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

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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 2" 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 2 consists of the following elements:

- Recitals (34) to (39a), (46) to (51), (57) to (58) and (63) to (71) of the proposed Regulation on medical devices Set out in Addendum 1
- Recitals (27) to (32a), (42) to (47aa), (54) and (59) to (66a) 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 III, VI, IX and X Set out in Addendum 3
- Article 15 of the proposed Regulation on medical devices together with related recitals and definitions Set out in Addendum 4
- Chapter III and Annex V of both proposals Set out in Addendum 5
- Chapter VI of the proposed Regulation on medical devices Set out in Addendum 6
- Chapter VI of the proposed Regulation on *in vitro* diagnostic medical devices Set out in Addendum 7
- Chapters IX and X of both proposals Set out in Addendum 8
- Annexes XIII and XIV of the proposed Regulation on medical devices Set out in Addendum 9
- Annex XII and XIII of the proposed Regulation on *in vitro* diagnostic medical devices Set out in Addendum 10
