PHARMAC
Pharmaceutical Management Agency

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29 June 2015

Dear Supplier

INVITATION FOR EXPRESSIONS OF INTEREST FOR THE SUPPLY OF FUNDED DIABETES MANAGEMENT PRODUCTS (INVITATION)

PHARMAC is interested in receiving expressions of interest (EOI(s)) from suppliers of diabetes management products (Products). These Products would be funded for eligible people in New Zealand with diabetes mellitus.

For the purposes of evaluation in respect of any EOI submitted, samples of the Products must be sent to PHARMAC with the EOI in order for an evaluation to be undertaken, which includes laboratory and end-user testing.

Subject to any EOIs received by PHARMAC this Invitation sets out the first stage of an anticipated two stage procurement process for the supply of the Products. No commercial proposals are sought at this stage.

Only suppliers that submit an EOI to this Invitation, and whose Products 'pre-qualify' via the PHARMAC evaluation, will be invited to participate in stage two of the procurement process which will seek commercial bids.

This Invitation incorporates the following schedules:

- Schedule 1 specifies the Products, sets out in the background to the Invitation, EOIs sought and also an overview of the procurement process
- Schedule 2 describes the process that PHARMAC expects to follow in relation to the Invitation
- Schedule 3 sets out information about the estimated size of the market for the Products, and
- Schedule 4 sets out the EOI form to complete and includes the information a supplier needs to include in its EOI.

If you wish to submit an EOI, you must submit it to PHARMAC by email no later than **5pm on 10 August 2015.**

Any questions can be sent to Bronwyn Hale, Therapeutic Group Manager, at bronwyn.hale@pharmac.govt.nz. or post your questions on the Government Electronic Tenders Service (www.gets.govt.nz).

We look forward to receiving your Expression of Interest.

Yours sincerely

Sarah Fitt
Director of Operations

Schedule 1

1. **Diabetes management products**

PHARMAC is interested in receiving an EOI from suppliers for any of the following products:

(a) self-monitoring blood glucose diagnostic test meters and blood glucose diagnostic test strips; and/or

(b) self-monitoring blood ketone diagnostic test meters and blood ketone diagnostic test strips; and/or

(c) self-monitoring blood glucose diagnostic test meters and blood ketone diagnostic test meters (dual meters) and test strips; and/or

(d) self-monitoring blood glucose diagnostic test meters and blood glucose diagnostic test strips (visually impaired);

For the avoidance of doubt, it is expected that any supplier interested in supplying a meter would also be able to supply appropriate diagnostic test strips for their device.

All Products must:

(i) meet Standard ISO 15197:2013. This ISO standard specifies requirements for in vitro glucose monitoring systems that measure glucose concentrations in capillary blood samples for specific design verification procedures and for the validation of performance by the intended users. All EOIs must provide documentation which either:

(A) shows that the Product(s) meet ISO 15197:2013; or

(B) indicates the Products are undergoing, or soon will be, assessed against ISO 15197:2013.

Products that do not meet (i) will not be considered.

2. **Background to Invitation**

The background to this Invitation is as follows:

Following a competitive process run in 2011/12, PHARMAC moved to sole supply of self-monitoring blood glucose diagnostic test meters and blood glucose diagnostic test strips, being the CareSens brand supplied by Pharmaco. The sole supply period for the CareSens brand ends on 1 July 2015. Until any decisions are made funding of CareSens meters will continue.

PHARMAC commissioned an evaluation report of the implementation of the sole supply arrangement in April 2013 and has considered the recommendations of this report and also stakeholder feedback received during the sole supply arrangement.

PHARMAC has consulted on a proposed approach for the future funding decision-making process for the Products, which was issued on 6 March 2015. Responses to this consultation have been considered and a summary of those responses has been published on our website.

PHARMAC now seeks EOIs from suppliers for the supply of the Products.

