



Brussels, 26 October 2015
(OR. en)

13325/1/15
REV 1

PHARM 46
SAN 349
MI 656
DELECT 145
ECO 130
ENT 224
COMPET 467

"I/A" ITEM NOTE

From: General Secretariat
To: Permanent Representatives Committee/Council

No. Cion doc.: 11804/15 PHARM 32 SAN 269 MI 549 DELACT 120 ECO 106 ENT 186
COMPET 445 + ADD 1 + ADD 2 + ADD 3

Subject: COMMISSION DELEGATED REGULATION (EU) No .../. of XXX
supplementing Directive 2001/83/EC of the European Parliament and of
the Council by laying down detailed rules for the safety features appearing
on the packaging of medicinal products for human use
- *Extension of the period for raising objections*

1. On 2 October 2015, the Commission submitted for scrutiny by the Council of the European Union and the European Parliament its draft Commission Delegated Regulation¹ supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use.
2. The legal basis for the draft Commission Delegated Regulation is Article 54a(2) of Directive 2001/83/EC on the Community code relating to medicinal products for human use².

¹ Document C(2015) 6601 final, Council document number 11804/15.

² OJ L 311, 28.11.2001, p. 67.

3. Article 121c(1) of that Directive provides that the European Parliament or the Council may object to a delegated act within a period of 2 months from the date of notification. and that that period shall be extended by 2 months at the initiative of the European Parliament or the Council.
 4. At the meeting of the Working Party on Pharmaceuticals and Medical devices on 19 October 2015, a simple majority of Member States (BG, DK, EE, IE, EL, ES, HR, IT, CY, LT, HU, MT, AT, PL, RO, SK, FI) requested that the period for raising objections be extended.
 5. Article 240(3) of the Treaty on the Functioning of the European Union provides that procedural decisions require a simple majority in the Council, which, in accordance with Article 238(1) TFEU, means a majority of its component members.
 6. The Permanent Representatives Committee is therefore invited:
 - to confirm that a simple majority of Member States supports that the period for raising objections be extended, and
 - to invite the Council to decide, as an "A" item on the agenda of one of its future meetings, that it requests that the period for raising objections be extended.
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