2017**. Late proposals will only be considered at PHARMAC's discretion, taking into account the need for fairness to other suppliers and maintaining the integrity of the RFP process.

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

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

   (c) The requirement for PHARMAC to pursue its statutory objective means that particular emphasis will be given to those aspects of proposals which demonstrate "health outcomes", and those aspects of proposals which demonstrate the impact on the "funding provided" for pharmaceuticals. Those FFC which relate directly to these aspects will be given the greatest weight by the Evaluation Committee but all FFC are important.

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

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

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

(iii) information on your ability to meet PHARMAC's Standard Terms and Conditions (attachment 2)

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

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

(B) information for patients (where applicable);

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

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

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

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

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

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

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

3. **PHARMAC may request further information**

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

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

4. **Negotiation**

(a) Negotiations will proceed on the basis that PHARMAC's standard terms and conditions for supply of medical devices, which are available as a download (Attachment 2) on GETS, will apply.

(b) You **must** complete and submit Attachment 3 of this RFP as part of your proposal. 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.

(c) 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.

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

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

5. **Consultation and approval**

(a) Any provisional agreement(s) will be conditional on consultation with suppliers and other interested parties, to the extent PHARMAC considers consultation to be necessary or appropriate, and on Board approval (or approval by the Board's delegate acting under delegated authority).

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

(c) The provisional agreement(s) and responses to consultation will be considered by PHARMAC's Board (or by the Board's delegate acting under delegated authority) in accordance with the FFC in PHARMAC's then current OPPs.

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

(e) The RFP process will be complete once PHARMAC has notified suppliers of either:

(i) the Board's or its delegate's decision to accept a negotiated agreement(s); or

(ii) the termination of the RFP process.

6. **Miscellaneous**

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

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

(ii) not to accept any proposal;

(iii) to seek clarification of any proposal;

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

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

(vi) to suspend this RFP process. For example, if during the RFP process (and before a provisional agreement is entered into) it becomes apparent to PHARMAC that further consultation is appropriate or required we may

suspend the RFP process in order to consult. In this situation, we may ask you to adapt and resubmit your proposal in light of consultation, or alternatively we may request that new proposals be submitted;

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

(viii) to re-advertise for proposals.

(b) PHARMAC may consult or seek clinical advice from PTAC or its relevant sub-committee at any stage of the RFP process. PHARMAC will notify you if the clinical advice results in any changes to the terms of the RFP.

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

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

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

(g) 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.

(h) 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 IR Consumable Products by PHARMAC's apparent acceptance and instead a separate agreement needs to be negotiated.

(i) 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.

(j) It is possible that more than one supplier may be awarded a contract as a result of this RFP. Nothing in this RFP prevents PHARMAC from entering into agreements with other suppliers in respect of IR Consumable Products or restricts the terms that may be agreed with any other supplier.

(k) PHARMAC will consider your proposal and information exchanged between us in any negotiations relating to your proposal, excluding information already in the

public domain, to be confidential to us and our employees, legal advisors and other consultants, the Ministry of Health and DHBs (**Confidential Information**). However, you acknowledge that it may be necessary or appropriate for PHARMAC to release Confidential Information:

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

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

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

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

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 November 2017;

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

(iii) consulting on a provisional agreement(s) from March 2018;

(iv) PHARMAC's Board, or the Board's delegate, considering the provisional agreement(s) in or after April 2018; and

(v) IR Consumable Products agreement(s) being approved, and agreement(s) finalised for listing from May 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 May 2018.

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 responses will only be considered at PHARMAC's discretion, taking into account the need for fairness to other suppliers and maintaining the integrity of the RFP process.

Requirement	Evidence / Information	Response
Pricing, IR Product types and sizes,	Detailed information about all proposed IR Consumable Products and any related conditions or proposed terms in **Attachment 1** (and **Schedule 4** as needed). **Any proposed IR Consumable Products that do not include a price will not be considered by PHARMAC (unless noted as provided at no cost to the DHB).**	Mandatory
WAND registration	All proposed IR Consumable Products must be WAND registered. WAND registration number must be provided for all IR Consumable Products in **Attachment 1**. Please **do not** provide WAND documents.	Mandatory
International compliance	Evidence of international compliance certificates must be provided (e.g. ARTG, CE Mark) for all IR Consumable Products in **Attachment 1.** Please **attach** copies of certificates.	Mandatory
GS1 (GTIN) and UNSPCS	Provide codes for each proposed IR Product in **Attachment 1.**	Desirable
DHB current usage data	Provide volume and pricing information by DHB for the period **1 July 2016 to 30 June 2017** for all line items submitted in **Financial Impact Analysis sheet Attachment 1**. Applicable where you are currently supplying a proposed IR Product to DHB Hospitals.	Mandatory (where applicable)
Current DHB Hospital contracts	Provide details of DHB Hospital contracts in place including expiry in **Schedule 4**, and any additional cost and volume information not already included in your **Financial Impact Analysis**. Applicable where you currently have an agreement with DHB Hospital(s) to provide IR Consumable Products.	Mandatory (where applicable)
	Provide details of any IR Consumable Products or supply options currently provided to DHB Hospitals that you have **not** included in this proposal, and rationale for this in **Schedule 4**.	Mandatory

