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COMMENTARY

Considerations for an Institution for Evaluation of Diabetes Technology Devices to Improve Their Quality in the European Union

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Abstract

All medical devices used for self-monitoring of blood glucose (BG), insulin injection, continuous subcutaneous insulin infusion, and continuous glucose monitoring in the European Union (EU) must have a Communauté Européenne (CE) mark. However, the approval process for obtaining this mark is different from that used by the European Medicines Agency in the EU for drugs or by the Food and Drug Administration in the United States for such medical and *in vitro* diagnostic devices. The notified bodies involved in the CE mark process perform this evaluation in cooperation with the manufacturers. They have only limited diabetes know-how; they have to handle all kinds of medical devices. There are devices for therapy on the market in the EU (i.e., they have market approval) that do not fulfill quality requirements, as indicated, for example, in the international norm ISO 15197 for BG test systems. Evaluation of the performance of such systems is usually provided by the manufacturers. What is missing in the EU is an independent institution that performs regular and critical evaluation of the quality of devices used for diabetes therapy before and also after their market approval. The work of such an institution would focus on BG test systems (these represent two-thirds of the market of medical devices for diabetes treatment) but would also evaluate the performance of other devices. It has to be clarified what legal framework is required for such an institution and how it can be financed; probably this can be done in a shared manner by the manufacturers of such devices and the health insurance companies. Positive evaluation results should be a prerequisite prior to any reimbursement for such devices.

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Abbreviations: (BG) blood glucose, (CE) Communauté Européenne, (DDTD) diabetes diagnostic and therapy devices, (DT) diabetes technology, (EU) European Union, (FDA) Food and Drug Administration, (ISO) International Organization for Standardization, (SKUP) Skandinavisk Utprøving av Laboratorieutstyr for PrimæRhelsetjenesten, (SMBG) self-monitoring of blood glucose

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