# DIABETES AUSTRALIA

# SUBMISSION

## AUSTRALIAN GOVERNMENT REVIEW OF PRODUCTS AND MEDICINES USED IN THE TREATMENT OF DIABETES:

## PHASE ONE: SELF-MONITORED BLOOD GLUCOSE TESTING FOR PEOPLE WITH TYPE 2 DIABETES MELLITUS

15 November 2012

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*About Diabetes Australia*

Diabetes Australia is the national peak body for diabetes, comprised of state consumer organisations and health professional and research bodies dedicated to diabetes.

## Executive Summary

Type 2 diabetes is a chronic, progressive condition. Optimal management of blood glucose levels is required to slow the progression of diabetes and to prevent the development of complications, e.g. retinopathy, nephropathy, cardiovascular disease. Glycated haemoglobin (HbA1c) is a measure of average blood glucose over the past 8-12 weeks; a target of 7% or less reduces the risk of complications. In Australia, the average HbA1c of people with type 2 diabetes is 7.9%.

Given than people with diabetes spend an average of just six hours per year with their healthcare professionals, more than 99% of diabetes care is self-care. This requires people with diabetes to be informed, active participants in their healthcare to maintain their health and well-being, and slow the progression of the condition. Self-management of diabetes incorporates lifestyle modifications, taking medications (tablets/insulin) as recommended, monitoring blood glucose, attending healthcare appointments, and managing risk. Due to its progressive nature, 50-75% of people with type 2 diabetes will eventually require insulin.

Self-monitoring of blood glucose (SMBG) is a self-management strategy that can help people with diabetes identify how their blood glucose patterns are affected by food, physical activity, medications, illness, stress and other variables. It enables them and their healthcare professionals to make timely decisions about how to manage the condition.

***Clinical outcomes and benefits of SMBG relative to HbA1c monitoring alone for people with type 2 diabetes not treated with insulin***

While many randomised controlled trials and systematic reviews have concluded that SMBG may be ineffective in people with non-insulin-treated type 2 diabetes, in the past three years high-quality evidence has mounted in support of the clinical effectiveness of a *structured* approach to SMBG, which can contribute to improved HbA1c and general emotional well-being. Structured SMBG is defined as blood glucose monitoring at defined intervals (e.g. seven times daily for three days) with timely interpretation of blood glucose patterns to inform appropriate pharmacologic and/or lifestyle adjustments.

Structured SMBG is important because it provides biofeedback, enabling people with non-insulin-treated type 2 diabetes to learn about the impact of diet, physical activity and oral medications on their blood glucose levels and ensure timely and aggressive management choices when HbA1c is not at target.

HbA1c monitoring alone is insufficient. As a measure of average blood glucose levels over the past 8-12 weeks, HbA1c is not sufficient to optimise diabetes self-management. Nor does it provide information about the potentially problematic high and low blood glucose fluctuations that occur throughout the day, as a direct result of food intake, physical activity, stress and medications. Furthermore, given the costs involved in visiting a GP, it is unclear whether people with type 2 diabetes have their HbA1c checked as frequently as recommended. Evidence indicates, however, that even when HbA1c has been checked, people with diabetes do not necessarily recall their most recent HbA1c value or understand its meaning.

***Risks of restricting or removing access to SMBG test strips***
Any proposal to restrict or remove access to blood glucose monitoring test strips for people with non-insulin-treated type 2 diabetes would be a fundamental change to the universal access rights of Australians with diabetes and must take into account the likelihood of serious and far reaching risks and adverse consequences. Risks include those related to hypoglycemia and hyperglycemia; delay of treatment escalation; perpetuating misconceptions that type 2 diabetes is not a serious condition; and discrimination. There is no clear evidence that restrictions on access would actually be cost-saving, given that people with non-insulin-treated type 2 diabetes currently use SMBG on average only once per day. Restricting or removing access to test strips may impact negatively on physical and mental health, and there would be new costs associated with implementation of any restrictive arrangements and in dealing with those negative impacts.

SMBG should be available and accessible to people who choose to check their blood glucose intermittently to inform their self-management decisions, and to people with diabetes risk factors who are on diabetogenic medications.

***Summary of evidence***
Taken as a whole, the evidence suggests that:

- there is no simple cause-effect relationship between SMBG and clinical outcomes for people with non-insulin-treated type 2 diabetes;
- valid assessment of the contribution of SMBG depends on applying the appropriate expectations and on taking into account the training, motivation and skills of people with diabetes and their health professionals;
- the role of individual preference for methods of monitoring glycaemic control is important;
- SMBG can play an important role in supporting self-management for people with non-insulin-treated type 2 diabetes by facilitating understanding of glycaemic control, providing biofeedback relating to diet/activity and medication choices in a convenient and practical manner, providing reassurance about successful self-management;
- a structured approach to SMBG can contribute to clinically significant improvements in HbA1c levels and general well-being;
- a structured approach to SMBG is likely to be cost-effective;
- healthcare providers should assess and consider individuals' psychological needs when assisting newly-diagnosed patients to commence SMBG; and
- reliance on HbA1c alone cannot replace the need for SMBG.

## Recommendations

Diabetes Australia makes the following recommendations in relation to SMBG for people with non-insulin-treated type 2 diabetes:

1. Structured SMBG should be supported as an appropriate and important element of effective self-management and person-centred, individualised care which provides meaningful and actionable information to clinicians and to people with diabetes. It is the quality use of SMBG (how the information is interpreted and acted upon) rather than SMBG per se, or the frequency of SMBG, that is crucial for effecting improvements in HbA1c and well-being.

2. Structured SMBG within the context of individualised care should be supported as being in the best interest of people with non-insulin-treated type 2 diabetes and as an opportunity to rationalise the use of blood glucose testing strips.

3. Structured SMBG requires that sufficient resources be made available to ensure people with diabetes and health care professionals have the necessary training and competence to perform, interpret and take action in relation to SMBG patterns.

4. The universal access rights of people with diabetes in Australia to access the National Diabetes Services Scheme should not be changed. If the Australian Government is to consider restrictive policies, this will need clear evidence of benefits and extensive consultation with Diabetes Australia and consumers to properly address the additional resources that would be required to administer new arrangements and ensure that the adverse consequences are identified and avoided or managed.

## 1. Utilisation and patterns of use of self-monitoring of blood glucose (SMBG) for people with type 2 diabetes

More than one million Australians living with diabetes are registered with the National Diabetes Services Scheme (NDSS). Of these, almost 900 000 have type 2 diabetes. Figure 1 shows the number of NDSS registrants with different types of diabetes.

