

Council of the European Union

> Brussels, 2 October 2015 (OR. en)

12040/1/15 REV 1 COR 1

Interinstitutional File: 2012/0266 (COD)

> 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) <u>of paragraph 1</u>*".

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

"In the context of the evaluation referred to in paragraph <u>10</u>,"

read

"In the context of the evaluation referred to in paragraph <u>0</u>,".

On page 222, in the last line of the first paragraph of Article 96, for

" referred to in Article 97(2) and 97(3)(<u>d</u>)"

read

"referred to in Article 97(2) and 97(3)(<u>ba</u>)".