

6 March 2015

Future funding approach for blood glucose meters and test strips

In 2012 PHARMAC moved to sole supply of self-monitoring blood glucose testing meters and strips – the CareSens brand supplied by Pharmaco. The sole-supply period for CareSens meters runs until 1 July 2015.

PHARMAC will be running a competitive process for the supply of self-monitoring blood glucose testing meters ('meters') and test strips during 2015. We are seeking your feedback on a proposed approach to the assessment of meters and test strips for funding.

Until any decisions are made, funding of CareSens meters will continue.

Seeking your feedback

PHARMAC welcomes feedback to our proposed approach. As well as general comments, we are seeking answers to the specific questions, to help inform our procurement process. We also welcome your views on any other related issues not covered in this consultation.

Please submit feedback by **Tuesday 7 April 2015**.

There are a number of ways to respond to this proposal:

1. It is our preference that people respond online at this link: http://consult-pharmac.objective.com/public/blood_glucose_meters/blood-glucose-meters
2. However, you could also:
 - a. email feedback to diabetesfeedback@pharmac.govt.nz
 - b. post feedback to PHARMAC – attention: Diabetes Feedback, PO Box 10 254, Wellington 6143

If you have any questions please contact PHARMAC on 0800 66 00 50

Feedback we receive is subject to the Official Information Act 1982 (OIA) and we will consider any request to have information withheld in accordance with our obligations under the OIA. Anyone providing feedback, whether on their own account or on behalf of an organisation, and whether in a personal or professional capacity, should be aware that the content of their feedback and their identity may need to be disclosed in response to an OIA request.

We are not able to treat any part of your feedback as confidential unless you specifically request that we do, and then only to the extent permissible under the OIA and other relevant laws and requirements. If you would like us to withhold any commercially sensitive, confidential proprietary, or personal information included in your submission, please clearly state this in your submission and identify the relevant sections of your submission that you would like it withheld. PHARMAC will give due consideration to any such request

Background

The sole supply period for the funded CareSens meters and test strips ends on 1 July 2015. The CareSens range of meters and test strips will continue to be subject to a supply contract and funded after 1 July 2015 until further decisions are made and announced. The Accu-Chek Performa and Freestyle Optium brands of meters and test strips and Sensocard test strips remain listed, subject to Special Authority criteria.

PHARMAC is now considering the next steps it should take in relation funding of meters and test strips.

Following the change to the CareSens meters and test strips, PHARMAC commissioned an evaluation of the implementation of the change from Allen & Clarke. PHARMAC has considered the recommendations of [this report](#) in deciding the next steps to take around funding of meters and test strips. We have also listened to stakeholder feedback that was received during the funding and sole-supply implementation of these products.

As a result, PHARMAC is planning to manage the future approach to determining funding of meters and test strips differently.

We will be providing a number of opportunities for stakeholder groups, individuals and suppliers to participate in the process before any funding decisions about meters and test strips are made. It may be up to 18 months before any decisions are made to ensure both clinical and consumer feedback is considered in our decision-making.

Proposed approach

PHARMAC is proposing the following three-step approach including a two-stage procurement process for meters and test strips:

i. Initial request for feedback about the proposed approach

This consultation, which will inform the steps ii and iii set out below.

ii. Request for Information (RFI)

Suppliers would be asked to provide information to PHARMAC in response to specific questions and to provide sample meters and test strips. The meters and test strip samples would be assessed and evaluated according to pre-defined criteria. Specific feedback on the proposed criteria to be used is set out below.

iii. Request for Proposals (RFP)

Similar to in 2011/12, a request for proposals will be issued seeking bids for a sole, dual, or multiple supply arrangement. All options will be considered and evaluated against criteria. Only those suppliers who respond and submit sample meters and test strips in response to the RFI, and whose meters and test strips meet the pre-qualification criteria, would be eligible to submit a competitive proposal.

An Evaluation Committee comprising PHARMAC staff would evaluate each proposal against criteria to select the preferred proposal(s). PHARMAC may also seek external advice on proposals as part of the evaluation process.

RFI Evaluation criteria

PHARMAC is seeking feedback on specific questions outlined below

Functions that a meter or strips must provide/perform

As well as measuring the glucose in blood samples, meters can provide a range of other functions and features that support people to manage their diabetes. For example (but not limited to):

- memory capacity
- backlight display
- coding/non-coding of strips
- packaging
- ability to provide testing averages over 1, 7, 14, 30 and/or 90 days
- ability to delete readings; and
- ability to download readings to GP practice software and patient tracking software

No single meter is likely to have all possible functions; however, we want to know what the most important functions that a meter should have for optimal management of diabetes.

