

Why new regulations of the European Parliament on medical devices are needed?

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Abstract

Medical devices contribute to the attainment of the highest standards of health for individuals, but at the same time the universe of medical devices is diverse with wide variations in potential severity of harm to the patient or user. That is why competent regulatory authority in each country should allocate its resources and imposes controls proportional to the potential for harm associated with medical devices. This will result to safety improvement and high performance of medical devices when placed on the market. As part of the European Union legislative framework, on April 2017 two new proposals on medical devices were adopted. The two new legal instruments include: - Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) 178/2002 and Regulation (EC) 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC; - Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU. The two new regulations will enter into force after a transition period of 3 for the Regulation on medical devices (spring 2020) and 5 years (spring 2022) for the Regulation on in vitro diagnostic medical devices. They will have as a result the ensurance of

consistently high level of health and safety protection for all European Union citizens as well as free and fair trade of the products throughout all Member states.

Keywords: medical devices, regulations of the European Parliament, health and safety protection.

Medical technology and services, including a large and highly skilled workforce, play a crucial role in keeping the European population healthy and productive through delivering innovation into healthcare, while also contributing to the European knowledge-based economy. The term medical device covers a vast range of equipment, from simple tongue depressors to haemodialysis machines. With innovation and the rapid advancement of technologies, medical devices are currently one of the fastest growing industries (1).

A standard is a document that provides requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose. One dictionary definition of standard is: “a document specifying nationally or internationally agreed properties of manufactured goods, principles for procedure, etc”. (New Shorter Oxford English Dictionary).

Standards are produced for many different products and services, and may be created for company, national, regional or global application (2). They may be used on a voluntary basis, or made mandatory by company policy, national or international regulation, or by law. The health care sector is unusual in the extent to which private providers are entrusted with important public roles, and the large amount of public money allocated to health spending in many countries (3).

In Europe there are three different categories of standard:

- **International standard** – a standard adopted by an international standardization organization;
- **European standard** – a standard adopted by a European standardization body;
- **National standard** – a standard adopted by a national standardization body and made available to the public.

Standards are jointly defined by manufacturers, traders, users, and scientists, based on set rules. One of the aims of standards is to determine minimum requirements for the quality of products, such as medical devices and dental materials (4).

Standards are intended to provide protection (e.g., of the consumers and the environment) and save costs by means of standardized elements. Standards are regularly revised to adjust them to the newest technological standards.

Harmonized standards play a special role in the EU. A harmonised standard is a European standard elaborated on the basis of a request from the European Commission to a recognised European Standards Organisation to develop a European standard that provides solutions for compliance with a legal provision. Such a request provides guidelines which requested standards must respect to meet the essential requirements or other provisions of relevant European Union harmonisation legislation. Their titles are published in the official journal of the EU (5).

A multiplicity of laws, standards, and recommendations regulate the marketing of medical devices. The medical doctor and the dentist should be informed about the European and international standards concerning medical devices and use only those for which appropriate information is available (6).

On 26 September 2012 the European Commission adopted a proposal for a Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009.

Parliament adopted its first reading position on 2 April 2014, however, negotiations with the Council did not start until the autumn of 2015 when on 5 October 2015 the Council adopted a General Approach in view of commencing early second reading negotiations with Parliament which began on 13 October 2015.

The Commission proposal and the subsequently agreed text for a new regulation replacing all existing directives seek to efficiently address some weaknesses while still maintaining and strengthening the current approval system. The initial Commission proposal was a solid starting point which was further strengthened by the subsequent amendments by Parliament and Council. New additional provisions and structures will fill in the gaps and increase the levels of protection of public health and safety while ensuring clear rules with regard to the roles and obligations of all actors operating on the market, without stifling the innovation that is an essential element of this industry.

Medical devices and dental materials are subject to legal specific regulations in EU (7). All these regulations deal with biocompatibility and effectiveness of the medical materials and devices. Everyone in the working in the field of medicine should be informed about the regulations and their responsibilities imposed by them (including adverse effect reporting) (8).

Expanding on the Commission's initial proposal for a scrutiny mechanism for Class III devices, the co-legislators introduced a provision for a second-level check, a special procedure during the conformity assessment and before certification, of the highest risk devices of class III implantable and class IIIb active devices administering or removing a medicinal product. The procedure involves the independent assessment by a special expert panel.

