In vitro diagnostic medical devices

2012/0267(COD) - 09/03/2017 - Commission communication on Council's position

The Commission stated that the Council's position **overall endorsed the objectives pursued by the Commission proposal**, namely to ensure an increased level of patient safety and public health protection, facilitate the smooth functioning of the internal market and support innovation in the in vitro diagnostic medical device (IVD) sector.

The Commission supported the position adopted unanimously by the Council.

The Commission can accept the **amendments made by the Council** to its initial proposal as regards:

- **information and counselling for genetic testing in the context of healthcare**: the Commission stated that: (i) it will report on the Member States' experience with the implementation of the obligations for information and counselling in the context of use of genetic tests; (ii) devices without any medical purpose, including those which are intended to directly or indirectly maintain or improve healthy behaviours, quality of life and wellbeing of individuals, are not covered under the definitions of the Regulation on in vitro diagnostic medical devices. Nonetheless, the Commission intends to monitor, on the basis of the market surveillance activities carried out by Member States, specific safety issues which might be linked to the use of these devices;
- **the exemption of devices manufactured and used in the same health institution** from some requirements of the legislation, although this exemption is introduced for the first time for medical devices, the position of the Council can be supported as it offers acceptable guarantees for control of these "in-house" devices;
- **financial coverage by manufacturers** in case of damage caused by defective medical devices: the Council's position accepts the spirit of the European Parliament's 1st reading position introducing a compulsory liability insurance for manufacturers, but by obliging the manufacturers to have measures in place to provide sufficient financial coverage in respect of their potential liability:
- **reinforcing the role and responsibilities for authorised representatives** who would be jointly and severally liable with the importer and manufacturer in case of damages suffered due to defective devices;
- **the identification and traceability related obligations and establishment of a Unique Device Identification (UDI) System**: contrary to the Commission's proposal which only sets out the legal basis and the main principles of the future UDI system, leaving the details to the implementation stage, the Council's position sets out detailed rules for the implementation of the UDI system.

The Commission is also in favour of the new provisions aimed at:

- improving transparency of the information contained in the European Medical Devices Database (EUDAMED);
- strengthening the requirements for the designation and oversight of notified bodies;
- providing for the consultation of an expert panel on certain high-risk devices;
- reinforced requirements for clinical investigations and clinical data and provide for a longer transition period for the coordinated procedure for assessment of applications for clinical investigations in more than one Member State;
- specifying the obligations of manufacturers to follow-up on the real-life use of their devices after their placing on the market.