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13 July 2015

Dear Submitter

INVITATION FOR EXPRESSIONS OF INTEREST FOR LISTING AGREEMENTS FOR THE SUPPLY OF STERILE WRAP AND ASSOCIATED CONSUMABLE PRODUCTS TO DHB HOSPITALS ("INVITATION")

PHARMAC invites Expressions of Interests ("EOIs") for the supply of sterile wrap and associated consumable products ("Products") to District Health Board hospitals ("DHBs") from parties who are able to supply or procure the supply of the Products ("Submitter(s)").

This Invitation is stage one of a two stage procurement process. A Submitter who is notified by PHARMAC that its EOI has been accepted is eligible to submit a proposal in response to any Request for Proposal ("RFP") which is issued by PHARMAC for the Products.

This Invitation for EOIs incorporates the following schedules:

- Schedule 1 sets out the background to the Invitation and a description of EOIs sought;
- Schedule 2 describes the process that PHARMAC expects to follow in relation to the Invitation;
- Schedule 3 specifies the information a Submitter needs to include with its EOI; and
- Schedule 4 specifies the Products which are in scope and out of scope for the purposes
 of this Invitation.

If you wish to submit an EOI in response to the Invitation, please submit it to the Government Electronic Tenders Service ("GETS") no later than 4.00 p.m. on 3 August 2015.

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

PHARMAC looks forward to receiving your EOI.

Yours sincerely

Sarah fitt

Sarah Fitt Director of Operations

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

1. Background to Invitation

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

2. Description of Expression of Interest Sought

The purpose of this Invitation is to seek submissions for the supply of the Products by registering an EOI.

Schedule 3 specifies the information required from the Submitter that needs to be included with the EOI, and Schedule 4 provides the Products which are in scope and out of scope for the purposes of this Invitation.

The EOI will be assessed by PHARMAC and as a result of that assessment Submitters will be notified whether its EOI has been accepted or not. PHARMAC reserves the right to issue an RFP at a later date to those submitters whose EOI is accepted.

Pricing proposals are not to be included with the EOI.

A listing agreement ("Agreement") may be entered into following acceptance of a proposal as a result of any RFP issued for the Products subsequent to the EOI. Such an Agreement would have the following features:

- (a) the listing in the Pharmaceutical Schedule shall be non-exclusive and will include a list price and specify details of the Products;
- (b) it will be discretionary for DHBs to purchase the Products from the supplier; and
- (c) any Agreement will be between the supplier and PHARMAC. DHBs will be able to purchase Products under the Agreement, and will not be required to individually approve the Agreement for it to come into effect.

Schedule 2: Invitation Process

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

1. Submission

- (a) EOIs must be submitted no later than 4.00 p.m. (New Zealand time) on 3 August 2015. EOIs submitted after this time will only be considered at PHARMAC's discretion.
- (b) All EOIs and any questions arising out of this Invitation must be submitted to PHARMAC via GETS.
- (c) Joint EOIs submitted to PHARMAC by one or more Submitters will be considered, provided the EOI provides full details of each Submitter and only one Submitter is identified as the point of contact with PHARMAC in relation to the EOI.
- (d) Submitters may submit written questions via GETS to clarify issues relating to the Invitation up to 20 July 2015
- (e) PHARMAC will normally respond to questions directly, however if PHARMAC deem the question/answer to be of significant importance to all Submitters, a copy of the question along with the answer will be posted on the GETS website. All respondents who have downloaded the Invitation document from the GETS website will be notified by GETS that there is additional information available in relation to this Invitation.

2. EOI Assessment

- (a) Following the deadline for submission in accordance with clause 1 above, any EOIs will be assessed by PHARMAC and PHARMAC will determine, at its sole discretion, whether to accept an EOI from a Submitter in relation to the Products.
- (b) PHARMAC will assess the EOIs 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) demonstration of experience and knowledge within the healthcare sector,
 - (ii) ability to provide a range of the Products as set out in Schedule 4 and that are appropriate for use;
 - (iii) quality of Products, as specified in Schedule 3;
 - (iv) ability to supply the Products, as specified in Schedule 3; and
 - (v) information required to be included with every EOI, as specified in Schedule 3.

As noted in Schedule 1 clause 2 above, price and/or cost effectivenessa would not be evaluated as part of the EOI, but would be considered as part of any RFP which is issued for the Products.

(c) PHARMAC may accept any number of EOIs for the Products.

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

3. Stage two of the Procurement Process

In the event an EOI is assessed and accepted, the Submitter is eligible to submit a proposal in response to any RFP which is issued by PHARMAC for the Products. For the avoidance of doubt it is at PHARMAC's discretion as to whether an RFP is issued and it makes no representation in this respect.

