Regulatory Profile for Glucose Self-monitoring Tools

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In 1989, the 42nd World Health Assembly (WHA) recognised that diabetes mellitus is a chronic, debilitating and costly condition, and that it represents a significant burden on the public health services of Member States. It also acknowledged that the problem is growing, especially in developing countries. The Assembly called on Member States to assess the national importance of diabetes and to *implement population-based measures, appropriate to the local situation, to prevent and control diabetes*.

Controlling diabetes requires management of glucose levels in people living with diabetes. Accurate measurement of glycaemic levels enables many people to self-manage to avoid the dire consequences of uncontrolled disease. One way that the Assembly's call for action can be realised, therefore, is through enabling greater access to accurate, affordable, quality diagnostic tools for the self-management of diabetes.

Self-monitoring has become a vital part of the solution for many people living with type 1 diabetes and for certain individuals living with type 2 diabetes. Along with self-monitoring blood glucose test systems (SMBGs), which require fingerstick-collected capillary blood, alternatives to testing, such as continuous glucose monitoring systems (CGMs), are enabling the individual to better achieve glycaemic targets with less inconvenience. The advent of insulin pensand pumps has also provided empowering self-management. The technology landscape is evolving quickly, and now CGMs can be linked with appropriate software and other hardware to automatically deliver appropriate doses of insulin. Standalone software applications are also providing the person with diabetes with improved self-management support. These technologies, when applied appropriately, can improve the lives and health of people with diabetes; however, there remains inequity as to who benefits from these technological innovations.

An important aspect of access is the regulation of the technologies used for self-monitoring of this condition. This document has been created to review the current regulatory practices in place for market authorisations of glucose self-monitoring tools (SMBGs and CGMs) used by individuals. It also reviews the assessment mechanisms employed at an international level to ensure access to safe, effective and quality devices for the self-monitoring of diabetes in LMICs. The aim is to gain an overall understanding of these mechanisms and identify opportunities for improvement.

The focus of the report is an evaluation of the regulatory assessment mechanisms employed by European Union (EU) and the United States of America (US). These two jurisdictions represent mature regulatory systems for such technologies, which in both are considered as medical devices and in vitro diagnostic (IVD) medical devices. Approvals of these devices

from the EU and US are recognised in various manners to expedite market access in many jurisdictions, regardless of a jurisdiction's economic status. Countries as diverse as Australia, Ghana, Malaysia, Switzerland and South Africa all use reliance mechanisms that include the recognition of Conformité Européenne (CE) mark (EU approval) or Food and Drug Administration (FDA) authorisation.

Understanding the regulatory assessment processes provides a means to understand the level of assurance that can be placed in the clinical safety and performance profile of a self-monitoring device. To provide context, the framework for regulation of devices is reviewed. To provide comparison, a high-level overview of the regulation of glucose self-monitoring devices in Tanzania and China is provided, as examples of countries with regulatory bodies that have committed to regulatory harmonisation efforts.

The report aims to identify some of the challenges and opportunities that arise due to the current state of regulation of these technologies. An emphasis is placed on identifying measures to help secure equitable access to quality devices for people living with diabetes, regardless of the location of their use. The scope of this report is limited to those devices that allow self-monitoring of glucose levels, i.e., SMBGs and CGMs.

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