Amendment 349
Marina Yannakoudakis
on behalf of the ECR Group

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

Proposal for a regulation
Article 15 – paragraph 3

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
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<tr>
<td>3. In the case of reprocessing of single-use devices for critical use, only reprocessing that is considered safe according to the latest scientific evidence may be carried out.</td>
<td>3. By way of derogation from paragraphs 1 and 2 of this Article and from Article 4(4), health institutions may reprocess single-use devices provided that:</td>
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<td>(a) the reprocessed devices are only used on patients of that health institution and are not made available on the market;</td>
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<td>(b) they notify the competent authority of the Member State in which they are located of the single-use devices that they are reprocessing and provide evidence that it is safe to do so;</td>
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<td>(c) comply with the requirements regarding minimum standards of reprocessing as set out in [new Article 15e];</td>
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<td>(d) report any serious incidents and field safety corrective actions referred to in Article 61(1) to the competent authority of the Member State in which the health institution is located.</td>
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<td>Health institutions shall take on the liability of a manufacturer in respect of any reprocessed single-use devices used by that health institution.</td>
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Or. en
4. The Commission, by means of implementing acts, shall establish and regularly update a list of categories or groups of single-use devices for critical use which may be reprocessed in accordance with paragraph 3. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).
Amendment 351
Marina Yannakoudakis
on behalf of the ECR Group

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

Proposal for a regulation
Article 15 – paragraph 6 – subparagraph 1 – point a

Text proposed by the Commission
(a) the reprocessing of single-use devices and the transfer of single-use devices to another Member State or to a third country with a view to their reprocessing;

Amendment
(a) the reprocessing of single-use devices, including by health institutions, and the transfer of single-use devices to another Member State or to a third country with a view to their reprocessing;

Or. en
Amendment 352
Marina Yannakoudakis
on behalf of the ECR Group

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

Proposal for a regulation
Article 15 a (new)

Text proposed by the Commission

Amendment

Article 15a

Standards for reprocessing of medical devices

1. Any natural or legal person, including health institutions as specified in Article 4(4), who reprocesses a device shall comply with the EU standards referred to in paragraph 2.

2. 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 of single use devices, including specific requirements for the manufacturers of reprocessed devices.

3. 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.

4. Where no harmonised standards exist or where relevant harmonised standards are not sufficient, the Commission shall be empowered to adopt common technical specifications (CTS), as referred to in Article 7 (1).
Amendment 353
Marina Yannakoudakis
on behalf of the ECR Group

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

Proposal for a regulation
Article 15b (new)

Text proposed by the Commission

Amendment

Article 15b
Report on the functioning of the system referred to in Articles 15 and 15a

No later than four years after the date of application of this Regulation, the Commission shall assess the application of Articles 15 and 15a 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