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Impact Assessment of Revision of the Regulatory Framework for Medical Device Directive in EU

Reasoning for Revision

The existing regulatory framework has been in place for 20 years; recently coming under harsh criticism in the media and the political arena, in particular after findings of the French health authorities that a French manufacturer (Poly Implant Protese, PIP) over several years used industrial silicone instead of medical grade silicone for manufacture of breast implants. Several weaknesses undermined the main objectives of the three medical device directives, i.e., safety of medical devices and their free circulation within the internal market were identified in public consultation held by Commission in 2008, and again in 2010. This revision aims at overcoming the flaws and gaps while maintaining the overall objectives of the legal framework.

Systemic Issues Identified

Oversight of notified bodies

Currently 78 notified bodies are designated under the three medical device directives. Authorities, manufacturers and Notified Bodies report significant differences as regards, on the one hand, the designation and monitoring of the notified bodies and the quality and depth of the conformity assessment performed by them; such as unannounced factory inspections or product checks, leading to uneven level of protection of patients and users safety as well as to a distortion of the competition between manufacturers of similar products.

Post-Market safety

Experience with the application of the vigilance system and other legal instruments available to Member States (e.g., safeguard clauses) has shown that national competent authorities do not have all the necessary information available and react in different ways to the same problems which begs the question of a harmonized level of protection.

Transparency and traceability

No exact data exist as regards the medical devices placed on the European market. Several Member States have set up their own electronic tools, and multiple registration requirements in individual member states placing a considerable administrative burden on manufacturers and authorized representatives when they want to market a product in different Member States. Some

have started imposing traceability requirements on economic operators. However, the national systems are not compatible with each other and do not allow traceability across borders which is necessary for an EU-wide high level of patient safety.

Access to external expertise

External experts are currently not involved in the regulatory process in a structured way.

Management of regulatory system

The management of the regulatory system at EU level has shown weakness which have been reported by various interested parties; it is considered as not sufficiently efficient and effective. There is no legal basis in the medical devices directives to ensure an overview of the situation at EU level and appropriate coordination between Member States. There is a lack of technical, scientific, and logistic support leading to a lack of uniform application of the rules and of common reactions in European market. The demarcation between the medical device directives and other regulatory frameworks is not always clear which leads to the application of different legal regimes. Obligations of economic operators are currently not clear or covered by the directives at all.

Specific Issues

Regulatory gaps exist with regard to certain products. For example, products manufactured utilizing non-viable human tissues or cells, implantable or other invasive products without a medical purpose, and the reprocessing of single-use devices are currently not regulated by EU legislation.

IVD's "in-house" tests are currently exempted from the IVD directive.

Another important issue, classification of IVD's: current approach for IVD classification is different from the classification approach taken from other medical devices and other medical devices.

Requirements of the IVD directive, needs to be adapted to technological, scientific, or regulatory developments.

For medical devices, some legal provisions, such as essential requirements and criteria for risk classification of devices, do not sufficiently reflect the technological and scientific developments.

EU legislation currently does not make provision for any coordination between Member States regarding the assessment of applications for clinical investigations on medical devices to be conducted in more than one Member State.

Moreover, this revision provides the opportunity to align the provisions regarding clinical investigations on medical devices, where appropriate, with the recently adopted Proposal for a Regulation on clinical trials on medicinal products for human use.

Proposed Revision

The current medical device directives are based on the treaty provisions regarding the establishment and functioning of the internal market (Article 114 TFEU). The Libson Treaty has added a legal basis in the area of public health for the adoption measures setting high standards of quality and safety of medical products (Article 168(4)(c) TFEU). The proposed revision of the existing directives will integrate the modification of the Libson Treaty, to improve the level of protection of public health for all European parties and users.

Harmonized rules and procedures will allow manufacturers and Subject Matter Experts (SMEs) to reduce costs related to national regulatory differences, while ensuring a high and equal level of safety.

Moreover, this revision provides the opportunity to align the provisions regarding clinical investigations on medical devices, where appropriate, with the recently adopted Proposal for a Regulation on clinical trials on medicinal products for human use.

Objectives

The revision pursues three overall Objectives:

A: ***To ensure a high level of protection of human health and safety***

B: ***To ensure the smooth functioning of the internal market***

C: ***To provide a regulatory framework which is supportive for innovation and the competitiveness of the European Medical device industry***

In addition, several specific objectives related to individual problems identified

Specific Objections	Preferred Policy Options
Problem 1: Oversight of Notified Bodies	
Objective 1: Uniform control of Notified Bodies	New minimum requirements for Notified Bodies, ***and*** either Designation and monitoring of Notified Bodies by an EU body or Designation and monitoring of Notified Bodies by Member States with involvement of "joint assessment teams" ***and*** Notification requirement regarding new applications for conformity assessment and possibility for ex ante control
Problem 2: Post-market safety (vigilance and market surveillance)	
Objective 2: Enhanced legal clarity and coordination in the field of post-market safety	Clarification of key terms and of the obligations of the parties involved in the field of vigilance ***and*** Central reporting of incidents and coordinated analysis of certain high risk incidents ***and*** Promotion of cooperation of market surveillance authorities

