Europe has to step up its efforts to produce innovative and safe diabetes technology

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Abbreviations

EU	European Union
EUDAMED	European Database on Medical Devices
IDF	International Diabetes Federation

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To the Editor: There is an ongoing (legislative) debate on medical devices and in vitro diagnostics at the European Union (EU) level that will influence the future of diabetes technology and, in particular, the safety and innovation of new devices.

Diabetes technology, such as insulin pumps and glucose meters, has experienced major advances over recent decades. This has changed their use from being termed ‘sporadic’ in the 1970s to now being widespread, and has led to significantly improved management and care of people with diabetes [1]. There are grounds for concern, however, about the safety of these increasingly complex devices. A relevant example is the ‘closed loop system’ or ‘artificial pancreas’ that will be available in Europe approximately 1 year from now. This system enables insulin pumps to automatically administer insulin with only limited intervention by patients. This is a breakthrough in diabetes care and has the potential to significantly improve the daily lives and long-term health of people with diabetes. However, its (semi) automatic character raises safety concerns, particularly in view of past and more recent research on the general performance of insulin pumps.

In 2009, Guilhem and colleagues reported that 36% of randomly selected pumps failed partially or completely after a median time of 15 months [2]. A recently published update confirmed that pump failure continues to be a common problem [3].

Unfortunately, the full scale of the problem remains unknown as there is only limited access to vigilance data. The EASD has monitored these developments and, in 2012, it added the safety of diabetes technology to its key strategic priorities. At around the same time, the European Parliament and the European Council started negotiating new legislation in this area following diverging interpretation of the current European directives and the fraudulent production of Poly Implant Prothèse (PIP) silicone breast implants in 2010 [4],

which highlighted weaknesses in the current legislative framework.

In statements (most notably a joint statement by the EASD and the ADA Diabetes Technology Working Group [5]), at conferences and during meetings with relevant stakeholders, the EASD has called upon the EU decision makers, industry and other stakeholders to work together towards safer diabetes technology. One of its focal points is the improved scrutiny for insulin pumps before and after they enter the European market.

Despite the recent adoption of legislation [6], the debate will continue. The coming 3 to 5-year implementation period entails the drafting of over 80 implementing or delegating acts that will provide answers to open questions in the legislative text, such as the level of public access to the soon-to-be refurbished European Database on Medical Devices (EUDAMED), the exact requirements for clinical evidence and the final conformity assessment procedures.

It is therefore key that the diabetes community continues to follow this topic. It must ensure that the final legislative text stimulates innovation while guaranteeing the highest levels of safety.

The EASD-EU Committee has recently highlighted the legislative questions around diabetes technology at a high level conference in the European Parliament, hosted by a member of the European Parliament, Bogdan Wenta [7]. The event, held on 31 May 2017, brought together a panel of speakers that included people with diabetes, academics, policy makers, politicians and industry representatives. In addition to the new legislation, innovation was one of the key topics of the conference.

From the event, it became clear that Europe and the USA are competing in the field of innovation of diabetes technology and medical devices, and in vitro diagnostics in general. Despite recent cuts in the US research budget, Europe is likely to remain at a disadvantage in this field in the short term. An example is the recent commercialisation of the artificial pancreas in the USA, while this technology is not expected to enter the European market prior to 1 year from now.

It is important that the latest innovations in diabetes technology can be accessed not just by the lucky few, but by all European people with diabetes. Cristina Petrut, board member of International Diabetes Federation (IDF) Europe, formulated this perfectly during the meeting by stating that ‘nothing is more frustrating for a patient to know there is a device out there that can significantly improve your daily life, but you are unable to obtain it’.

Further to promoting equitable access by means of coherent and transparent legislation, a number of other tools were mentioned during the event that could stimulate innovation, including increased efforts to bring researchers in this field together, a new scientific journal dedicated to this topic and

increasing the number and resources of European academic centres focusing on diabetes (technology).

This meeting demonstrated both the differences between the different stakeholders and their strong commitment to collaboration. Presentations by Professor Andrew Boulton, chair of the Alliance for European Diabetes Research (EURADIA), and Professor Sehnaz Karadeniz, President of IDF Europe, showed that broad access to EUDAMED, strict guidelines for clinical research, and pre-market tests for efficacy and safety are the main priorities for these organisations during the upcoming implementation of the legislation. The EASD supports these strategic priorities and calls upon all members of its community to discuss them with their peers, as well as with national and European politicians and policy makers.

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