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2 April 2014

Dear Submitter

INVITATION FOR REGISTRATIONS OF INTEREST FOR LISTING AGREEMENTS FOR THE SUPPLY OF INTERVENTIONAL CARDIOLOGY PRODUCTS TO DHB HOSPITALS

PHARMAC invites Registrations of Interest (ROIs) for listing agreements for the supply of Interventional Cardiology Products via listing on the Pharmaceutical Schedule to District Health Board hospitals from parties who are able to supply or procure the supply of the Interventional Cardiology Products (Submitter(s)).

This Invitation for ROIs incorporates the following schedules:

- Schedule 1 sets out the background to the Invitation, and provides indicative commercial terms for which PHARMAC is inviting ROIs;
- Schedule 2 describes the process that PHARMAC expects to follow in relation to the Invitation for ROIs;
- Schedule 3 specifies the information a Submitter needs to include with its ROI; and
- Schedule 4 specifies the details, specifications and pricing a Submitter needs to include with its ROI.

If you wish to submit a response to the Invitation, please submit it to PHARMAC no later than 4.00 p.m. on **2nd May 2014**.

If you have any questions about this Invitation, please send an email to devices@pharmac.govt.nz.

PHARMAC looks forward to receiving your ROI.

Yours sincerely



Sarah Fitt
Director of Operations

Schedule 1: Background to Invitation for Registrations of Interest and Description of Interest Sought

1. Background to Expression of Interest

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. In August 2012, Cabinet approved an accelerated plan for transitioning this work to PHARMAC. The goal of this decision is to help achieve national consistency in managing medical devices, improve transparency of decision-making and improve the cost-effectiveness of public spending to generate savings for re-investment into health.

PHARMAC sought feedback from stakeholders in May 2013 on a number of identified medical device categories to commence initial procurement work to generate benefits for the District Health Boards over the next 12-18 months and to begin building a Pharmaceutical Schedule of medical devices. The Interventional Cardiology category is one of the categories identified.

PHARMAC recognises that the use of medical devices touches a wide group of health professionals; therefore, during the initial procurement phase District Health Board hospitals will be permitted to purchase Interventional Cardiology Products outside of the Pharmaceutical Schedule, including new technology. DHBs will be encouraged to utilise the Schedule as there will be benefits in choosing medical devices from nationally negotiated agreements.

PHARMAC is aware the National Health Committee has recently released a consultation on draft advice relating to a number of procedures in interventional cardiology. PHARMAC will consider any final advice that arises from this process where it is relevant to any provisional listing agreements that arise from this ROI.

PHARMAC intends to establish listing agreements with suppliers to gain the best price for Interventional Cardiology Products that are required for use in the District Health Board hospitals. It is expected that medical devices subject to a listing agreement will be listed in the Schedule. It is also anticipated that multiple suppliers of equivalent products will be listed, where appropriate.

2. Description of Interest Sought

The purpose of this Invitation is to seek submissions for the supply of Interventional Cardiology Products by registering an interest, by way of a ROI.

Schedule 3 specifies the information required from the Submitter that needs to be included with the ROI, and Schedule 4 provides specific details regarding the Interventional Cardiology Products, and information regarding the requirement to complete a spreadsheet of details, product specifications and pricing relating to the Interventional Cardiology Products.

The ROI will be assessed by PHARMAC and may lead to a listing agreement with the Submitter for listing in the Pharmaceutical Schedule for access by the District Health Board hospitals.

For the avoidance of doubt this Invitation is the only process PHARMAC expects to run prior to negotiation with Submitter(s), in order to determine whether the

Interventional Cardiology Products are contracted and listed in the Pharmaceutical Schedule.

In the event a listing agreement is entered into with a Submitter and the Interventional Cardiology Products are listed in the Pharmaceutical Schedule:

- (a) the listing shall be non-exclusive and will include pricing and details of the Interventional Cardiology Products;
- (b) it will be discretionary for District Health Board hospitals to purchase the Interventional Cardiology Products from the nominated Submitter in particular, and under the Pharmaceutical Schedule in general;
- (c) PHARMAC will consider options with the Submitter including volume based discount arrangements, rebates and arrangements that guarantee listing in the Pharmaceutical Schedule for a set period of time;
- (d) PHARMAC may offer listing protection in the Pharmaceutical Schedule for a period of up to 3 years, meaning that PHARMAC will not enter any other arrangement with effect in that period that would result in the removal of the protected product from the Schedule; and
- (e) Any resultant listing agreement will be between the Submitter and PHARMAC. DHBs will be able to purchase under the PHARMAC listing agreement, and will not be required to individually approve the agreement for it to come into effect.

