

# Proposed New European Medical Device Regulations

After more than 20 years of broadly accepted success, the European directives on medical devices are in line for a major overhaul. The European Commission has recently published its proposals for regulations on medical devices and *in vitro* diagnostic medical devices. This article highlights selected revisions of the medical device proposal.

## Maria Donawa

On 26 September 2012, the European Commission adopted a “package on innovation in health” consisting of the “Communication on safe, effective and innovative medical devices and *in vitro* diagnostic medical devices for the benefit of patients, consumers and healthcare professionals”<sup>1</sup>, a proposal for the regulation of medical devices<sup>2</sup> and a proposal for the regulation of *in vitro* diagnostic (IVD) medical devices.<sup>3</sup> The proposed medical device regulation will cover in one regulation devices that are currently the subject of two separate directives, the Active Implantable Medical Devices Directive (AIMDD; 90/385/EEC) and Medical Devices Directive (MDD; 93/42/EEC). The use of regulations instead of directives is important because regulations are directly in force across all countries in the European Union (EU), whereas directives must be transposed into national law in each member state. The transposition process led to variations in national implementation of the directives, which should be avoided by the use of regulations.

It is not surprising that the medical device proposal reflects a more stringent approach to European device regulation; however, the number and level of stringency of some of the proposed provisions is surprising and in some cases perplexing. Of course, important changes could still be made before it is published as a final regulation, which is expected to be during

2014. In any case, readers are strongly encouraged to thoroughly review the proposal to gain a general understanding of the depth and range of the proposed revisions. This will take time because the entire proposal is 194 pages and includes 13 pages of an explanatory memorandum, 13 pages of recitals (“whereas” statements), 73 pages containing 97 articles, 75 pages containing 16 annexes, and a 20-page legislative financial statement. This article provides only an introduction to the proposed regulation; future articles will discuss some of the proposed revisions in more detail.

### Broadened scope and regulatory reach

The proposed regulation includes several important new categories of products that are either currently outside the scope of the European medical device directives or where there is doubt of coverage. These include:

- Products manufactured utilising nonviable human tissues or cells, or their derivatives that have undergone substantial manipulation, unless they are covered by the regulation on advanced therapy medicinal products.
- Certain implantable or other invasive products without a medical purpose that are similar to medical devices in terms of characteristics and risk profile, such as noncorrective contact lenses and implants for aesthetic purposes.
- Products manufactured from or with nanomaterials in the range 1 to 100 nm.



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- Devices that have been identified by their manufacturers as single-use products that have been reprocessed with a view to being reused in the context of a clinical procedure. The organisation carrying out the reprocessing will be considered the legal manufacturer for the purposes of placing such devices on the market, and any indication of the original manufacturer must be removed from the device.
- Replacement parts that significantly alter the characteristics of devices would be considered devices in their own right and subject to the full CE marking process.

### Proposed scrutiny procedure

The proposal calls for the formation of an expert committee called the Medical Device Coordination Group (MDCG), made up of members appointed by the member states and chaired by the European Commission. One of the major—and most controversial—roles of this group would be to subject a number of conformity assessment files for innovative, high-risk devices to an additional central scrutiny procedure. Under this procedure, Notified Bodies would be obligated to notify the Commission of applications for conformity assessments of new Class III devices. The Commission would pass details of the new device to the MDCG. The group would then have 28 days to decide whether or not to request the Notified Body to

submit a summary of the preliminary conformity assessment prior to issuing a certificate.

The MDCG would have to submit comments on the summary within 60 days; during the first 30 days, the MDCG may request additional information that “for scientifically valid grounds are necessary for the analysis of the Notified Body’s preliminary conformity assessment.” The Notified Body would need to give due consideration to any comments received from the MDCG and provide the Commission with an explanation of how these comments have been taken into consideration. The explanation would have to include any justification for not following the comments received and the Notified Body’s final decision regarding the conformity assessment in question.

As proposed, this procedure would add a significant layer of bureaucracy to the proposed regulation that already contains other provisions meant to strengthen the evaluation of new Class III devices; its health benefit is difficult to understand.

### Qualified person

Under Article 13, Person responsible for regulatory compliance, manufacturers would need to have available within their organisations at least one qualified person who possesses expert knowledge in the field of medical devices. The expert knowledge would need

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to be demonstrated by either specified educational qualifications or five years of professional experience in regulatory affairs or in quality management systems related to medical devices. The qualified person would be responsible for ensuring that:

- device conformity is appropriately assessed before each batch is released;
- technical documentation and declaration of conformity are drawn up and kept up-to-date;
- vigilance reporting obligations are fulfilled;
- in the case of investigational devices, the statement would be issued indicating that the investigational device conforms to general safety and performance requirements, apart from the aspects covered by the clinical investigation (referred to in point 4.1, Annex XIV).

These responsibilities have their origin in pharmaceutical legislation, which requires a “qualified person” for batch release reporting of adverse events. These responsibilities are already fulfilled in the typical medical manufacturing organisation, regardless of size, under quality systems enshrined in Annexes II, V and VI of the MDD.

Authorised representatives would also be required to have available within their organisation at least one qualified person who possesses expert knowledge regarding European medical device regulatory requirements.

### Common technical specifications

Article 7, Common technical specifications, would allow the Commission to publish common technical specifications (CTS) where no harmonised standards exist or where relevant harmonised standards “are not sufficient.” Their purpose would be to provide a presumption of conformity with the general safety and performance requirements of Annex I. CTS are already used in the IVD sector, but will be new to other manufacturers.

Any judgement by the Commission that a harmonised standard is not sufficient should be made carefully, with adequate input from those who are knowledgeable of the use of the standard. Otherwise, there is a danger that standards, historically recognised as state of the art within the New Approach framework, are no longer recognised as such. This has the potential to compromise global acceptance of international consensus standards. If the Commission seeks to influence the acceptability of standards, it might be more productive for it to send its subject-matter experts to standardisation technical committee and working group meetings.

### More revisions

Examples of other important proposed revisions include:

- how Notified Bodies are notified and monitored by Competent Authorities;



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- making unannounced audits by Notified Bodies mandatory;
- an obligation for manufacturers of Class III and implantable devices to make publicly available a summary of safety and clinical performance, including key parts of supporting clinical data;
- a requirement for devices to include a unique device identification (UDI);
- the provision of a card to patients receiving implants that details the device, its expected lifetime and relevant warnings and precautions.

### Uncertainties remain

The proposal must now be submitted for review by the European Parliament and European Council. This process could take between one and two years for a common position to be reached. Once the final wording of the regulation is published in the Official Journal of the European Communities, it will enter into force 20 days from publication and come into full effect three years after entry



What is your opinion on the proposed new European medical device regulations? Discuss the proposal in the *EMDT* group on LinkedIn: <http://linkd.in/Q4ISpN>.

into force. Thus, it is likely to be 2017 before manufacturers are required to comply with the new requirements, although there is a provision in the proposal for manufacturers to be able to conform at any time after entry into force.

Prudent medical device companies will keep a very close watch on this process and, where possible, make their views known, for example, through their industry associations, if they believe that the proposed revision is likely to be more detrimental than beneficial to European citizens.

### References

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3. Proposal for a Regulation of the European Parliament and of the Council on *in vitro* diagnostic medical devices; [http://ec.europa.eu/health/medical-devices/files/revision\\_docs/proposal\\_2012\\_541\\_en.pdf](http://ec.europa.eu/health/medical-devices/files/revision_docs/proposal_2012_541_en.pdf)

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