Medical devices

2012/0266(COD) - 26/09/2012 - Legislative proposal

PURPOSE: to revise the existing regulatory framework on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009.

PROPOSED ACT: Regulation of the European Parliament and of the Council

BACKGROUND: the current EU regulatory framework for medical devices, other than in vitro diagnostic medical devices, consists of Council Directive 90/385/EEC on active implantable medical devices (AIMDD) and Council Directive 93/42/EEC on medical devices (MDD) which cover a huge spectrum of products.

The existing regulatory framework has demonstrated its merits but has also come under harsh criticism, in particular after the French health authorities found that a French manufacturer (Poly Implant Prothèse, PIP) had for several years apparently used industrial silicone instead of medical grade silicone for the manufacture of breast implants contrary to the approval issued by the notified body, causing harm to thousands of women around the world.

In an internal market with 32 participating countries and subject to constant technological and scientific progress, substantial divergences in the interpretation and application of the rules have emerged, thus undermining the main objectives of the Directives, i.e. the safety of medical devices and their free movement within the internal market. Moreover, regulatory gaps or uncertainties exist with regard to certain products e.g. products manufactured utilising non-viable human tissues or cells and implantable or other invasive products for cosmetic purposes.

Triggered by the PIP breast implants scandal, the European Parliament adopted on 14 June 2012 a Resolution on defective silicone gel breast implants made by the French company PIP and called for an adequate legal framework to guarantee the safety of medical technology.

IMPACT ASSESSMENT: a separate impact assessment has been carried out by the Commission.

LEGAL BASIS: Article 114 and Article 168(4)(c) of the Treaty on the Functioning of the European Union.

CONTENT: this revision of the current regulatory framework aims to overcome the flaws and gaps and to further strengthen patient safety. A robust, transparent and sustainable regulatory framework is to be put in place that is fit or purpose. The proposed framework is supportive of innovation and the competitiveness of the medical device industry and should allow rapid and cost-efficient market access for innovative medical devices, to the benefit of patients and healthcare professionals.

It should be noted that this proposal is adopted alongside a proposal for a Regulation on in vitro diagnostic medical devices (IVDs), such as blood tests, which are covered by Directive 98/79/EC. The horizontal aspects that are common to both sectors are aligned whilst the specific features of each sector require separate legal acts.

The main elements of the proposal are as follows:

Scope: the scope of the proposed Regulation corresponds to a large extent to the combined scopes of Council Directives 90/385/EEC and 93/42/EEC, i.e. it covers all medical devices other than in vitro diagnostic medical devices. However:

- the scope is extended to some products currently not covered by the AIMDD/MDD;
- some products which, in some Member States, are placed on the market as medical devices are excluded from its scope.

The extension of the scope concerns:

- products manufactured utilising non-viable human tissues or cells, or their derivatives, that have undergone substantial manipulation (e.g. syringes prefilled with human collagen), unless they are covered by Regulation (EC) No 1394/2007 on advanced therapy medicinal products. Human tissues and cells, or products derived from human tissues or cells, that are not substantially manipulated and that are regulated by Directive 2004/23/EC are not covered by the proposal;
- certain implantable or other invasive products without a medical purpose that are similar to medical devices in terms of characteristics and risk profile (e.g. non-corrective contact lenses, implants for aesthetic purposes).

Additional provisions as regards products that are not covered by the Regulation have been included, and concern:

- products that contain or consist of viable biological substances (e.g. living microorganisms);
- food covered by Regulation (EC) No 178/2002. Medical devices are excluded from the scope of Regulation 178/2002 (diagnostic probes or cameras, even when introduced orally, are therefore clearly excluded from the food legislation).

As regards products composed of substances or combinations of substances that are intended to be ingested, inhaled or administered rectally or vaginally and that are absorbed by or dispersed in the human body, those products which fall under the definition of a medical device are classified in the highest risk class and should comply with the relevant requirements of Annex I of Directive 2001/83/EC on the Community code relating to medicinal products for human use.

Definitions: this section has been significantly extended, aligning the definitions in the field of medical devices with well established European and international practice, such as the New

Legislative Framework for the Marketing of Products.

Making available of devices, obligations of economic operators, reprocessing, CE marking, free movement: this chapter contains provisions that are typical for product-related internal market legislation and sets out the obligations of the relevant economic operators (manufacturers,

authorised representatives of non-EU manufacturers, importers and distributors). The regulatory instrument of common technical specification (CTS), which has proven useful in the context of the IVDD, has been introduced in the broader field of medical devices to allow the Commission to further specify the general safety and performance requirements (laid down in Annex I) and the requirements on clinical evaluation and post-market clinical follow-up (laid down in Annex XIII). The legal obligations on manufacturers are proportionate to the risk class of the devices they produce.

Minimum contents of key documents for the manufacturer to demonstrate compliance with the legal requirements are laid down in Annexes II and III.

