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Council of the European Union

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"A" ITEM NOTE

From:	General Secretariat of the Council
To:	Council
No. prev. doc.:	12039/15 PHARM 35 SAN 280 MI 566 COMPET 409 CODEC 1192
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** *- General Approaches*

1. At its meeting on 19 June 2015, the Council reached partial General Approaches on the draft Regulation on medical devices[1] and on the draft Regulation on *in vitro* diagnostic medical devices.[2]

[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.

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2. The aim of the proposals and the procedural steps that led to the partial General Approaches are outlined in the Note to the June Council (EPSCO).[3]

3. As all linguistic versions of the draft Regulation on *in vitro* diagnostic medical devices were not available at the time of the above Council meeting, it was agreed to grant a language derogation.

4. At that meeting, the Council instructed its preparatory bodies to examine the recitals and check the enacting terms of the two draft Regulations for technical inconsistencies with a view to preparing complete General Approaches.

5. At its meeting on 23 September 2015, the Permanent Representatives Committee (Part 1) examined the draft Regulation on medical devices set out in document 12040/1/15 REV 1+ ADD 1 and the draft Regulation on *in vitro* diagnostic medical devices set out in document 12042/15 + ADD 1 and noted that the Working Party on Pharmaceuticals and Medical Devices had reached agreement at technical level on recitals that reflect the contents of the two draft Regulations and on corrections of technical inconsistencies.

6. At that meeting, it was noted that all delegations apart from the German delegation could support the two texts referred to in Point 5. A qualified majority in favour of the draft General approaches therefore exists.

7. The Committee consequently agreed to forward the two texts to the Council with a view to reaching General Approaches on the draft Regulation .on medical devices and on the draft Regulation on *in vitro* diagnostic medical devices.

[3] 9773/15 PHARM 28 SAN 178 MI 393 COMPET 306 CODEC 860.

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CONCLUSION

The Council is invited to

- **agree its General Approach on the draft Regulation on medical devices as set out in document 12040/1/15 REV 1 + ADD 1,**

and to

- **agree its General Approach on the draft Regulation on *in vitro* diagnostic medical devices as set out in document 12042/15 + ADD 1.**

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