Council of the European Union

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ADD 1 COR 1

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.