Requirement	Evidence / Information	Response
	Applicable where your proposal does not include all IR Consumable Products that you currently provide to DHB Hospitals (contracted or non-contracted).	(where applicable)
Financial analysis of your proposal	Provide an overview of how your proposed pricing compares to the contracted/non-contracted pricing **currently** offered to DHBs in **Schedule 4.** Provide **(in Excel format as part of Attachment 1)** a detailed **Financial Impact Analysis** of your proposal for each DHB for each IR Product included in your proposal. This will include: a) The product description and code; b) Your current (as at Sept 2017) and proposed prices; and the following calculations: c) Current price x annual DHB volume sold (1 July 2016 – 30 June 2017) d) Proposed price x annual DHB volume sold (1 July 2016 – 30 June 2017) e) The difference between c) and d). f) The impact of any current or proposed rebates (Applicable where a proposed IR Product is currently supplied to DHB Hospital(s)).	Mandatory Mandatory
Distribution and supply arrangements	Provide information relating to your ability to ensure continuity of supply of products to DHB Hospitals in **Schedule 4**.	Mandatory
Other major markets	Provide information about IR Product supply in other major markets, and give three reference sites in **Schedule 4**. **ONLY** applicable where your IR Product supply experience is for countries other than New Zealand DHBs.	Mandatory (where applicable)
Organisational information	Provide information about your organisation in **Schedule 4**. Please **attach** copies of insurance certificates.	Mandatory (Certificates are

Requirement	Evidence / Information	Response
		desirable)
Quality management systems	Indicate whether or not your organisation and relevant parties in your supply chain conform to ISO 9000-Quality management or ISO 1345:2016 Medical devices quality management systems in **Schedule 4**.	Desirable
	Provide information about your current or proposed complaints management processes, including ability to recall stock, refund or credit for damaged or faulty goods in **Schedule 4.**	Mandatory
DHB Hospital education and training requirements	Provide a statement of your understanding of DHB Hospital educational requirements and your experience in providing training and product support for the proposed IR Consumable Products in **Schedule 4**.	Mandatory
	Provide information about your ability to support DHB transition to your products in **Schedule 4.** Please **attach** an example of a detailed transition plan.	Mandatory Mandatory
	Provide information about the instructions and guides that would be provided to DHB Hospitals that procure your proposed IR Consumable Products in **Schedule 4.** Please **do not** provide full instruction manuals for any proposed IR Consumable Products.	Mandatory
Consignment stock arrangements	Provide information related to your ability to support consignment products in **Attachment 1** and **Schedule 4**. Applicable where a proposed IR Product is available on consignment.	Mandatory
Working with PHARMAC and other stakeholders	Provide information about how you envisage working with PHARMAC and other key stakeholders in **Schedule 4**.	Mandatory

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/-Sarah Penno
Device Category Manager

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

Dear Sir/Madam

Proposal for the supply of Interventional Radiology Products

In response to your request for proposals (**RFP**) dated 22 September 2017 we put forward the following proposal in respect of Interventional Radiology 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 and 4 as part of your proposal.]

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

(a) Our contact details:

Full legal trading name in NZ	
Key Contact person	
Address	
Phone	
Mobile phone	
Facsimile	
Email address	

(b) Key features of our proposal and associated services available:

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

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

[Expiry dates]

[Additional cost and volume data/information]

[Other relevant information about current contracts in place with DHB Hospitals]

*[IR Consumable Products currently provided to DHB Hospitals that are **not** included in proposal, and reason for this]*

(e) Financial analysis of our proposal:

[Overview of how pricing compares to that currently offered to DHB Hospitals]

*[**Attach** detail in Excel format]*

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

[Whether you are a manufacturer or distributor of the proposed IR Consumable Products]

[Terms of any distribution agreements, if you are not the manufacturer, for example the duration and exclusivity of the distribution agreement]

[Details of distribution and stock-holding in New Zealand]

[Delivery frequency and lead in times, including under stable demand situations, in the event of supply disruptions, and when there is an unexpected surge in demand]

[Specific measures to secure stock for New Zealand from international production, including information about agreements in place with other parties in supply chain and notice periods required for any changes]

[Any freight and delivery costs to DHB Hospitals]

[Minimum shelf life of products]

[Other relevant supply chain arrangements]

(g) Information about our other major markets and previous supply performance (applicable only for products **not** currently supplied to DHBs):

[Private New Zealand market(s)]

[International markets]

[Recent tenders awarded]

*[please give **three reference sites** where proposed products are used in similar ways and settings to DHBs, and sales volumes for 1 July 2016 to 30 June 2017]*

(h) Information about our organisation:

[Organisational structure]

[Information on ability to manage liability in event of a major product recall or failure to supply]

*[Current Insurance levels with certificates **attached**]*

[Management, technical skills, experience and qualifications of staff in relation to the proposed IR Consumable Products]

[Customer support hours for troubleshooting and advice]

[Other relevant information about your organisation].

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

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

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

[*Include information on instructions and guides for IR Consumable Products (as applicable) proposed for clinical personnel. Please **do not** include copies of full manuals]*

(k) Information about our ability to support DHB transition to our products:

*[Overview of transition support with detailed transition plan **attached**]*

(l) Information about our instructions and/or educational resources for patients

[Overview of patient information resources for IR Consumable Products - where appropriate]

(m) Information about our current (and/or proposed) consignment stock management system:

[Risk and liability arrangements] *[Responsibility for stock management]* *[Auditing arrangements]* *[Other relevant consignment stock management information]*

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

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

v) Reasons why PHARMAC should accept our proposal:

w) Additional information that PHARMAC should consider when evaluating our proposal:

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