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The European Commission proposes new rules for medical devices

On 26 September 2012 the European Commission ("Commission") presented its proposal to the European Parliament and the Council regarding two new regulations on medical devices. The Parliament and the Council will now consider the proposals and then decide jointly on a new legislation. The first proposal concerns a new regulation for medical devices that will replace Directive 90/385/EC on the approximation of the laws of the Member States relating to active implantable medical devices and Directive 93/42/EC concerning medical devices ("the Directives"). The second proposal relates to a new regulation to replace Directive 98/79/EC on in vitro diagnostic medical devices ("the in vitro directive"). Partner Elisabeth Eklund and associate Jenny Crafoord here comment on the proposals for the new regulations.

The current regulatory framework for medical devices

The European Union's ("EU") current regulatory framework for medical devices covers a wide range of products. In Sweden the three directives are implemented through the Swedish Act on medical devices. Since 1 September 2001 the MPA is the supervisor of medical devices and their manufacturers under the Ordinance on medical devices. The MPA is also responsible for the regulations needed to clarify the requirements specified in Section 6 of the Act on Medical Devices.

The Swedish National Board of Health and Welfare oversees the medical devices used in health care and the products that are manufactured in health care and which are intended to be used only in the health care.

According to the current regulations, the manufacturer of a medical device is responsible for making an analysis of whether the product is suitable for its intended use and is safe, including the risk of side effects and adverse events, before placing the product on the market. This analysis should be based on the design, production and intended use. Medical devices are divided into four classes of risk according to the risk a possible failure of the product may cause to patients or staff. Each medical device placed on the market must comply with the rules, regardless of how and by whom the product is used and regardless of the risks associated with its use. As a sign that the product complies with the regulatory requirements it must be CE marked. The process of CE marking is depending on the class in question. A product that has been assessed and CE marked in one country has access to the entire EEA market.

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Products with little risk, Class I products (e.g. patches and spectacles) are CE marked without identification number. The manufacturer's self-control in combination with technical documentation, classification and risk analysis, and a declaration that the product meets the essential requirements, is usually sufficient. The manufacturer or the manufacturer's representative in Sweden must register the product to the MPA.

For products with higher risk, Class II a (e.g. dental filling material), II b (e.g. X-rays) and III (e.g. heart valves, hip replacements, breast implants and pacemakers), requires an assessment by an independent so called Notifying Body.

The manufacturer shall have traceability or a monitoring system to ensure that it receives and processes reports of anomalies concerning the product after the product was put on the market, to enable the product to be called back from the market if necessary. This requirement of traceability means that the manufacturer must note the name and address of recipients of free samples handed out at trade fairs or exhibitions.

Background to the review of the current regulatory framework

In 2008 the Commission launched a review of the three existing directives, regulating market access, international trade and competition conditions for medical devices, and has among other things conducted two open consultations in 2008 and 2010.

The purpose of the review is to align the legal framework with the technical and scientific progress and create simpler and clearer rules that both promote innovation and ensure patient safety.

A further reason for the revision is also the scandals with defective breast and hip implants that recently affected thousands of people both in Europe and worldwide. As a result of these, responsible authorities faced strong criticism for the inadequacy of systems which currently should ensure the quality of medical devices. Demands have also been made for the EU to increase controls of medical devices.

A regulation, unlike directives which must be implemented through national legislation, are binding in its entirety and directly applicable in all Member States, i.e. it does not require a Member State to take any legislative measures for the regulation to apply as national law. Thus through the currently proposed regulations a more uniform regulatory framework for medical devices in the EU is created. To implement the change in the legal framework through regulations ensure a uniform application throughout the EU, unlike the current situation where each Member State has interpreted and implemented the directives in its own way.

The proposal for a new regulation on medical devices

When is the regulation applicable?

The proposed regulation largely corresponds to the overall scope of the Directives, i.e. all medical devices, except medical devices for in vitro diagnostics for which a

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specific proposal for a Regulation has been presented, are covered. The scope has been expanded to some products that are not currently covered by the Directives, while some products, which in some Member States have been placed on the market as medical devices, are no longer covered.

The purpose of the new rules

The purpose of the new regulations is that they should be fit for purpose, more transparent and better adapted to scientific and technical progress. They also aim to make it easier for patients, consumers, health care professionals and manufacturers by among other things broadening and clarifying the scope of the EU legislation on medical devices to ensure that the product's safety and performance are properly assessed before being placed on the EU market. The provisions will also be aligned with international guidelines in order to facilitate international trade.

New products which are included

The following new products which are included are:

- Products made from non-viable human tissues and cells or derivatives thereof which have undergone substantial modifications (e.g. syringes pre-filled with human collagen), unless they are covered by the European Parliament and Council Regulation (EC) No 1394/2007 of 13 November 2007 on advanced therapy medicinal products. The proposal does not include human tissues and cells, or products derived from such tissues and cells, which have undergone significant modifications and regulated by the European Parliament and Council Directive 2004/23/EC of 31 March 2004 on setting standards of quality and safety for donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.
- Certain implantable devices or other invasive devices that have no medical purpose, but which have similar characteristics and risk profiles as medical devices (e.g., contact lenses without strength and esthetic implant).