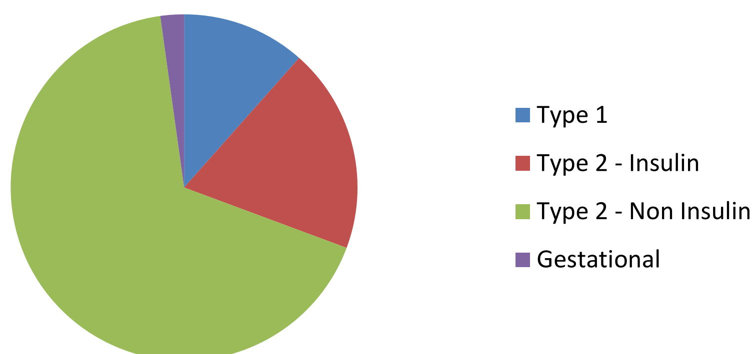


**Figure 1: NDSS Registrants (as at 30 June 2012)**
Type 1: 119 227 Type 2 insulin: 197 411 Type 2 non-insulin: 693 119 Gestational: 22 679

Not all NDSS registrants access supplies and services. Between 1 July 2011 and 30 June 2012, access by registrants with type 1 diabetes remained relatively stable, while the number of registrants with type 2 diabetes accessing services and supplies increased by just over 8% (with a 7.15% increase by registrants with non-insulin treated type 2 diabetes). Of all NDSS registrants with type 2 diabetes, 58% purchase blood glucose testing strips. Just over 12% more people with non-insulin-treated type 2 diabetes purchased testing strips in 2011-12 than in 2010-11.

Table 1 shows that the average number of blood glucose testing strips purchased per registrant with non-insulin treated type 2 diabetes has remained relatively stable, with only a 1.5% increase over the past year and an increase of just over 2% since 2008-09. Averaging just over 300 strips a year (less than one per day) per registrant, use does not appear to be excessive. (Current NDSS data do not include information about how, when and under what circumstances testing strips are used.)

**Table 1: Average number of blood glucose testing strips purchased per accessing registrant (packs of 100 strips)**

| Diabetes type | 2008-09 | 2009-10 | 2010-11 | 2011-12 | 4-yr increase | 1-yr increase |
|---|---|---|---|---|---|---|
| Type 1 | 10.3 | 10.7 | 11.1 | 11.5 | 12.4% | 4.0% |
| Type 2 - insulin | 5.5 | 5.7 | 5.9 | 6.4 | 16.9% | 8.6% |
| Type 2 – non insulin* | 3.064 | 3.088 | 3.088 | 3.135 | 2.3% | 1.5% |
| Total type 2 | 3.9 | 4.0 | 4.0 | 4.1 | 5.5% | 3.1% |

*additional decimal places show slight variations in average packs purchased

## 2. Clinical outcomes and benefits of self-monitoring of blood glucose (SMBG) relative to HbA1c monitoring alone for people with type 2 diabetes not treated with insulin

### 2.1 What should be expected from SMBG?

In responding to the issue of clinical outcomes and benefit of SMBG, Diabetes Australia believes that it is important to understand the role and limitations of SMBG.

As a device that produces information, a blood glucose meter should be thought of as a *tool* rather than an *intervention* -- or, as 'a diagnostic measure for modifying patient behaviour and therapeutic decisions by doctors'.[1]

Understanding the role of SMBG has important implications for expectations about what may or may not happen in relation to its use. Expecting measurable improvements in clinical outcomes from SMBG has been described as being akin to expecting a fever to be lowered as a result of using a thermometer to take your temperature[2].

This is an important point, as there is a faulty assumption inherent in the PBAC's request for comments about 'clinical outcomes and benefits of SMBG': that is, that SMBG, *per se*, can be held responsible for clinical outcomes and benefits. In our view, clinical outcomes and benefits cannot reasonably be expected to arise from the use of a measurement tool. What really needs to be asked is: what are the circumstances in which SMBG can be a useful strategy for people with non-insulin-treated type 2 diabetes?

We would also suggest that 'clinical outcomes' is an overly-narrow end-point which ignores many well-established goals of diabetes self-management (see section 2.7). The International Diabetes Federation (IDF) has determined that SMBG offers people with non-insulin-treated type 2 diabetes a range of important potential benefits.[3] These relate to facilitating diabetes education and understanding of the condition; fostering behavioural changes through the provision of biofeedback on the impact of lifestyle, special situations and medications; and optimising therapy by supporting the healthcare team in developing individually-tailored advice about lifestyle components and blood glucose-lowering medication.

### 2.2 Assessing the evidence for and against SMBG

In assessing the evidence, we have found that many systematic reviews and randomised controlled trials published over the past decade have questioned the effectiveness of SMBG

among people with non-insulin-treated type 2 diabetes. Conversely, since 2009, evidence has mounted indicating significant clinical and psychological benefits of a *structured approach* to SMBG embedded within an educational and collaborative care model. Results include clinically and statistically significant improvements in HbA1c, diabetes-related self-confidence, and general emotional well-being.

The recent systematic review published by the Cochrane Collaboration[4] is the latest attempt to resolve the question of whether SMBG is effective (and cost-effective) among people with non-insulin-treated type 2 diabetes. To the extent that the review treated SMBG as an intervention rather than a tool to inform intervention, however, it is unsurprising that little evidence was found to support anything other than minimal impact of SMBG for people with non-insulin-treated type 2 diabetes.

Among the factors that will influence the effective use of SMBG are:

- agreement and understanding of clinical question to be addressed;
- establishment of blood glucose targets;
- recommended frequency and timing of SMBG;
- training of health professional in interpretation of SMBG data;
- training of the person with diabetes in use of the blood glucose meter and interpretation of SMBG results;
- support and enthusiasm of health professional for SMBG;
- appropriate feedback of SMBG data to the person with diabetes;
- a plan for how to intervene to improve the blood glucose levels, e.g. to change diet/activity level or medications;
- action, i.e. a change in diet/activity level or medications, and reflection on the effectiveness of changes made; and
- motivation of the person with diabetes to use SMBG, which may be contingent on all of the above to ensure that it is not a frustrating experience producing meaningless or demoralising information.

Few studies have incorporated all factors and, therefore, it is unsurprising that findings are somewhat inconsistent.

In summary: where education and support for SMBG are minimal (ie, where SMBG itself is regarded as an intervention rather than a tool to inform intervention), then the benefits for HbA1c are minimal; where education and support for SMBG are optimised and particularly where *structured* SMBG is utilised, then the clinical outcomes and other benefits can be substantial.

### 2.3 Structured and unstructured approaches to SMBG

The IDF *Global guideline on self-monitoring of blood glucose in non-insulin treated type 2 diabetes*, released in 2009, advocates a structured approach to SMBG (where 'structured' refers to the gathering of data according to a defined regimen, then interpreted and utilised to make appropriate pharmacologic and/or lifestyle adjustments). The Guideline recommends that SMBG should be used only when people with diabetes and their clinicians, 'have the knowledge, skills and willingness to incorporate SMBG monitoring and therapy adjustment into their diabetes care plan in order to attain agreed treatment goals'. It also recommends

performing SMBG initially and then periodically to obtain information from blood glucose profiles.[5] We believe that the Guideline and its recommendations remain valid. The Guideline is likely to be updated in 2014.

