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Committee on the Environment, Public Health and Food Safety

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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 *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
(10729/4/2016 – C8-0105/2017 – 2012/0267(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Peter Liese

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.

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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 *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
(10729/4/2016 – C8-0105/2017 – 2012/0267(COD))

(Ordinary legislative procedure: second reading)

The European Parliament,

– having regard to the Council position at first reading (10729/4/2016 – C8-0105/2017),

– 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)0541),

– 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. Takes note of the Commission statements annexed to this resolution;

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

4. 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;

5. 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*;

6. 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)0267.

ANNEX TO THE LEGISLATIVE RESOLUTION

Commission statement regarding the provisions for information and counselling in the field of genetic testing in Article 4 of the Regulation on in vitro diagnostic medical devices

No later than five years after the date of application of the Regulation and in the framework of the review of the functioning of Article 4 foreseen in Article 111 of the Regulation, the Commission will report on the Member States' experience with the implementation of the obligations in Article 4 for information and counselling in the context of use of genetic tests. In particular, the Commission will report on the different practices in place in light of the double objective pursued by the Regulation, namely to ensure a high level of patient safety and guarantee the smooth functioning of the internal market.

Commission statement regarding genetic testing used for lifestyle and wellbeing purposes

With respect to genetic tests intended for wellbeing or lifestyle purposes, the Commission stresses that devices without any medical purpose, including those which are intended to directly or indirectly maintain or improve healthy behaviours, quality of life and wellbeing of individuals, are not covered by Article 2 (Definitions) of the Regulation on in vitro diagnostic medical devices. Nonetheless, the Commission intends to monitor, on the basis of the market surveillance activities carried out by Member States, specific safety issues which might be linked to the use of these devices.

SHORT JUSTIFICATION

Procedure

On 26 September 2012 the Commission adopted a proposal for a Regulation of the European Parliament and of the Council on in vitro diagnostic medical devices (COM(2012)0541 – C7-0317/2012 – 2012/0267(COD)).

Parliament already dealt with the issue in first reading on 22 October 2013 and suspended the final vote in order to start negotiations with the Council. However as the Council was not ready to enter yet negotiations, Parliament finally adopted its first reading position on 2 April 2014. 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 an 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

Protection for the patients but no unnecessary bureaucracy

The medical devices regulatory system in Europe was shaken by a number of device scandals which exemplified the existing weaknesses and stressed the urgent need to tighten up the loose ends in the framework. For example, there has been an HIV test on the market for many years, which significantly more often than not showed false negative results. That means the test was negative even though the HI virus was present. The Commission proposal and the subsequently agreed text for a new regulation replacing all existing directives seeks 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. At the same time it is very important to avoid unnecessary bureaucracy. This would not be acceptable for a very innovative part of the industry that creates a lot of jobs but more importantly it would prevent innovation that can help patients.

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

the agreed text:

Unannounced inspections

A major improvement in 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 and controls have to be on the spot. This is in your rapporteur's view the most important improvement that will avoid scandals in future.

Notified Bodies - better fit for the job

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. 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.

Reference Laboratories and Special Procedure for Certain High Risk Devices

Expanding on the Commission's initial proposal for a scrutiny mechanism for Class D devices, these will be subject to an extra check of conformity from a European reference laboratory. Furthermore, the co-legislators introduced a provision (Article 48) for a second-level check, a special procedure during the conformity assessment and before certification (Section 4.9 of Annex IX), of the highest risk innovative devices - class D where no Common Specifications are available for these devices and where it is also the first certification for that specific type of device. The procedure involves the independent assessment by a special expert panel references in the Medical Devices regulation (Article 106 there). 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.

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 XIII). 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.

Genetic counselling

The issue of information, informed consent and counselling in cases of use of genetic tests was one of the central issues in the Parliament's first reading position on IVD. It is Parliament's conviction that a minimum set of rules need to set the framework for the use of such tests. The Council strongly resisted the initial Parliament position but an agreement was reached on Article 4 which lays down the basic foundation that individuals being tested with a genetic test should be provided with all relevant information on the nature, the significance and the implications of the genetic test, including appropriate access to counselling in the case where the test provides information on the genetic predisposition for medical conditions and/or diseases which are generally considered to be untreatable. The Commission, in light of its obligations under Article 111 and the evaluation of the functioning of the current regulation, will in particular examine the application of Article 4, as also confirmed in its statement annexed to the negotiated text.

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 risk classes C and D which 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.