In vitro diagnostic medical devices

2012/0267(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 *in-vitro* diagnostic medical devices which replaces Council Directive 98/79/EC and Commission Decision 2010/227/EU.

The proposed Regulation aims to put in place a robust, transparent and sustainable regulatory framework for ***in vitro*** **diagnostic medical devices for human use** in the European Union (e.g. HIV blood tests, pregnancy tests, blood sugar monitoring systems for diabetics). It shall apply to **performance studies** concerning such in vitro diagnostic medical devices and accessories conducted in the Union.

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.

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 *in vitro* diagnostic medical devices before they can be placed on the market.

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.

The Council's position sets out the verification by a designated reference laboratory of the performance claimed by manufacturers and a consultation with an expert panel as regards the evaluation for certain **high-risk devices**.

Information and counselling for genetic testing: Member States shall ensure that where a genetic test is used on individuals in the context of healthcare, the subject to the testing must be provided with **relevant information** on the nature, significance and implications of the test, as appropriate. In particular, there should be appropriate access to counselling where genetic testing provides information on diseases that are considered to be untreatable.

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 Council's 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.

Classification: 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.

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.