

# Proposed Amendments to the Medical Devices Directives

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As 2005 came to a close, the European Commission issued its formal proposal for a Directive amending the medical devices Directives. This article discusses certain aspects of the proposed amendments and encourages readers to review them in their entirety.

## Commission proposal

On 22 December 2005, the European Commission issued a proposal for a Directive to amend the Medical Device Directive (93/42/EEC), the Active Implantable Medical Device (AIMD) Directive (90/385/EEC) and the Biocides Directive (98/8/EC). The Biocides Directive needs to be amended to exclude in vitro diagnostic medical devices from its scope and will not be discussed further. It was also decided to amend the AIMD Directive to align it with the MD Directive and In Vitro Diagnostic Directive (98/79/EC). The Commission's proposal can be downloaded from its website: [http://europa.eu.int/comm/enterprise/medical\\_devices/index\\_en.htm](http://europa.eu.int/comm/enterprise/medical_devices/index_en.htm). In addition, the same site contains an "impact assessment working document," which discusses some of the major non-legislative initiatives being undertaken to improve the implementation of the medical devices Directives. Table I provides background information on the activities leading to the Commission's proposal.

Before adoption, the Commission's proposal for the amending Directive must be forwarded to the European Parliament and Council for co-decision. The amount of time this will take is uncertain. Once the Directive has been formally adopted, it will then be necessary for Member States to amend their national laws and regulations, which transpose the Directives. If the proposed timeframes are adopted, the Directive will enter into force on the 20th day following the day of its publication in the *Official Journal of the European Union*. Member States will have

12 months to adopt and publish laws, regulations and administrative provisions necessary to comply with the Directive, and will have 12 months to apply the provisions. Therefore, it is possible that more than two years will pass before the adopted amendments become mandatory.

## Proposed amendments

The proposed amendments are described in various articles of the Commission's proposal. Article 1 covers those related to the AIMD Directive. They include provisions related to the authorised representative, European databank, health protection measures, medical devices incorporating stable derivatives of human blood or human plasma, and other provisions. Annex I of the proposal includes the proposed amendments to Annexes 1 to 5 of the AIMD Directive. The proposed amendments related to the MD Directive are in Article 2 of the Commission's proposal. They range from simple clarifications to the addition of new requirements. Annex II of the proposal includes proposed amendments to Annexes I to X of the MD Directive.

A description of all proposed amendments is beyond the scope of this article; however, readers should carefully review all the proposed amendments. This is because it is difficult to characterise which proposed amendments are the most important. That is to say, the importance of a particular proposed amendment, even one that seems to be a relatively simple clarification or addition, may have



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a significant regulatory and/or economic impact on a particular manufacturer or on others involved in complying with the provision. For example, the proposed amendments to software, which are discussed later, will be important to manufacturers of devices containing software or to software developers, but perhaps not to other companies. The more important amendments regarding clinical data are also discussed, which will affect nearly all companies.

### New software requirements

The Commission's proposal includes a proposed amendment to Article 1, Definitions, scope, of the MD Directive to include "software" in the definition of medical device. This means that this type of software would be a medical device and therefore subject to the MD Directive. There is also a proposed amendment to Section 9 of Annex I, Essential Requirements, which would require the validation of software incorporated into devices or software that itself is considered medical software, according to the state-of-the-art, taking into account the principles of development lifecycle, risk management, validation and verification. The same amendment related to validation is being proposed for Section 12, Requirements for medical devices connected to, or equipped with, an energy source. In addition, a proposed amendment to Section 1.4 of Annex IX, Classification, would be the addition of a sentence that states that standalone software is considered to be an active medical device.

Some may argue that the proposed amendments concerning the requirement for software validation are clarifications and not new requirements because all medical devices, including those with software, must meet the Essential Requirements. However, in the absence of a clear requirement, the consistent and adequate validation of software incorporated into medical devices or medical standalone software cannot be reasonably expected. Therefore, if adopted, these amendments would help ensure appropriate safety, performance and quality of these types of software. In addition, they are also consistent with United States (US) requirements related to software and would facilitate the acceptance of these products when manufacturers wish to export their products to the US. In spite of these potential benefits, the regulatory and economic impact of these proposed new requirements would be significant to those companies affected by the changes and should be acknowledged.

### Improving clinical data

The need to improve the adequacy and evaluation of clinical data for all classes of medical devices was of particular concern to many Competent Authorities. As a result, there are a number of important proposed amendments relating to clinical data and evaluation. For example, a proposed amendment to Article 1, Definitions, scope, is to include a definition of "clinical data." A proposed amendment to Article 14a, European databank, would require that the

databank contain data related to clinical investigations. This would allow Competent Authorities to be aware of multicentre studies and to more effectively co-ordinate their surveillance activities regarding these studies. A proposed amendment to Article 15, Clinical investigations, would require that Member States communicate to other Member States unfavourable decisions regarding the commencement of clinical investigations. Another proposal would require that Member States base their decisions for allowing the start of clinical investigations on favourable ethics committee reviews that include a review of the clinical investigation plan.

