



**COUNCIL OF  
THE EUROPEAN UNION**

**Brussels, 28 May 2009**

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**Interinstitutional File:**

**2008/0261 (COD)  
2008/0257 (COD)  
2008/0260 (COD)  
2008/0255 (COD)  
2008/0256 (COD)**

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**10183/09**

**LIMITE**

**MI 223  
SAN 148  
ECO 85  
ENT 116  
CODEC 754**

**NOTE**

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from : Presidency  
to : Council (EPSCO)

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No. prev. docs. : 10180/09, 10181/09, 10182/09

No. Cion props. : 17504/08, 17501/08, 17502/08, 17498/08, 17499/08

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Subject : **Pharmaceuticals package**

(a) 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

(b) Proposal for a Regulation of the European Parliament and of the Council amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (LA) and

Proposal for a Directive of the European Parliament and of the Council amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use (LA)

(c) Proposal for a Regulation of the European Parliament and of the Council amending, as regards information to the general public on medicinal products for human use subject to medical prescription, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (LA) and

Proposal for a Directive of the European Parliament and of the Council amending, as regards information to the general public on medicinal products subject to medical prescription, Directive 2001/83/EC on the Community code relating to medicinal products for human use (LA)

- Progress reports / Exchange of views

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Following the meeting of the Permanent Representatives Committee on 27 May 2009, delegations will find in the addenda to this note Presidency progress reports intended for the Council (EPSCO) on 8 and 9 June 2009.

**The Council is invited to take note of the Presidency progress reports and to hold an exchange of views.**

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