Medical devices

2012/0266(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 this important sector covering more than 500 000 products.

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:

- **the inclusion of certain products without a medical purpose in the scope** of the medical devices Regulation, even though the inclusion of the listed groups of products in the scope of the medical devices legislation is not automatic, as the Commission proposed, but is dependent on the adoption of the common technical specifications;
- **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;
- **reprocessing of single-use medical devices**: the approach taken by the Council differs from the Commission's which foresaw that all reprocessors would be considered as manufacturers and that single-use devices for critical use could not be reprocessed. Nevertheless, the Commission considered that the Council's position appears to be an acceptable way forward to establish EU-wide minimum rules applicable to the reprocessing of single-use medical devices and can therefore be supported;
- **the use of hazardous substances in invasive medical devices**: if the Council's position diverges from that of the Commission, it is nevertheless acceptable as regards the possibilities for identifying and tracking the devices which the new system will guarantee;
- **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;
- specifying the obligations of manufacturers to follow-up on the real-life use of their devices after their placing on the market.