Diabetes Subcommittee of PTAC meeting held 8 December 2011

(minutes for web publishing)

Diabetes Subcommittee minutes are published in accordance with the *Terms of Reference for the Pharmacology and Therapeutics Advisory Committee (PTAC) and PTAC Subcommittees 2008*.

Note that this document is not necessarily a complete record of the Diabetes Subcommittee meeting; only the relevant portions of the minutes relating to Diabetes Subcommittee discussions about an Application or PHARMAC staff proposal that contain a recommendation are generally published.

The Diabetes Subcommittee may:

(a) recommend that a pharmaceutical be listed by PHARMAC on the Pharmaceutical Schedule and the priority it gives to such a listing;
(b) defer a final recommendation, and give reasons for the deferral (such as the supply of further information) and what is required before further review; or
(c) recommend that PHARMAC decline to list a pharmaceutical on the Pharmaceutical Schedule.

These Subcommittee minutes are yet to be reviewed by PTAC. However, the Chair of PTAC has endorsed these minutes to be made public prior to PTAC's review given PHARMAC's current public consultation on proposals for these products.

Some material has been withheld, in accordance with the Official Information Act 1982 (OIA) to:

(i) protect information where the making available of the information would be likely to unreasonably prejudice the commercial position of the person who supplied or who is the subject of the information (section 9(2)(b)(ii)); and/or
(ii) enable PHARMAC to carry on, without prejudice or disadvantage, negotiations (including commercial and industrial negotiations (section 9(2)(j)).

Contents

1 Diabetes Request for Proposals (RFP) – Insulin Pumps

Discussion

1.1 The Subcommittee noted the Diabetes RFP document dated 26 August 2011 which invited proposals for various diabetes management products including insulin pumps and consumables. The Subcommittee noted that [withheld under OIA (section 9(2)(b)(ii) and/or section 9(2)(j))] preferred proposals had been selected by PHARMAC staff and members were asked to evaluate the technical aspects of the insulin pumps and consumables.

1.2 The Subcommittee considered that the important technical capability of an insulin pump are low basal flow rate and small increments, bolus calculation functionality, alarms for flow blockage, and good screen size with back lighting. The Subcommittee considered that the functions should be intuitive to use, utilising universal icons, and that it should be supported with a clear instruction manual. The Subcommittee considered the quality and robustness of the device to be very important. Members noted that it is important that the pump utilises generic and not specialised batteries so that replacements can be obtained easily.

1.3 The Subcommittee considered that other useful features of an insulin pump may include a Continuous Glucose Monitoring system and remote control operation.

1.4 The Subcommittee considered that a download-able or a web based support system for the device is an important feature to improve the clinical team to patient link.

1.5 The Subcommittee noted that it evaluated [withheld under OIA (section 9(2)(b)(ii) and/or section 9(2)(j))] insulin pumps and corresponding consumables as requested by PHARMAC staff. The Subcommittee considered that the [withheld under OIA (section 9(2)(b)(ii) and/or section 9(2)(j))] insulin pumps offered very basic technical features were not accompanied by useful instructions and that the devices were not as robust as other pumps on the market. The Subcommittee considered both pumps to be of poor quality and with suboptimal technical features compared to other available insulin pumps.

1.6 The Subcommittee considered that the [withheld under OIA (section 9(2)(b)(ii) and/or section 9(2)(j))] insulin pump offered acceptable functionality although it was a very basic pump. The Subcommittee noted that it was accompanied by decent instructions however the Subcommittee were concerned about the durability of the device. The Subcommittee noted that most DHBs in making purchasing decisions had opted not to purchase these pumps despite the higher cost of other devices. Overall, the Subcommittee considered the [withheld under OIA (section 9(2)(b)(ii) and/or section 9(2)(j))] pump to be barely acceptable for funding, and that from both a clinician and patient point of view it would not be a preferred device.

1.7 The Subcommittee considered that a variety of consumables should be available to patients. The Subcommittee noted that 5 to 6 mm needles would be required for paediatric patients, that Teflon rather than steel cannulae provide more comfort and that a 90 degree insertion angle can be easier to insert. The Subcommittee noted that the ability to disconnect the cannulae from the set is very important.

1.8 The Subcommittee considered that the service provision for insulin pumps is an essential component of supply. The Subcommittee noted that service specifications should include 24 hour technical support including the operation of a 0800 number, an expedient replacement service, training and support for clinical staff and patients by expert staff. The Subcommittee noted that the supplier would be expected to provide technical support and training for insulin pump users however under no circumstances should the supplier be providing clinical advice to patients. This may constitute part of the service and supply agreement.

1.9 The Subcommittee considered correspondence from two clinicians supporting the addition of three small patient groups to the Special Authority criteria for insulin pumps. The Subcommittee considered that it would be reasonable to include patients with neonatal diabetes and type 1 equivalent patients such as patients post pancreatectomy and patients with cystic fibrosis related diabetes. However, the Subcommittee considered that in light of its concerns around the [withheld under OIA (section 9(2)(b)(ii) and/or section 9(2)(j)))] insulin pumps reviewed, it may be necessary to revise the approach to funding insulin pumps and that this may involve amendments to the Special Authority criteria or assessing patients' eligibility through a panel.

1.10 The Subcommittee noted that the utility values used in the CUA for reducing hypoglycaemic episodes may not reflect the health gain and agreed to review the evidence PHARMAC had used in its CUA.

2 Diabetes RFP – blood glucose strips and meters

2.1 The Subcommittee considered the Diabetes RFP with respect to the supply of blood glucose test strips and meters. The Subcommittee noted the preferred proposal which had been selected by PHARMAC staff offered three different blood glucose meters, CareSens Pop, CareSens II and CareSens N with two corresponding types of blood glucose test strips, CareSens II and CareSens N.

2.2 The Committee noted that the CareSens N meter is not currently funded however it met the criteria in the assessment performed by Christchurch Diabetes Service. The Committee considered that the meter offered acceptable functionality and was intuitive to use, however it noted that it had not seen evidence of the devices software interface which is an important aspect of the device.

2.3 The Subcommittee considered that the meters ability to detect faulty or damaged test strips is essential and that further information should be sought from the supplier to confirm the device offers this function.

2.4 The Subcommittee noted that it would be useful if the date and time didn't need to be reset when the battery was removed.

2.5 The Subcommittee considered the supply of blood glucose test strips and meters and noted that if a sole supply arrangement were to come into force, it would be preferred if the products were manufactured at more than one site.

2.6 The Subcommittee noted a paper by PHARMAC staff regarding the commercial and contractual benefits a sole supply agreement. The Subcommittee considered that offering a range of meters would be important however, considered that there would be

benefits for clinicians and patients to simplify the range of funded meters to avoid having to learn to operate many devices.

2.7 The Subcommittee noted that a where a large scale meter swap out was necessary, the supplier would need to ensure adequate device and software training to healthcare providers. The Subcommittee noted the scale of the potential swap out and considered that an implementation plan should be developed to ensure a smooth transition. The Subcommittee considered that pharmacy would be a key point of contact with patients to facilitate the swap out and should be equipped with a supply of meters and be able to undertake patient education on the use of the new meter.

2.8 The Subcommittee considered that a transition period of six months should be suitable to ensure that all patients under the care of a GP or specialist diabetes care team receive a prescription for a new meter, or to be informed and referred by other healthcare providers.

2.9 The Subcommittee noted that maintaining supply of blood ketone testing would be important, and that it would be necessary to list the corresponding blood ketone meter.