



European Device Regulatory Revolution: A Personal View

Manufacturers entering the European medical device market in recent years may not be aware of the complexities of trying to achieve this objective 20 years ago. Significant progress has been made, although much remains to be done. This article provides a personal view of the innovative approach to medical device regulation introduced in Europe in the early 1990s.

No two systems alike

Before the introduction of the medical device directives nearly 20 years ago, European regulation of medical devices was a patchwork of differing requirements. No two countries had the same system for regulating medical devices. Some countries had published regulations for certain types of medical products, such as sterile medical devices; others maintained lists of devices that were regulated based on perceived risk or national experience; certain countries classified some devices as medicinal products while subjecting others to specific device regulations. In yet other countries, medical devices were not subject to a regulatory regime or were regulated under voluntary systems of control. These differences represented a significant barrier to trade, which also affected other industrial sectors.

At that time, many will agree that the strongest point of reference for a comprehensive system of regulating medical devices rested with the United States (US) Food and Drug Administration (FDA). The US Medical Device Amendments of 1976 and the establishment of the Bureau of Medical Devices, later merged with the Bureau of Radiological Health to become the Center for Devices and Radiological Health, allowed FDA to provide a specific set of requirements for medical devices, which differed in important ways from the manner in which it regulated pharmaceuticals and other products.

The US system was certainly known to European regulators. I am aware of regulators in one European country that carefully studied FDA's approach to medical device regulation and compared it with their approach, which had been defined in a national law published in 1986. Subsequently, the European Commission pressured countries to stop the development of their own systems for regulating medical devices, because European harmonisation efforts were underway. Other contacts between the United States and

Europe included the Tripartite Subcommittee for Medical Devices, which fostered a mutual awareness of US and UK device regulatory systems. The Tripartite Subcommittee consisted of senior officials of the medical device authorities of the United States, United Kingdom and Canada and produced through its Toxicology Subgroup, the Tripartite Biocompatibility Guidance for Medical Devices of 1987, to which FDA still refers today. In spite of this close contact, Europe chose to adopt a system for regulating medical devices that differed in significant ways from the United States or other regulatory regimes.

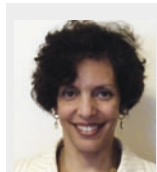
An innovative approach

As a result of considerable effort by a number of interested parties, including industry segments, medical devices were included in the products covered by Europe's "New Approach" to technical harmonisation. This approach, introduced by a European Council resolution in 1985, addressed a persistent and frustrating problem in Europe unofficially termed *Eurosclerosis*. This unfortunate condition meant that by the time European directives containing very detailed technical provisions were adopted, they were already obsolete.

To counter this, the New Approach directives referenced a list of essential requirements that become legally binding when transposed into national laws and regulations. The detailed technical provisions are provided in harmonised standards adopted and updated by European standards organisations CEN and CENELEC. Although these standards are voluntary, they confer a presumption of conformity with the relevant essential requirements. Products that are in compliance with the directives are then able to circulate throughout the European Economic Area.

The medical device directives are New Approach directives. The Active Implantable Medical Devices Directive (90/385/EEC) →

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→ (AIMDD) was adopted on 20 June 1990 and became mandatory on 1 January 1995. The Medical Devices Directive (93/42/EEC) (MDD) was adopted on 14 June 1993 and became mandatory on 15 June 1998. The In Vitro Diagnostic Medical Devices Directive (98/79/EC) (IVDD) was adopted on 27 October 1998 and became mandatory on 7 December 2003. Medical devices that comply with the relevant directive, as transposed by each European country into national laws and regulations, can be sold throughout Europe, which addresses the previous dramatic lack of medical device harmonisation in the region. Most readers will be aware that some differences persist from country to country, most notably national language and registration requirements, but the situation is markedly improved from 20 years ago.

Successful aspects

I have always believed that the European regulatory framework for medical devices is, in many ways, an elegant approach to regulating an exceedingly complex array of products. It is a risk-based system, with the stringency of requirements increasing in relation to the risk level of the device. Device classification, which is necessary for devices subject to the MDD, is the responsibility of the manufacturer, who must use a set of rules laid out in the MDD instead of consulting a list of products, which can become obsolete over

time. Under the IVDD, the manufacturer must determine the correct regulatory risk level by consulting certain articles and annexes in the directive.