Strengthening of the control of notified bodies

The regulation also aims at better coordination and enhanced supervision of the independent bodies performing the assessments. In recent years, the system of approval and monitoring of notified bodies have been criticized due to big differences in the quality and depth of the assessments they make. Due to this the regulation proposes which requirement that will be made on national authorities with the responsibility to appoint the notifed body. Member States will be ultimately responsible for appointing and monitoring the notified bodies on the basis of detailed criteria of the regulation. These bodies should also be given more powers and responsibilities to ensure that the products are tested thoroughly and that the manufacturers are regularly checked, for example by unannounced inspections and spot checks. A further novelty is the inclusion of the requirement that the manufacturer's organization should have a qualified person who is responsible for legal compliance (similar requirements as in EU legislation on medicinal

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products). In the case of parallel trade, conditions for companies that re-mark and/or re-pack medical devices are clarified, because the various Member States apply the principle of free movement of goods in considerably different ways and in several cases in practice forbids this practice.

Rules on reconditioning of disposable products
The proposal includes strict rules for reconditioning of disposable products in order to ensure a high level of protection of health and safety and to create clear conditions for reconditioning. Reconditioning of disposable products is considered as manufacturing of new products and the company which reconditions a product has the same obligations as a manufacturer. Reconditioning of disposable products for critical use (i.e. products that are intended for surgical invasive procedures), should according to the proposal be generally prohibited. Since some Member States is of the opinion that the reconditioning of disposable products may pose safety problems, they have the right to retain or introduce a general ban on reconditioning of disposable products, transfer of disposable products to another Member State or to a third country for reconditioning and supply in their market of reconditioned disposable products.

The European database is being expanded
The European database for medical devices set up in 2010 (EUDAMED) should be expanded in order to provide comprehensive, public information about the products on the EU market. This will ensure that both patients and healthcare professionals and the public have access to important information about the medical devices that are available so that they can make informed decisions about their use.

Improved traceability
The traceability of products throughout the supply chain will be improved, so that possible security issues can be quickly and effectively responded to. A system for unique product identification will be introduced to increase the safety of medical devices already on the market, helping to reduce medical errors and prevent counterfeit products.

Changes in the classification rules
The system of classification into four classes remains. However, the classification rules are adapted to the technical progress and the Commission's experience in monitoring and market surveillance. Manufacturers are solely responsible for the conformity assessment of products in Class I, as these products have a low risk potential. However, in the case of products in Class I with a measuring function or sold in a sterile condition, a notified body control aspects concerning the measurement function or sterilization process. For products in Classes II a, II b and III a notified body has to participate to such extent as is appropriate in relation to the class. With regard to products in Class III design or product type and quality management must explicitly be approved before they can be marketed.

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Miscellaneous
The rights and responsibilities of the manufacturers, importers and distributors will be clarified by the new regulations, including in terms of diagnostic services and electronic commerce. The regulation will also set out stricter requirements for clinical evaluation and clinical follow-up after placing the product on the market in order to ensure the safety of patients and consumers.

The proposal for a new regulation on medical devices for in vitro diagnostics

Scope
Along with the proposal for a regulation for medical devices a draft regulation on medical devices for in vitro diagnostics is adopted, e.g. blood samples. The proposal regarding medical devices for in vitro diagnostics is very similar to the proposal for a regulation on medical devices why this proposal will only be discussed briefly here.

Traceability and publication of documentation
The proposal requires that operators should be able to specify who has supplied a product and to whom they have supplied an in vitro diagnostic device. It also requires manufacturers to provide products with a unique product identification so they can be traced. The proposal requires that manufacturers/authorized representatives and importers, and the products they place on the EU market must be registered in a central EU database. Further the regulation introduces a duty for manufacturers of high-risk products to publish a summary of safety and performance, and the main parts of the clinical documentation.

European database
Medical devices for in vitro diagnosis are also covered by the proposal for an expanded database for registration. Through the establishment of a central database for the registration a high degree of transparency is ensured, while the last years' different national registration requirements which have greatly increased the economic operators' costs of compliance with regulations will be avoided. It will also help to reduce the administrative burden for manufacturers.

A new classification system
A new classification system for the in vitro products is proposed where they are divided into four groups: A (lowest risk), B, C and D (highest risk). The procedures for conformity assessment have been adapted to meet each of these four classes of products, and the existing modules as determined under the "New Approach" have been used. Manufacturers will as a general rule, have the responsibility for the conformity assessment of products in Class A, as these products have a low risk potential. In the case of products in Class A intended for near-patient testing, which have a measurement function or are sold in a sterile condition, a notified body shall verify the design aspects and measurement function or sterilization process. In the case of a Class B, C and D a notified body must participate according to what is deemed appropriate in relation to the class, while products in Class D requires that the design or the type and quality management are expressly

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approved before they can be marketed. In the case of a Class B and C product the notified body controls the quality management and for class C, a representative selection of the technical documentation. In addition to the initial certification, the notified bodies shall regularly evaluate the assessment after the placement on the market.

Miscellaneous

As is the case with the proposal for a new regulation for medical devices, the proposal for a regulation for in vitro diagnostics it is proposed that the manufacturer's organization must have a qualified person who is responsible for compliance. Furthermore, there are also provisions that focus on parallel trade and repackaging/re-labeling of medical devices for in vitro diagnostics.

The continued legislative process

The Commission's proposals will now be considered by the European Parliament and the Council which have to make identical decisions for the new regulations to take effect. It is not possible in the current situation to comment on how long the EU's decision-making process will take. According to information from the Commission they are expected to be ready for adoption in 2014 and will then enter into force progressively over the period 2015-2019. The current legislation is effective until further notice. The new regulation for medical devices will take effect three years after the entry into force and the new rules on in vitro diagnostics five years after its entry into force in order to provide manufacturers, notified bodies and Member States time to adapt to the new requirements.

We will monitor the legislative process and report on the development of this in upcoming newsletters.

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