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REV 1

PHARM
SAN
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COMPET

COMMUNICATION

NOTICE OF MEETING AND PROVISIONAL AGENDA

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Subject: Working Party on Pharmaceuticals and Medical Devices

Date: 13 January 2016

Time: 14.30

Venue: COUNCIL
JUSTUS LIPSIUS BUILDING
Rue de la Loi 175, 1048 BRUSSELS

In this revised document a new point 2 is added to the draft agenda

1. Proposal for a Regulation of the European Parliament and of the Council on **medical devices** and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009

Proposal for a Regulation of the European Parliament and of the Council on *in vitro* **diagnostic medical devices**

– *Continued examination*

2. COMMISSION DELEGATED REGULATION (EU) No .../.. of XXX supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the **safety features appearing on the packaging of medicinal products** for human use

– *Question whether any delegation objects to adoption*

11804/15 PHARM 32 SAN 269 MI 549 DELACT 120 ECO 106 ENT 186 COMPET 445

3. Any other business
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NB: Council documents are available on Extranet. A limited stock of documents produced immediately prior to the meeting will be available in the meeting room. Room attendants will provide copies on request at the earliest opportunity.

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