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Committee on the Environment, Public Health and Food Safety

2012/0266(COD)

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***II
DRAFT RECOMMENDATION FOR SECOND READING

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 93/428/EEC
(10728/4/2016 – C8-0104/2017 – 2012/0266(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Glenis Willmott

Symbols for procedures

*	Consultation procedure
***	Consent procedure
***I	Ordinary legislative procedure (first reading)
***II	Ordinary legislative procedure (second reading)
***III	Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

Amendments to a draft act

Amendments by Parliament set out in two columns

Deletions are indicated in ***bold italics*** in the left-hand column. Replacements are indicated in ***bold italics*** in both columns. New text is indicated in ***bold italics*** in the right-hand column.

The first and second lines of the header of each amendment identify the relevant part of the draft act under consideration. If an amendment pertains to an existing act that the draft act is seeking to amend, the amendment heading includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend.

Amendments by Parliament in the form of a consolidated text

New text is highlighted in ***bold italics***. Deletions are indicated using either the ▌ symbol or strikeout. Replacements are indicated by highlighting the new text in ***bold italics*** and by deleting or striking out the text that has been replaced.
By way of exception, purely technical changes made by the drafting departments in preparing the final text are not highlighted.

CONTENTS

Page

DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

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
(10728/4/2016 – C8-0104/2017 – 2012/0266(COD))

(Ordinary legislative procedure: second reading)

The European Parliament,

– having regard to the Council position at first reading (10728/4/2016 – C8-0104/2017),

– having regard to the opinion of the European Economic and Social Committee of 14 February 2013[1],

– having regard to its position at first reading[2] on the Commission proposal to Parliament and the Council (COM(2012)0542),

– having regard to Article 294(7) of the Treaty on the Functioning of the European Union,

– having regard to Rule 67a of its Rules of Procedure,

– having regard to the recommendation for second reading of the Committee on the Environment, Public Health and Food Safety (A8-0000/2017),

1. Approves the Council position at first reading;

2. Notes that the act is adopted in accordance with the Council position;

3. Instructs its President to sign the act with the President of the Council, in accordance with Article 297(1) of the Treaty on the Functioning of the European Union;

4. Instructs its Secretary-General to sign the act, once it has been verified that all the procedures have been duly completed, and, in agreement with the Secretary-General of the Council, to arrange for its publication in the *Official Journal of the European Union*;

5. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

[1] OJ C 133, 9.5.2013, p. 52.
[2] Texts adopted: P7_TA(2014)0266.

SHORT JUSTIFICATION

Procedure

On 26 September 2012 the Commission adopted a 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 (COM(2012)0542 – C7-0318/2012 – 2012/0266(COD)).

Parliament adopted its first reading position on 2 April 2014, however, negotiations with the Council did not start until the autumn of 2015 when on 5 October 2015 the Council adopted a General Approach in view of commencing early second reading negotiations with Parliament which began on 13 October 2015 under the Luxembourg Presidency.

Following ten rounds of negotiations in total, the Parliament and the Council reached a political agreement on 25 May 2016 under the Dutch Presidency. The agreed text was subsequently endorsed with an overwhelming majority by the ENVI Committee on 15 June 2016. On the basis of the committee's approval, the Chairman of the Committee undertook in his letter from 16 June 2016 to the Chair of Coreper to recommend to the plenary to approve Council's position at first reading without amendment. Following legal-linguistic verification, Council adopted its first reading position confirming the agreement on 7 March 2017.

Content

The medical devices regulatory system in Europe was shaken by a number of device scandals that exemplified the existing weaknesses and stressed the urgent need to tighten up the loose ends in the framework. The Commission proposal and the subsequently agreed text for a new regulation replacing all existing directives seek to efficiently address these weaknesses while still maintaining and strengthening the current approval system.

The initial Commission proposal was a solid starting point which was further strengthened by the subsequent amendments by Parliament and Council. New additional provisions and structures will fill in the gaps and increase the levels of protection of public health and safety while ensuring clear rules with regard to the roles and obligations of all actors operating on the market, without stifling innovation that is an essential element of this industry.

In this respect, your Rapporteur would like to highlight in particular the following elements of the agreed text:

Special Procedure for certain High Risk Devices

Expanding on the Commission’s initial proposal for a scrutiny mechanism for Class III devices, the co-legislators introduced a provision (Article 54) for a second-level check, a special procedure during the conformity assessment and before certification (Section 5.1 of Annex IX), of the highest risk devices of Class III implantable and Class IIb active devices administering or removing a medicinal product. The procedure involves the independent assessment by a special expert panel (Article 106). In an overall decentralised system of

conformity assessment and certification in Europe, this new provision aims to ensure that when it comes to the highest risk devices there is an additional level of supervision on EU level conducted by experts re-evaluating the clinical evaluation assessment reports of the notified bodies for such devices.

