

European Medical Device Regulation: A New Era?

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Image: PhotoDisc

By the spring of 2005, the European Commission hopes to present the first draft of the revisions to the Medical Device Directive to the European Council and Parliament. However, these revisions represent only part of the changing European regulatory scenario. This article discusses a tangible shift in European medical device regulatory policy and some actions that companies can take to understand and prepare for these policies.

A shift in regulatory attitude

The European medical device industry was instrumental in the inclusion of medical devices under the New Approach Directives. Industry associations and experts were also actively involved in drafting the medical device Directives. In fact, during the phase of the national implementation of these Directives, the relationship between industry and Notified Bodies was characterised as a partnership in ensuring that medical devices were safe and performed as intended by the manufacturer. It was also evident that although some national authorities were more active than others in their oversight of the correct implementation of the Directives, an adversarial nature between industry and national authorities was generally, and thankfully, lacking. Much more emphasis was placed on the need for cooperation between regulatory bodies and industry to accomplish the common goals of public safety and access to beneficial medical devices.

Some aspects of this positive approach to the European regulation of medical devices seem to be changing. In some cases, there is less openness and accessibility to regulatory information and policies, although this is not the case with all national authorities. In addition, Member States are increasingly willing to initiate legal action against medical device manufacturers and other parties involved in complying with the Directives. All this is occurring at the same time that the medical device Directives in general, the MD Directive (93/42/EEC) in particular, and national regulatory policies and practices are being examined and refined to improve the clarity of the

Directives and the manner in which they are being implemented. For this reason, readers should pay extremely close attention to changing European regulatory policies. However, this is not always easy given the nature of how European policy is developed, discussed and adopted.

Increased market surveillance

Member States are increasing their market surveillance activities. That is, some Member States are beginning to check the correct implementation of the Directives by visiting or requesting information from manufacturers, importers, distributors and authorised representatives. This should not be viewed as a negative development. For some time now, some medical device companies that are expending considerable effort and resources in an effort to comply with the requirements of the Directives have noted that some colleagues in other companies are not doing the same. In addition, manufacturers of Class I devices are not always aware of the correct interpretation of the Directives. Responsible surveillance programmes that are based on sufficient knowledge and a reasoned regulatory interpretation of the Directives benefit those companies. Indeed, these programmes are valuable to all parties involved with ensuring that medical devices on the European market meet the regulatory requirements that are applicable to them. However, the manner in which national authorities are conducting their market surveillance and the information that they provide on their internal regulatory policies and interpretations varies dramatically. →



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Therefore, to avoid unexpected and costly problems resulting from these increasingly active and variable surveillance programmes, manufacturers should ensure that they fully comply with the requirements. In addition, manufacturers should ensure that any activities performed on their behalf by distributors or authorised representatives are fully compliant. For example, some manufacturers allow their distributors to translate labelling into international languages without exercising any control over this action. This is unacceptable. Although translations may be managed by distributors, the manufacturer should have full control over this activity.

Review of the MD Directive

Readers can gain some understanding of the changes that are taking place in Europe with regard to the overall regulation of medical devices by reviewing certain documents related to the recent formal review of the MD Directive. These are available on the European Commission's website and include the Report on the Functioning of the MD Directive¹ and the Commission Communication on medical devices.² A related document is the Commission Communication on enhancing the implementation of the New Approach Directives.³

The MD Directive requires, no later than five years after the date of implementation of the Directive, that the European Commission present a report to the European Council on the functioning of the Directive with regard to vigilance, clinical investigations and consultations with pharmaceutical authorities. The Report of the Functioning of the MD Directive, which was issued in June 2002 by the Medical Devices Experts Group (MDEG), formed the basis of the report required by the MD Directive. However, a decision was made to broaden the review process to an overall assessment of the functioning of the Directive. Therefore, the MDEG report identifies issues, concerns and proposed action items for improving the overall operation of the MD Directive. The MDEG report was discussed in a previous article.⁴

The MDEG report concludes that the medical device Directives provide in themselves an appropriate legal framework for medical devices. However, it also states that some improvements in the implementation of the Directives need to be made as well as some revisions to the Directives to improve the regulatory framework.

Areas of greatest concern

The Commission Communication on medical devices should be reviewed because it is the formal report required by the MD Directive, and it also contains the Commission response to the MDEG report. Readers should review this report because it covers a subset of the information provided in the MDEG report and concentrates on only those areas of greatest concern. Readers should also review the Commission Communication on enhancing the implementation of the New Approach Directives, mentioned previously. This is because the medical device Directives are based on the New Approach and some of

the issues discussed in this Communication are also applicable to medical devices.

MD Directive revisions

By reviewing the MDEG report, readers can begin to understand the issues and concerns that were identified by national authorities and others involved in the review process. This is also the only practical way for the majority of readers to anticipate the revisions to the MD Directive that may be made because the formal proposed revisions will not be widely available for some time. In early October 2004, the European Commission circulated to the MDEG a document incorporating the proposed revisions into the text of the MD Directive. The Commission has stated that it expects to present a first draft of the proposed revisions to the European Council and Parliament in spring 2005.

Be prepared

Prudent companies will not wait until the spring of 2005 to begin assessing their operations in terms of the concerns expressed by national authorities and others regarding the implementation of the MD Directive. They will begin now to inform themselves of these concerns, address any shortcomings that they identify, and ensure full compliance with the Directives. At the same time, national authorities should base their actions on sound scientific and regulatory principles and make information on national requirements and policies easily available to affected parties.

References

1. Report on the Functioning of the Medical Device Directive (93/42/EEC of 14 June 1993), Medical Devices Experts Group, 5 June 2002, downloadable from http://europa.eu.int/comm/enterprise/medical_devices/index.htm then click on "Review Process" under "Current Policy Areas"
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4. M.E. Donawa, "Review of the Medical Device Directive," *Med. Dev. Tech.*, **14**, 2, pp. 20–23 (2003). [mdt](#)

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