



Council of the
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PHARM 36
SAN 281
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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 26, for:

"(a) The particulars referred to in points 19.2. (a), (c), (e), (f), (**fa**), (k), (l), ~~and~~ (n) **and (r)**."
read:

"(a) The particulars referred to in points 19.2. (a), (c), (e), (~~f~~) (**fa**), (k), (l), ~~and~~ (n) **and (r)**".

On page 39, for:

" Name, registered trade name or registered trade mark, single registration number..."
read:

"Name, registered trade name or registered trade mark and single registration number..."

On page 39, for:

"5. Risk class of the device in accordance with Annex VII;"

read:

"5. Risk class of the device in accordance with the rules set out in Annex VII;"

On page 82, for:

"= a *the scientific preclinical literature search and*"

read:

"= *the scientific preclinical literature search and* ".

On page 94, for :

"6. In calculating the duration referred to in ~~Chapter I~~, Section 1 continuous use means:"

read:

"6. In calculating the duration referred to in Chapter I, Section 1 continuous use means:"

On page 96, in Section 3.4., the fourth indent, which reads:

"- are in class IIa in all other cases, including devices principally intended to manage the micro-environment of a ~~wound~~ *injured skin or mucous membrane*."

should be deleted.

On page 127 Section 3.1a. should be deleted.