# Medical devices

2012/0266(COD) - 09/10/2013 - Committee report tabled for plenary, 1st reading/single reading

The Committee on the Environment, Public Health and Food Safety adopted the report by Dagmar ROTH-BEHRENDT (S&D, DE) on the proposal for a regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009.

The committee recommends that the position of Parliament adopted in first reading following the ordinary legislative procedure should amend the Commission proposal as follows:

**Scope:** devices for **aesthetic purposes** should also fall within the scope of the regulation. Furthermore, the Regulation shall not impede the continued application of measures within Directive 2002/98/EC and its five Daughter Directives setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components.

The risk of the use of nanomaterials shall be taken into account in the risk assessment process.

**Assessment procedure for medical devices**: for high risk medical devices, such as devices in class III, implantable devices and devices incorporating medicinal products, the report proposes to introduce the **possibility of providing an opinion on a case-by-case basis**, based on the **robustness of the clinical data** and the evidence that the device can be safely placed on the EU market.

To this end, Members proposed the **creation of an Assessment Committee for Medical Devices (ACMD)** in order to provide the case-by-case assessment where its members deemed it necessary to ask for the review of the clinical data.

The ACMD, placed under the aegis of the Commission, should be composed of the best specialists in various medical fields, as listed in categories or subgroups, which can be subject of modifications, notably in light of technical progress. Patients' representatives and a representative from the European Medicines Agency should also take part in the ACMD and contribute to the case-by-case assessments.

On the basis of this assessment of the clinical data, the Commission will adopt an opinion, which will be binding upon the Special notified body.

Notified bodies: Members proposed to strengthen provisions relating to the personnel in the national authorities responsible for the designation and monitoring of notified bodies. Personnel must have sufficient qualifications to audit the notified bodies for which they are responsible. Moreover, it should be ensured that notified bodies have permanent "in house" competent personnel.

**Subcontracting must be the exception**. Where subcontracting takes place, notified bodies should make publicly available the names of subcontractors and the precise tasks for which they have been awarded a contract. Once a year, notified bodies should be required to send documents to the relevant national authority to enable the verification of the subcontractors' qualifications.

**Fees:** Members welcomed the Commission's introduction of fees charged by national authorities for their activities related to the designation and monitoring of notified bodies. However, they added that those fees should be made public and comparable across Member States.

**Special notified bodies**: for high risk medical devices, such as devices in class III, implantable devices and devices incorporating medicinal products, the conformity assessment should be the responsibility of special notified bodies.

Those bodies should be designated by the European Medicines Agency (EMA) on the basis of the reinforced requirements on staff qualification and training.

The EMA shall establish, host, coordinate and manage the network of special notified bodies. The network shall contribute to the pooling of knowledge regarding medical devices.

**Labelling and disposal of single use devices**: Members considered that devices labelled as single-use should be really single-use and that **there should be only two options: single-use and reusable.** Furthermore, activities encompassed in the reprocessing of devices should be subject to stricter and more transparent standards.

As a result, only devices labelled as reusable should be reprocessed. To ensure the highest patient safety in the EU, **a list of single-use devices unsuitable for reprocessing** should be set up by the Commission after consultation of the Medical Device Advisory Committee.

**Clinical investigations**: since manufacturers must collate data to prove that their devices meet performance and safety requirements, Members have introduced definitions on "performance" or "safety".

**Performance** should notably be understood broadly so as to encompass efficacy and benefit to the patient, which must be checked in cases where clinical investigations apply.

Where clinical investigations are obligatory by virtue of the regulation, they must include **randomised clinical investigations** in the appropriate target population and well-controlled investigations.

Authorisation for conducting a clinical investigation shall be granted only after examination and approval by an **independent ethics committee**.

**European databank on medical devices (EUDAMED):** in order to strengthen the transparency of information, Members propose to ensure adequate levels of access for the public and healthcare professionals to those parts of Eudamed's electronic systems which provide key information on medical devices that may pose a risk to public health and safety.

**Vigilance and market surveillance**: Members wanted to ensure that the **reporting of incidents** and corrective measures through the electronic system includes date and place of incidents, and where available, information on the patient or user and healthcare professional, in full respect of privacy.

**Coordination between Member States and Medical Device Advisory Committee (the MDCG):** Members propose to set up a multidisciplinary advisory committee of experts and representatives of stakeholders and civil society organisations in order to provide scientific advice to the MDCG, and also to the Commission, and the Member States.

**Penalties:** Member States are invited to set and enforce serious penalties for manufacturers that commit fraud and cheat with regard to medical devices. Those penalties should be at least as large as the revenue gains from fraud or cheating. Penalties may include imprisonment.