Manufacturers' Liability

Given recent experiences with defective devices and the consequences for affected users, an aspect that was extremely important for Parliament to be addressed in the new regulatory framework, and that was missing from the Commission proposal, was manufacturers' liability insurance. This was also linked with frequent cases where patients were unable to access the relevant information in order to prove a causal link between defect and damage, as required by the Product Liability Directive. To this end, a compromise was reached with the Council whereby under Article 10, on manufacturers' obligations, a provision was added requiring that manufacturers should, in a manner that is proportionate to the risk class, type of device and the size of the enterprise, have measures in place to provide sufficient financial coverage in respect of their potential liability under the above Directive. In addition, further rules were agreed concerning the facilitation, by a competent authority, of the provision of information to persons who may have been injured by a defective device.

Substances that are carcinogenic, mutagenic or toxic for reproduction and substances having endocrine disrupting properties

Parliament's first reading position amendment to the Commission proposal provisions on these substances in Annex I called for a total ban for certain concentrations of these substances in certain devices subject to a range of derogations. Although such full ban was unacceptable to both the Council and the Commission due to the potential impact on industry and issues of implementation, the agreed text strengthens a lot what was initially proposed and paves the way for encouraging manufacturers to seek substitution of these substances since the permission for their use above a certain concentration would only be possible subject to manufacturers providing a strictly defined justification (Annex I, section 10.4)

Clinical Investigation/Evaluation - alignment to Clinical Trials regulation

Building on existing provisions in the current directives on conducting clinical investigations for medical devices (the equivalent of clinical trials in the field of medicinal products), the new regulation lays down detailed provisions for the entire process with clearly defined rules and obligations on manufacturers, sponsors, participating subjects and the relevant authorities (Chapter VI and Annex XV). Given that the Clinical Trials Regulation was agreed and adopted ahead of the medical devices regulation, the negotiated text sought to align the latter as much as possible including all provisions related to informed consent, ethics committees, incapacitated subjects, minors, pregnant women, transparency and a provision for the mandatory application of the coordinated assessment procedure (where investigations are conducted in more than one Member State) seven years after the date of application of the current regulation.

Reprocessing of single use devices

Legal provisions did not exist under the medical devices directive with regards to

reprocessing of single use devices apart from an obligation for the Commission to produce a report on this practice and in light of it submit a proposal if deemed appropriate. Establishing common provisions on a divergent practice in the Member States appeared challenging, however, the legislators found a common solution, also supported by the Commission, which for the first time channels the practice, sets obligations and ensures a level of safety for the use of reprocessed devices. The agreed text stipulates that reprocessing may only take place if allowed under national law and is in accordance with Article 17 of the current regulation, however, Member States may go beyond these provisions in further restricting or prohibiting this practice on their territory. Reprocessors are to be considered the manufacturer of the reprocessed device and should accordingly assume the obligations of manufacturers. Under certain circumstances, Member States may apply exceptions from the rules for devices reprocessed within health institutions. The Commission is tasked with producing common specifications for reprocessing of single use devices.

Notified Bodies provisions

One of the major amendments to the old system is the strengthening of the provisions on the designation, organisation, monitoring and expertise of the Notified Bodies (NBs) conducting the conformity assessment and certification for all devices on the Union market. Chapter IV and Annex VII address all aspects of these procedures. Some of the additional provisions introduced by Parliament and agreed by the Council relate to the permanent availability of sufficient administrative, technical and scientific personnel of NBs for them to successfully conduct their conformity assessment activities. The joint assessment at designation, continuous monitoring and annual re-assessment of NBs with on-site audits, including unannounced visits, is another measure to ensure the continued quality of expertise and observation of legal requirements by all NBs in the Union. A major improvement to the new legislation to be stressed is that notified bodies are obliged to do unannounced inspections on the production site. For high-risk devices, it is no longer sufficient to just check the papers but controls have to be on the spot. This is in your rapporteur's view the most important improvement that will avoid scandals in future. Last but not least, to provide for a level-playing field and transparency among them all in the different Member States, a new provision initiated by Parliament now requires that NBs establish lists of standard fees charged for conformity assessment procedures, which are made public.

Vigilance and Post-Market Surveillance

Apart from strengthening the authorisation procedures, one of the key pillars of the new proposal is an enhanced overall system for traceability of devices, vigilance and post-market surveillance to ensure constant monitoring and swift reaction should problems arise (Chapter VII). In addition to the Commission proposal, the co-legislators introduced an obligation for manufacturers, proportionate to the risk class of the device, to plan, establish, document, implement, maintain and update a post-market surveillance system for each type of device in order to gather, record and analyse all relevant data associated with the safety of the device throughout its lifecycle. Similar to medicinal products, periodic safety update reports were introduced for all risk classes but Class I, and for the higher ones these need to be updated at least annually. The co-legislators also oblige Member States to take the necessary measures to encourage and empower healthcare professionals, users and patients to report suspected serious incidents at national level using harmonised formats.

Recommendation

As Council's first reading position is in conformity with the agreement reached during the interinstitutional negotiations, your Rapporteur recommends endorsing it without amendments.