The following concepts are also new in the field of medical devices:

- a requirement has been introduced that within the manufacturers organisation a 'qualified person' should be responsible for regulatory compliance;
- clear conditions are set for enterprises involved in relabelling and/or repackaging medical devices;
- patients who are implanted with a device should be given essential information allowing it to be identified and containing any necessary warnings or precautions to be taken;
- strict rules on the reprocessing of single-use devices.

Identification and traceability of devices, registration of devices and economic operators, summary of safety and clinical performance, Eudamed: this chapter addresses one of the main shortcomings of the current system: its lack of transparency. It consists of the following requirements:

- economic operators must be able to identify who supplied them and to whom they have supplied medical devices;
- manufacturers must fit their devices with a Unique Device Identification (UDI) which allows traceability;
- manufacturers/authorised representatives and importers must register themselves and the devices they place on the EU market in a central European database;
- manufacturers of high-risk devices must make publicly available a summary of safety and performance with key elements of the supporting clinical data;
- further development of the European databank on medical devices (Eudamed), set up by Commission Decision 2010/227/EU, which will contain integrated electronic systems on a European UDI, on registration of devices, relevant economic operators and certificates issued by notified bodies, on clinical investigations, on vigilance and on market surveillance. A large part of the information in Eudamed will become publicly available.

The establishment of a central registration database will also do away with diverging national registration requirements which have emerged over recent years and which have significantly increased compliance costs for economic operators.

Notified bodies: the proposal sets out requirements for national authorities responsible for notified bodies. It leaves the ultimate responsibility for designating and monitoring notified bodies, based on stricter and detailed criteria laid down in Annex VI, with the individual Member State. At the same time, the position of notified bodies vis-à-vis manufacturers will be significantly strengthened, including their right and duty to carry out unannounced factory inspections and to conduct physical or laboratory tests on devices. The proposal also requires rotation of the notified body's personnel involved in the assessment of medical devices at appropriate intervals.

Classification and conformity assessment: the proposal keeps to the well established approach of dividing medical devices into four classes. The classification rules (laid down in Annex VII) have been adapted to technical progress and experience gained from vigilance and market surveillance. The different conformity assessment procedures are laid down in Annexes VIII to X and have been tightened and streamlined. The proposal also:

- reinforces the powers and responsibilities of notified bodies;
- introduces the obligation for notified bodies to notify an expert committee of new applications for conformity assessment of high-risk devices.

Clinical evaluation and clinical investigations: this chapter lays down the key obligations of manufacturers as regards the performance of the clinical evaluation needed to demonstrate the safety and performance of their devices. More detailed requirements are set out in Annex XIII which addresses the pre-market clinical evaluation and post-market clinical follow-up that together constitute a continuous process during the life cycle of a medical device.

The process for conducting clinical investigations is further developed, particularly through the concept of sponsor. Non-commercial clinical investigations that do not pursue a regulatory purpose are not covered by this Regulation. Every clinical investigation must be registered in a publicly accessible electronic system which the Commission will set up.

Vigilance and market surveillance: the proposal introduces an EU portal where manufacturers must report serious incidents and corrective actions they have taken to reduce the risk of recurrence. The information will be automatically forwarded to the national authorities concerned. Where the same or similar incidents have occurred, or where a corrective action has to be taken, in more than one Member State, a coordinating authority will take the direction in coordinating the analysis of the case.

As regards market surveillance, the main objectives of the proposal are to reinforce the rights and obligations of the national competent authorities, to ensure effective coordination of their market surveillance activities and to clarify the applicable procedures.

Governance: a central role in achieving harmonised interpretation and practice will be assigned to an expert committee (the Medical Device Coordination Group or MDCG).

The proposal mandates the Commission to provide technical, scientific and logistic support to the MDCG. It empowers the Commission to adopt either implementing acts to ensure uniform application of the Regulation or delegated acts to complement the regulatory framework for medical devices over time.

With this proposal, other Union legislation is amended where a link exists with medical devices, including Regulation (EC) No 1223/2009 on

cosmetic products and the Food Regulation 178/2002.

The future Regulation replaces and repeals Council Directives 90/385/EEC and 93/42/EEC.

BUDGETARY IMPLICATIONS: the operational resources necessary for the implementation of the initiative are covered by the appropriations proposed in the context of the proposed Health for Growth programme 2014-2020.

Estimated impact on expenditure (operational credits): EUR 48.376 million, of which

- Specific objective 1: establishing mechanisms to ensure harmonised implementation of the rules by all Member States with credible management at EU level with access to expertise: total EUR 29.782 million;
- Specific objective 2: enhancing transparency regarding medical devices on the EU market, including their traceability (Eudamed): total EUR 18.594 million.

Impact on administrative expenditure: EUR 20.369 million.

Total appropriations for the period are EUR 68.745 million.

DELEGATED ACTS: the proposal contains provisions empowering the Commission to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union (TFEU).