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LETTER

Regulation of medical devices used in diabetology in Europe: Time for reform?

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Abbreviations

CE	Conformité Européene
CGM	Continuous glucose monitoring
CSII	Continuous subcutaneous insulin infusion
EMA	European Medicines Agency
HBGM	Home blood glucose monitoring
NB	Notified body

To the Editor: A series of high-profile failures of medical devices in recent years has resulted in much debate in Europe as to the approval process and subsequent regulation of devices used in medical practice [1, 2]. Such is the concern about the perceived lack of regulation and monitoring of devices that barely a week has passed in early 2012 without reports or comments on device failures in the medical literature. These have ranged from the spontaneous rupture of Poly Implant Prosthèse (PIP; La Seyne-sur-Mer, France) silicone gel breast implants [3] and the dangers of metal on metal hip implants [4, 5], to deaths caused by the likely failure of implantable cardioverter–defibrillator leads [6, 7].

Fortunately, to date and to our knowledge, such serious failures have not been reported for devices used in the management of patients with diabetes. However, faced with the rapid increase of device usage in the treatment of diabetes, the EASD earlier this year hosted a meeting of interested parties from the diabetes associations, industry, academia and the European Commission to discuss European perspectives on medical devices used in diabetes [8]. In this letter, we review the usage of devices in diabetes treatment, describe the current European regulations for device registration and monitoring, and outline the urgent need for reform of the entire process.

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Background: use of devices in diabetes

Ever since the discovery of insulin nearly 90 years ago, devices have been in widespread use in diabetes care. These include insulin syringes and pens, tools used in screening for complications, such as ophthalmoscopes, and instruments for assessing the integrity of the peripheral nervous system. Over the last four decades there has been an explosion in device usage, starting with home blood glucose monitoring (HBGM) [9, 10] and the introduction and, later, widespread adoption of continuous subcutaneous insulin infusion (CSII) in certain groups of type 1 diabetic patients [11]. In 2012, HBGM is in widespread use among insulin-treated patients worldwide, and CSII usage is rapidly increasing in western countries [12] and has even been recommended as the treatment of choice in young people with type 1 diabetes [13]. The most recent device development has been the increasing adoption of continuous glucose monitoring (CGM) in clinical practice [14]. Real-time CGM now has the potential not only to improve glycaemic control but also to improve quality of life in patients with type 1 diabetes [15].

With increasing usage of devices in diabetes, there is also an increasing chance of problems caused by human error or device failure. Diabetic ketoacidosis is always a potential risk in those with type 1 diabetes, and early in the history of

CSII usage, this risk was realised [16]. Ketoacidosis can result from human error, pump failure or unnoticed catheter disconnection. However, whereas failure of either the insulin or the device could have very serious consequences, strict regulations by the European Medicines Agency (EMA) control the licensing of all medications, including insulin, and there is a requirement for randomised controlled trials; in contrast, registration of devices does not, at present, require such rigorous testing and trials.

Potential problems with the present system of device registration and regulation in Europe were highlighted by Wentholt et al in *Diabetologia* in 2005 [17]: a non-invasive CGM device, working by impedance spectroscopy, had been introduced in 2003. A post-marketing reliability study showed this device to be inaccurate—with a >50% mean absolute difference between the glucose readings from the device and those from patients' HBGM, and with >4% of the device readings being potentially dangerous [17]. This sparked a debate as to how best to assess and compare the accuracy of CGM [18].

European device regulation in 2012

The regulation of medical devices in Europe was streamlined and harmonised in the 1990s. Before their introduction into clinical practice, devices have to be approved and certified, obtaining a Conformité Européene (CE) mark. Devices are assigned to one of four groups according to risk [19]: Class I devices are low risk and include instruments such as stethoscopes and ophthalmoscopes. Manufacturers are permitted to self-declare that they have conformed with requirements, then affix a CE mark and register the device with a 'competent authority' (e.g. the Medicines and Healthcare Products Regulatory Agency [MHRA] in the UK).

Equipment used for HBGM, CGM and home blood pressure monitoring are defined as Class IIa devices, whereas pumps used for CSII are Class IIb. Most of the devices used in bariatric surgery for obese type 2 diabetic patients, such as gastric bands and the EndoBarrier [20], are also classed as IIb devices. Class III devices carry the highest risk and are generally implantable devices such as pacemakers. Any new moderate (Class II a/b) or high risk (Class III) device needs to undergo a conformity assessment procedure by a 'notified body' (NB). There are more than 70 NBs, some of which are not even in the European Union. European NBs are generally monitored by a 'competent authority' in the member state where they are based. The NBs are generally independent commercial organisations who are supported in part by the fees paid by the device manufacturing companies. To register a new CGM device, for example, the company can choose any NB, to which it pays a fee; the NB then ensures that the device meets the required specifications issued by the EU Council directives. A certificate is issued by the NB, and the company can then affix a CE mark to its device. The company then has a 'free trade passport' to market the device throughout the European Union. Thus, there are no requirements for independent standardised studies or trials before a device is marketed, and neither is there any agreed post-marketing vigilance system by the national or European health authorities.

Conclusions

We would agree with the recent comments by Cohen [4] who stated that 'after a series of high-profile failures, device regulation in Europe is in need of radical change'. We endorse the proposal by our colleagues at the European Society of Cardiology that, similar to the EMA, which oversees medications, there should be a single, coordinated European system to oversee the evaluation, approval and post-marketing surveillance of medical devices [2]; there could, for example, be a sub-division for device regulation within the EMA. However, although the EU directives regarding medical devices are currently being revised, it seems unlikely that a central European device registry will be established, owing to the current fiscal restraints within Europe.

The safety of our patients with diabetes who use devices in their day to day treatment and monitoring is of paramount importance: hence the EASD has organised a symposium on this topic at its 2012 meeting and has established working committees on devices in diabetes. We plan to submit our preferred solutions on device regulation in Europe in 2013. In the meantime, it is hoped that, at the very least, the EU will reform the functioning of existing NBs and establish both surveillance and vigilance procedures for medical devices in Europe.

Duality of interest The authors declare that there is no duality of interest associated with this manuscript.

Contribution statement Both authors were responsible for the conception, design and drafting of the manuscript and approved the final version for publication.

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