Since the release of the IDF Guideline, more studies have been conducted which focus on the impact of SMBG among people with non-insulin-treated type 2 diabetes. The findings of these studies highlight the differences that can result from a structured versus an unstructured approach.

*2.3.1* *Unstructured approach to SMBG*

The evidence suggests that, where SMBG is undertaken in an unstructured way (ie, with minimal education and support and outside a collaborative care model), the clinical benefits associated with SMBG tend to be minimal or non-existent.

The recent Cochrane review concluded that for people with non-insulin-treated type 2 diabetes, SMBG offers little if any clinical benefit. A similar conclusion was drawn by Farmer and colleagues[6] following their meta-analysis of six randomised controlled trials. They found that there was limited benefit, and no clinically meaningful effect, from SMBG. In both cases, none of the studies reviewed used a structured approach to SMBG, and many did not involve training to either the person with diabetes or to the doctor/health professional to ensure that results could be interpreted and actioned appropriately.[7]

Despite the Cochrane review, and the meta-analysis by Farmer and colleagues reporting a 'statistically significant' improvement in HbA1c with SMBG, the improvements were not considered 'clinically significant'. Farmer and colleagues noted that there was no investigation of other important endpoints, such as psycho-social outcomes. The Cochrane review found there was insufficient data on the effects of SMBG on other outcomes, such as patient satisfaction, general wellbeing or general health-related quality of life. The Cochrane review also noted that more research is needed to explore the psychological impact of SMBG – and that there is some evidence that structured, rather than unstructured, SMBG is associated with improved general wellbeing.[8] Given the significant rates of diabetes-related anxiety, distress and depression among Australian adults with type 2 diabetes, this is an important finding.[9,10]

*2.3.2* *Structured approach to SMBG*

A structured approach optimises the education and support provided for SMBG. In a structured approach:

- skills training is provided for people with diabetes and their health professionals;
- data are gathered according to a defined regimen;
- data are interpreted with structured feedback loops; and
- there is an action plan that allows for appropriate pharmacological and/or lifestyle adjustments according to the results.

The following clinical recommendations for structured use of SMBG were developed following a qualitative study of the perspectives of people with type 2 diabetes[11]:

- Education about SMBG should be ongoing and tailored to individual needs at any stage in the person's diabetes management;

- Individuals should be given clear, consistent signals from the various health professionals whom they consult regarding the need for SMBG relative to their personal situation and clinical outcomes and how they should interpret readings;
- Clear management goals should be negotiated and agreed between clinicians and individuals with diabetes;
- How to respond to readings that are out of target range (lower or higher readings) should be a key aspect of self-management education;
- People with type 2 diabetes should have a clear understanding about the relationship between individual readings and patterns in blood glucose results; and
- The connections between HbA1c and SMBG should be made explicit, to enable better understanding of the relation between, and importance of, short, medium, and long term glycaemic control.

A recent comprehensive review by Parkin and colleagues highlights the differences between structured and unstructured approaches to SMBG.[12] It concluded that trials of structured SMBG demonstrate significant clinical outcomes and other patient-important benefits. In contrast, SMBG conferred no benefits when participants were not advised about how to interpret or respond to their SMBG data and when healthcare providers were asked to make no medication changes – in other words, when SMBG data were gathered but not acted upon, in contradiction to IDF recommendations.[13]

The overall findings of this review led the authors to conclude that:

> ‘glucose information from structured SMBG appears helpful in managing T2DM when those data are used to make appropriate therapeutic changes, lifestyle and/or drug interventions. Within this framework, SMBG serves as an effective means of communicating relevant data to achieve desired, individualized therapy goals’.

They further noted that:

> ‘… when incorporated into a comprehensive intervention that encourages strong collaboration between patients, physicians and other members of the healthcare team, structured SMBG guides pharmacologic therapy and facilitates healthy lifestyle changes. These interventions are not only *clinically effective*, but they are practical and easily applied within primary care settings where the majority of patients are treated.’ [emphasis added]

These findings are consistent with those of other researchers who have noted that regular reinforcement, counselling and collaborative intervention approaches are key factors in the likelihood of SMBG leading to lowered HbA1c.[14]

Beyond the traditional endpoint of HbA1c, additional benefits of structured SMBG include:

- significant improvements in weight, BMI, waist circumference, blood glucose, blood pressure, cholesterol, and HbA1c, as well as physical and mental health and general emotional wellbeing[15];

- empowerment of people with type 2 diabetes to achieve nutritional and physical activity goals[16] -- significant because healthy diet and physical activity can improve glycaemic control, and SMBG is the only tool available to people with type 2 diabetes to visualise

immediate the effects of food pattern and exercise on blood glucose levels;

- facilitating more timely and aggressive treatment changes[17]--significant because studies have shown that early and intensive treatment improves insulin production and reduces cardiovascular risk in type 2 diabetes[18,19];

- a positive impact on a person's ability to cope with diabetes 'at the level of lifestyle and general attitude or a shift of the locus of control toward the patient'[20] and greater self-confidence in diabetes management and a strong belief in the individual's own ability to manage their diabetes; furthermore, that these positive attitudinal changes are significantly associated with improvements in glycemic control[21];

- apparent cost-effectiveness, as structured SMBG (e.g., a seven-point blood glucose profile taken on three consecutive days one week before the GP visit, four times per year) is relatively inexpensive and naturally rationalises the use of blood glucose testing strips to predefined times when SMBG is likely to be most meaningful and positive action taken -- this also suggests that it is not the frequency of SMBG, but the quality use of SMBG, that matters.

> '*Structured SMBG provides crucial information that allows clinicians to identify and address specific patterns of hyperglycemia and hypoglycemia when they are evident, evaluate the effects and efficacy of therapy changes, and monitor glycemic control on an ongoing basis to address emerging issues as diabetes progresses. Also, the availability of structured SMBG data seems to facilitate more timely diabetes treatment and persistent therapeutic adjustments*.'[22]

### 2.4 Gaps and weaknesses in the evidence about SMBG for people with non-insulin-treated type 2 diabetes

The existence and significance of gaps and weaknesses – in the actual findings of studies as well as in their interpretation – must be taken into account when assessing the evidence. The recent Cochrane Collaboration review also acknowledges the limitations of many studies, as well as the potential contributions of SMBG to patient self-management (see section 2.7 re self-management).[23]

It is difficult to draw confident conclusions about the evidence concerning the efficacy of SMBG in non-insulin-treated type 2 diabetes, given the inconsistencies in, and limitations of, the findings of various studies. Differences in study designs, populations, and interventions have contributed to these inconsistencies and limitations.[24] The analysis of one major multi-centre study alone identified more than 60 possible confounders.[25]

Gaps, weaknesses and fallacies in the evidence include:

- Treating SMBG as an intervention rather than a tool. This is the 'thermometer and fever' problem: assuming a direct cause/effect relationship between a measuring tool and a clinical outcome, when the relationship is actually more complex. Unless blood glucose data are used to guide lifestyle or therapy decisions, it seems unreasonable to expect a positive (or linear) relationship between SMBG and glycaemic control.

