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Subject:	**Employment, Social Policy, Health and Consumer Affairs Council** meeting on 17 June 2016 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** ***-*** *Information from the Presidency* (Any Other Business item)

Introduction

1. On 28 September 2012, the Commission submitted to the European Parliament and the Council the package of two proposals for Regulations replacing the current Directives 90/385/EEC[1] and 93/42/EEC[2] on medical devices and Directive 98/79/EC[3] on *in vitro* diagnostic medical devices.

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. On 2 April 2014, the European Parliament adopted its legislative resolutions[4] on the two proposals and thus concluded its first reading. Following the elections to the European Parliament in June 2014, the Committee on the Environment, Public Health and Food Safety (ENVI), on 5 November 2014, mandated the Rapporteurs to enter into negotiations with the Council aiming to reach an agreement.

3. On 19 June 2015, the Council (EPSCO) reached partial General Approaches[5] on the two draft Regulations. This was a result of a thorough examination and detailed discussions at the meetings of the Working Party on Pharmaceuticals and Medical devices as well as several debates at Coreper during the Cyprus, Irish, Lithuanian, Greek, Italian and Latvian Presidencies.

4. On 5 October 2015, the Council (EPSCO) adopted complete General Approaches[6], after the examination by the Working Party of recitals and corrections of inconsistences in the enacting terms in the partial General Approaches.

5. The first informal trilogue during the Luxembourg Presidency took place already on 13 October 2016. It was followed by four further informal trilogues and seven meetings at technical level, during which the entire proposals were opened for negotiations and some tentative agreements were reached[7].

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

5 Doc. 9773/15 and references therein.

6 12040/1/15 REV 1 + ADD 1 (Medical devices), 12042/15 + ADD 1 (*In vitro* diagnostic medical devices) + corresponding "A"-item note 12388/15.

7 Doc. 14215/15

Work during the Netherlands' Presidency

6. Following proper preparation with the European Parliament at technical level and in the Council preparatory bodies, the sixth informal trilogue took place on 17 February 2016, at which the following issues were discussed:
   - Scrutiny of high-risk devices;
   - Liability for damage caused by devices;
   - Clinical evaluation of medical devices.

7. Discussions at the following three informal trilogues on 16 March, 7 April and 11 May concentrated on:
   - Scrutiny of high-risk devices;
   - Liability for damage caused by device;
   - Reprocessing of single-use devices;
   - Use in devices of substances that are Carcinogenic, Mutagenic or toxic to Reproduction;
   - Classification rules;
   - Periodic Safety Update Reports;
   - Use of Delegated and Implementing acts;
   - Genetic counselling in relation to IVD;
   - Performance evaluation of IVD;
   - Exemptions from certain requirements for medical devices based on Well-established technologies;
   - IVDs for Near-patient testing;
   - Transitional provisions.

8. The last (tenth) informal trilogue on 25 May focused on the outstanding issues:
   - Scrutiny of high-risk IVD;
   - Genetic counselling;
   - Exemptions from certain requirements for medical devices based on Well-established technologies;
   - the Co-ordinated procedure for application for clinical investigations and performance studies;
   - Obligations regarding Second-hand sales;
   - Transitional provisions, notably regarding application of provisions depending on the functionality of data bases, validity of certificates and sell-out of devices in stock.

9. At this informal trilogue, the representatives of the European Parliament and the Presidency acting on behalf of the Council reached a tentative agreement on both proposals. The Commission representatives were unable to support the compromise texts because of issues relating to reprocessing of single-use devices and the interaction with national legislation relating to public access to official documents and regarding freedom of the press and freedom of expression in other media.

10. In addition to the informal trilogues, around twenty meetings at technical level involving representatives of the three Institutions were held to examine differences between the texts of the Council and of the European Parliament as regards technical issues. As the regulatory frameworks for medical devices and IVDs should be very similar, diverging only where this is justified by the inherent differences between these two categories of devices[8], the texts of the two draft regulations are to a large extent identical. Therefore particular attention was paid to ensuring the coherence and the alignment of the two texts.

11. The Working Party on Pharmaceuticals and Medical devices was actively involved in the preparation of the negotiations and was regularly informed about the progress. The Working Party met on about fifteen occasions during the Netherlands Presidency.

[8] Medical devices are used on, or in, the human body and *in vitro* diagnostic medical devices are laboratory equipment.

12. The Permanent Representatives Committee prepared the Council's positions for all informal trilogue meetings, agreeing on negotiation mandates for the Presidency. The Coreper was informed by its Chairperson about the outcome after each informal trilogue.

13. On 15 June 2016, the Permanent Representatives Committee analysed the texts with a view to final agreement. In order to reach a stable agreement that could be supported also by the Commission, Coreper decided to amend the preliminary agreement between the Council and the European Parliament on two points - reprocessing of single-use devices and interaction with national legislation relating to public access to official documents and regarding freedom of the press and freedom of expression in other media. Representatives of the European Parliament had before the Coreper meeting informally confirmed that they could agree to these last changes. The Commission could thus confirm its support for the compromise texts, which are set out in document 9364/3/16 REV 3 for the draft Regulation on medical devices and in document 9365/3/16 REV 3 for the draft Regulation on *in vitro* diagnostic medical devices.

14. The European Parliament ENVI Committee in a vote taken on 15 June 2016 unanimously supported the compromise and informed the Chair of Coreper accordingly.

Future steps

15. During the summer 2016, the compromise texts will be translated into all official languages and thereafter submitted to the Council for political agreement (expected in September). As the compromise texts will be unchanged from those agreed by Coreper on 15 June, except for corrections of possible obvious errors, the political agreement will be handled as an "A"-item.

16. Following the political agreement, the two texts will be revised by legal linguists and submitted to the Council for adoption of formal positions at first reading in accordance with Article 294, paragraph 5 TFEU. They will then be transmitted together with the Council's Statements of reasons to the European Parliament in accordance with Article 294, paragraphs 5 and 6 TFEU.

17. The European Parliament is, based on the outcome of the vote in ENVI on 15 June 2016, expected to agree to the two regulations in accordance with Article 294, paragraph 7, letter (a).

18. The Presidency consequently concludes that the road now lies open towards the entry into force and the application of the new EU regulatory framework for medical devices.

CONCLUSION

The Council is invited to take note of this report.