4. **EOI Process Completion**

The EOI process will be complete once PHARMAC has notified:

- (a) Submitters who are eligible to submit a proposal in response to any RFP which is issued by PHARMAC for the Products;
- (b) Submitters who are not eligible to submit a proposal in response to any RFP which is issued by PHARMAC for the Products; or
- (c) the termination of the Invitation process.

5. Miscellaneous

- (a) PHARMAC reserves the right:
 - to make such adjustments to the above Invitation 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 EOI;
 - (iv) to seek clarification of any EOI;
 - (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 EOI in light of consultation, or alternatively PHARMAC may request that new EOIs be submitted;
 - (vi) to terminate this Invitation process at any time, by notifying Submitters who submitted EOIs, and
 - (vii) to re-advertise for EOIs.
- (b) The Submitter must not initiate or engage in any communication with other Submitters in relation to the Invitation whether before or after submitting its EOI.
- (c) 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 DHBs, with a view to influencing the outcome of this Invitation process.

- (d) The Submitter must pay its own costs for preparing and submitting the EOI.
- (e) The Submitter must limit the information provided to that which is requested in Schedule 3 and provide it succinctly and clearly.
- (f) EOIs are submitted in reliance on the Submitter's own knowledge, skill, and independent advice, and not in reliance on any representations made by PHARMAC.
- (g) The submission of an EOI as part of the Invitation process will be taken as acceptance of the terms contained in this Invitation. PHARMAC may exclude the Submitter's EOI if it does not comply with any of the terms contained in this Invitation.
- (h) This is an Invitation for EOIs and not a tender. The Invitation is not an offer capable of being converted into a listing agreement by PHARMAC's apparent acceptance.
- (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 the Submitter or any other person in relation to this Invitation.
- (j) PHARMAC will consider the Invitation process and information exchanged between the parties in any negotiations relating to the EOI, 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) 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) or (ii) 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 EOIs, PHARMAC anticipates:
 - (i) the Invitation assessment process to be completed 24 August 2015
 - (ii) Invitation questions close 20 July 2015
 - (iii) Invitation closes for EOI submissions 3 August 2015
 - (iv) Submitters notified of Invitation process outcome 28 August 2015

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 process take longer than anticipated.

7. 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 EOI

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

- (a) completion of a spreadsheet containing information on the Submitter's Products and specifications. Please refer to GETS for access to the template for this spreadsheet;
- (b) full legal name of Submitter and proposed supplier (if different);
- (c) contact person;
- (d) contact details (including but not limited to physical address, telephone and email addresses);
- (e) a detailed logistic and supply chain summary for the Products;
- (f) details of the Products and any associated services available and key features of the EOI;
- (g) information on current usage of the Products by DHBs;
- (h) any overseas market (including site referees);
- (i) confirmation that any parties who will be supplying the 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, with DHBs or experience in overseas markets;
- (k) 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;
- (I) proposals/suggestions about products and any associated services not expressly identified in the Invitation that PHARMAC may wish to consider;
- (m) the Submitter's own rationale for why it considers PHARMAC should accept its EOI;
- (n) any particular information that the Submitter considers PHARMAC should take into account when assessing the EOI; 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 process or performance under any listing agreement if successful.

(p) Please confirm your ability to meet the following criteria and provide evidence where required:

REQUIREMENTS	CONFIRM RELEVANT AS/NZ STANDARD & PROVIDE EVIDENCE
Wrap meets standard	
Pouches/ Rolls meet standard	
Chemical Indicators meet standard	
Biological Indicators meet standard	
Bowie-Dick tests meet standard	
Tray liners meet standard	
Load Control Devices meet standard	
Lead Free Autoclave tape	

Schedule 4: In Scope and Out of Scope Products

PHARMAC invites EOIs from Submitters for Products in the in scope product categories stated below:

In Scope Product Categories:

- (a) Sterile Wrap;
- (b) Pouches (self-sealing and heat sealing);
- (c) Flat rolls and rolls with gussets;
- (d) Biological & Chemical Indicators;
- (e) Trays and Tray Liners;
- (f) Load Control Devices (PCD); and
- (g) Indicator Tapes.

Out of Scope Product Categories:

- (a) Sterilisation Containers;
- (b) Gas Cartridges/Cassettes;
- (c) Tamper Evident Arrows;
- (d) Steriliser Printer Paper;
- (e) Labels / Audit sheets/ Batch Cycle record cards;
- (f) Cassette Collection Boxes; and
- (g) Security Seals.

NB: PHARMAC is not seeking proposals for the out of scope product categories as part of this Invitation process, but may consider these categories at a later date.