EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
Medicinal products – authorisations, European Medicines Agency
Head of unit

Brussels,
SANCO/D5/MP/iv(2013)ddg1.d5.211672

Dear Madam,
Dear Sir,

Subject: **Invitation to a Pharmaceutical Committee Meeting on a) the delegated act on post-authorisation efficacy studies and b) other issues**

With reference to our letter of 9/11/2012 announcing the 70th meeting of the Pharmaceutical Committee **(Human),** I would like to confirm this meeting. You can now proceed with your travel reservation. The meeting will take place in Brussels on **27 March 2013** from **10.00 am** to **6.00 pm,** at the Conference Centre Albert Borschette (CCAB), 36 Rue Froissart, 1040 Brussels, meeting **room AB-0B.**

Please note that the meeting will start with a consultation on the delegated act on post-authorisation efficacy studies, which the Commission may adopt in accordance with Article 10b of Regulation (EC) 726/2004 and Article 22b of Directive 2001/83/EC in order determine the situations in which those studies may be required.

In preparing this delegated act, the Commission wishes to consult experts from the national authorities of all the Members States. The consultation will build on the results of the public consultation, which is currently on-going.[1]

The Pharmaceutical Committee is in this respect an expert group that can be consulted for this purpose. The Pharmaceutical Committee has been registered in the Register of Commission Expert Groups[2]

The rest of the meeting will be devoted to other issues usually dealt with by the Pharmaceutical Committee. The draft agenda of the meeting will be sent to you shortly.

The Commission reimburses travel expenses (economy flight or first class train) for one expert per Member State, as well as Croatia (except Belgium). Please complete the attached registration form and send it back to sanco-pharmaceuticals-d5@ec.europa.eu or by fax **before 20 March 2013**.

[1] http://ec.europa.eu/health/files/pharmacovigilance/2012_11_28_pc_paes.pdf.

[2] http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=2858

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Personal data will be handled in accordance with the rules attached.

Yours sincerely,

Sabine Jülicher