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NOTE

From:	Presidency
To:	Council
No. prev. doc.:	12388/15 PHARM 39 SAN 299 MI 586 COMPET 424 CODEC 1250
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:	**Employment, Social Policy, Health and Consumer Affairs Council** meeting on 7 December 2015 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 on the state of play* (Any Other Business item)

Introduction

1. At its meeting on 19 June 2015, the Council (EPSCO) reached partial General Approaches on the draft Regulation on medical devices[1] and on the draft Regulation on *in vitro* diagnostic medical devices.[2] The aim of the proposals and the preparation that led to the partial General Approaches are outlined in the note[3] submitted to that Council meeting.

[1] 9769/15 PHARM 26 SAN 176 MI 391 COMPET 304 CODEC 858 + ADD 1.
[2] 9770/15 PHARM 27 SAN 177 MI 392 COMPET 305 CODEC 859 + ADD 1.
[3] 9773/15 PHARM 28 SAN 178 MI 393 COMPET 306 CODEC 860.

2. As the partial General approaches did not cover the recitals, the Council, at that meeting, also instructed its preparatory bodies to examine the recitals and to check the enacting terms of the two draft Regulations for technical inconsistencies with a view to preparing complete General Approaches.

Preparation of General Approaches

3. During the first half of the Luxembourg Presidency, the Working Party on Pharmaceuticals and Medical devices concentrated on the work necessary to prepare complete General Approaches that would, in accordance with the Council instructions, constitute the bases for negotiations with the European Parliament.

4. In the technical re-examination of the texts, it was realised that the provisions on transitional measures (Article 94 in the Regulation on medical devices, Article 87 in the Regulation on *in vitro* diagnostic medical devices) had to be improved to deal with possible problems of availability of devices at and immediately after the date of application of the two new Regulations. Before that date a sufficient number of notified bodies must be designated in accordance with the strengthened requirements introduced by the present proposals so that devices can be assessed from the safety and performance point of view.

5. On 5 October the Council (EPSCO) reached General Approaches[4] on the two proposals in which there were, due to mainly technical reasons, some changes to parts of the texts from June, including transitional measures to resolve the problems outlined under point 4. The General Approaches also included recitals.

[4] The General Approaches were "A"-items on the Council agenda.
12388/15 PHARM 39 SAN 299 MI 586 COMPET 424 CODEC 1250
12040/1/15 REV 1 PHARM 36 SAN 281 MI 567 COMPET 410 CODEC 1193 + ADD 1 and
12042/15 PHARM 37 SAN 282 MI 568 COMPET 411 CODEC 1194 + ADD 1.

Negotiations with the European Parliament

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

7. During September 2015, the Working Party re-focused its efforts towards examining the differences between the Positions of the European Parliament at first reading and the Council General Approaches under preparation, which helped the Presidency to prepare the forthcoming negotiations.

8. The regulatory frameworks for medical devices and *in vitro* diagnostic medical devices should be the same, diverging only where this is justified by the inherent differences[6] between these two categories of devices. As a consequence, the texts of the two Regulations were, as proposed by the Commission, and should when the Regulations are adopted, to a large extent be identical. Due to the size of the proposals it was decided to divide them into four thematic blocks, three of which, for the reasons outlined above cover issues in both proposals and one of which covers "the IVD-specific issues". The contents of the blocks are listed in Annex I.

9. On 13 October 2015, the first informal trialogue was held in Brussels, at which the negotiations on Block 1 were opened. The starting position for the Council were the texts of the two General Approaches.

10. In the second informal trialogue, held in Strasbourg on 28 October 2015, Block 2 was opened, and negotiations on political issues in Block 1 continued.

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5 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 CODEC 2292 PHARM 57 SAN 394 MI 887 COMPET 729 PE 462 and 14936/13 CODEC 2291 PHARM 56 SAN 393 MI 886 COMPET 728 PE 461.

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

11. The discussions in the third informal trialogue held on 10 November 2015 concentrated mainly on Block 3 ('IVD-specific issues'). The fourth trilogue on 18 November then focused on further discussion on political issues opened in the preceding informal trialogues.

12. On 3 December 2015 a fifth informal trialogue was held in Brussels, at which Block 4 was opened and a discussion was held on the procedure for scrutiny of high-risk devices (both as regards medical devices and as regards *in vitro* diagnostic medical devices).

13. The Permanent Representatives Committee has been involved in the preparation of two of the informal trialogues (in the others the text of the Council General Approaches were used as the basis for the negotiations) and has been regularly informed about the outcome after each informal trialogue, most recently on 4 December.

14. In addition to the informal trialogues, six 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 more technical issues. A final technical meeting under the Luxembourg Presidency is scheduled for 11 December.

15. A list of main political issues covered in the informal trialogues is set out in Annex II.

16. The Working Party on Pharmaceuticals and Medical devices has been actively involved in the preparation of the negotiations and has been regularly informed about the progress. The Working Party met on 12 occasions during the Luxembourg Presidency and a final meeting is scheduled for 14 December.

17. While it is noted that nothing is agreed until everything is agreed, the Presidency deems that there is an emerging agreement on Chapters I, II and III in both proposals, except for Article 15 (reprocessing) in the medical device proposal. The Presidency is, now that discussions on all blocks have been opened, convinced that the ground has been laid for an agreement between the Institutions.

CONCLUSION

The Council is invited to take note of this report.

ANNEX I

List of the blocks and their contents

Block 1 consists of Chapter I (Scope), Chapter II (Obligations of economic operators) except Article 15 of the draft Regulation on Medical Devices, Chapter V, section I (Classification), and the related annexes.

Block 2 consists of Chapter III (Identification and traceability), Chapter VI(Clinical evaluation for medical devices and performance evaluation for IVDs), Chapter IX (Confidentiality and data protection), Chapter X (Final provisions, including transitional measures), and the related annexes.

Block 3 consists of IVD-specific issues, notably rules on IVDs for self-testing and genetic testing as well as classification rules and parts of the provisions on performance evaluation.

Block 4 consists of Chapter IV (Notified bodies), Chapter V. section II (Conformity assessment), Chapter VII (Surveillance of the market), Chapter VIII (Cooperation between Member States, notably the Medical Device Coordination Group), and the related annexes.

The definitions and recitals relating to a specific block are examined together with the enacting terms of that block.

ANNEX II

List of main political issues covered in the informal trialogues

- Aesthetic devices, *i.e.* devices without a medical purpose (Article 1 and Annex XV MD, Block 1),
- In-house products (Article 4, Block 1),
- Liability insurance for manufacturers of devices (Article 8, Block 1),
- Implant card and information to patients implanted with devices (Article 16 MD, Block 1),
- Classification rules (Article 41 MD, Article 39 IVD, Annex VII, Block 1),
- Use of Cancerogenic, Mutagenic and Reprotoxic substances and Endocrine Disrupting Substances in devices (Annex I, Block 1),
- Reprocessing of single-use devices (Article 15 MD, Block 2),
- Traceability of devices (Chapter III, Block 2),
- Transitional measures, in particular regarding validity of certificates (Articles 94 and 97 MD, Articles 87 and 90 IVD, Block 2),
- Prescription rules (Article 1 IVD, Block 3),
- Devices for genetic tests (Article 2 IVD, Block 3),
- Companion diagnostics (Articles 2 and 40 IVD, Annex I IVD, Annex VIII IVD, Block 3),
- Genetic counselling (New Article 4a proposed by the European Parliament, Block 3),
- Self-testing and near-patient testing (Annex VIII IVD, Block 3),
- The scrutiny procedure for high-risk devices (Chapter V, Annex VIII, Block 4).