3. **EOIs sought**

EOIs are required to provide samples of the Products for testing as set out in Schedule 2 and completion of the EOI form as set out in Schedule 4.

4. **Overview of the anticipated procurement process**

This Invitation sets out stage one of an anticipated two stage procurement process for the supply of the Products.

Stage one (this Invitation) requires suppliers to provide samples of the Products for testing purposes and for PHARMAC to gain an understanding of those Products from information submitted by the supplier (via the EOI form in Schedule 4). Testing at stage one will include laboratory testing and end-user testing by health professionals.

Stage two is intended to be a Request for Proposals (RFP) where PHARMAC would seek commercial proposals from suppliers with Products which have 'pre-qualified' via the evaluation process undertaken as part of stage one (this EOI). Commercial proposals would be sought for sole, dual or multiple supply of the Products for funding in the community and purchase by public hospitals in New Zealand. Further end-user testing of a short-list of Products (i.e. those which are preferred by PHARMAC following its commercial evaluation) will be conducted at this stage by people living with diabetes mellitus.

Further detail of testing is set out in Schedule 2.

Only suppliers that submit an EOI to this Invitation, and whose Products 'pre-qualify' via the PHARMAC evaluation, will be invited to participate in stage two of the procurement process.

Schedule 2

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

1. Submission

(a) You may submit more than one EOI for each type of Product. Each EOI will be considered as a separate EOI.

(b) For the purposes of the evaluation

i. four blood glucose diagnostic test meters and 400 blood glucose diagnostic test strips (i.e. eight vials of 50 test strips) from at least two different batches of test strips; and/or

II. four self-monitoring blood ketone meters plus 80 blood ketone test strips from at least two different batches of test strips; and/or

III. four self-monitoring blood glucose and blood ketone meters (dual meters) plus 400 blood glucose test strips from at least two different batches of test strips and 80 blood ketone test strips for use with meter; and/or

IV. four self-monitoring blood glucose meters for the visually impaired plus 400 meter test strips from at least two different batches of test strips for use with meter.

need to be submitted with the EOI.

(c) EOI forms must be submitted no later than 5pm (New Zealand time) on 10 August 2015. Late EOIs will only be considered at PHARMAC's discretion.

(d) All Product samples must be received by PHARMAC no later than 5pm (New Zealand time) on 10 August 2015. Late Product samples will only be considered at PHARMAC's discretion.

(e) You cannot withdraw your EOI, once submitted, while the evaluation process commences and is continuing.

(f) All EOI forms must be submitted on GETS at (www.gets.govt.nz) or direct to PHARMAC for the attention of Bronwyn Hale, Therapeutic Group Manager, either by hand delivery, by courier, by post or email (and not by facsimile).

(g) The email address is bronwyn.hale@pharmac.govt.nz and the physical address is Level 9, Simpl House, 40 Mercer Street, PO Box 10-254, Wellington 6143, New Zealand.

(h) All Product samples must be submitted to PHARMAC for the attention of Bronwyn Hale, Therapeutic Group Manager, either by hand delivery, by courier or by post. The address is PHARMAC at Level 9, Simpl House, 40 Mercer Street, PO Box 10-254, Wellington 6143, New Zealand.

2. Evaluation

Following the deadline for submitting an EOI, each EOI form and Product sample will be evaluated. The basis on which PHARMAC will evaluate each EOI form and Product sample and the weight to be given to the criteria and any other matters is to be determined by PHARMAC at its sole discretion.

Product samples will be evaluated as follows:

Laboratory testing

(a) Laboratory testing will be conducted by New Zealand based laboratories using an independently developed protocol.

(b) The costs of the laboratory testing service must be met by the supplier for each Product evaluated. The supplier will directly reimburse the laboratory responsible for testing the Product(s). For the avoidance of doubt, for the purposes of testing, a Product means each meter evaluated by the laboratory for the purposes of this clause 2.

