

COUNCIL OF THE EUROPEAN UNION

Brussels, 21 May 2012

**GENERAL SECRETARIAT** 

CM 3061/2/12

REV 2

**PHARM** 

**SAN** 

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**ECO** 

**ENT** 

## **COMMUNICATION**

REVISED NOTICE OF MEETING AND PROVISIONAL AGENDA

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Subject: Working Party on Pharmaceuticals and Medical Devices

Date: Friday, 25 May 2012 (10h00)

Venue: COUNCIL, JUSTIS LIPSIUS BUILDING

Rue de la loi 175, 1048 BRUSSELS

- 1. Adoption of the agenda
- 2. Review of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)
  - Information from the Commission

3. 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

8566/2/12 REV 2 MI 233 PHARM 21 SAN 74 ECO 48 ENT 86 CODEC 936 (to follow)

- Continuation of the examination
- 4. A.O.B.