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Current medical device regulation: Is that enough?

Regulación actual de los productos sanitarios: ¿es suficiente?

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The field of activity of pharmacists includes a range of products within their competence: medicines, medical devices (MD), cosmetic products, personal care products, or antimicrobials for clinical and personal use. These products differ regarding their regulation, marketing requirements, and post-marketing surveillance[1]. European legislation has always sought the free movement of these products within the internal market of the European Union (EU), and to establish a high level of protection for consumer health and safety.

The 1990s saw the implementation of European regulations on these products with the adoption of three directives on MDs, implantable MDs, and *in vitro* diagnostic MDs. A legislative approach that had been recently applied to industrial products was adapted to these directives on MDs. The main characteristics of this legislative focus, known as the "New Approach Directives", are the fulfilment of essential requirements, reference to technical standards, assessment independent of national authorities, mutual recognition of conformity assessment procedures conducted by Notified Bodies (NB), free movement of products with positive conformity assessment results and with the EC marking.

Over time, these directives have been modified to improve the free movement of MDs and citizen safety. Thus, the European Commission recognised the need to update the regulations, adapting them to technological advances and establishing additional guarantees that would ensure product safety and patient health. As a result, two new regulations were published on MDs and *in vitro* diagnostic MDs[2,3].

These new regulations reinforced some key elements of the current regulatory approach, which are addressed in the following sections.

Authorization and marketing

Prior to marketing an MD, an assessment must be conducted of its conformity with the essential requirements (general safety and performance requirements), depending on the class and type of the product. The conformity assessment is conducted by the NBs, which are impartial independent entities accredited for conducting this activity. The NBs are designated by each Member State and are included in a European Commission list. Their correct functioning is essential to guarantee a high level of health protection and to provide citizens with confidence in the system. For this reason, it has been considered necessary to establish a group of controls at the EU level and a responsible NB authority that, among its other functions, will supervise and ensure that the NBs continue to fulfil the requirements and obligations for which they have been designated. In Spain, the AEMPS is the only NB appointed by the Spanish Ministry of Health (number 0318). The AEMPS also acts as the Health Authority, and so it must define its role in each case and possible conflicts of interest. However, this situation is not always the case, because it often outsources to private entities with profit motives.

The new regulations set high standards for the quality and safety of MDs. Thus, the rules applicable to marketing MDs and their introduction in the EU have been harmonized and ensure, among other aspects, that the data obtained in clinical studies are reliable and robust, while protecting the safety of participants.

Manufacturers should summarize the main safety and performance aspects of implantable and class III devices, and the results of their clinical evaluation should be made public.

In the case of implantable Class III devices and active Class IIb devices for drug delivery, NBs are required to direct their expert panels to review the clinical evaluation reports.

Surveillance and market control

Manufacturers must have a quality management system and post-marketing follow-up appropriate to the risk and MD class to ensure conformity once devices are in the market and that the feedback obtained from their use is implemented in the production process. In order to minimize risks and prevent device-related incidents, manufacturers must establish a system for

risk management and for reporting incidents and safety corrective actions. The risk management system must be carefully adapted to the device's clinical evaluation, which itself should include aspects of the risk management system. Thus, clinical risks should be taken into account and be included in the clinical studies, clinical evaluation, and post-marketing clinical follow-up.

Furthermore, patient information and MD traceability have been improved to better protect health and improve safety (unique identification of devices, general safety and performance requirements, technical documentation, classification rules, conformity assessment procedures, and clinical studies, etc.).

Implant patients have to be given clear and easily accessible essential information that allows the device to be identified as well as any other relevant information about the product.

Regarding traceability, the implementation of a Unique Device Identification system, based on international guidelines, will improve the effectiveness of activities related to post-marketing safety. To this end, the creation of the European Database on Medical Devices (Eudamed) is essential. Eudamed will integrate information on marketed MDs, relevant economic agents, conformity assessment, NBs, certificates, clinical studies, market surveillance and control, and so on.

During post-marketing MD follow-up, manufacturers should systematically and actively collect information on the experience of using their devices. To achieve this, they should establish a general post-market surveillance system within the framework of their quality management system. The information obtained will be used to: a) update the benefit-risk determination and improve risk management; b) update information on design and manufacturing, instructions for use, and labelling; c) update the clinical evaluation; d) update the safety and clinical performance summary; e) detect the need for preventive corrective actions or field safety corrective actions; f) determine possible improvements in the usability, performance, and safety of the device; g) contribute, where appropriate, to the post-market surveillance of other devices; and h) detect and report trends.

In addition, class IIa, IIb, and III MD manufacturers will prepare a periodic safety update report (PSUR) for each device. The PSUR is similar to that required for medicinal products. European regulations establish how often the PDUR is updated and remitted to the competent authority.

Moreover, from a health-care perspective, there is an MD surveillance system that includes the notification of adverse events, their recording and assessment by the health authorities, the adoption of appropriate measures to protect health, and the reporting of these measures to the interested agents[4,5]. In this system, a key role is that of the MD surveillance manager, who supervises and coordinates the incidents notified by the health professionals in their centre, acts as spokesperson with the health authorities, and guarantees the emission of the informative notes/MD alerts issued by the AEMPS. In order for the system to function properly, incidents must be reported to the centre's MD Surveillance Manager.

Finally, we must mention Spanish Royal Legislative Decree 1/2015, which states that hospital pharmacists should, among their other functions, "Participate in and coordinate the management of the medicinal products and medical devices procurements for the hospital to ensure efficiency". Differences between Spanish autonomous communities has led to differences in the level of participation of hospital pharmacists in the management of MDs, and therefore, it is unfeasible to apply criteria similar to those applied in the assessment, selection, and acquisition of medicines.

In conclusion, the health and safety of citizens could be compromised by the fact that the current system of MD conformity assessment and post-market surveillance needs further improvements to ensure that the agents involved are able to fulfil their obligations. Thus, the systematic reporting of incidents must be ensured, and the role of hospital pharmacists should be maximized, not only as MD Surveillance Managers, but as main agents in the comprehensive management of MDs as guarantors of their traceability, safety, and evidence-based effectiveness/performance. The implementation of the actions established in the new MD regulations will clearly improve these aspects.

Conflict of interests

No conflict of interest.

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