(c) The laboratory testing of the Products will assess the effect of interferences, including but not limited to:

(i) maltose, galactose, paracetamol, ascorbic acid, pO2 level, uric acid and haematocrit

(ii) differences in venous and capillary testing of accuracy

(iii) differences in temperature, and

(iv) differences in humidity.

A testing protocol is currently being independently developed and this will be made available to suppliers who submit an EOI.

For the avoidance of doubt; the independently developed testing protocol will replace the protocol for evaluation of self-monitoring blood glucose systems which is set out in the PHARMAC's 'Guidelines for Funding Applications'.

End-user testing

(a) As described in Schedule 1, health professionals will be the 'end-users' for the first round of end-user testing in this stage. Further end-user testing will occur with people living with type one and type two diabetes during stage two (following receipt of commercial proposals).

(b) The end-user testing for Products may include, but is not limited to, a qualitative assessment of the following:

(i) ability to provide test averages

(ii) backlighting and/or port lighting

(iii) size and clarity of date, time and glucose readings

(iv) testing time

(v) memory capacity

(vi) accessories supplied with Products, such as lancing device and log books

(vii) ease of strip canister/packaging for opening

(viii) physical attributes, such as size and colour of Products

(ix) ability to download the Product's readings and the functionality of the program used for the download;

(x) integration with practice management systems in both hospital and community care, and

(xi) any other functions or attributes the Product may possess.

3. Anticipated Timeline

Stage One: Expressions of Interest (EOI)	Activity	Anticipated Time Period
	EOI issued	29 June 2015
	Closure for EOI form receipt	10 August 2015
	Closure for Product sample receipt	10 August 2015
	Laboratory assessment of EOI responses commences	17 August
	End-user assessment of EOI responses commences	14 September
	Suppliers informed of EOI evaluation outcomes	6 November 2015
Stage Two: Requests for Proposals (RFP)	RFP issued	12 November 2015

The above timeframes are only approximate and may be extended, without notice being required from PHARMAC, if any stages of the Invitation take longer than anticipated.

The Invitation will be complete once PHARMAC has notified suppliers of the completion of the Invitation process and PHARMAC has issued an RFP.

4. Miscellaneous

(a) PHARMAC reserves the right:

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

(ii) to seek clarification of any EOI

(iii) to meet with any supplier in relation to its EOI

(iv) to suspend this Invitation process. For example, if during the Invitation process it becomes apparent to PHARMAC that further consultation is appropriate or required we may suspend the Invitation process in order to consult. In this situation we may ask you to resubmit your EOI in light of consultation, or alternatively we may request that a new EOI be submitted

(v) to terminate this Invitation process at any time, by notifying suppliers who submitted an EOI

(vi) to readvertise for EOIs.

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

(c) You must not at any time initiate any communication with PHARMAC's directors or officers, the Ministry of Health, the Minister of Health, District Health Boards or end-user testers, with a view to influencing the outcome of this Invitation process.

(d) You must pay your own costs for preparing and submitting your EOI including the costs associated with the laboratory testing as stated in Schedule 2, Clause 2(b).

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

(f) Your submission of an EOI will be taken as acceptance of the terms contained in this Invitation. PHARMAC may exclude your EOI if you do not comply with any of the terms contained in this Invitation

(g) This is an invitation for expressions of interest and not a tender. Your EOI is not an offer capable of being converted into a contract for the supply of the Products. A supplier's submission of an EOI would enable a supplier to submit a response to any RFP issued as part of stage two of the procurement process.

(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 you or any other person in relation to this Invitation.

(i) PHARMAC will consider your EOI and information exchanged between us in any negotiations relating to your EOI, 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) 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 (ii) 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.

Schedule 3

The following information relates to the estimated Product subsidised unit volumes. The information is approximate and indicative only. PHARMAC makes no representation as to the accuracy of this information and, while PHARMAC has taken all reasonable care in preparing the information set out below, it accepts no liability for any errors or omissions in the information. PHARMAC is not obliged to notify you in the event of any change to the figures below.

