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#### **INFORMATION NOTE**

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From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
Subject:	<b>ADOPTION OF LEGISLATIVE ACTS FOLLOWING THE EUROPEAN PARLIAMENT'S SECOND READING</b>  Proposal for a Regulation of the European Parliament and of the Council on in vitro diagnostic medical devices – Outcome of the European Parliament's second reading (Strasbourg, 3 to 6 April 2017)

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#### **I. VOTE**

Since no amendment had been adopted, the President of the European Parliament declared the Council's position at first reading approved.

The text of the European Parliament's legislative resolution is annexed to this note.

## **II. ADOPTION OF LEGISLATIVE ACTS FOLLOWING THE EUROPEAN PARLIAMENT'S SECOND READING**

Since the European Parliament has approved the Council's position at first reading, the act in question is deemed to have been adopted in the wording which corresponds to the Council's position at first reading, as provided for in Article 294 (7)(a) of the TFEU.

After signature by the President of the European Parliament, the President of the Council and the Secretaries-General of the two Institutions, the act in question will be published in the *Official Journal* of the European Union.

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## **In vitro diagnostic medical devices \*\*\*II**

**European Parliament legislative resolution of 5 April 2017 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<sup>1</sup>,
  - having regard to its position at first reading<sup>2</sup> 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 (A8-0069/2017),
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;

<sup>1</sup> OJ C 133, 9.5.2013, p. 52.

<sup>2</sup> Texts adopted: P7\_TA(2014)0267.

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.

## **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.

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