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PBS Post-Market
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Prescription Medicine

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Post Market Review of Products Used In the Management of Diabetes

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Dear Sir or Madam,

Boehringer Ingelheim welcomes the opportunity to submit to the Post Market Review of Products Used in the Management of Diabetes (Review).

Diabetes mellitus is a National Health Priority Area, which highlights the importance of preventing and treating this chronic condition in all Australians. Diabetes is associated with many other medical conditions including coronary heart disease, stroke, peripheral vascular disease, blindness, limb amputation, kidney failure and diabetic neuropathy. Some of these complications can lead to an increase in deaths. The Australian Institute of Health and Welfare noted in its recent report *Australia's Health 2012*¹ that there was a marked increase in the age-standardised prevalence of diabetes from 1.5% in 1989-90 to 4.1% of the population in 2007-08. The prevalence is likely to increase as the population ages.

¹ Australian Institute of Health and Welfare 2012. Australia's health 2012. Australia's health series no. 13. Cat. No. AUS 156.

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Data from the AusDiab study indicate that a significant proportion of diabetes cases go undiagnosed². The survey found that half of the cases detected in the survey had not been previously diagnosed with diabetes. Type 1 diabetes usually occurs in children or adolescents. Type 2 diabetes, also known as adult-onset diabetes or non-insulin-dependent diabetes, is characterised by peripheral insulin resistance and/or inadequate insulin secretion. Gestational diabetes is a form of diabetes that can develop during pregnancy. Individuals with type 2 diabetes have the capacity to produce insulin but this production is qualitatively and/or quantitatively insufficient to maintain normal blood glucose levels. It is estimated that only 30 to 50% of Australians with type 2 diabetes achieve control in their HbA_{1c} (glycosylated haemoglobin) levels³.

The Diabetes Australia/Royal Australian College of General Practitioners management guidelines are the most widely used diabetes guidelines in Australia⁴. It is recommended that all patients with type 2 diabetes undertake self-monitoring of blood glucose (SMBG). Patients may vary the frequency of testing depending on disease stage and treatment goals. SMBG can help patients and their clinicians identify hypoglycaemic episodes and guide treatment decisions. The ability of patients to self-monitor blood glucose levels is a component of patient managed care, which is increasingly recognised as having an important role in effective diabetes management.

The utilisation and patterns of use of blood glucose test strips should be considered in the context of their clinical effectiveness and cost-effectiveness, not just total cost. This may vary between different patients and by disease severity. SMBG can improve glucose control when patients make decisions based on measured glucose levels. These can include changes in diet, changes in physical activity or modification of pharmacological treatments. Self-monitoring may also help improve compliance in many patients with type 2 diabetes, especially in patients with unstable glucose levels, or to assess the impact of changes in treatment. Clinical efficacy is therefore influenced by the frequency of testing, degree of patient adherence and compliance as well as the level of patient engagement. These factors will also influence the cost-effectiveness of SMBG. This may vary between patients, for example those with well controlled HbA_{1c}

² AusDiab Report, 2005. International Diabetes Institute, 2005.

³ Bereznicki L. Australian Pharmacist, June 2012: 566-569

⁴ Diabetes Management in General Practice, Guidelines for Type 2 Diabetes.2010. Diabetes Australia/Royal Australian College of General Practitioners.

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levels compared with poorly controlled HbA_{1c} levels. The cost-effectiveness may also be different in patients initiating new treatments compared with patients who are in the maintenance phase of treatment.

Please feel free to contact me should you require any additional information.

Yours sincerely,

Peter Germanos
Head of Market Access, Pricing and Outcomes Research