Schedule 2: Invitation for Registrations of Interest Process

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

1. Submission

- (a) ROIs must be submitted no later than 4.00 p.m. (New Zealand time) on 2nd May **2014**. ROIs submitted after this time will only be considered at PHARMAC's discretion.
- (b) All ROIs must be submitted to PHARMAC by email to devices@pharmac.govt.nz.
- (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. Assessment

- (a) Following the deadline for submission in accordance with clause 1 above, any ROIs will be assessed by PHARMAC and PHARMAC will determine, at its sole discretion, whether to seek a listing agreement in relation to the Interventional Cardiology Products.
- (b) PHARMAC will assess the ROIs in accordance with its Operating Policies and Procedures. The matters to be taken into account by PHARMAC will include but not be limited to:
 - (i) cost and value for money, including indicative pricing and the potential for volume-based pricing;
 - (ii) demonstration of experience and knowledge within the healthcare sector, and District Health Board hospitals in particular;
 - (iii) ability to provide a range of the Interventional Cardiology Products that are appropriate for use;
 - (iv) information required to be included with every ROI, as specified in Schedules 3 and 4; and
 - (v) any other matters that PHARMAC considers to be relevant.
- (c) Each ROI will be assessed on the basis that the indicative pricing offered and any other terms included in the ROI are the best that the Submitter is able to offer. A list price will be transparent in the Pharmaceutical Schedule in the event it is included.
- (d) PHARMAC may select any number of ROIs for equivalent Interventional Cardiology Products.
- (e) PHARMAC may consult with interested parties to the extent PHARMAC considers consultation to be necessary or appropriate at any stage.

3. **Negotiation**

- (a) Following assessment, PHARMAC may negotiate with Submitters of ROIs.
- (b) Given that PHARMAC expects the ROI to be the best the Submitter can offer, PHARMAC does not intend to initiate negotiation with the Submitter on price. However, PHARMAC does not exclude the possibility that the final price agreed will be different from the price put forward in the ROI, as a result of the impact that other negotiated terms may have on price.
- (c) PHARMAC may negotiate and enter into provisional listing agreements with Submitters of ROIs.

4. **Consultation and Approval**

- (a) Any provisional listing agreement will be conditional on consultation (at PHARMAC's discretion) with 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 listing agreement and responses to any consultation will be considered by the Board (or its delegate).
- (d) The Invitation for ROI process will be complete once PHARMAC has notified Submitters of either:
 - (i) PHARMAC's decisions regarding the Interventional Cardiology Products it will include on the Pharmaceutical Schedule; or
 - (ii) the termination of the Invitation for ROI process.

5. **Miscellaneous**

- (a) PHARMAC reserves the right:
 - (i) to make such adjustments to the above Invitation for ROI process as it considers appropriate, at any time during the process, provided that it notifies Submitters affected by those changes;
 - (ii) to meet with any Submitter in relation to its proposal;
 - (iii) not to accept any ROI;
 - (iv) to seek clarification of any ROI;
 - (v) to enter into a listing agreement or arrangement that differs in material respects from that envisaged in this Invitation for ROIs;
 - (vi) to suspend this Invitation for ROI process. For example, if during the process (and before a provisional listing agreement is entered into) 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;

- (vii) to terminate this Invitation for ROI process at any time, by notifying Submitters who submitted ROIs, and, following termination, to negotiate with any Submitter(s) on whatever terms PHARMAC thinks fit;
- (viii) to re-advertise for ROIs.

The Submitter must not initiate or engage in any communication with other Submitters in relation to the Invitation for ROIs whether before or after submitting the ROI, until such time as a provisional listing agreement is accepted by the PHARMAC Board or its delegate.

