



**COUNCIL OF THE
THE EUROPEAN UNION**

Brussels, 24 September 2012

**Interinstitutional File:
2012/0023 (COD)**

**13918/12
ADD 1**

**CODEC 2168
MI 564
PHARM 66
SAN 198
ECO 112
ENT 217
OC 508**

ADDENDUM TO THE "I/A" ITEM NOTE

from : General Secretariat of the Council
to : COREPER / COUNCIL

No. Cion prop.: 6551/12 MI 106 PHARM 8 SAN 32 ECO 19 ENT 38 CODEC 389

Subject : Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 726/2004 as regards pharmacovigilance (**first reading**)
- Adoption of the legislative act (**LA + S**)
=Statement

COMMON GUIDELINES

Consultation deadline: 2.10.2012

Statement by the Commission

on establishing fees related to pharmacovigilance activities

On 18 June 2012, the Commission launched a public consultation on a concept paper concerning the introduction of fees for Pharmacovigilance, as set out in Regulation (EU) No 1235/2010 and Directive 2010/84/EU, which was open for comments until 15 September 2012. After examination of the comments received, the Commission will prepare an impact assessment which is one of the necessary steps in the legislative process before the Commission puts forward a legislative proposal. The Commission will continue to work on this file as a priority with the intention of presenting a legislative proposal as soon as possible to the European Parliament and the Council.