In vitro diagnostic medical devices

2012/0267(COD) - 26/09/2012 - Legislative proposal

PURPOSE: to propose a new legislative framework for in vitro diagnostic medical devices.

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

BACKGROUND: the current EU regulatory framework for in vitro diagnostic medical devices ('IVDs') consists of Directive 98/79/EC. It has demonstrated its merits but has also come under criticism in recent years. In an internal market with 32 participating countries and subject to constant scientific and technological progress, substantial divergences in the interpretation and application of the rules have emerged, thus undermining the main objectives of the Directive, i.e. the safety and performance of IVDs and their free movement.

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. It aims to put in place a robust, transparent and sustainable regulatory framework for in vitro diagnostic medical devices that is 'fit for purpose'. The framework is supportive of innovation and the competitiveness of the in vitro diagnostic medical device industry and should allow rapid and cost-efficient market access for innovative IVDs to the benefit of patients and healthcare professionals.

It should be noted that this proposal is adopted alongside a proposal for a Regulation on medical devices that are currently covered by the AIMDD and the MDD. While the specific features of IVDs and of the IVD sector require the adoption of a specific legislation distinct from the legislation on other medical devices, the horizontal aspects common to both sectors have been aligned.

The main elements of the proposal are as follows:

Scope and definitions: to a large extent, the scope of the proposed Regulation matches the scope of Directive 98/79/EC, i.e. it covers in vitro diagnostic medical devices. The proposed changes clarify and extend the scope of the IVD Directive. They concern:

- high-risk devices manufactured and used within a single health institution, which are subject to most of the requirements set out in the proposal;
- tests providing information about the predisposition to a medical condition or a disease (e.g. genetic tests) and tests providing information to predict treatment response or reactions (e.g. companion diagnostics), which are considered as in vitro diagnostic medical devices;
- medical software, which is explicitly mentioned in the definition of IVDs.

To support Member States and the Commission in determining the regulatory status of products, the Commission may set up, in accordance with its internal rules, a group of experts from various sectors (such as IVDs, medical devices, medicinal products, human tissues and cells, cosmetics and biocides).

Definitions: this section has been significantly extended, aligning the definitions in the field of in vitro diagnostic medical devices with well-established European and international practice.

Making available of devices, obligations of economic operators, CE marking, free movement: this chapter covers mainly horizontal issues similar for both medical devices and IVDs. It 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). It also provides clarification with regard to the adoption and the scope of common technical specifications (CTS) for in vitro diagnostic medical devices.

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 new in the field of IVDs:

- a requirement has been introduced that within the manufacturer's organisation a 'qualified person' should be responsible for regulatory compliance. Similar requirements exist in EU legislation on medicinal products and in the national laws transposing the Directive on medical devices in some Member States.
- since in the case of 'parallel trade' with in vitro diagnostic medical devices application of the principle of free movement of goods varies considerably from one Member State to another and, in many cases, de facto prohibits this practice, clear conditions are set for enterprises involved in relabelling and/or repackaging IVDs.

Identification and traceability of devices, registration of devices and of economic operators, summary of safety and 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 IVDs;
- 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 performance studies, 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 . Any new designation and, in regular intervals, the monitoring of notified bodies are made subject to 'joint assessments' with experts from other Member States and the Commission, thus ensuring an effective control at Union level.

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 introduces a new risk-rule based classification system, built on GHTF principles, which replaces the current list of IVD medical devices in Annex II to Directive 98/79/EC.

In the new classification system, IVDs will be divided into four classes of risk: A (lowest risk), B, C and D (highest risk). The conformity assessment procedures have been adapted to match each of these four device classes. The proposal tightens and streamlines the different conformity assessment procedures during which the notified body audits the manufacturer's quality management system, checks the technical documentation, examines the design dossier or approves the type of a device. These are laid down in Annexes VIII to X. One conformity assessment procedure provided for under the IVD Directive (EC verification) has been deleted and the concept of batch testing has been clarified.

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 evidence: the proposal spells out the requirements for clinical evidence for in vitro diagnostic medical devices that are proportionate to the risk class. The key obligations are set out in Chapter VI while more detailed provisions are laid down in Annex XII. While most clinical performance studies follow an observational design and therefore the results obtained are not used for patient management and do not impact treatment decisions, specific requirements have been introduced in Annex XIII for the conduct of interventional clinical performance studies and other clinical performance studies where the conduct of the study, including specimen collection, involves invasive procedures or other risks for the subjects of the studies.

The concept of 'sponsor' is introduced. The scope of the proposal remains restricted to clinical performance studies carried out for regulatory purposes, i.e. for obtaining or confirming regulatory approval for market access. Non-commercial clinical performance studies that do not pursue a regulatory purpose are not covered by this Regulation. Every interventional clinical performance study and other clinical performance study involving risks for the subjects of the study shall 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) made up of members appointed by the Member States due to their role and experience in the fields of medical devices and in vitro diagnostic medical devices and set up by Regulation on medical devices. The proposal mandates the Commission to provide technical, scientific and logistic support to the MDCG.

It empowers the Commission to adopt, where appropriate, either implementing acts to ensure uniform application of this Regulation, or delegated acts to complement the regulatory framework for in vitro diagnostic medical devices over time.

The future Regulation will replace and repeal Directive 98/79/EC.

BUDGETARY IMPLICATIONS: this proposal does not have any direct financial implications given that the cost-relevant arrangements are already covered in the proposal for a Regulation on medical devices.

To recap, 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).