Amendment 375
Mairead McGuinness, Peter Liese
on behalf of the PPE Group

Report
Dagmar Roth-Behrendt
Medical devices
COM(2012)0542 – C7-0318/2012 – 2012/0266(COD)

Proposal for a regulation
Article 15 – paragraphs 6 a-c (new)

Text proposed by the Commission

6a. The Commission shall, by means of implementing acts, and in collaboration with the International Medical Devices Regulatory Forum and international standardisation bodies, define a clear set of quality and safety standards for reprocessing devices, including specific requirements for the manufacturers of reprocessed devices.

6b. In drawing up these quality and safety standards, the Commission shall in particular include:

– cleaning, disinfection and sterilisation processes in line with the risk assessment for the respective devices;

– requirements in relation to systems for hygiene, infection-prevention, quality management and documentation applicable to the natural or legal persons reprocessing the medical devices;

– functionality testing of the devices after reprocessing.

These standards shall be consistent with the latest scientific evidence and guarantee the highest level of quality and safety, in accordance with the severity of the condition, as reflected in European standards from the European standardisation organisations, where the latter take into account the provisions of
relevant international standards, in particular those the ISO and IEC.

6c. The natural or legal person referred to in paragraph 7 shall comply with EU standards referred to in paragraph 7 to ensure the quality of the reprocessing of medical devices and the safety of reprocessed devices.

6d. Where no harmonised standards exist or where relevant harmonised standards are not sufficient, the Commission shall be empowered to adopt CTS, as referred to in Article 7(1).

6e. No later than four years after the date of application of this Regulation, the Commission shall assess the application of Article 15 and draw up an evaluation report, without prejudice to paragraph 6. The report should pay particular attention to the practice of reprocessing in hospitals. The report shall be submitted to the European Parliament and the Council. Where appropriate, the report shall be accompanied by a legislative proposal.
Amendment 376
Mairead McGuinness, Peter Liese
on behalf of the PPE Group

Report
Dagmar Roth-Behrendt
Medical devices
COM(2012)0542 – C7-0318/2012 – 2012/0266(COD)

Proposal for a regulation
Article 15 e (new)

Text proposed by the Commission

Amendment

Article 15e

Reprocessing of medical devices labelled as reusable

1. The Commission shall, by means of implementing acts, and in collaboration with the International Medical Devices Regulatory Forum and international standardisation bodies, define a clear set of high quality and safety standards for reprocessing devices, including specific requirements for the manufacturers of reprocessed devices.

2. In drawing up these quality and safety standards, the Commission shall in particular include:

– cleaning, disinfection and sterilisation processes in line with the risk assessment for the respective devices;

– requirements in relation to systems for hygiene, infection-prevention, quality management and documentation applicable to the natural or legal persons reprocessing the medical devices;

– functionality testing of the devices after reprocessing.

These standards shall be consistent with the latest scientific evidence and guarantee the highest level of quality and
safety, in accordance with the severity of the condition, as reflected in European standards from the European standardisation organisations, where the latter take into account the provisions of relevant international standards, in particular those of ISO and IEC, or any other international technical standards able to guarantee, at the very least, a higher level of quality, safety and performance than ISO and IEC standards.

3. Any natural or legal person, including health institutions as specified in Article 4(4), shall comply with EU standards referred to in paragraph 1 to ensure the quality of the reprocessing of medical devices labelled as ‘reusable’ and the safety of reprocessed devices.

4. Where no harmonised standards exist or where relevant harmonised standards are not sufficient, the Commission shall be empowered to adopt CTS, as referred to in Article 7(1).

Or. en
Proposal for a regulation
Article 15 f (new)

Text proposed by the Commission

Amendment

**Article 15f**

Report on the functioning of the system

No later than four years after the date of application of this Regulation, the Commission shall assess and draw up an evaluation report. The report shall be submitted to the European Parliament and the Council. Where appropriate, the report shall be accompanied by a legislative proposal.

Or. en