Medical devices must be safe and perform as intended by the manufacturer instead of having to be safe and effective, as under the US system. As long as it can be shown that the benefits of using the device outweigh the risks, the manufacturer, not a regulatory authority or third party, establishes device performance. All devices must meet a set of general essential requirements concerning safety and performance and other more specific essential requirements depending upon the particular type of device.

All devices require risk analysis, which is much more clearly defined than in other regulatory regimes, including the US system. Manufacturers can choose a conformity assessment procedure to demonstrate compliance with the appropriate directive. The conformity assessment procedures selected most often by manufacturers are based upon the correct functioning of the manufacturer's quality system, which means that compliance with the selected procedure generally covers more than one device. By contrast, other regulatory regimes, including the US system, in most cases clear or approve one device at a time. Under US requirements, some devices can be grouped in one regulatory submission; however, this is frequently not possible.

The implementation of many of these aspects of the European device regulatory system has been generally successful in spite of the recognition that improvements are needed, as is the case with any regulatory process.

Improvement needed

What are some aspects of the system that need improvement? Reputable medical device manufacturers expend significant resources ensuring that their devices meet regulatory requirements. Effective market surveillance programmes help ensure that less reputable companies are identified and that appropriate regulatory action is taken to protect the public from unsafe devices that do not perform as claimed. The effectiveness of enforcement programmes across Europe, however, is extremely variable.

Notified Bodies are a vital element of the European regulatory system, as they are responsible for assessing technical documentation and issuing certificates needed for the CE marking process. They need to be competent to carry out these critical tasks, yet not all Notified Bodies have equivalent resources and expertise. Measures are being taken to improve this situation; the publication of best practices guides by the Notified Bodies Operations Group set up by the European Commission and member states is one example. Not all member states are equally effective in overseeing the Notified Bodies operating within their territories. If a manufacturer contracts with a Notified Body that is unable to perform as needed, many parties are potentially adversely affected, not least of which are the patients and users of the devices concerned. The quality of Notified Bodies needs to be better ensured and the variability in competence minimised.





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The European database, EUDAMED, was meant to be fundamental to information exchange, but was never financed properly, and until now is not functioning across Europe. This has led to the promulgation of a variety of different and sometimes overly complex and burdensome national device registration schemes. Directive 2007/47/EC revising the AIMDD and MDD required the European Commission to ensure that EUDAMED begin to function by 5 September 2012 at the latest, and report on the operation of the system by 5 October 2012. Notably, a European Commission decision published on 19 April 2010 formally established EUDAMED and requires member states to start using it from 1 May 2011, with all current data entered by 30 April 2012 at the latest.

The Global Medical Device Nomenclature (GMDN) is a system of internationally recognised coded descriptors in the format of preferred terms, with definitions used to generically identify medical devices and related healthcare products. Its purpose is to provide authorities, healthcare providers, medical device manufacturers and suppliers, conformity assessment bodies and others with a single naming system to support the exchange of data between competent authorities and others and the exchange of postmarket vigilance information, and for inventory purposes. After a promising start, progress stalled, and the programme is only now beginning to move forward. The system is far from ideal, however, with new terms being added and existing terms becoming outdated and unaccept-

able for some national registration schemes. In addition, manufacturers must purchase codes, so use of GMDN by manufacturers, particularly those outside Europe, has been slow. Some believe that access to codes must be free if GMDN is to achieve its objective of becoming truly global.

Future directions

The European approach to medical device regulation is under constant evaluation and scrutiny. Instead of concentrating on improving the existing system, some parties wish to drastically change the regulation of medical devices and adopt procedures similar to those used for the approval of medicinal products. Medical devices are far too diverse and different from medicinal products to benefit from such a simplistic approach. The current European system of regulating medical devices is not perfect, but it only needs improvement, not a complete overhaul. The European Commission, in concert with competent authorities, industry, Notified Bodies, and other stakeholders, is working on a "recast" of the directives, with an anticipated date of implementation before the end of 2015. It is to be hoped that *revision* rather than *rewrite* will be foremost on the Commission's mind. ©

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