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NOTE

From: General Secretariat of the Council
To: Working Party on Pharmaceuticals and medical devices

No. prev. doc.: 14473/15 PHARM 50 SAN 398 MI 749 COMPET 540 CODEC 1568
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**

Delegations will find in the addenda to this document the tentatively agreed compromise text as regards "Block 4" set out in tables together with the positions at the beginning of the negotiations.

The compromise text is still subject to confirmation by the European Parliament and the Council.

Block 4 consists of the following elements:

- Recitals (40) to (45a), (51a) to (56a) and (59) to (62) of the proposed Regulation on medical devices Set out in Addendum 1.
- Recitals (33) to (36), (38) to (41), (47b) to (52a) and (55) to (58) of the proposed Regulation on *in vitro* diagnostic medical devices Set out in Addendum 2.
- The definitions in Chapter I of both proposals that are directly linked to Chapters IV, V (Section 2), VII and VIII Set out in Addendum 3
- Chapter IV and Annex VI of both proposals Set out in Addendum 4
- Chapter V (Section 2) of both proposals with Annex XII (MD) and XI (IVD) Set out in Addendum 5.
- Chapter VII and Annex IIa of both proposals Set out in Addendum 6.
- Chapter VIII of both proposals Set out in Addendum 7.
- Annex VIII of both proposals Set out in Addendum 8.
- Annexes IX and X of both proposals Set out in Addendum 9
- Annex XI of the proposed Regulation on medical devices Set out in Addendum 10.