- (b) The Submitter must not at any time initiate any communication with PHARMAC's Board members or staff, the Ministry of Health, the Minister of Health or District Health Boards, with a view to influencing the outcome of this Invitation for ROI process.
- (c) The Submitter must pay its own costs for preparing and submitting the ROI.
- (d) The Submitter must limit the information provided to that which is requested in Schedules 3 and 4 and provide it succinctly and clearly.
- (e) ROIs are submitted in reliance on the Submitter's own knowledge, skill, and independent advice, and not in reliance on any representations made by PHARMAC.
- (f) The submission of a ROI as part of the Invitation for ROI 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 ROIs and not a tender. The Invitation is not an offer capable of being converted into a listing agreement by PHARMAC's apparent acceptance, and instead a separate listing agreement (or agreements) needs to be negotiated.
- (h) PHARMAC is not liable in any way whatsoever for any direct or indirect loss (including loss of profit), damage or cost of any kind incurred by the Submitter or any other person in relation to this Invitation.
- (i) PHARMAC will consider the Invitation for ROI 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 listing agreement entered into with a Submitter; or
 - (iii) in publicly notifying any approval by PHARMAC of that listing agreement; or

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

PHARMAC may consult with the Submitter before deciding whether to disclose Confidential Information for the purposes described in sub-clauses (i) to (iv) above. The Submitter acknowledges, 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.

6. **Anticipated timetable**

(a) Following receipt of ROIs, PHARMAC anticipates:

- (i) the assessment process to be completed in May 2014
- (ii) negotiating with Submitter(s) of one or more ROIs in June 2014;
- (iii) PHARMAC's Board or its delegate considering listing agreement(s) on or after 31 July 2014;

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

7. **Governing Law**

This Invitation for ROIs 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

(A spreadsheet containing information on the Submitter's Interventional Cardiology Products, specifications and pricing also requires completion and submitting. See separately attached GETS document for this spreadsheet).

The following information should be included in or form part of the ROI:

- (a) full legal name of Submitter and proposed supplier (if different);
- (b) contact person;
- (c) contact details (including but not limited to physical address, telephone and email addresses);
- (d) a logistic and supply chain summary for the Interventional Cardiology Products;
- (e) details of the Interventional Cardiology Products and any associated services available and key features of the ROI;
- (f) confirmation that the Interventional Cardiology Products proposed by the Submitter meet the relevant standards and regulatory requirements for its intended use;
- (g) indicative pricing (GST exclusive), including any related conditions or proposed terms affecting cost for PHARMAC;
- (h) information on current usage and expenditure of the Interventional Cardiology Products by DHBs;
- (i) confirmation that any parties who will be supplying the Interventional Cardiology Products have a business continuity plan(s) with a brief summary of the plan(s);
- (j) demonstration of experience and knowledge within the healthcare sector, and specifically with District Health Board hospitals;
- (k) Evidence of:
 - how the Submitter envisages working with PHARMAC and other key stakeholders;
 - availability of training, education and product support;
 - the Submitter's organisational infrastructure, including legal status; and
 - an indication of pricing as appropriate for provision of the Interventional Cardiology Products.
- (l) proposals/suggestions about devices and any associated services not expressly identified in the ROI that PHARMAC may wish to consider;
- (m) the Submitter's own rationale for why it considers PHARMAC should accept its ROI;

- (n) any particular information that the Submitter considers PHARMAC should take into account when assessing the ROI; and
- (o) 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 for ROI process or performance under any listing agreement if successful.

Schedule 4: Interventional Cardiology Product Details, Specifications and Pricing

PHARMAC invites suppliers of Interventional Cardiology Products to submit its range of products as applicable to the Interventional Cardiology categories set out below. Interventional Cardiology Products listed on the Pharmaceutical Schedule would be accessible at the discretion of the District Health Board hospitals.

In Scope Interventional Cardiology Categories:

- Catheters (includes guide sheaths)
- Access Devices
- Balloons
- Angioplasty Guide Wires
- Stents
- Ancillary Devices
- Structural Devices
- Miscellaneous

Out of Scope Cardiology Categories:

- Electrophysiological Studies consumables
- Products used in Cardiac Surgery
- Rhythm Disturbance consumables/equipment

We are not specifically seeking proposals for products in these areas as part of the Invitation for ROI process, but may consider them at a later date.

Schedule of Interventional Cardiology Categories Spreadsheet

A Schedule of Interventional Cardiology Categories spreadsheet is separately attached on GETS and must be completed and submitted as part of the Submitter's response.

When completing the spreadsheet, please ensure the instructions below are followed:

- Please do not alter the spreadsheet format in any way.
- In the submission please list all sizes in the range of products on a separate line.
- Please submit the spreadsheet in an excel format document (not pdf).