



**COUNCIL OF
THE EUROPEAN UNION**

GENERAL SECRETARIAT

Brussels, 10 May 2012

CM 2929/12

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COMMUNICATION

NOTICE OF MEETING AND PROVISIONAL AGENDA

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Subject: Working Party on Pharmaceuticals and Medical Devices
Date: Wednesday, 16 May 2012 (10h00)
Venue: COUNCIL, LEX BUILDING
Rue de la loi 145, 1048 BRUSSELS

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

8566/1/12 REV 1 MI 233 PHARM 21 SAN 74 ECO 48 ENT 86 CODEC 936
(to follow)

- Continuation of the examination

3. Draft COMMISSION REGULATION (EU) No .../. of XXX concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin
9264/12 PHARM 28 SAN 89 MI 270

Draft COMMISSION REGULATION (EU) No .../. of XXX amending Commission Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products
9425/12 PHARM 30 SAN 92 MI 277

- Information from the Presidency on the preparation of a Council decision

4. A.O.B.
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