

### **Medical Devices in Diabetes Care** **A statement on behalf of the European Association for the Study of Diabetes**

The European Association for the Study of Diabetes is calling for an urgent overhaul of the current CE Marking procedure for the evaluation and approval of medical devices in Europe. As it currently stands, this system could result in situations that may seriously threaten the lives of people with diabetes because of its inadequacies.

Medical devices are an essential element of successful diabetes care. Blood glucose self-monitoring is an integral part of insulin treatment. Self monitoring enables patients to achieve appropriate metabolic control, avoiding hypoglycaemia and reducing the likelihood of developing long term complications of hyperglycaemia such as blindness or renal failure.

Insulin pumps enable numerous patients to achieve excellent metabolic control and together with other devices such as subcutaneous glucose sensors, and, in the future, closed loop systems, facilitate diabetes care in such a way as to maximize patient care whilst minimizing patient discomfort.

However, the proper functioning of these devices is absolutely essential for people with diabetes; malfunctions can have serious consequences and in some cases could result in death.

#### **Insufficient CE Marking evaluation protocol**

At present, there is a low level of regulation and control of medical devices in the European Union. This is a continuous threat to the health of people with diabetes. Medical devices in the EU must have a CE Marking; however, obtaining this CE Marking for medical devices and the lack of post-marketing surveillance can in no way be compared to the rigorous processes required to gain approval for pharmaceutical products, and thereafter the post-marketing surveillance. Drugs are reviewed prior to admission onto the open market by the European Medicines Agency, the EU's counterpart to the Food and Drug Administration in the United States of America. The EASD has previously called for an improvement of the current European system for device registration, which, to date, has failed to be realized [1].

The CE Marking claims to guarantee the safety of the device being sold. However, it does not, in any respect, represent an independent confirmation of its quality. In addition, so called "notified bodies", located all over Europe, which are involved in the CE Marking process have little if any knowledge about diabetes care, diabetes treatment or in fact how a device which is being inspected will be used by a member of the public. The disastrous events in relation to hip implants and PIP breast implants [2], [3], [4] which have been detected in recent years have demonstrated the inefficiency of the current system.

The notified bodies do not control the fulfilment of the current ISO standard for blood glucose test systems (DIN EN ISO 15197:2003, currently under review). Furthermore, the new proposals from the European Commission for the improvement of the current system will, essentially, not change this unsatisfactory and insecure system of control which is criticized by leading scientists [5].

#### **EASD calls for urgent action**

It is the position of the EASD that in order to protect people with diabetes, the following actions are essential:

- Firstly, since the procedure for obtaining a CE Marking and the role of notified bodies have proven to be ineffective, medical devices in diabetes care should be evaluated by independent research institutions. The standard of this evaluation should be the respective ISO-norm.
- Not only *in vitro* standards will have to be evaluated but also, and more importantly, real-life settings and situations will need to be evaluated.
- A continuous post-marketing surveillance of random samples should be a pre-requisite.

# EASD

## European Association for the Study of Diabetes

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When trying to improve the quality management of medical devices in diabetology, the European Union can look to specific examples in certain European countries which could serve as a model for change.

The Scandinavian evaluation of laboratory equipment for primary health care, SKUP, (<http://www.skup.nu>), for example, which is based in Norway, has, in collaboration with Denmark and Sweden, set up an excellent system for the control of blood glucose monitoring devices.

Their methodology of evaluation and the subsequent open-publishing of study results, which are carried out by independent research institutions, are a perfect model of what might happen in the European Union. The European Association for the Study of Diabetes will work in close collaboration with SKUP to promote the results of their evaluations and bolster their claim that people with diabetes should be informed about the outcomes of these evaluations. Health authorities should also base their reimbursement policies upon these outcomes.

### **Post-marketing evaluation of insulin pumps jeopardizes patient safety**

In Europe the level of quality control for insulin pumps is as ineffective as it is for blood glucose monitoring. Here again the control is based upon the same form of CE Marking procedure by notified bodies which have no knowledge with respect to the clinical problems of insulin pumps.

The current post-marketing surveillance is below any proper medical standard. No proper data on pumps are collected and therefore potential malfunction or flaws in pumps will rarely be discovered. It is absolutely essential to continuously evaluate insulin pump treatment using registries of people with diabetes. The European Association for the Study of Diabetes will work closely with the registries in Europe to develop models on how to continuously evaluate insulin pumps.

Only those insulin pumps which undergo and pass such continuous evaluation and inspection should be approved for use and reimbursement by medical health insurance companies.

In future, the evaluation of glucose sensors and closed-loop systems for the treatment of diabetes will require intense collaboration between specialists involved in diabetes care and in technology. EASD will further promote research in this area.

Unfortunately, without substantial improvement to the present evaluation process established by the European Union disasters are likely to occur, a situation which the European Association for the Study of Diabetes will strive to prevent.

Professor Andrew J. M. Boulton MB, BS (Hons), MD, DSc (hon), FRCP  
President, European Association for the Study of Diabetes  
Professor of Medicine, Universities of Manchester and Miami, Florida, and Consultant Physician,  
Manchester Royal Infirmary

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Prof J Zierath, Sweden

*Office:*  
Executive Director:  
Vice Director:  
  
secretariat@easd.org  
www.easd.org

Dr V Jörgens  
Dr M Grüsser

Rheindorfer Weg 3  
40591, Düsseldorf, Germany  
Phone: +49-211-758469-0  
Fax: +49-211-758469-29