- The difficulty of making valid comparisons between studies when the circumstances under which SMBG is performed and used may differ and may not have been described adequately -- for example, whether SMBG is 'structured' or 'unstructured', the extent of patient education, the extent of health professional support/intervention, the failure to consider whether or how study participants have been taught to take action on test results and whether and to what degree SMBG data were used to guide treatment changes[26]; the failure to consider the physiological, behavioural, and social circumstances in which SMBG is carried out[27].

- The difficulty of making meaningful comparisons between intervention and control groups in some studies because of the 'Hawthorne effect' -- where participants' outcomes improve as a result of being part of an experiment or study.

- Questionable interpretations and conclusions due to a lack of clarity about the degree to which study participants performed the tests as and when required[28].

- Questionable interpretation of relatively small movements from baseline levels in some studies – for example, whether it is reasonable to expect clinically significant improvements when baseline HbA1c was close to optimal; or, alternatively, whether apparent improvements in HbA1c following SMBG simply reflect a normalisation of levels in response to a worsening of glycaemic control prior to the start of SMBG[29].

- The failure of studies to consider the performance of monitoring equipment under real-world conditions.

- The unknown applicability of non-Australian SMBG studies to the Australian diabetes care context.

- The presence of other methodological and statistical problems, particularly in observational studies. For example, observational studies may show no relationship between SMBG and glycaemic control because SMBG frequency may be related to both optimal and sub-optimal glycaemic control – that is, people with sub-optimal glycaemic control may monitor frequently (in an effort to remedy this situation) or infrequently (contributing to their high HbA1c); and those who have optimal glycaemic control may monitor frequently (explaining how they achieve their optimal outcomes) or infrequently (as they do not perceive a need to do so).[30]

In short, while the methodological rigour of many studies has been appropriate, relatively few have been designed to answer the right questions:

(a) does a structured approach to SMBG in which people with diabetes (and their health professionals) have the requisite education, motivation and skills lead to measurable changes in lifestyle and/or medications, and

(b) do such changes effect improvements in biomedical outcomes (e.g. HbA1c, weight) and psychosocial outcomes (e.g. wellbeing, confidence).

Given the limitations of many of the current studies, we support Baker IDI Heart & Diabetes Institute's call for better studies and for more information about potential variables that may affect the role of SMBG in achieving glycaemic control.[31]

Diabetes Australia is aware of one ongoing Australian study, which is an implementation trial of the US STeP Study[32] (using a structured SMBG approach), which began this year, funded by Roche Diagnostics Australia and led by an independent advisory board which includes Professor Jane Speight, Foundation Director at the Australian Centre for Behavioural Research in Diabetes.

**2.5 How does SMBG compare to HbA1c monitoring alone?**

Glycated haemoglobin (HbA1c) is an average measure of glycaemic control over the past 8–12 weeks. It is used reliably as an indicator of future health due to its linear relationship with the risk of complications. However, our assessment of the evidence indicates that it is doubtful that this test can replace the need for SMBG, even among those with non-insulin-treated type 2 diabetes.

HbA1c does not provide insight into daily fluctuations (the high and low blood glucose levels) that may have occurred over the preceding 8-12 week period. In addition, the results of this test do not provide specific guidance on how to improve the HbA1c. This makes it difficult for healthcare providers to tailor a management plan to an individual's needs or to discuss blood glucose control in a meaningful way with the individual. For someone with non-insulin-treated type 2 diabetes who is seeking to optimise day-to-day self-management, it is unlikely that HbA1c alone can provide the necessary information.

Parkin makes the comparison this way:

> 'Although A1C is commonly used to assess long-term glycemic control, it does not provide information about intraday glucose excursions. You cannot problem-solve with an A1C [HbA1c] value. Structured SMBG fills this information deficit by identifying significant glycemic excursions throughout the day and night.'[33]

Medicare allows for up to four HbA1c tests per year, but a medical consultation and pathology attendance is required which adds a cost and a barrier. As a result, HbA1c may not be tested as often as recommended, which can cause delay in responding to the negative impact of lifestyle changes, and may not allow for timely adjustment of treatment for both newly diagnosed and those who may be progressing to medication/insulin. Although intensification of treatment is currently usually driven by HbA1c, it relies on medical consultation and pathology visit, which can be a deterrent for some people. This is particularly concerning in those with HbA1c above target. SMBG, on the other hand, does not require pathology visits.

Furthermore, those people with diabetes who understand and undertake structured SMBG may be more likely to visit their healthcare professional to seek out intensification of treatment if they perceive their blood glucose patterns to be sub-optimal.

**2.6 Evidence summary**

Taken as a whole, the evidence suggests that:

- there is no simple cause-effect relationship between SMBG and clinical outcomes for people with non-insulin-treated type 2 diabetes;

- valid assessment of the contribution of SMBG depends on applying the appropriate expectations and on taking into account the training, motivation and skills of people with diabetes and their health professionals;
- the role of individual preference for methods of monitoring glycaemic control is important;
- SMBG can play an important role in supporting self-management for people with non-insulin-treated type 2 diabetes by facilitating understanding of glycaemic control, providing biofeedback relating to diet/activity and medication choices in a convenient and practical manner, providing reassurance about successful self-management;
- a structured approach to SMBG can contribute to clinically significant improvements in HbA1c levels and general well-being;
- a structured approach to SMBG is likely to be cost-effective;
- healthcare providers should assess and consider individuals' psychological needs when assisting newly-diagnosed patients to commence SMBG; and
- reliance on HbA1c alone cannot replace the need for SMBG.

In our view, the evidence supports the recommendation of the Baker IDI Heart & Diabetes Institute[34] that:

> 'the use of SMBG may be encouraged as part of diabetes self-management in most people with non-insulin treated type 2 diabetes, provided there is adequate education, supervision and assessment. In particular, SMBG is associated with greater individual engagement with ones' own glycaemic control and lifestyle related needs.'

### 2.7 SMBG and self-management for type 2 diabetes

The section explains the context of diabetes self-management and the role of SMBG in self-management and individualised care.