Products	**Unit volumes** **FYR* 2012/13**	**Unit volumes** **FYR 2013/14**	**Unit volumes** **FYR** 2014/15**
Blood glucose diagnostic test meters (with 50 lancets)	66,009	12,961	7,285
Blood glucose diagnostic test strips ***	54,434,600	54,819,450	52,987,350
Blood glucose diagnostic test strips (visually impaired) ***	84,400	102,850	81,200
Ketone diagnostic test meter	688	1,224	1,393
Ketone diagnostic test strips	86,760	101,130	115,760

* PHARMAC's financial year runs 1 July – 30 June

**Incomplete financial year. From 1 July 2014 to 31 March 2015

*** 1 unit= 1 test strip

NB: Transition to the sole supply of CareSens meters commenced on 1 September 2012 (which means that the meters & strips were listed from that date) with implementation of the sole supply period commencing on 1 March 2013 (i.e. all other meters and strips were delisted).

INVITATION FOR EXPRESSIONS OF INTEREST FOR THE SUPPLY OF FUNDED DIABETES MANAGEMENT PRODUCTS (INVITATION)

Schedule 4: Expression of interest form

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

NOTE: a separate expression of interest form should be filled out and supplied for each separate meter & its related strips. It is expected that with each different meter, test strips also be supplied as part of the expression of interest.

[*Supplier to insert date*]

Bronwyn Hale
Therapeutic Group Manager
PHARMAC

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

Expression of interest for the supply of diabetes management products.

In response to your invitation for expressions of interest dated 29 June 2015 we put forward the following expression of interests in respect of diabetes management products (the Products).

Set out below is further information in support of our expression of interest.

(a) Our contact details:

Name of supplier	
Contact person	
Address	
Phone	
Facsimile	
Email address	

(b) Details of pharmaceutical presentation:

Product name	
Form [(e.g. strip)]	
Brand name	
Pack size [(e.g. 50)]	
Packaging type [(e.g. foil or tube)]	

(c) Operating information about the Products (to be filled in as appropriate):

Coding required	
Temperature range of operation	
Time taken for test	

Volume of blood required	
Battery type,e.g. CR1032 and number required	
Backlight and/or portlight present	
Averaging function and specifications of averaging, e.g. 7 days	
Ability to download results	
Memory capacity	
Alternative site testing	
Open and unopened strip vial stability	
Strip expiry detection	

(d) Key features of our expression of interest.

PHARMAC is interested in receiving additional information here such as technologies (e.g. voice readings, software functions, blue tooth capability) that are features of the Products. This also includes accessories i.e. lancing devices and meter cases.

(e) Evidence of market approval and any other required consents:

Date of notification to WAND database (if available)	
Evidence of blood glucose meter meeting the ISO 15197:2013 standard	
Insert any other countries approvals for pharmaceutical, for example FDA and/or EU certification (if available)	

(f) Information about current international market share of Products

(g) Information about our ability to ensure the continuity of supply of the Products:

(h) Information about previous supply performance and relevant expertise:

(i) Other relevant information about our brand of Products:

Current availability of an 0800 number (incl. hours of operation)	
Repair/replacement policy	
Other customer services	

(j) Additional information that PHARMAC should consider when evaluating our expression of interest:

Included with this expression of interest are (check where applicable):

☐ four self-monitoring blood glucose meters plus 400 blood glucose meter test strips from at least two different batches of test strips for use with meter.

☐ four self-monitoring blood ketone meters plus 80 blood ketone test strips from at least two different batches of test strips.

☐ four self-monitoring blood glucose and blood ketone meters (dual meters) plus 400 blood glucose test strips from at least two different batches of test strips and 80 blood ketone test strips for use with meter.

☐ four self-monitoring blood glucose meters for the visually impaired plus 400 meter test strips from at least two different batches of test strips for use with meter.