



**COUNCIL OF  
THE EUROPEAN UNION**  
  
**GENERAL SECRETARIAT**

**Brussels, 12 April 2012**

**CM 2489/12**

**PHARM  
SAN  
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**COMMUNICATION**

**NOTICE OF MEETING AND PROVISIONAL AGENDA**

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Subject: Working Party on Pharmaceuticals and Medical Devices  
Date: Friday, 20 April 2012 (10h00)  
Venue: COUNCIL, JUSTIS LIPSIUS BUILDING  
Rue de la loi 175, 1048 BRUSSELS

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1. Adoption of the agenda
2. Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 726/2004 as regards pharmacovigilance

Proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC as regards pharmacovigilance

(Document 8566/12 MI 233 PHARM 21 SAN 74 ECO 48 ENT 86 CODEC 936  
(to follow))

- Continued examination

3. Amended proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC as regards information to the general public on medicinal products subject to medical prescription

Amended proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 726/2004 as regards information to the general public on medicinal products for human use subject to medical prescription

(Documents 6549/12 MI 104 PHARM 6 SAN 30 ECO 17 ENT 36 CODEC 387 + 6550/12 MI 105 PHARM 7 SAN 31 ECO 18 ENT 37 CODEC 388)

- Examination of key issues

4. REGULATION (EU) No 1235/2010 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 December 2010 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, and Regulation (EC) No 1394/2007 on advanced therapy medicinal products

- Need for a corrigendum

(Document 8568/12 PHARM 22 SAN 75 MI 234 ECO 49 ENT 87)

- Presentation

5. A.O.B.

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