Self-management refers to what people with a chronic disease or condition do to actively manage their own health and well-being. It has been broadly defined as: involving individuals with a chronic condition working in partnership with their families/carers and health professionals so that they can:

- know their condition and various treatment options;
- negotiate a plan of care;
- engage in activities that protect and promote health;
- monitor and manage the symptoms and signs of the condition;
- manage the impact of the condition on physical functioning, emotions and interpersonal relationships; and
- have confidence in their ability to use support services

Successful self-management includes ensuring that people with diabetes feel that their treatment plan makes sense, that it is effective, and that they have the ability to succeed in helping to manage their condition. This is important because there are links between better self-management and lower levels of anxiety and distress and better glycaemic control.[35] SMBG has been found to not only engage individuals in self-management, but to help them understand where there may be a problem, allow them to help in devising a solution, and 'they leave the office visit knowing what to do, why to do it, how to assess the results of their efforts, and what they need to do if they do not get the desired results.'[36] Individuals

themselves have endorsed this view, with participants in the structured SMBG group in the STeP study stating that the intervention helped them better understand their diabetes and the effects of their medications and behaviours on their glucose control. They also felt that the data collection provided a focal point for more meaningful discussions with clinicians.[37]

Self-management principles have underpinned diabetes education and service delivery for many years. The overall aim is for people to be informed, active participants in their health care to maintain health, and prevent or slow the progression of their disease or condition. Self-management also plays a key role in reducing health services utilisation.[38]

Encouraging active self-management in chronic disease has featured in chronic disease framework and strategic documents adopted at both the federal and State/Territory levels. In Victoria, for example, the Department of Health's Chronic Disease Management guidelines, Integrated Chronic Disease Management Guiding Principles and Health Independence guidelines all emphasise self-management as a foundation of service delivery to people with diabetes and other chronic conditions.

*2.7.1 SMBG as a self-management tool*

Diabetes requires people to actively manage their condition throughout the day, every day. Because individuals are responsible for so much of their own care, which focuses on glycaemic control, they need immediate and ongoing feedback. They also need to assess the significance of the information generated by their glucose monitoring and use that information to make appropriate changes in health-related behavior.

SMBG is a self-management tool or strategy which can help people with diabetes understand how their blood glucose levels may be affected by food, lifestyle choices, medications, illness and stress and other variables. Structured SMBG provides immediate and important feedback which helps individuals make better sense of their treatment regimen by showing the connections between their actions and their blood glucose levels.

Not everyone with diabetes wants to utilise SMBG, and some may not do it effectively; however, those who do benefit from testing should be able to continue, and attention should be given to improving use which is non-productive or sub-optimal.

SMBG need not be a standard recommendation for everyone with type 2 diabetes but should be accessible to those with high or unstable blood glucose measures and to those who find it useful. In the case of those with high or unstable blood glucose levels, both ongoing SMBG and intermittent SMBG are options, with readings used to specifically inform behaviour change or medical therapy intensification.

> *'In my practice all those who are diet controlled, on oral hypoglycemic agents that do not induce hypoglycaemia, or are on oral hypoglycemic agents and are well controlled, are given the option of, after an initial two month period to understand how diet impacts on glucose levels, of either continuing with testing regularly or testing at their discretion, with the understanding that as their disease progresses regular testing will become a necessary part of management.'*
> – Endocrinologist, Victoria

Diabetes Australia believes that assessing the value of SMBG based only on 'clinical

outcomes and benefits' is unnecessarily limited, given the role of SMBG in supporting self-management through education and understanding and encouraging and supporting behavioural changes. The benefits of SMBG in these contexts, as well as in the context of clinical outcomes, depend not so much on whether SMBG is used, but on how the resulting information is used.

The relationship between SMBG and self-management for diabetes has been highlighted by the IDF, who have noted that the effective use of SMBG can contribute to both education and treatment by providing:

- support to enhance a diabetes care program that aims to educate people about their condition;
- an instrument for objective feedback on the impact of daily lifestyle habits, special situations (illness, stress) and medication on glucose levels, and thereby to foster self-management and empower the individual to make the necessary changes; and
- support to the healthcare team in providing individually tailored advice about lifestyle components and blood glucose-lowering medication.[39]

As an added benefit, SMBG within the context of individualised care also helps to address any wastage that may be present in the system due to the use of different blood glucose meters and testing strips. Some people with type 2 diabetes may purchase the necessary equipment for SMBG but either test more often than needed, or decide not to test at all. The effective use of SMBG would help to individualise SMBG and rationalise use of supplies.

*2.7.2 Supporting self-management in type 2 diabetes*

Interventions designed to improve metabolic control rely substantially on the ability to influence patient self-care or self-management.[40]

The capacity of people with diabetes to participate in and contribute to their own care is a crucial factor in the value and success of self-management programs and services. Individuals need the ability to identify and understand health messages, to access information and services, to decide what information is useful, and to apply information appropriately. Although people with diabetes and other chronic conditions may acquire extensive lay knowledge and experience in coping with and managing their chronic condition on a daily basis, many may not be aware of, or have the ability to, access and use health information resources effectively to enhance self-management – in other words, their ability to self-manage may be affected by their level of health literacy.

Health literacy influences health outcomes for people with diabetes in terms of acquiring new knowledge, improving self-efficacy and adherence with self-care behaviours.[41] In fact, health literacy has been described as the foundation for self-management programs.[42] With the growing emphasis on chronic disease self-management, and with the majority of Australians having less than adequate levels of health literacy,[43] Diabetes Australia has called for a national health literacy strategy.[44]

It has become clear, however, that psychological and behavioural interventions are often necessary to make the most of initiatives designed to increase knowledge and understanding. Research into factors which contribute to optimal self-management (and such research continues to be a priority) indicates that successful self-management involves constructive interactions with health care providers, including feedback about goals and achievements in blood glucose levels.

SMBG provides immediate feedback to individuals, thus supporting their involvement in the control of their diabetes through improved problem-solving and decision-making skills which also involve their healthcare providers. This type of collaboration is seen as essential for optimising patient outcomes.[45]

The changing age profile of type 2 diabetes diagnosis, as well as the overall increase in the proportion of the population with the condition, means that learning and putting into practice 'what works' will have enormous consequences. As with the management of a number of other chronic diseases and conditions, the answer is likely to involve some flexibility rather than 'one size fits all'.

In this regard, there are important messages emerging from the literature about the value of individualised care for people with type 2 diabetes and, within the context of individualised care, about the role of SMBG. Helping people overcome the challenges of managing their condition should be a priority: we know that good glycaemic control can slow the progression of type 2 diabetes and reduce the risk of some complications, but only about half of Australians with diabetes are achieving a blood glucose level of 7% or less.[46]

Managing blood glucose patterns is an important part of management plan. Blood glucose meters store information about test results, providing a comprehensive record of results to for patients to discuss with their health care providers. Meters also look for patterns of high and low blood glucose levels, which can also help patients recognise how to achieve their targets.

Effective team care systems and appropriate support to individuals with type 2 diabetes will be important in improving outcomes and reducing demands on the health care system. Consumer-focused approaches will also be crucial in empowering individuals and their carers to optimise diabetes management and in ensuring that consumer perspectives and concerns are heard and understood.

