Council of the European Union
General Secretariat

Brussels, 1 February 2016

CM 1372/16

PHARM
SAN
PROCED

COMMUNICATION

WRITTEN PROCEDURE

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Subject:	WRITTEN PROCEDURE WITH REPLY BY 25 JANUARY 2016 17H00 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 *– End of the written procedure*

Delegations are informed that the written procedure initiated by CM 1208/16 on 20 January 2106 has been completed.

The following delegations replied that the Council should not object to the draft Commission Delegated Regulation set out in document 11804/15 PHARM 32 SAN 269 MI 549 DELACT 120 ECO 106 ENT 186 COMPET 445: BE, BG, CZ, DK, DE, EE, IE, EL, ES, HR, IT, CY, LV, LT, HU, MT, NL, AT, PL, PT, RO, SI, FI, SE, UK.

The following delegations replied that the Council should object to the draft Commission Delegated Regulation: LU, SK.

It is thus concluded that a qualified majority is established and that the qualified majority does not support that the Council should raise objections to the delegated act. It is furthermore noted that EE, LT and MT issued the statement set out in the Annex to the Note in document 5289/1/16 REV 1.