COUNCIL OF THE THE EUROPEAN UNION

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REVISED ADDENDUM TO THE "I/A" ITEM NOTE

from:	General Secretariat of the Council
to:	COREPER / COUNCIL
No. Cion prop.:	17504/08 MI 566 SAN 355 ECO 198 ENT 334 CODEC 1889
Subject:	Proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC as regards the prevention of the entry into the legal supply chain of medicinal products which are falsified in relation to their identity, history or source **(first reading)** - Adoption of the legislative act (**LA** + **S**) = Statements

STATEMENT BY BELGIUM, GREECE AND ITALY

Belgium, Greece and Italy today have systems in place that allow the identification at the point of dispense of all individual packs of medicinal products subject to reimbursement. Belgium, Greece and Italy have requested the introduction of transitional measures for Member States that already have systems with a similar function as the future Union safety feature referred to in the new Point (o) of Article 54 that will be added to Directive 2001/83/EC by the Directive now adopted. Belgium, Greece and Italy note that the second indent of Point (b) of Paragraph 2 of Article 2 of this Directive contains such a provision and conclude that their systems are sufficiently similar in purpose to that of the future Union safety feature to entitle them to an additional transitional period of 6 years for the introduction of the Union safety feature and are therefore in a position to vote in favour of this Directive.

STATEMENT BY LATVIA

Latvia supports the objective of the Directive to eliminate, by all practical means, the risk of falsified medicines entering the legal supply chain in the European Union. However, Latvia has concerns regarding the measures chosen to achieve this objective.

Latvia is in favour of application of new safety features to those medicinal products that are in the high risk category of being falsified, namely, prescription medicinal products. Latvia cannot accept the inclusion of non-prescription medicinal products in the scope of application as it would, in our opinion, create disproportionate costs to both operators in the legal supply chain as well as patients.

Taking into account the above mentioned, Latvia abstains from the voting of the adoption of the draft Directive.