Recasting the EU Medical Device Legislation

Elisabethann Wright and *Fabien Roy* examine the European Commission's public consultation on recasting the medical device directives and industry's response.

When the European Commission published its public consultation document on the so-called "recast" of the current EU legislation on medical devices on 7 May, it did not come as a great surprise to the informed public. In its communication to the European Parliament and the Council of the European Union in 2005 on "Implementing the Community Lisbon programme", the commission had already indicated its intention to recast two of the three basic EU directives governing medical devices into a simplified regulation. The subsequent proposal may have been "much awaited", as the commission's own press release claimed. It was not, however, in the form of a regulation.

Moreover, there was a certain level of disappointment that the 2005 proposal, as finally submitted, did not constitute the overhaul of the existing medical device legislation that was hoped for in some corners. No explanation as to the change of legislative approach was given in either the impact assessment report for the commission's proposal or in the explanatory memorandum that accompanied the proposal.

Even before the resultant modifications[1] to the Active Implantable Medical Devices Directive[2] and the Medical Devices Directive[3] had been adopted, there were already rumblings that it was time for a complete revision of EU medical device law. EU member states are still implementing the amendments to the two directives mentioned above and manufacturers are still trying to determine how those changes are likely to affect their products. At the same time, the commission is proposing a revision of this existing framework "to improve and strengthen the legal framework for the regulation of medical devices in Europe".

The consultation

According to the new public consultation document, experience indicates that the current system does not always offer a uniform level of protection of public health in the EU[4,5]. New and emerging technologies, the commission says, present new challenges to the current framework, highlighting gaps and pointing to a certain scarcity of expertise. However, the medical device industry disputes this. In what is, arguably, a fair historical comment, the European medical technology industry association Eucomed has asked why the need to protect public health has come to the fore now when it was not considered such a fundamental priority during the recently finished review of some aspects of EU medical device legislation.

The procedure for CE marking is already fairly comprehensive. Moreover, while there are undoubtedly areas of concern, such as the appearance of counterfeit devices on the European market, there does not appear to be any marked increase in public health issues related to the CE-marking process itself. Added to this are the commission's own recent actions; these include the publication of very practical and useful guidelines on a medical device vigilance system. Admittedly, the guidelines do not have legal effect. Moreover, there are reports that the competent authorities in a number of EU member states refuse to accept incident reports in the formats laid down in the annex to the guidelines. However, there is a growing set of provisions, both legislative and guidance, to help ensure that medical devices placed on the EU market do not present a threat to public health.

Lack of uniformity

The commission's new consultation document refers to the fact that a number of different legislative provisions govern medical devices. The commission considers the current legislative framework too fragmented and difficult to follow. This situation is further compounded by national variations. National decisions on whether a product is a medicinal product or a medical device can vary from member state to member state. This means that there are differences in the way they classify the same type of devices. The commission thus wishes to recast the existing medical device legislation, possibly adopting a single regulation governing all types of device. This approach may address concerns regarding the current inconsistencies between the way in which the national authorities of the EU member states have implemented medical device legislation.

Directives are EU legislative acts that require EU member states to achieve a particular result without dictating the means of achieving that result. Regulations are self-executing and do not require any implementing measures. Transforming the existing legislation into a single regulation, therefore, would at least reduce the number of inconsistencies in the content and application of EU legislation between EU member states.

There is an argument to be made for having separate legislative provisions governing differing types of medical devices, rather than a single provision governing all types. Eucomed, however, believes that, for a highly complex and diversified sector such as the medical device/technology industry, nine directives are appropriate. The organisation does not oppose the consolidation of the existing legislation. However, this would be on the condition that no major changes be made to the current legislative framework.

Notified bodies

One of the aspects of existing EU medical device legislation that the commission considers in need of revision is the role and function of notified bodies. The commission predicates the proposed modifications on the fact that, since 1993, the number of EU member states increased from 12 to 27 and the number of notified bodies to 80.

Notified bodies play an important, and generally useful, role in the CE marking of medical devices in the EU. The commission's proposal that the role of the notified bodies be revisited has provoked a debate as to whether

Elisabethann Wright is a counsel, and **Fabien Roy** a legal assistant, at the Brussels office of Hogan & Hartson LLP.

they should be replaced with either national authorities in EU member states or a single supranational body. Indeed, the commission proposes the creation of a new committee in the European Medicines Agency (the EMEA) to complement the existing CE-marking process for medical devices, including notified bodies.

While the number of EU member states and notified bodies has increased, so has the variety and, in many instances, the complexity of medical devices. However, legislation and guidelines have not always kept pace with this evolution. As a result, notified bodies have, in some cases, reportedly taken on roles that are not provided for in the existing EU legislation. Replacing notified bodies, which are usually private organisations, with national authorities, would seem unlikely to have any great impact as compared to the current European process. Nevertheless, increasingly detailed rules aimed at uniformity of approach and obligations would arguably be beneficial.

The commission argues for the involvement of the EMEA in the evaluation of medical devices, by creating a specific medical device component of the agency. It notes that the EMEA has over ten years of experience in the protection and promotion of public health, through the evaluation and supervision of medicines for human and veterinary use in Europe. The commission adds that the EMEA already works with member states' national authorities, many of whom have dual responsibility for both medicinal products and medical devices.

There can be no disputing the level of expertise available in the EMEA. This is, however, as the commission acknowledges, in the area of human and veterinary medicinal products. It can be expected that, particularly given the means by which EU legislation currently functions in the CE marking of medical devices, arguments will be raised as to whether such expertise can easily be transferred to what many may consider to be an entirely different type of product.

Quasi medical devices

The most recent revisions to the medical device legislation, combined with the adoption of the advanced therapies regulation[6], were intended to ensure clarity concerning the classification of all types of currently available medical device. However, as the commission's consultation document mentions, there are some medical devices that are still not regulated at EU level. These are "products containing or consisting exclusively of non-viable human or animal cells and/or tissues, which do not contain any viable cells or tissues and which do not act principally by pharmacological, immunological or metabolic action". Prior to the adoption of the advanced therapies regulation, there was debate as to how such products should be classified. It appears from the variety of options presented in the consultation document that this will continue to be a subject of debate.

The commission proposes that some implantable or invasive products that are not currently regulated at the EU level should be considered "quasi medical devices". The need to create a new category of quasi medical devices to cover products that the commission itself acknowledges are not covered by the current detailed definition of what constitutes a medical device can be expected to give rise to debate. Creating a category of products that falls, to some extent, within the term "medical device", although they do not fall within the definition of these devices as provided for in existing EU legislation, may well lead to confusion. Perhaps a more simple solution would be to create a new term and new criteria for determining which products fall within this classification.

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