In an overall decentralised system of conformity assessment and certification in Europe, this new provision aims to ensure that when it comes to the highest risk devices there is an additional level of supervision on EU level conducted by experts re-evaluating the clinical evaluation assessment reports of the notified bodies for such devices.

Given recent experience with defective devices and the consequences for affected users, an aspect that was extremely important for Parliament to be addressed in the new regulatory framework, and that was missing from the Commission proposal, was manufacturers' liability insurance. This was also linked with

frequent cases where patients were unable to access the relevant information in order to prove a causal link between defect and damage, as required by the Product Liability Directive. To this end, a provision was added requiring that manufacturers should, in a manner that is proportionate to the risk class, type of device and the size of the enterprise, have measures in place to provide sufficient financial coverage in respect of their potential liability under the above Directive. In addition, further rules were agreed concerning the facilitation, by a competent authority, of the provision of information to persons who may have been injured by a defective device.

Individually identifiable health information should be collected, used, and/or disclosed only to the extent necessary to accomplish a specified purpose(s) and never to discriminate inappropriately (9).

Parliament's first reading position amendment to the Commission proposal provisions on substances that are carcinogenic, mutagenic or toxic for reproduction and substances having endocrine disrupting properties in Annex I called for a total ban for certain concentrations of these substances in certain devices subject to a range of derogations. Although such full ban was unacceptable to both the Council and the Commission due to the potential impact on industry and issues of implementation, the agreed text significantly strengthens what was initially proposed and paves the way for encouraging manufacturers to seek substitution of these substances since the permission for their use above a certain concentration would only be possible subject to manufacturers providing a strictly defined justification.

One of the major amendments to the old system is the strengthening of the provisions on the designation, organisation, monitoring and expertise of the Notified Bodies conducting the conformity assessment and certification for all devices on the Union market. Some of the additional provisions introduced by Parliament and agreed by the Council relate to the permanent availability of sufficient administrative, technical and scientific personnel of NBs for them to successfully conduct their conformity assessment activities. The joint assessment at designation, continuous monitoring and annual re-assessment of NBs with on-site audits, including unannounced visits, is another measure to ensure the continued quality of expertise and observation of legal requirements by all NBs in the Union. A major improvement to the new legislation to be stressed is that notified bodies are obliged to do unannounced inspections on the production site.

For high-risk devices, it is no longer sufficient to just check the papers but controls have to be on the spot. This is in your rapporteur's view the most important improvement that will avoid scandals in future. Last but not least, to provide for a level-playing field and transparency among them all in the different Member States, a new provision initiated by Parliament now requires that NBs establish lists of standard fees charged for conformity assessment procedures, which are made public.

Apart from strengthening the authorisation procedures, one of the key pillars of the new proposal is an enhanced overall system for traceability of devices, vigilance and post-market surveillance to ensure constant monitoring and swift reaction should problems arise. In addition to the Commission proposal, the co-legislators introduced an obligation for manufacturers, proportionate to the risk class of the device, to plan, establish, document, implement, maintain and update a post-market surveillance system for each type of device in order to gather, record and analyse all relevant data associated with the safety of the device throughout its lifecycle. Similar to medicinal products, periodic safety update reports were introduced for all risk classes but Class I, and for the higher risk classes these need to be updated at least annually.

The co-legislators also oblige Member States to take the necessary measures to encourage and empower healthcare professionals, users and patients to report suspected serious incidents at national level using harmonised formats.

As part of the European Union legislative framework, on April 2017 two new proposals on medical devices were adopted. The two new legal instruments include:

1. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) 178/2002 and Regulation (EC) 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC;
2. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

The two new regulations will enter into force after a transition period of 3 for the Regulation on medical devices (spring 2020) and 5 years (spring 2022) for the Regulation on in vitro diagnostic medical devices.

The new regulations will have as a result the ensurance of consistently high level of health and safety protection for all European Union citizens as well as free and fair trade of the products throughout all Member states (10).

Medical devices contribute to the attainment of the highest standards of health for individuals, but at the same time the universe of medical devices is diverse with wide variations in potential severity of harm to the patient or user. That is why competent regulatory authority in each country should allocate its resources and imposes controls proportional to the potential for harm associated with medical devices. This will result to safety improvement and high performance of medical devices when placed on the market.

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