Council of the
European Union

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NOTE

From:	Presidency
To:	Council
No. prev. doc.:	9048/15 PHARM 21 SAN 147 MI 331 COMPET 238 CODEC 750
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** **-** *Partial General Approach*

Introduction

1. The Council is invited to examine the texts set out in documents 9769/15 + ADD 1 and 9770/15 + ADD 1 with a view to reaching a Partial General Approach for the proposed Regulation on medical devices and a Partial General Approach for the proposed Regulation on *in vitro* diagnostic medical devices.

Aim of the proposals

2. The proposals aim to replace the existing EU regulatory framework for medical devices, consisting of Council Directive 90/385/EEC ('AIMDD') on active implantable medical devices[1], Council Directive 93/42/EEC ('MDD') on medical devices[2] and Directive 98/79/EC of the European Parliament and of the Council on *in vitro* diagnostic medical devices[3] which together cover a huge spectrum of products (from sticking plasters to hip replacements, pacemakers and laboratory tests for assessment of medical interventions) which are developed in an environment of rapid technological and scientific progress.

3. The proposed legislative framework aims to address substantial divergences in the interpretation and application of the existing Directives, to overcome flaws and gaps that have been discovered, to support innovation and the competitiveness of the medical device industry, to allow rapid and cost-efficient market access for innovative medical devices and to further strengthen patient safety.

4. The proposals have been thoroughly prepared by the Commission, a first impact assessment being done in 2008 shortly after the adoption of Directive 2007/47/EC of the European Parliament and of the Council[4], which updated the AIMDD and the MDD.

Procedure

5. On 26 September 2012, the Commission adopted its Proposals for a Regulation on medical devices and a Regulation on *in vitro* diagnostic medical devices and submitted them to the Council and to the European Parliament.

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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.
4 OJ L 247, 21.9.2007, p. 21.

6. 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.

7. 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[5].

8. The European Data Protection Supervisor was consulted by the Commission and issued an opinion on 8 February 2013[6].

9. Invited by the Council, the European Economic and Social Committee issued its opinion on the Proposals on 14 February 2013[7]. 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.

10. On 2 April 2014, the European Parliament adopted its legislative resolutions[8] on the two proposals and thus concluded its first reading. Following the elections, the Committee on the Environment, Public Health and Food Security (ENVI) of the European Parliament on 5 November 2014 mandated the Rapporteurs to enter into negotiations with the Council aiming to reach an agreement on these proposals.

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5 http://www.ipex.eu/

6 Document 5590/13.

7 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.

8 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.

State of play in the Council

11. The Working Party on Pharmaceuticals and Medical devices started its examination in October 2012. The Council (EPSCO) was informed about the progress on four occasions (at its meetings in 2013 and 2014) and invited its preparatory bodies to continue the examination of the proposals with the aim of achieving an agreement within the Council as soon as possible.

12. Due to the size and technical nature of the proposals, the expert work in the Working Party concentrated on the enacting terms and no comprehensive examination of the recitals has so far been done by the Council preparatory bodies.

13. The Working Party met in total 50 days under the Cyprus, Irish, Lithuanian, Hellenic and Italian Presidencies.

14. During the Latvian Presidency the Working Party met 18 days[9] to examine the proposals, addressing in particular ten issues identified during previous Presidencies[10] and the Presidency set itself the goal of establishing compromise texts covering, for both proposals, all articles and annexes.

15. The Presidency is of the opinion that the two texts it prepared are balanced compromises that while being internally consistent seek to respond to the plenitude of amendments suggested by delegations[11] and the concerns raised by them. The Presidency underlines that those texts should be seen as a package and recommends to the Council to reach Partial General Approaches on both proposals without making any changes to the texts.

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9 Four of these meetings were "attachés only". In addition, the Permanent Representatives Committee was informed twice about the progress.

10 See Point 12 in document 16116/14.

11 There are more than 300 meeting documents issued and documents 17097/14 and 17152/14 contain, respectively, 1185 and 1534 footnotes.

Examination by the Permanent Representatives Committee

16. On 10 June 2015, the Permanent Representatives Committee prepared the Council meeting scheduled for 19 June.

17. An overwhelming majority of delegations agreed that the texts prepared by the Presidency should be forwarded to the Council with the aim of reaching Partial General Approaches covering all enacting terms. One delegation spoke in favour of limiting the Partial General Approaches to a few Chapters and most Annexes of both proposals. Some delegations drew the attention to some technical inconsistencies and mistakes.

18. It was concluded that the texts should be forwarded to the Council with the view to reaching Partial General Approaches and that the Council should be invited to instruct its preparatory bodies to prepare complete General Approaches for both proposals. In that preparatory work, the Working Party should elaborate texts for all recitals and check the enacting terms for technical inconsistencies. Following examination by the Permanent Representatives Committee, the texts of the General Approaches could be approved as "A" items at a forthcoming Council meeting, with the view to serving as bases for negotiations with the European Parliament.

19. Since the Council Secretariat had indicated that it might not be possible to prepare the text elaborated by the Latvian Presidency for the proposed Regulation on *in vitro* diagnostic medical devices in all 24 languages applicable for a Regulation in time for the meeting of the Council (EPSCO) on 19 June 2015 it was agreed to recommend to the Council to approve the Partial General approach for that proposal based on the available language version(s). Before approval as an "A" item at the forthcoming Council meeting, all language versions would be required.

CONCLUSION

The Council is invited to

- **examine the Presidency compromise text set out in document 9769/15 + ADD 1 with a view to reaching a Partial General Approach (excluding recitals) for the draft Regulation on medical devices,**
- **examine the Presidency compromise text set out in document 9770/15 + ADD 1 with a view to reaching a Partial General Approach (excluding recitals) for the draft Regulation on *in vitro* diagnostic medical devices,**

and to

- **instruct its preparatory bodies to examine the recitals and check the enacting terms for technical inconsistencies with a view to preparing complete General Approaches for the two draft Regulations.**