



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

**Brussels, 15 November 2013**

**CM 5135/1/13  
REV 1**

**PHARM  
SAN  
MI  
COMPET**

**COMMUNICATION**

**REVISED NOTICE OF MEETING AND PROVISIONAL AGENDA**

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Subject: Working Party on **Pharmaceuticals and Medical Devices**  
Date: Monday, 18 November 2013 (**09h30**)  
Venue: COUNCIL, Justus Lipsius Building  
Rue de la loi 174, 1048 BRUSSELS

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The document number for Item 2 was incorrect in the provisional agenda sent out 6 November.

1. Adoption of the agenda
2. Proposal for a Regulation of the European Parliament and of the Council on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC  
**13463/3/13 REV3 PHARM 47 SAN 328 MI 739 COMPET 634 CODEC 1981**  
- Continued examination

The following point will be treated in the afternoon, starting at 14h30:

3. Proposal for a Regulation of the European Parliament and of the Council on fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities in respect of medicinal products for human use  
15719/13 PHARM 61 SAN 427 MI 957 COMPET 771 CODEC 2453 (will become available by 12 November 2013)  
- Continued examination

4. Any other business.

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NB: To reduce costs, only documents produced in the week preceding the meeting will be available in the meeting room.

NB: Delegates requiring day badges to attend meetings should consult document 14387/1/12 REV 1 on how to obtain them.