Medical devices

2012/0266(COD) - 23/03/2017 - Committee recommendation tabled for plenary, 2nd reading

The Committee on the Environment, Public Health and Food Safety adopted the recommendation for second reading contained in the report by Glenis WILLMOTT (S&D, UK) on the Council position at first reading with a view to the adoption of a regulation of the European Parliament and of the Council on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

The committee recommended the European Parliament to approve, without amendment, the Council position at first reading.

Councils first reading position is in conformity with the agreement reached during the interinstitutional negotiations. The report is accompanied by a short justification which highlights the following elements of the approved text:

- the introduction of a special procedure involving an independent assessment carried out by a special expert panel of the highest risk devices of class III implantable and class IIb active devices administering or removing a medicinal product;
- the obligation for the manufacturer to put in place measures to provide sufficient financial coverage in respect of their potential liability regarding defective devices;
- strengthening the initial proposal which encourages manufacturers to seek substitution of substances that are carcinogenic, mutagenic or toxic for reproduction and substances having endocrine disrupting properties;
- the introduction of detailed provisions on conducting clinical investigations for medical devices with clearly defined rules and obligations on manufacturers, sponsors, participating subjects and the relevant authorities on informed consent, ethics committees, incapacitated subjects, minors, pregnant women, transparency;
- the introduction of provisions for the reprocessing of single use devices: reprocessing may only take place if allowed under national law, however, Member States may go beyond these provisions in further restricting or prohibiting this practice on their territory;
- the strengthening of provisions on the designation, organisation, monitoring and expertise of the notified bodies conducting the conformity assessment and certification for all devices on the Union market. These bodies shall have permanent availability of sufficient administrative, technical and scientific personnel for them to successfully conduct their conformity assessment activities;
- the strengthening of the authorisation procedures and the overall system for traceability of devices through the obligation for manufacturers to apply a post-market surveillance system according to the risk class and the type of device.