



Brussels, 2 October 2015  
(OR. en)

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**Interinstitutional File:  
2012/0266 (COD)**

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12040/1/15  
REV 1 COR 1

PHARM 36  
SAN 281  
MI 567  
COMPET 410  
CODEC 1193

**NOTE**

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

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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

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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

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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)*".

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