



Council of the
European Union

Brussels, 31 May 2016
(OR. en)

9261/16

Interinstitutional Files:

2012/0266 (COD)
2012/0267 (COD)

PHARM 26
SAN 203
MI 361
COMPET 307
CODEC 705

NOTE

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

No. prev. doc.: 12800/15 PHARM 42 SAN 326 MI 616 COMPET 447 CODEC 1310
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 1" 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 1 consists of the following elements:

- Recitals (1) to (30) and (32), (33) and (39b) of the proposed Regulation on medical devices Set out in Addendum 1.
- Recitals (1) to (26) of the proposed Regulation on *in vitro* diagnostic medical devices Set out in Addendum 2.
- Chapter I of both proposals and Annex XV of proposed Regulation on medical devices - definitions that are directly linked to chapters that are not in Block 1 are not included. Set out in Addendum 3.
- Chapter II except Article 15 of both proposals Set out in Addendum 4.
- Chapter V, Section I of both proposals Set out in Addendum 5.
- Annex I of both proposals Set out in Addendum 6.
- Annex II both proposals Set out in Addendum 7.
- Annex III and IV of both proposals Set out in Addendum 8.
- Annex VII of the proposed Regulation on medical devices Set out in Addendum 9.
- Annex VII of the proposed Regulation on *in vitro* diagnostic medical devices Set out in Addendum 10.
