

Blood Glucose Meter Market: This World Is Undergoing Drastic Changes

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The market for self-monitoring of blood glucose (SMBG), with all its blood glucose (BG) meters and test strips, has experienced a constant increase in sales for a number of years with a good margin. If you attended the 2012 European Association for the Study of Diabetes meeting in Berlin, you would have gained the impression that this is a truly prosperous business. At least 20 companies from all over the world—most of the smaller ones are from Southeast Asia—offered their products. The giants of this business—Roche Diagnostics, Bayer, LifeScan—had large booths similar to those of pharmaceutical companies such as Novo and Eli Lilly. Interestingly enough, Abbott had no booth at this meeting. Could this be the writing on the wall?

For people who are interested in the diabetes technology market, it is important to acknowledge that it is a single product—BG meter/test strips—that fuels this market to at least two-thirds. No precise numbers of the worldwide sales for this market are available, but it is a safe guess that it is multibillion dollar/Euro market. However, it is clear that this is a business that will undergo drastic changes in the future. At one time, Bayer was considering selling this whole section of its business to focus more on its pharmaceutical business, but in January 2013, the company announced that they no longer plan to sell their diabetes unit.¹ Abbott Laboratories has divided its company into two parts: (1) medical products (including BG monitors), and (2) research-based pharmaceuticals. The medical products company will retain the Abbott name. The research-based pharmaceuticals company will be called AbbVie.² Sanofi has entered the BG monitoring business.³

Rumors indicate that all SMBG companies are under high pressure from the insurance companies, with regard to product sales in a number of significant markets. Payers are attempting to cut back the expenses for a particular segment: BG monitoring. A critical issue is that, for some payers, the costs of BG meters is the only criteria that counts; for them, all meters are the same, which means that differences in performance (e.g., higher accuracy) are irrelevant. A Canadian nonprofit organization funded by the Ontario Ministry of Health and Long-Term Care has recommended decreased frequency of BG testing.⁴

In the United States, the fiscal cliff bill addresses how Medicare pays for BG monitoring strips. Under the terms of the Medicare Modernization Act, the Centers for Medicare and Medicaid Services has been developing a competitive bidding program to pay for many products, including durable medical equipment, which includes strips. The competitive bidding program is underway in parts of the United States. The fiscal cliff bill states that, beginning July 1, 2013, the Centers for Medicare and Medicaid Services will have to pay retail pharmacies the same amount for diabetes

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medical equipment, including testing supplies, as the payment amount for mail order suppliers. It is expected that many retail pharmacies will then narrow their range of brand name diabetes testing strips, because name brand supplies will not be able to get their costs down to match brands distributed through the mail order process. If retail pharmacies stop selling a certain brand of test strip, then the patient with diabetes will no longer be able to use their current BG monitor. Patients might find that pharmacies cannot afford to sell certain brands because the amount Medicare is paying is too little to reimburse the costs for these brands.⁵

Indications for SMBG use in patients with non-insulin-treated type 2 diabetes have been controversial.⁶ Studies have demonstrated that structured testing with information being used to make decisions about treatment can improve control.⁷ Meanwhile, some funding government bodies and insurance companies are cutting back coverage for BG test supplies in this setting. It remains to be seen whether these patients will receive adequate coverage from payers or whether their testing costs will have to be out-of-pocket.

Brand name glucose monitors often contain features to enhance the monitoring experience, such as better human factors, pattern recognition software, wireless health capabilities, and service centers. Furthermore, a concern has been raised that some BG monitors that have adequate analytical performance capabilities for regulatory approval might not retain their high level of performance following the approval process. Three articles published in this journal in the past 8 months have raised this concern.⁸⁻¹⁰

Because of the constant increase in the number of patients with diabetes, the total SMBG market probably will not change or decrease. If price controls become more widespread, however, it would be expected that profit margins will come under pressure.

An additional concern for BG monitoring companies is the emergence of counterfeit strips in the supply chain. This clearly can create medical risk for patients and liability for manufacturers. In December 2012, a medical products distributor was convicted of federal criminal charges of introducing misbranded medical devices into interstate commerce and entry of goods into the United States by means of false statements. He had been accused of importing approximately 6000 boxes of fake Johnson & Johnson OneTouch diabetes test strips from suppliers in the United States and China and selling them to wholesalers in the United States in 2006.¹¹ Counterfeit strip sales will cause strip manufacturers to strengthen the safety of their supply chains and to monitor markets to detect fake versions of their products, all of which will add to the cost of their products.

Until now, diagnostic companies had deep pockets, allowing them to support many patient-oriented and other activities in the field of diabetes technology; however, their willingness and ability to continue such programs has decreased for obvious reasons.

For many patients, it is common to have more than one BG meter at home and to get a new meter every other year. For these people, these costly devices have no value. One wonders how long the companies can continue their policy of offering meters for free and earning their money via the test strips.

Acknowledging the fact that both of us are strong believers in SMBG, we recommend a discussion round of all parties interested in this topic, which would allow different viewpoints to be presented and discussed. To protect the best interest of patients with diabetes, we should arrive at a solution in which availability and use of SMBG is not driven by commercial aspects alone.

Disclosures:

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