Council of the European Union

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REV 1

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From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
No. prev. doc.:	10035/16 PHARM 35 SAN 245 MI 434 COMPET 365 CODEC 855
No. Cion doc.:	14493/12 PHARM 71 SAN 215 MI 597 COMPET 600 CODEC 2305 + COR 1 14499/12 PHARM 72 SAN 216 MI 598 COMPET 599 CODEC 2312 + COR 1
Subject:	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 Proposal for a Regulation of the European Parliament and of the Council on ***in vitro* diagnostic medical devices** *- Political agreement*

1. The Commission adopted its proposals for new Regulations replacing the current Directives 90/385/EEC[1] and 93/42/EEC[2] on medical devices and 98/79/EC[3] on *in vitro* diagnostic medical devices on 26 September 2012 and submitted them to the Council and to the European Parliament.

[1] OJ L 189, 20.7.1990, p. 17.
[2] OJ L 169, 12.7.1993, p. 1.
[3] OJ L 331, 7.12.1998, p. 1.

2. The proposals aim at modernising the existing legislative framework for the marketing of medical devices and to overcome legal gaps, thereby supporting innovation and the competitiveness of the medical device industry. The new Regulations will allow rapid and cost-efficient market access for innovative medical devices and further strengthen patient safety, notably through the introduction of more stringent procedures for conformity assessment and through requirements on manufacturers to generate clinical data.

3. The legal basis for the two proposals is Article 114 and point c) of Article 168(4) of the Treaty on the Functioning of the European Union. The ordinary legislative procedure is applicable.

4. In accordance with Protocol No 2 annexed to the Treaties, the Member States' national parliaments were consulted on the compliance of the proposed provisions with the principle of subsidiarity. None of the national parliaments objected to the proposals[4].

5. The European Data Protection Supervisor was consulted by the Commission and issued an opinion on 8 February 2013[5].

6. Invited by the Council, the European Economic and Social Committee issued its opinion on the Proposals on 14 February 2013[6]. The Committee of the Regions decided not to deliver any opinion given the low impact of the measures proposed on the local or regional authorities.

7. On 2 April 2014, the European Parliament adopted its legislative resolutions[7] on the two proposals and thus concluded its first reading. Following the elections, the Committee on the Environment, Public Health and Food Security of the European Parliament ("the ENVI Committee") on 5 November 2014 mandated the Rapporteurs to enter into negotiations with the Council in order to reach an agreement on these proposals.

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4 http://www.ipex.eu/

5 5590/13.

6 Opinion available in document INT/665-666-667 - CES2185-2012_00_00_TRA_AC - 2012/0266 (COD) and 2012/0267 (COD) of 14 February 2013.

7 The EP adopted its amendments to the two proposals already at the Plenary on 22 October 2013. They are set out in documents 14936/13 and 14937/13.

8. On 5 October 2015, the Council reached General Approaches on the draft Regulation on medical devices[8] and on the draft Regulation on *in vitro* diagnostic medical devices[9].

9. In October 2015, negotiations with the European Parliament were started and five informal trilogues held under the Luxembourg Presidency. These were followed by five further informal trilogues during the Netherlands Presidency. In addition, a large number of meetings at technical level were held between representatives of the Council, the European Parliament and the Commission. The Presidency negotiating mandates were prepared in the Working Party on Pharmaceuticals and Medical devices and agreed in the Permanent Representatives Committee.

10. On 15 June 2016, the Permanent Representatives Committee held a final discussion on the two proposals and agreed on the compromise text for the draft Regulation on medical devices[10] and on the compromise text for the draft Regulation on *in vitro* diagnostic medical devices[11]. As these compromise texts had been adjusted compared to the texts resulting from the final informal trilogue on some points[12] important to the Commission, it could also give its full support.

11. On the same day those texts were supported by all members in a vote in the ENVI Committee.

12. In two letters dated 16 June 2016, the Chair of the ENVI Committee informed the Chair of the Permanent Representatives Committee (Part 1) that should the Council formally transmit to the European Parliament the two compromise texts thus agreed, subject to legal-linguistic finalisation, as its positions at first reading, he would, together with the two Rapporteurs, recommend to the Plenary that the Council's positions be accepted without amendments at Parliament's second reading.

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8 12040/1/15 REV 1 + ADD 1.
9 12042/15 + ADD 1.
10 9364/3/16 REV 3. (In this text changes to the Commission proposal are indicated. A "clean" text is available in all languages in document 10617/16.)
11 9365/3/16 REV 3. (In this text changes to the Commission proposal are indicated. A "clean" text is available in all languages in document 10618/16.)
12 10035/16.

13. As the compromise texts have been translated and are available in all official languages, a formal political agreement can now be reached at Council level.

14. During the translation procedure a few corrections have been introduced in the two draft Regulations[13]. As these are of a purely linguistic nature, it is appropriate that the draft Regulations be treated as "A" items at the forthcoming meeting of the General Affairs Council on 20 September.

15. Following the political agreement, the two draft Regulations will be subject to legal-linguistic finalisation following which the finalised texts will be submitted to the Council for formal adoption as its position at first reading. They will subsequently be transmitted to the European Parliament together with the Council's Statements of Reasons in accordance with Article 294, paragraphs 5 and 6, of the Treaty on the Functioning of the European Union.

CONCLUSION

The Permanent Representatives Committee is invited to agree to

- **recommend to the Council to confirm, as an "A" item, the political agreement on the draft Regulation on medical devices set out in the Annex to document 11662/16,**

and to

- **recommend to the Council to confirm, as an "A" item, the political agreement on the draft Regulation on *in vitro* diagnostic medical devices set out in the Annex to document 11663/16.**

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[13] The draft Regulation on medical devices is set out in document 11662/16 + COR 1 and the draft Regulation on *in vitro* diagnostic medical devices in document 11663/16. The changes compared to the texts in documents 10617/16 and 10618/16 are listed in documents 10617/1/16 REV 1 and 10618/1/16 REV 1, respectively.