Specific Objections	Preferred Policy Options
Problem 3: Regulatory status of products	
Objective 3: Cross-sectoral solution of "borderline" cases	Creation of a cross-sectoral expertise on borderline issues and possibility to determine the regulatory status of products at EU level in certain sectors
Problem 4: Lack of transparency and harmonised traceability	
Objective 4: Enhanced transparency regarding medical devices on the EU market, including their traceability	Central registration of economic operators and listing of medical devices placed on the EU market ***and*** Requirement for the traceability of medical devices
Problem 5: Access to external expertise	
Objective 5: Enhanced involvement of external scientific and clinical expertise	Designation of an expert panel and EU reference laboratories
Problem 6: Unclear and insufficient obligations and responsibilities of economic operators, including in the fields of diagnostic services and internet sales	
Objective 6: Clear obligations and responsibilities of economic operators, including in the fields of diagnostic services and internet sales	Alignment with Decision 768/2008, additional requirements for authorised representatives and clarification of obligations in the field of diagnostic services ***and*** Addressing internet sales by soft-law action
Problem 7: Management of the regulatory system	
Objective 7: Governance - efficient and effective management of the regulatory system	*either* Extension of the responsibility of the European Medicines Agency (EMA) to medical devices and creation of a Medical Device Expert Group at this agency *or* Management of the medical device regulatory system by the European Commission and creation of a Medical Device Expert Group supported by this institution

The new legislation will be in the form of regulations – which are directly enforceable in Member States – in contrast to the current regime, which is based on Directives.

The following table indicates the preferred policy options in the field of medical devices

Issues relevant for medical devices other than in vitro diagnostic medical devices	
Specific Objectives	**Preferred Policy Options**
Problem MD-1: Scope - regulatory gaps or uncertainties	
Objective MD-1: Covering of legal gaps and loopholes	Regulate products manufactured utilising non-viable human cells and tissues as medical devices ***and*** Regulation of certain implantable or other invasive devices without a medical purpose within the MDD ***and*** Harmonized regulation of the reprocessing of single-use medical devices
Problem MD-2: Adaptation of legal requirements to technological, scientific and regulatory developments	
Objective MD-2: Appropriate legal requirements taking into account technological, scientific and regulatory developments	Review of the classification rules and essential requirements regarding specific devices or technologies
Problem MD-3: Clinical evaluation and clinical investigations, in particular those carried out in more than one Member State	
Objective MD-3: Enhanced legal certainty and coordination in the field of clinical evaluation and investigations, in particular those conducted in more than one Member State	Introduction of the term "sponsor" for clinical investigations and further clarification of key provisions in the field of clinical evaluation and investigations ***and*** Coordinated assessment of multi-national investigations by the Member States where the investigation is performed

The following tables indicate the preferred policy for in vitro diagnostic devices

Issues relevant for** in vitro **diagnostic medical devices (IVD)	
Specific Objectives	**Preferred Policy Options**
Problem IVD-1: Scope – regulatory gaps or uncertainties	
Objective MD-1: Covering of legal gaps and loopholes	Clarify the scope of the exemption for "in house" tests, require a mandatory accreditation for "in house" test manufacturers and subject high risk (class D) "in house" tests to the requirements of the IVDD Amendment of the legal definition of an IVD to include tests providing information "about the predisposition to a medical condition or a disease" Regulation of companion diagnostics under the IVD regulations and interaction with the medicinal products sector

Summary of Revision

The regulation proposal was submitted to European Parliament and the council. There was speculation there would be word from Parliament in September 2016, however that has not happened. The major difference however, is that the new legislation will be in the form of regulations – which are directly enforceable in Member States – in contrast to the current regime, which is based on Directives.

The new regulations cover a wide range of products, from sticking plasters to hip replacements, pacemakers to laboratory tests for the assessment of medical interventions. They also opened up the policy to a host of other medical technologies – aesthetic devices, weight loss surgery and apps among them.

As it currently stands (according to the Council text which is the basis for trilogue discussions), the proposed new regime will mean the following:

- Greater transparency for patients – in particular those taking part in clinical trials;
- Manufacturers and importers will have to register themselves and the devices they place on the EU market in a central database – the European databank on medical devices (Eudamed);
- Manufacturers of medical devices will have to fit their products with a unique device identification to ensure traceability;
- Reinforced rules governing clinical evaluation throughout the life of the device, including the introduction of the concept of a 'sponsor', as well as a new requirement for manufacturers to have a 'qualified person' responsible for regulatory compliance;
- New rules for the reprocessing of single-use medical devices to make them suitable for further use;
- The creation of an EU portal where manufacturers would have to report serious incidents and any corrective actions they have taken to reduce the risk of recurrence;
- A post-market surveillance system detailing manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market. These include annual periodic safety update reports (PSURs) – a step which brings medical devices into line with pharmaceutical reporting requirements;
- A tightening of the rules for the designation of notified bodies, the monitoring of their assessment activities by national competent authorities and cooperation between competent authorities. The new rules would also give notified bodies the right and duty to carry out spot checks in the form of unannounced factory inspections;
- Extension of the scope of medical device regulation to cosmetic/aesthetic devices (e.g. contact lenses or fat-removal devices), as well as 'ingested products';
- The introduction of a new expert group (the Medical Device Coordination Group), which will have the power to review and comment on Notified Body assessments of high-risk medical devices before the device is put on the market.

Resources

European Union (2012), Executive Summary of the Impact Assessment on the Revision of, the Regulatory Framework for Medical Devices. SWD(2012) 274 Final. Brussels. Resource