Medical devices

2012/0266(COD) - 08/03/2017 - Council position

The Council adopted its position at first reading with a view to the adoption of a Regulation of the European Parliament and of the Council on medical devices.

The aim of the proposed Regulation is to lay down rules on the placing on the market, the putting into service of medical devices for human use and their accessories in the Union. It replaces Council Directives 90/385/EEC and 93/42/EC which are no longer adequate to regulate the sector.

Its objective 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 new rules must take into account the experience of metal-on-metal artificial hips and faulty silicone breast implants.

Scope: this Regulation shall also apply, as from the date of application of common specifications (CS), to the groups of products without an intended medical purpose such as contact lenses, equipment for liposuction, lipolysis or lipoplasty.

The CS would apply as of six months after their entry into force or date of application of the Regulation.

Notified bodies: the Council position strengthens the rules regarding notified bodies in order to ascertain that notified bodies are designated and operate under harmonised conditions throughout the Union. These rules provide a stronger mandate to independent notified bodies in their assessment of medical devices before they can be placed on the market.

Reinforced requirements for clinical investigations and clinical data: the procedures for authorisation of clinical investigations have been further aligned with the rules on clinical trials on medicinal products, particularly as regards provisions on informed consent and protection of vulnerable subjects.

The Council position foresees a consultation with an expert panel applicable to certain high-risk devices.

Liability: manufacturers' responsibilities are clearly set out for the follow-up of the quality, performance and safety of devices placed on the market. The Council requested that manufacturers should put in place measures to provide sufficient financial coverage in respect of their potential liability under Directive 85/374/EEC concerning liability for defective products.

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

Identification and traceability related obligations: the Councils position sets out detailed rules for the implementation of the Unique Device Identification (UDI) system. The main features of the position are the requirement for manufacturers to have the UDI code assigned to their devices by the date of application and the requirement for the UDI carrier to be placed on the device and all higher levels of packaging gradually depending on the risk class of the device.

Reprocessing of single-use medical devices: according to the Council's position, reprocessing of single-use medical devices may only take place when authorised under national law and in accordance with the provisions of the medical devices Regulation. When reprocessing is allowed, the reprocessor must assume the obligations of a manufacturer.

European Medical Devices Database (EUDAMED): the proposed Regulation ensures greater transparency of information on devices placed on the market by setting up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU.