



Council of the
European Union

Brussels, 2 October 2015
(OR. en)

Interinstitutional File:
2012/0266 (COD)

12040/1/15
REV 1 COR 1

PHARM 36
SAN 281
MI 567
COMPET 410
CODEC 1193

NOTE

From: General Secretariat of the Council
To: Permanent Representatives Committee/Council

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

On page 171, in the first line of paragraph 1b, for

"referred to in *point (a)*"

read

"referred to in *point (a) of paragraph 1*".

On page 178, in the first line of paragraph 2, for

"*In the context of the evaluation referred to in paragraph 10,*"

read

"*In the context of the evaluation referred to in paragraph 0,*".

On page 222, in the last line of the first paragraph of Article 96, for
" *referred to in Article 97(2) and 97(3)(d)*"
read
" *referred to in Article 97(2) and 97(3)(ba)*".