Diabetes Australia believes that the role of SMBG in diabetes self-management is likely to increase with improved research and associated improvements to diabetes education and management.

## 3. Consideration of clinical criteria for eligibility for subsidised access to blood glucose test strips under the PBS and NDSS, accounting for clinical benefits offered through SMBG compared to regular HbA1C monitoring

The assumption implicit in this point is that clinical criteria are needed to determine eligibility for subsidised access to blood glucose test strips. Again, Diabetes Australia suggests that such assumptions are potentially misguided and ignore key issues.

Diabetes Australia believes that consideration must be given to the context of individualised care and to the potential for adverse outcomes if access to SMBG is restricted or eliminated.

### 3.1 SMBG in individualised care

SMBG needs to be individualised because no two people with type 2 diabetes are the same; they are at various stages of the condition; using various management strategies and

medications; and they have various preferences, lifestyles, co-morbidities, risks related to hypoglycaemia, and capabilities and interests in self-management.

Within the context of individualised care, clear guidelines for individuals and health care providers can be used to support decision-making about structured SMBG, addressing questions such as when to test, how often to test and what to do with the results. As Parkin explains:

> 'New guidelines from the International Diabetes Federation specify that the timing and frequency of SMBG regimens should be individualized to address each patient's specific educational, behavioral, and clinical requirements and to meet clinicians' needs for data on glycemic patterns and to monitor the impact of therapeutic decision-making. Whatever the defined testing regimen may be, it should be designed to meet each patient's individual needs with a specific information goal in mind.'[47]

Diabetes Australia supports the IDF's 2009 Guideline that the following circumstances will contribute to the constructive and beneficial use of SMBG for people with non-insulin-treated type 2 diabetes:

- when they and/or their care-givers and healthcare providers have the knowledge, skills and willingness to incorporate SMBG and therapy adjustment into their diabetes care plan in order to attain agreed treatment goals;

- at the time of diagnosis to enhance the understanding of diabetes as part of individuals' education and to facilitate timely treatment initiation and titration optimisation;

- as part of ongoing self-management education to assist people with diabetes to better understand their disease and provide a means to actively and effectively participate in its control and treatment, modifying behavioural and pharmacological interventions as needed, in consultation with their healthcare provider;

- where SMBG protocols (intensity and frequency) are individualised to address each person's specific educational/behavioural/clinical requirements (to identify/prevent/manage acute hyper- and hypoglycaemia) and provider requirements for data on glycaemic patterns and to monitor impact of therapeutic decision-making;

- where the person with diabetes and the healthcare provider agree and document the purpose(s) of performing, and using data from, SMBG;

- where SMBG use involves an easy procedure for individuals to regularly monitor the performance and accuracy of their glucose meter.

Diabetes Australia therefore believes that it is important that people with non-insulin-treated type 2 diabetes have access to subsidised blood glucose test strips to undertake SMBG in the following circumstances:

- Following diagnosis: to give people with newly diagnosed type 2 diabetes the opportunity to learn about the impact of diet and physical activity on their blood glucose levels, and how they can intervene (without recourse to medication) to improve blood glucose levels. This strategy can help them to understand that diabetes is a serious condition, regardless of treatment type or duration. This can be reinforced by learning how to monitor,

knowing that SMBG can be undertaken initially as a learning exercise, continued regularly if required or at their discretion, and with the understanding that as their condition progresses, regular SMBG is likely to become a necessary part of diabetes management.

- People with type 2 diabetes who are on oral agents, putting them at risk of hypoglycaemia.

- People whose HbA1c is optimal, and who are not using oral agents that cause hypoglycaemia, may elect to use SMBG intermittently to inform self-management. It is important to note, however, that most people with non-insulin-treated type 2 diabetes have sub-optimal HbA1c, which, without careful management, is likely to become worse over time.

- When changes occur that may impact on blood glucose levels, such as medication change or ill-health.

- Preceding a healthcare review: to facilitate joint decision-making around therapy changes.

- When HbA1c levels are sub-optimal: to ensure more timely and aggressive management. This is important because type 2 diabetes is a progressive condition and only around half of Australians with type 2 diabetes reach their glycaemic target of HbA1c <7%; among those aged less than 40 years, only around 36% meet the target)[48]. In Australia, the average HbA1c of people with type 2 diabetes is 7.9%.[49] In one Australian study, only 47.7% of patients with type 2 diabetes seen in general practice had an HbA1c of <7.0%, and 25% had an HbA1c of >8.5%[50]. SMBG results can inform timely management decisions for this group, which can help delay the progression of diabetes.

**3.2 Potential adverse outcomes of restricted access to subsidised test strips**

There are likely to be a range of adverse outcomes – for the Government, health services, and individuals -- if access to subsidised test strips is restricted or removed.

For people with type 2 diabetes, especially older people, who are treated in community health settings, key aspects of care may rely on access to subsidised test strips. Should these individuals be unable to access test strips to undertake appropriate SMBG, it is the health care system which will face the risk of higher costs as a consequence of their diabetes being less well controlled.

The increased risks to individuals from the restriction or removal of access to subsidised test strips include:

1. Risks related to hypoglycemia:
   a) Driving risks are a key issue, as without subsidised strips, SMBG is likely to be limited, increasing the risk to personal safety (and the safety of others) due to hypoglycaemia. This is relevant to private drivers and to those whose livelihood involves driving.
   b) Work-related risks across a range of occupations, including those which involve operating mechanical equipment, and looking after young children.

2. Risks related to hyperglycemia:
   a) Due to illness, cortico-steroid medications, atypical anti-psychotic medication, inactivity or dietary change.
   b) Can result in increased risk of hospitalisation due to late detection of unstable blood glucose levels. This is especially important for frail older people who are at risk of Hyperglycaemia Hyperosmolar State(HHS) which can lead to delirium, falls, depression and impaired self-care.

3. Delayed treatment adjustments or intensification, which is particularly concerning considering the progressive nature of diabetes and the fact that sub-optimal glycaemic control can lead to the development of complications.

4. Risk of increasing misconceptions about the seriousness of diabetes: it is important that diabetes, of whatever type, is seen as a serious condition and not 'just a touch of sugar' or 'mild diabetes'. Limiting or removing access to blood glucose testing strips would imply that diabetes is only serious if treatment involves insulin.

5. Discriminatory treatment of people with non-insulin-treated type 2 diabetes in terms of self-management support:
   a) People who wish to proactively manage their diabetes with SMBG should have the right and means to do so.
   b) Restrictions would mean that, for those who want to SMBG, there would be additional financial burdens, which may have a negative socioeconomic and psychological impact and, potentially limit their ability to avoid/delay onset of complications.

