ELISABETHANN WRIGHT AND FABIEN ROY

Discussing devices

Advancing technology and an expanded EU has prompted an update of medical devices provision

When the European Commission published its public consultation document on the recast of the current provision governing medical devices in May it was no great surprise to the informed public. 'Implementing the Community Lisbon programme' – a Communication to the European Parliament and the EC in 2005 – had already indicated its intention to simplify two of the three basic EU directives governing medical devices.

The subsequent proposal may well have been "much awaited" as the Commission claimed but it was not yet in the form of a regulation. There was also disappointment in some corners that the proposal, as finally submitted, did not constitute an overhaul of the existing medical device legislation.

No explanation as to the change of legislative approach was provided 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 to Directive 90/385/EEC and Directive 93/42/EEC had been adopted there were rumblings that it was time for a complete revision of EU medical device law. Member states are still implementing the last set of amendments to the medical devices directives, and manufacturers continue to determine the likely impact of these for their products.

Meanwhile the EC is proposing a revision of this existing framework in order "to improve and strengthen the legal framework for the regulation of medical devices in Europe".

HEALTH PROTECTION

In the Consultation document the Commission acknowledges from experience that the current system does not always offer a uniform level of protection of public health in the EU. It feels that new and emerging technologies present challenges to the framework, highlighting gaps and pointing to a certain scarcity of expertise. The industry disputes this, medical devices company Eucomed has asked why the need to protect public health has come to the fore now when it was not considered to be such a fundamental priority during the recent revisions of aspects of EU legislation.

> "There are areas of concern, such as the appearance of counterfeit devices"

The procedure towards CE (Conformité Européene) marking is already fairly comprehensive. There are undoubtedly areas of concern, such as the appearance of counterfeit devices in the European market but there does not appear to be any marked increase in public health issues related to the CE marking process itself. The Commission recently provided very practical and useful guidelines on a medical device vigilance system – although, admittedly, these do not have legal effect.

Yet, there are reports that the competent authorities in a number of member states refuse to accept incident reports in the formats laid down in annex to these guidelines. There is an increasing amount of legislation and guidance, to help ensure that medical devices placed on the EU market do not present a threat to public health.

SINGLE AND SIMPLIFIED

The Commission considers that the current legislative framework is too fragmented and difficult to follow. This situation is further compounded by national variations which include:

- different decisions on whether an item is a medicinal product or a medical device
- differences in the classification of the same type of devices
- different registration requirements.

Adopting a single regulation governing all types of device may address concerns about inconsistencies between the manner in which national authorities have implemented legislation. Directives are EU legislative acts which require member states to achieve a particular result without dictating the means of achieving it. Regulations are self-executing and do not require any implementing measures. A single regulation should result in fewer inconsistencies in the content and application of legislation between member states.

SEPARATE AND SPECIFIC

There is a case for having separate legislative provisions governing

In Brief

Online research pilot

The European Commission has launched a pilot project that will give unrestricted online access to EU-funded research results. The pilot is part of the EU's 7th Research Framework Programme (FP7) and will cover around 20 per cent of its €50bn budget, in areas such as health, energy, environment, social sciences and information and communication technologies. The project will run until the end of FP7 in 2017 and aims to ensure that the results from EU-funded research are progressively made available to all. Grant recipients will deposit peer-reviewed research articles or final manuscripts, resulting from their FP7 projects, in an online repository. They will have to ensure open access to these articles within either six or twelve months after publication, depending on the research area. This embargo period will allow scientific publishers to get a return on their investment. Open access to research articles, which were previously accessible through journal subscriptions, can help to increase the impact of the EU's €50bn R&D investment and avoid wasting time and valuable resources on duplicative research. Small and medium-sized businesses and entrepreneurs can also benefit from improved access to the latest research developments to speed up commercialisation and innovation.

EMEA regulation access

A new section has been created on the European Medicines Agency (EMEA) website to make it easier to access the main regulatory and procedural guidance documents.

differing types of medical device – rather than a single provision governing all types.

Eucomed considers that, for a highly complex and diversified sector such as the medical device/technology industry, as many as nine directives are appropriate. The company does not oppose the consolidation of the existing legislation, on condition that there are no major changes to the current legislative framework.

> "Notified bodies play an important, and generally useful, role in CE marking"

NOTIFIED BODIES

One of the aspects of existing medical device legislation that the EC 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 member states has 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 proposal by the Commission that the role of the notified bodies be revisited has provoked debate as to whether these bodies should be replaced with either national authorities in member states or a single supra-national 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.

COMPLEX AND VARIED

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

A ROLE FOR THE EMEA

The Public Consultation document suggests that the The European Medicines Agency (EMEA) could be involved in the evaluation of medical devices. The agency has over 10 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. It already works with national authorities in member states, many of whom have dual responsibility for both medicinal products and medical devices.

There can be no disputing the EMEA's level of expertise available in the area of human and veterinary medicines. Given the means by which EU legislation currently functions in the CE marking of medical devices, such expertise may be transferred easily despite the differences between the two products groups.

CLASSIFICATION CLARITY

The most recent revisions to the medical device legislation combined with the adoption of the Advanced Therapies Regulation were intended to ensure clarity concerning the classification of all types of currently available medical device. However, as the Commission's Public 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".

Before 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 Public Consultation document that this will continue to be a subject of debate.

> "A simpler solution maybe to create a new term and new criteria"

TERMS AND CRITERIA

The Commission proposes that some implantable or invasive products that are not currently regulated at the EU level should be considered "quasi-medical devices". Instead of creating a new category for products, that the Commission itself acknowledges are not covered by the current detailed definition, a simpler solution may be is to create a new term and new criteria for determining which products fall within this classification.

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The section includes links to key legislative texts, regulatory guidelines, procedural advice, templates and standard operating procedures. All of the information available through this section of the site is already published online – elsewhere on the EMEA site or by other sources such as the International Conference on Harmonisation (www.ich.org). However this area of the website enables the documents to be accessed via a comprehensive index through a single entry point. See: www.emea.europa.eu/htms/human/raguidelines/intro.htm

Cross-border healthcare

The European Commission has adopted a draft Directive on the application of patients' rights to cross-border healthcare, which provides a Community framework for safe, high quality and efficient cross-border healthcare. Although most people receive healthcare in their own country, sometimes the best care is provided abroad – this can be the case in highly-specialised care or in border areas where the nearest appropriate facility is in another country. The Commission has developed a legal proposal which will provide more clarity about the possibilities of seeking healthcare in another member state. The proposal will also make clear who is responsible for quality and safety of care in cross-border settings. It will strengthen cooperation in different areas, such as networks of 'centres of reference' for specialised care. This proposal aims to help patients to access the healthcare they need, and to help member states ensure the accessibility, quality and financial sustainability of their healthcare systems.