



PBS Post-Market
Department of Health and Ageing
MDP 900
GPO Box 9848
CANBERRA ACT 2601

2 July 2013

Dear Review Committee

Thank you for the opportunity to submit to *the Post-Market Review of Products Used in the Management of Diabetes* (the Review). Diabetes Australia has also separately responded to your request for information with detail regarding various types of medications. This letter comments on the broad themes of concern regarding the regulation of diabetes medicines, including the need for:

- more clarity around the triggers for, and integration of, various stages of the diabetes reviews
- More recognition of the progressive nature of type 2 diabetes and the need for treatments to vary depending on the stage of diabetes when diagnosed
- more consideration of benefits of some medicines beyond simply HbA1C, and including quality of life benefits
- more individualised approaches to treatment of diabetes
- modernisation and updating of current PBS restrictions to reflect best clinical practice
- higher value placed on clinician and patient choice

As you would be aware diabetes is the fastest growing chronic disease in Australia and all types of diabetes are increasing in prevalence. At least 1.5 million Australians have diabetes, including diagnosed diabetes as well as silent, undiagnosed type 2 diabetes.¹

Given the dramatic growth in the burden of all types of diabetes, Diabetes Australia sees it as timely that access to diabetes treatments and technologies supported through the PBS should now be reviewed with the objective to enhance access and improve outcomes for all Australians with diabetes. Our recently released National Diabetes Strategy and Action Plan calls for a regulatory and approval system which:

- ensures that all Australians with all types of diabetes have affordable access to a range of medicines to enable clinicians to tailor management and best prevent complications and burden”
- takes account of measures and benefits beyond HbA1c and includes wellbeing measures and
- reflect best clinical practice”².

Diabetes reviews

¹ *Diabetes: The Silent Pandemic and its impact on Australia* (2012). Baker IDI Heart and Diabetes Institute

² *National Diabetes Strategy and Action Plan* (2013) Diabetes Australia

The rationale for various stages of diabetes reviews is unclear, and there are concerns that there has not been a cohesive, comprehensive review process, but rather a number of selective reviews that do not appear integrated.

In addition, there is concern among stakeholders that the review is driven by a search for savings within the scheme (as shown in the terms of reference that relate to cost-effectiveness) rather than delivering the best possible health outcomes for people living with diabetes, as well as achieving greater consistency with international best practice.

Recommendation: Diabetes Australia recommends that the post market review committee publish a statement which contextualises all stages of the review, the expected outcomes, and how they may deliver the best possible health outcomes for people with diabetes.

Individualised approach to treatment

It is important to note the international evidence strongly suggests that we need more individualised approaches to optimise the management of diabetes. As type 2 diabetes is a progressive condition, treatment targets and approaches can and should vary based on the stage of diabetes in individual patients.

Targets for optimal diabetes management may be different in certain patient groups. People who are newly diagnosed or in the early stages of Type 2 diabetes who are without complications may benefit from more “aggressive” treatment, and evidence suggests long term benefits to reduction in cardiovascular complications under this treatment. However, people diagnosed and/or treated in later stages of diabetes with existing complications should not have the same “aggressive” treatment.

Recommendation: Diabetes Australia recommends that the review work toward a more flexible approach, allowing clinicians and patients to select treatments according to the stage of the patient’s condition, and fully considering other complicating conditions the patient may have.

Self management

It is also important to note that lifestyle management is the first stage of blood glucose management, and Type 2 diabetes management more generally. Self management is a critical part of this, hence the need to consider SMBG (the first stage of Diabetes Reviews) as a very important, integrated component from the perspective of patients and health professionals supporting diabetes management.

Recommendation: Diabetes Australia recommends that clearer connections be drawn between the three stages of the review, demonstrating that self management is as critical as medication in the best practice management of diabetes.

Management Algorithm

The current Pharmaceutical Benefits Advisory Committee (PBAC) framework for evaluating evidence and recommending restrictions around diabetes medicines does not adequately provide a clinician with the ability to select a treatment inclusive of other considerations: medication side effects for consumers; weight gain; hypoglycaemia; and patient-centric benefits of convenience or other features which can facilitate compliance.

Blood glucose level (HbA1c) is only one part of the management picture. Optimal management of people with type 2 diabetes also targets blood pressure, lipid management, weight management and quality of life/wellbeing measures. These are important considerations for people living with type 2 diabetes and must be central to any post-market review.

The current treatment algorithm is contained in the 2009 endorsed NHMRC *National Based Guideline for Blood Glucose Control in People with Type 2 Diabetes*³. This algorithm was based on available evidence at the time however it only included treatments available through the PBS and took into account any PBS-related prescribing limitations at the time.

An algorithm based on current evidence, and applied regardless of PBS restrictions, would be quite different. A draft, new management algorithm for type 2 diabetes was attached to our technical advice provided separately. Specifically, this includes gliptins and GLP-1 agonists (and when available SGLT2 inhibitors) as options at various steps.

Recommendation: Diabetes Australia has recommended a draft new management algorithm that is consistent with the latest international guidelines and algorithm, and encourages the committee to consider whether current restrictions reflect best practice.

Triple oral therapy

Triple oral therapy is a widely used and effective treatment for improving diabetes management in many patients with type 2 diabetes. The preferred international option for triple oral therapy is metformin + SU + gliptin and the lack of this triple oral therapy as a PBS reimbursed option in Australia is a major limitation to achieving good quality care.

In addition it is important that the Diabetes Review consider the policy consequences of disincentives to bringing new therapies to the Australian market. This presents particular risk if innovative therapies are forced to demonstrate cost-effectiveness against older products with decreasing clinical relevance and falling prices due to generic price disclosure.

In conclusion diabetes is a complex disorder, and clinicians and patients need a range of options to treat it effectively. This will not only improve the lives of people living with diabetes, but will also ensure the best use of limited funds for the PBS and the health budget more generally.

³ National Health & Medical Research Council. 2009. *National Based Guideline for Blood Glucose Control in People with Type 2 Diabetes*.

<http://www.nhmrc.gov.au/files/nhmrc/publications/attachments/di19-diabetes-blood-glucose-control.pdf>

Again, we thank you for the opportunity to contribute across the stages of the Diabetes Reviews and look forward to further opportunity to work with the PBAC to ensure the PBS provides the best possible access to medicines and technology to achieve the best possible health outcomes for all Australians with diabetes.

Sincerely,

A handwritten signature in black ink that reads "Greg Johnson". The signature is written in a cursive style with a large initial 'G'.

Prof. Greg Johnson
Chief Executive Officer
Diabetes Australia