## 4. Recommendations

Diabetes Australia makes the following recommendations in relation to SMBG for people with non-insulin-treated type 2 diabetes:

1. Structured SMBG should be supported as an appropriate and important element of effective self-management and person-centred, individualised care which provides meaningful and actionable information to clinicians and to people with diabetes. It is the quality use of SMBG (how the information is interpreted and acted upon) rather than SMBG per se, or the frequency of SMBG, that is crucial for effecting improvements in HbA1c and well-being.

2. Structured SMBG within the context of individualised care should be supported as being in the best interest of people with non-insulin treated type 2 diabetes and as an opportunity to rationalise the use of blood glucose testing strips.

3. Structured SMBG requires that sufficient resources be made available to ensure people with diabetes and health care professionals have the necessary training and competence to perform, interpret and take action in relation to SMBG patterns.

4. The universal access rights of people with diabetes in Australia to access the National Diabetes Services Scheme should not be changed. If the Australian Government is to consider restrictive policies, this will need clear evidence of benefits and extensive consultation with Diabetes Australia and consumers to properly address the additional

resources that would be required to administer new arrangements and ensure that the adverse consequences are identified and avoided or managed.

**REFERENCES**

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[1] International Diabetes Federation (IDF), 2009, *Guideline on Self-Monitoring of Blood Glucose in Non-Insulin Treated Type 2 diabetes*, p.13.

[2] Parkin CG, Buskirk A, Hinnen DA, Axel-Schweitzer M, 2012, Results that matter: structured v s unstructured self-monitoring of blood glucose in type 2 diabetes. Review. *Diab Research & Clin Prac* 97: 6-15

[3] IDF, 2009

[4] Malanda UL,Welschen LMC, Riphagen II, Dekker JM, Nijpels G, Bot SDM, 2012. Self-monitoring of blood glucose in patients with type 2 diabetes mellitus who are not using insulin. *Cochrane Database of Systematic Reviews*. Issue 1. Art. No.: CD005060. DOI: 10.1002/14651858.CD005060.pub3

[5] IDF, 2009

[6] Farmer, A J, Perera, R, Ward, A, Heneghan, C, Oke, J, Barnett, A H, Davidson, MB, Guerci, B, Coates, V, Schwedes, U, O'Malley, S, 2012. Meta-analysis of individual patient data in randomised trials of self monitoring of blood glucose in people with non-insulin treated type 2 diabetes. *BMJ*, 344:e486

[7] Brown J, Hendrieckx C and and Speight, 2012, Letter: Meta-analysis of individual patient data in randomised trials of self monitoring of blood glucose in people with non-insulin treated type 2 diabetes. *BMJ* 8 Mar. At: http://www.bmj.com/content/344/bmj.e486?tab=responses

[8] Polonsky WH, Fisher L, Schikman CH, Hinnen DA, Parkin CG, Jelsovsky Z, Petersen B, Schweitzer M, Wagner RS, 2011. Structured self-monitoring of blood glucose significantly reduces A1C levels in poorly controlled, noninsulin-treated type 2 diabetes: results from the Structured Testing Program study. *Diabetes Care* Feb;34(2):262-7.

[9] Australian Institute of Health and Welfare (AIHW), 2011. Diabetes and poor mental health and wellbeing: an exploratory analysis. Diabetes series No. 16. Cat.No. CVD 55. Canberra: AIHW

[10] Sawchuck CN, Olatunji BO, 2011. Anxiety, health risk factors, and chronic disease. *American Journal of Lifestyle Medicine* 5:531-541

[11] Peel E, Douglas M, Lawton J, 2007. Self monitoring of blood glucose in type 2 diabetes: longitudinal qualitative study of patients' perspectives. *BMJ* ;335:493

[12] Parkin et al, 2012

[13] Parkin et al, 2012

[14] Fisher WA, 2007. Barriers and behaviours in blood glucose monitoring. *US Endocrine Disease*, 2:51-53

[15] Kempf K, Kruse J, Martin S, 2010. ROSSO study, ROSSO-in-praxi: a self-monitoring of blood glucose-structured 12-week lifestyle intervention significantly improves glucometabolic control of patients with type 2 diabetes mellitus. *Diabetes Technol Ther.* Jul;12(7):547-53

[16] Durán A, Martín P, Runkle I, Pérez N, Abad R, Fernández M, Del Valle L, Sanz MF, Calle-Pascual AL, 2010. Benefits of self-monitoring blood glucose in the management of new-onset Type 2 diabetes mellitus: the St Carlos Study, a prospective randomized clinic-based interventional study with parallel groups. *J Diabetes*, 2010 Sep;2(3):203-11

[17] Polonsky et al, 2011

[18] Weng J, Li Y, Xu W, Shi L, Zhang Q, Zhu D, et al., 2008. Effect of intensive insulin therapy on beta-cell function and glycaemic control in patients with newly diagnosed type 2 diabetes: a multicentre randomised parallel-group trial. *Lancet* 371(9626):1753–60

[19] Chen HS, Wu TE, Jap TS, Hsiao LC, Lee SH, Lin HD, 2008. Beneficial effects of insulin on glycemic control and betacell function in newly diagnosed type 2 diabetes with severe hyperglycemia after short-term intensive insulin therapy. *Diabetes Care* 31(10): 1927–32