A proposed amendment to Annex VII, EC Declaration of Conformity, would require that technical documentation include clinical evaluation in accordance with Annex X to allow assessment of the conformity of the product with the requirements of the MD Directive. Currently, Annex VII requires that the technical documentation include clinical data in accordance with Annex X only "where appropriate." The purpose of this amendment is to ensure that there is adequate clinical data for Class I and Class IIa devices where Annex VII is either the sole means of conformity assessment or is used with another Annex to demonstrate conformity to the MD Directive.

The proposed amendments of Annex X, Clinical Evaluation, include not only clarifications, but also new requirements and significantly expanded general provisions. For example, Section 1.1 of Annex X of the MD Directive currently states that as a general rule, the evaluation of undesirable side effects and other characteristics of the device must be based on clinical data. The proposed amendment to this Section would require the evaluation of side effects and the acceptability of the benefit/risk ratio to be based on clinical data. In addition, this requirement would apply to all devices. The proposed amendment would also require the evaluation of clinical data to follow a defined and methodologically sound procedure that is based on:

- a critical evaluation of the relevant scientific literature where there is demonstration of equivalence of the device to the device to which the data relate, and where the data adequately demonstrate compliance with the relevant essential requirements, or



**Table I:** The activities leading up to the European Commission's proposal.

A review of the functioning of certain provisions of the MD Directive was required under Article 11, Conformity assessment procedures, of that Directive. This requirement, and the related report by the Medical Devices Experts Group (MDEG), were discussed in a previous article.<sup>1</sup> The report concluded that the medical devices Directives provide an appropriate legal framework, but that there is a definite need for improved implementation and clarification of certain requirements. The European Commission presented its own conclusions, which were based on the issues highlighted in the MDEG report, in a Communication to the European Council and European Parliament.<sup>2</sup> The Communication was welcomed by the Council in a Conclusion on medical devices<sup>3</sup> and discussed by the European Parliament, which adopted a resolution on health implications of the MD Directive.<sup>4</sup>

- a critical evaluation of the results of all clinical investigations made, or
- a critical evaluation of the literature combined with the results of clinical investigations.

Another proposed amendment to the general provisions would require clinical investigations to be conducted for all implantable devices and devices in Class III, unless there is sound justification for relying on existing clinical data. The MD Directive specifies the importance of clinical data for these types of devices, but does not specify the need for clinical investigations. Therefore, this proposed amendment is also significant from a regulatory and economic point of view.

### Clinical study adverse events

Section 2.3.5 of Annex X of the MD Directive requires that all adverse events such as those specified in Article 10, Information on incident occurring following placing of devices on the market, are fully recorded and notified to the Competent Authority. In spite of this provision, Competent Authorities have stated that there has been inconsistent compliance with this requirement. A proposed amendment to this section would require that all serious adverse events (SAEs), whether device related or not, be fully recorded and immediately notified to the Competent Authority of the Member State in which the event occurred, and that a summary of SAEs be provided on a periodic basis, to all Competent Authorities of the Member States in which the clinical investigation is being performed. Therefore, the type of adverse events that would need to be reported would be much more appropriate with relevant events that may occur during the conduct of clinical investigations and consistent with the management of adverse events as specified in the EN ISO14155 standards, which are European harmonised standards for clinical investigations.

### Other proposed amendments

There are many other proposed amendments; they include those related to

- demarcation between devices and medicinal products
- custom-made devices
- the inclusion of human tissue engineered products incorporated into a medical device as an integral part with an action that is ancillary to the device
- the possibility of providing information supplied by the manufacturer by other means
- classification of medical devices
- the requirement to designate a single authorised representative where a manufacturer does not have a registered place of business in a Member State
- the modification of confidentiality requirements
- other areas.

### Better operating practices

It is important that readers review the proposed amendments so that they are aware of the changes that could affect their operations well ahead of the time of adoption.

Some companies may consider certain proposed amendments as unjustifiably stringent. Other companies will view some of the amendments as ideas for better operating practices, which can be implemented before the adoption of the amending Directive because they are not in conflict with current requirements such as basing the evaluation of side-effects and the acceptability of benefit/risk ratio on clinical data. In other cases, it would not be appropriate to implement the proposed amendments because they are in conflict with the existing provisions of the MD Directive.

### References

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3. "Council Conclusions on 2 December 2003 on Medical Devices" (2004/C 20/02), *Official Journal of the European Union*, C 20/1, (24.1.2004)
4. European Parliament Resolution on the Health Implications of Council Directive 93/42/EEC Concerning Medical Devices (2001/2270(INI)), *Official Journal of the European Union*, C 68E/85, 18.3.2004 [mdt](#)

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