Post Market Review of Products Used In the Management of Diabetes: Review of Blood Glucose Test Strips.

November 2012

Executive Summary

Sanofi supports the use of self monitoring of blood glucose (SMBG) in people with Type 2 diabetes not treated with insulin in-line with evidence based guidelines and recognises that, whilst not all people with Type 2 diabetes need to monitor their blood glucose on a daily basis, it is very important that SMBG remains an accessible option to ensure individual needs are met to ensure safe and effective control of diabetes.

Sanofi believes that:

- Treatment of Type 2 diabetes must be individualised to enable patients to control their condition effectively and this includes ensuring SMBG remains an available option to those patients that require it.

- SMBG should be reimbursed as part of a structured monitoring program to ensure the best blood glucose control is achieved.

- Withdrawal of funding for SMBG would be a step backwards in diabetes care, and rather than empowering patients to adapt their treatment to their lifestyle it could negatively affect the lifestyle choices of many individuals who are active in the management of their disease.

Introduction

Sanofi welcomes the opportunity to contribute to this post market review of blood glucose monitoring test strips as part of the overall review of products used in the management of Diabetes.

Sanofi supplies the BGStar® blood glucose monitoring test strips which are intended for use with BGStar® and iBGStar® Blood Glucose meters (BGM) for the quantitative measurement of glucose in fresh capillary whole blood for use at home by persons with diabetes, or in the clinical setting by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

Clinical need for SMBG

Self monitoring of blood glucose (SMBG) is an important task in the management of diabetes mellitus. International and local evidence based clinical guidelines and reports assessing SMBG recommend its use be considered for people with diabetes mellitus in order to manage diabetes and achieve a desired level of blood glucose control[1,2,3,4]. SMBG assists in improving clinical outcomes and safety by detecting hypoglycaemia and hyperglycaemia and can help by motivating patients to improve their glycaemic management. It also assists healthcare professionals in making appropriate treatment choices and adjustments. Data resulting from SMBG can be used in educating patients and health carers as to the consequences of lifestyle and behavioural choices and adherence to treatment regimens[2].

The International Diabetes Federation (IDF) Clinical Guidelines Task force released Global Guidelines for Type 2 Diabetes in 2012[1], making these guidelines one of the most relevant and up-to-date of any international guideline. The guidelines include a comprehensive assessment of the evidence available for the use of SMBG in Type 2 diabetes. The guidelines make a series of evidence based recommendations for SMBG, including its use by people with Type 2 diabetes not treated with insulin. The recommendations made by the IDF are summarised in Box 1.

Box 1: Recommendations for SMBG: IDF Guidelines for Type 2 Diabetes 2012[1].

- SMBG should only be made available to people with diabetes when they have the knowledge, skills and willingness to use the information obtained through testing to actively adjust treatment, enhance understanding of diabetes and assess the effectiveness of the management plan on glycaemic control.

- The purpose(s) of performing SMBG and using SMBG data should be agreed between the person with diabetes and the health-care provider.

- SMBG on an ongoing basis should be available to those people with diabetes using insulin.

- SMBG should be considered for people using oral glucose lowering medications as an optional component of self-management, and in association with HbA1c testing:
    - To provide information on, and help avoid, hypoglycaemia.
    - To assess changes in blood glucose control due to medications and lifestyle changes.
    - To monitor the effects of foods on postprandial glycaemia.
    - To monitor changes in blood glucose levels during intercurrent illness.

- Regular use of SMBG should not be considered part of routine care where diabetes is well controlled by nutrition therapy or oral medications alone.

- SMBG protocols (intensity and frequency) should be individualised to address each individual's specific educational/ behavioural/clinical requirements, and provider requirements for data on glycaemic patterns to monitor therapeutic decision making.

- Structured assessment of self-monitoring skills, the quality and use made of the results obtained, and of the equipment used, should be made annually.

Sanofi supports the use of SMBG in people with Type 2 diabetes not treated with insulin in-line with evidence based guidelines, and believes that SMBG offers this patient group an important tool in the management of their disease, helping individuals understand their

condition and how lifestyle choices impact glycaemic control, empowering individuals to make informed healthcare choices. It is particularly important for people who are treating their diabetes with agents that can cause hypoglycaemia such as a sulfonylurea. Restricting access to tools that allow for successful SMBG takes away an individuals ability to track their condition. This may negatively impact an individual's ability to safely conduct a "normal" life in terms of conducting everyday activities such as driving or participation in recreation activities that require close control of blood sugar levels.

For SMBG to be of real value for insulin naïve patients, Sanofi supports the view that it needs to be used in conjunction with a structured management program in people unable to establish and maintain adequate glycaemic control and are motivated and have been educated to use SMBG in an appropriate manner.

Withdrawal of funding for SMBG would be a step backwards in diabetes care, and rather than empowering patients to adapt their treatment to their lifestyle it could negatively affect the lifestyle choices of many individuals who are active in the management of their disease.

Sanofi and Diabetes Care.

Sanofi offers a range of personalized diabetes solutions integrated across diagnostics, therapies, devices and services including the provision of Lantus® (insulin glargine), Apidra® (insulin glulisine), Amaryl® (glimepride), BGStar®, iBGStar®, SoloSTAR®, ClikSTAR® and the STARcare support program.

Sanofi has a responsibility to ensure the safe and effective use of the medications it provides and believes that SMBG plays an important role in ensuring this not only for insulin, such as Lantus® (insulin glargine) and Apidra® (insulin glulisine) but also for non insulin products such as Amaryl® (glimepride).

The BGStar® / iBGStar® BGM system has been designed to help users control their diabetes effectively and have functionality that compliments use within a structured monitoring program. The BGStar® Diabetes Management Software, integrated with the BGStar® devices, gives patients and physicians the ability to analyse long-term trends as well as specific, detailed information for each test. The iBGStar® offers connectivity with the Apple iPhone® and iPod touch® and allows blood glucose data to be easily displayed, managed, logged and communicated via the iBGStar® Diabetes Manager App. Such functionality means that data collected via BGStar® / iBGStar® devices can easily be incorporated into

structured management programs with the aim of helping patients and their healthcare professional make better-informed decisions in managing diabetes. Blood Glucose readings can be automatically managed by the device software ensuring that test results are not lost, or misreported, as can be the case if test results are recorded manually.

An additional benefit of the BGStar® / iBGStar® devices is that the BGStar® test strips do not require coding with the meters. This eliminates potential wastage of strips, which can occur if the coding chip is misplaced for test strips that require coding, or the chance for inaccurate results being obtained due to miscoding.

Sanofi also provides users of its diabetes products with access to STARcare, a program which provides diabetes support, education, expert technical and monitor advice for HCPs via diabetes support partners as well as customer care for devices such as BGStar® / iBGStar® BGMs.

References

1. International Diabetes Federation (IDF) Clinical Guidelines Task Force. Global Guideline for Type 2 Diabetes 2012.

2. NHMRC. National Evidence Based Guideline for Blood Glucose Control in Type 2 Diabetes 2009 (available at http://www.nhmrc.gov.au/guidelines/publications/di19).

3. NHS Diabetes Working Group. Self monitoring of blood glucose in non-insulin-treated Type 2 Diabetes.

4. RACGP. Diabetes management in general practice: Guidelines for type 2 diabetes. 2011/2012