[20] Kolb H, Martin S, Lodwig V, Heinemann L, Scherbaum WA, and Schneider B, 2009. Are Type 2 Diabetes Patients Who Self-Monitor Blood Glucose Special? The Role of Confounders in the Observational ROSSO Study. *J Diabetes Sci Technol* 3(6): 1507–1515
[21] Fisher L, Polonsky WH, Parkin CG, Z Jelsovsky , Petersen P and Wagner RS, 2012. The impact of structured blood glucose testing on attitudes toward self-management among poorly controlled, insul-naïve patients with type 2 diabetes. *Diab Res Clin Pract* May; 96(2):149-55
[22] Parkin CG, Deborah A. Hinnen DA, and Tetrick DL, 2011. Effective Use of Structured Self-Management of Blood Glucose in Type 2 Diabetes: Lessons From the STeP Study. Clinical Diabetes 29: 4, 131-8
[23] Malanda et al, 2012
[24] IDF, 2009
[25] Kolb et al, 2009
[26] Parkin et al, 2012
[27] Hirsch IB, Bode BW, Childs BP, Close KL, Fisher WA, Gavin JR, Ginsberg BH, Raine CH, Verderese CA, 2008. Self-Monitoring of Blood Glucose (SMBG) in insulin- and non-insulin-using adults with diabetes: consensus recommendations for improving SMBG accuracy, utilization, and research, *Diabetes Technol Ther.* Dec; 10(6):419-39
[28] Parkin et al, 2012
[29] Kolb et al, 2009
[30] Fisher WA, Barriers and behaviors in blood glucose monitoring, 2007. Touch Briefings - US Endocrine Disease, p.51-53. http://www.touchbriefings.com/pdf/3049/fisher.pdf
[31] Australian Diabetes Educators Association (ADEA), 2011. Self-monitoring blood glucose (SMBG) in non-insulin treated type 2 diabetes: a review of the literature, Aug. http://www.adea.com.au/asset/view_document/979317370
[32] Polonsky et al, 2011
[33] Parkin et al, 2011
[34] ADEA, 2011
[35] Parkin et al, 2011
[36] Parkin et al, 2011
[37] Parkin et al, 2011
[38] Australian General Practice Network. http://www.agpn.com.au/programs/chronic-disease-prevention-and-management2/chronic-disease-self-management
[39] IDF, 2009, p.14
[40] WHO, 'Adherence to long-term therapies: evidence for action', WHO, Geneva 2003
[41] KL Cavanaugh, Health literacy in diabetes care: explanation, evidence and equipment. *Diabetes Management*, 2011, March 1(2):191-199
[42] NJ Glasgow, Y-H Jeon, SG Kraus and CL Pearce-Brown, Chronic disease self-management support: the way forward for Australia. *Med J Aust* 2008; 189 (10): 14
[43] Australian Bureau of Statistics (2008) Health Literacy, Australia., Catalogue No. 4233.0. www.abs.gov.au (last accessed 10 Nov. 2012).
[44] Diabetes Australia, *Diabetes National Election Agenda 2013-2015 - Type 2 diabetes: The 21st Century Pandemic*, 2012, p.2, 2012. At www.diabetesaustralia.com.au
[45] Parkin et al, 2012.
[46] Michaelides C, Daja M, Peterson D, Conroy D, 2008. An HbA1c mapping tool helps identify where interventions and strategies for change need to be targeted. At: http://www.glycomate.com/changingdiabetes/
[47] Parkin et al, 2011, p.132
[48] Baker IDI Heart & Diabetes Institute, Diabetes: the silent pandemic and its impact on Australia, 2012, p.37. At http://www.diabetesaustralia.com.au/Documents/DA/What's%20New/12.03.14%20Diabetes%20management%20booklet%20FINAL.pdf

[49] National Association of Diabetes Centres, *Final Report: ANDIAB 2009 - Australian National Diabetes Information Audit & Benchmarking*, 2009. Executive Summary, p.B. At: http://www.health.gov.au/internet/main/publishing.nsf/Content/604583860EBA6282CA25770A001769B8/$File/and09ex.pdf

[50]Macisaac RJ, Jerums G, Weekes AJ, Thomas MC, 2009. Patterns of glycaemic control in Australian primary care (NEFRON 8*). Intern Med J* 39:512‑8

**ATTACHMENT**

## LETTERS OF SUPPORT

Diabetes Australia – Victoria

Diabetes WA

Diabetes Queensland

Diabetes Tasmania

diabetes australiavic

14 November, 2012

To whom it may concern

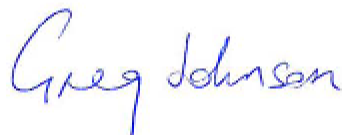
**Re: Submission to the Australian Government's review of products and medicines used in the treatment of diabetes: Self-monitored blood glucose testing for people with type 2 diabetes mellitus**

We are writing to express full support for the Diabetes Australia submission to the Australian Government's review of self-monitored blood glucose testing, for people with non-insulin-treated type 2 diabetes.

As the peak body for Diabetes in Victoria, we recognise the importance of people with type 2 diabetes having the choice to use self-monitored blood glucose testing as a tool in their diabetes self-management, and fully support the key points raised in the Diabetes Australia submission.

Please do not hesitate to contact me for further information or clarification.

Yours sincerely



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**Chief Executive, Diabetes Australia - Vic**

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

14 November 2012

Dear Sir

**Re: Submission to the Australian Government's review of products and medicines used in the treatment of diabetes: Self-monitored blood glucose testing for people with type 2 diabetes mellitus**

Diabetes Western Australia strongly supports the position of Diabetes Australia in regard to the above submission.

Self Monitoring of Blood Glucose (SMBG) is a key self-management tool to assist people with diabetes understand how their blood glucose levels may be affected by what they eat, lifestyle choices, illness and many other variables.

For those newly diagnosed with type 2 diabetes structured SMBG is particularly important as it provides an opportunity to learn about the impact of diet and exercise on their blood glucose. Also for people struggling with less than optimal HbA1c levels regular self-monitoring is an important management and information tool.

Of great concern is that if there are restrictions applied to accessing subsidised blood glucose strips the potential for adverse outcomes is heightened, especially in regard to the management of hypoglycaemia.

Finally, diabetes is a serious disease and limiting access to blood glucose testing strips implies that if you don't require insulin then your diabetes is not serious. Diabetes is a progressive disease and we know that 75% of people with type 2 diabetes will require insulin, so it is important that people are managing their disease as effectively as possible and as early as possible. To do this they need to be self-monitoring their blood glucose.

We strongly believe that SMBG should continue to be available to all Australians with non-insulin treated type diabetes as it is a significant element of self-management and consequently better health outcomes for people with diabetes.

Please don't hesitate to contact me should you require any further information.

Yours sincerely

ANDREW WAGSTAFF
Chief Executive Officer
Diabetes WA

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PO Box 1606, Subiaco WA 6904 | p 9325 7699 | f 9221 1183 | e info@diabeteswa.com.au | www.diabeteswa.com.au
Patrons – His Excellency Dr Ken Michael AC, Governor of Western Australia, and Mrs Michael

14th November 2012

To whom it may concern,

I write in support of the Australian Government's review of products and medicines used in the treatment of diabetes: Self-monitored blood glucose testing for people with type 2 diabetes mellitus.

Diabetes Queensland fully endorses the submission by Diabetes Australia to this review, which highlights the importance of good monitoring and control of blood glucose levels as a tool to support self management of type 2 diabetes and the prevention or delay of costly complications.

Supporting people with type 2 diabetes to test their blood glucose levels through the subsidisation of testing strips is an important contribution of the Commonwealth government towards managing the impact of this chronic disease and we support the call for the continuation of this program.

Diabetes Queensland looks forward to continuing to participate, through Diabetes Australia, in further stages of this review, on behalf of the 190,000 Queenslanders living with diabetes who are registered with the National Diabetes Services Scheme.

Sincerely,

**Taryn Black**
**Chief Operations Officer**

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**Patron in Chief:** Her Excellency Ms Penelope Wensley, AO Governor of Queensland
**Patrons:** Noel Whittaker and Dr Alan Stocks AM MB, BS, FRCP Ed, FRACP, Diabetologist
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14 November 2012

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CANBERRA ACT 2601

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We strongly believe that SMBG should continue to be available to all Australians with non-insulin treated type diabetes as it is a significant element of self-management and consequently better health outcomes for people with diabetes.

Please don't hesitate to contact me should you require any further information.

Yours sincerely

**CAROLINE WELLS**
Chief Executive Officer