In vitro diagnostic medical devices

2012/0267(COD) - 05/04/2017 - Final act

PURPOSE: to ensure the proper functioning of the internal market with regards to in vitro diagnostic medical devices and to improve the safety of medical devices for the benefit of patients.

LEGISLATIVE ACT: Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

CONTENT: the Regulation lays down rules concerning the placing on the market of in vitro diagnostic medical devices for human use and accessories for such devices in the Union (e.g. HIV blood tests, pregnancy tests, blood sugar monitoring systems for diabetics.) It also applies to performance studies concerning such in vitro diagnostic medical devices and accessories conducted in the Union.

The purpose of the Regulation is to enhance patient safety by: (i) introducing more stringent procedures for conformity assessment and for post-marketing surveillance, and (ii) requiring manufacturers to produce clinical safety data, performance and unknown side-effects.

The classification system for medical devices, and, even further, the classification system for in vitro diagnostic medical devices have been adapted to correspond to the rapid increase in scientific, medical and technical knowledge and to the resulting development of more and more advanced device.

Devices manufactured and used in the same health institution are exempted from the Regulation, with the exception of the relevant general safety and performance requirements, if a number of conditions are fulfilled.

Notified bodies: the Regulation strengthens the provisions on the designation, organisation, monitoring and expertise of the notified bodies, which conduct the conformity assessment and certification for all in vitro devices before they are placed on the market and it strengthens monitoring by national authorities of notified bodies. The new rules also ensure that notified bodies meet the same high safety standards throughout the EU. Notified bodies made have sufficient administrative, technical and scientific personnel for them to successfully conduct their conformity assessment activities. On-site audits, including unannounced visits, must be carried out.

Availability of clinical data: the requirements on collection of data in clinical investigations on medical devices and performance studies on in vitro diagnostic medical devices have been considerably strengthened and aligned to those applicable for clinical trials on medicinal products for human use, particularly as regards provisions on informed consent and protection of vulnerable subjects (e.g. incapacitated subjects, minors, pregnant women.

Obligations of manufacturers: the Regulation sets out the obligations of manufacturers regarding monitoring the quality, performance and safety of devices placed on the market.

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 Directive 85/374/EEC;
- a system regarding the monitoring of quality and a post-market surveillance system for each type of device.

The authorised representative would be jointly and severally liable with the importer and manufacturer in case of damages suffered due to defective devices.

The Regulation also requires Member States to take the measures necessary to allow health professionals, users and patients to report suspected serious incidents at national level using harmonised formats.

High-risk devices: the Regulation provides for the verification by a designated reference laboratory of the performance claimed by manufacturers of class D IVDs and a consultation with an expert panel applicable to Class D IVDs devices, in the case of their first certification and when common technical specifications are not available. While the notified body would not be bound by the opinion, it would have to provide a justification for not following it.

Genetic counselling: the Regulation provides that individuals being tested with a genetic test should be provided with all relevant information on the nature, the significance and the implications of the genetic test, including appropriate access to counselling in the case where the test provides information on the genetic predisposition for medical conditions and/or diseases which are generally considered to be untreatable.

Identification and traceability of devices: in order to ensure that measures may be taken quickly if problems arise, the Regulation contains provisions regarding the registration of devices and of economic operators as well as detailed rules to ensure the traceability of medical devices right through the supply chain and all higher levels of packaging, thanks to the establishment of a Unique Device Identification (UDI) System.

Manufacturers must have the UDI code assigned to their devices by the date of application and the UDI carrier must be placed on the device and all higher levels of packaging gradually depending on the risk class of the device.

European Databank on Medical Devices (EUDAMED): the Regulation establishes a central data bank aimed at providing patients, health professionals and the public with full information on the products available in the EU, which will enable them to take decisions more easily.

ENTRY INTO FORCE: 25.5.2017.

APPLICATION: from 26.5.2022.

DELEGATED ACTS: the Commission may adopt delegated acts to amend non-essential elements of the Regulation. The power to adopt such acts is conferred on the Commission for a period of five years (renewable) from 25 May 2017. The European Parliament or the Council have

the right to object to a delegated act within three months (which may be extended by thee months) from the date of notification of the act.