1. Which functions must a blood glucose meter provide/perform?
2. Which functions do you consider are *optional* (i.e. would be nice to have but are not essential)?

Usability

By 'usability' we mean the ease with which people can learn and use a meter and test strips. PHARMAC intends to assess usability as part of the RFI.

International literature does not indicate a definitive way to assess usability; however, based on our research and initial discussions PHARMAC has identified the following three approaches:

- a. Individuals with diabetes attend a clinic/laboratory and are observed performing a few simple tasks with a meter and test strips after having the opportunity to read through the instructions/quick guide. These tasks could include setting date/time and performing a control solution test.
- b. Individuals with diabetes are sent a meter and test strips. They are asked to use it for a 3-4 week period, then provide feedback/assessment based on a structured questionnaire.
- c. Focus groups of up to 10 people with diabetes are held with diabetes nurse specialists as 'facilitators'. The meter and test strips are introduced to the group and they learn and assess the meter and test strips in a group situation.

We think it's important that the individuals or members of groups include a range of people representing New Zealanders with diabetes (for the avoidance of doubt, this would include people who rely on their parents, whanau or caregivers to help them to manage their diabetes). It may be that individuals would assess many different meters, or individual meters may be assessed by different people.

3. What do you consider to be the pros and cons of each of the three approaches outlined above?
4. Do you think that usability testing should use one of these approaches or a combination of these three approaches?
5. Are there any other methods of usability testing you think would be better?
6. What criteria should be used when assessing the usability of a blood glucose meter?

Accuracy/clinical assessment

Meters and test strips would also undergo accuracy testing and clinical assessment. We expect that all meters and test strips submitted for pre-qualification during the RFI would meet the International Standards Organization (ISO) standard (ISO 15197:2013) and, potentially, be FDA and EU approved.

Meters and strips may also need to be tested against other indicators including:

- venous and capillary testing of accuracy;
- temperature assessment;
- humidity assessment; and
- interferences of a physiological nature such as (but not limited to) maltose, galactose, acetaminophen (and other medications), ascorbic acid, pO₂ level, uric acid and haematocrit.

7. What further accuracy and clinical assessment criteria should be considered, ie what further analytical functions should a meter and test strips have?
8. Have you been involved in the testing of meters and test strips or can you suggest who could conduct testing of this type?

Other

We also welcome your views on any other related issues:

9. What support (i.e. educational, information) from suppliers of meters would be desirable?
10. What accessories should be provided with meters - for example a case, lancing device etc?
11. Should different types of meters and test strips be funded for people who are taking different medications (ie a different meter for those administering insulin versus those on oral diabetic medications) or who have differencing clinical circumstances (i.e. are visually impaired or who test for blood glucose and blood ketones)?
12. What software and data capabilities of funded meters are both practical and desirable?
13. Are there any other comments you wish to make related to this proposed approach?

Proposed timeframe

Our anticipated timeline for the proposed two-step procurement process is set out below. If there are delays at any stage, this would likely have flow-on effects to the subsequent stages.

	Activity	Purpose	Time period
Stage One	Consultation	Gather feedback about the proposed approach	6 March 2015 - 7 April 2015
	Evaluation of feedback	Analyse and understand feedback received. Determine next steps.	April, May 2015
Stage Two	Request for information (RFI)	Seek information and samples from all suppliers interested in the supply of funded meters and test strips.	June 2015
	Evaluation of responses	Assess meters and test strips against criteria (such criteria to be determined following stage one feedback).	July to September 2015
	Inform suppliers	Advise suppliers whether their meters and test strips meet the pre-qualification criteria and would (or would not) be eligible to submit a proposal.	September 2015
Stage Three.	Request for proposals (RFP)	Seek competitive bids for supply of funded meters and test strips.	October 2015
	Evaluation of bids received	Determine preferred supplier(s)	November / December 2015
	Negotiation of provisional agreement(s)	Contract negotiations.	December 2015 / January 2016
	Consult on any proposed funding changes	Gather feedback on the proposed supply arrangements.	February 2016
	PHARMAC Decision	The PHARMAC Board or its delegate would make a decision.	March 2016
	Notification	Announcement of the decision	April 2016
	Schedule changes (if any)	Funding arrangements (if any changes) commence	1 June 2016