Council of the European Union

Brussels, 2 October 2015
(OR. en)

Interinstitutional File:
2012/0267 (COD)

12042/15
ADD 1 COR 1

PHARM 37
SAN 282
MI 568
COMPET 411
CODEC 1194

NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
No. Cion doc.:	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 ***in vitro*** **diagnostic medical devices**

On page 21, for

"(vii) ~~Where applicable,~~ the unique device identification (UDI) ***carrier according to Article 24 and Annex V Part C***;"

read

"(vii) ~~Where applicable,~~ the unique device identification (UDI) ***carrier according to Article 22 and Annex V Part C***;".

On page 24, for

"***- for companion diagnostics, the INN (International Non-proprietary Name) of the associated drug for which it is a companion test.***"

read

"***- for companion diagnostics, the INN (International Non-proprietary Name) of the associated medicinal product for which it is a companion test.***".

On page 29, for

" ***In the case of the following devices, other…***"

read:

"***17.3.1a.*** ***In the case of the following devices, other…***".

On page 42, for

"***a post-market performance follow-up plan according to Part B of Annex XII, or a justification why a post-market performance follow-up is not deemed necessary or appropriate.***"

read

"***a post-market performance follow-up plan according to Part B of Annex XII, or a justification why a post-market performance follow-up is not applicable.***".

On page 45, for

" **Information to be submitted with the registration of devices in accordance with Article 23*a*** "

read

"**Information to be submitted with the registration of devices *and economic operators* in accordance with Article 23*a***".