EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

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

Brussels,
SANCO/D5/FS/ci D(2013) 1014218

To the Permanent Representations of the
EU Member States, Croatia and of the EEA Contracting States

Dear Madam, Dear Sir,

Subject: Invitation to a meeting of an expert group to discuss the delegated act on post-authorisation efficacy studies – human medicinal products

The new pharmacovigilance legislation (Directive 2010/84/EU and Regulation No 1235/2010) refers to the possibility of requesting the marketing authorisation holder to conduct post-authorisation efficacy studies (PAES) complementing efficacy data that are available at the time of the initial authorisation. In order to determine the situations in which post-authorisation efficacy studies may be required, the Commission is mandated to adopt, by means of a delegated act, measures supplementing the provisions of Directive 2001/83/EC and Regulation (EC) No 726/2004[1].

In preparing this delegated act, the Commission wishes to consult experts from the national authorities of all the Member States, which will be responsible for implementing the delegated acts once they have been adopted. An expert group has been set up by the Commission as a subgroup to the Pharmaceutical Committee[2].

A kick-off discussion has taken place in the framework of the last plenary of the Pharmaceutical Committee on 27 March 2013.

We would like to invite you to a follow-up meeting of this expert group on **4 June 2013**, at 10 a.m., at the *Centre de Conférence Albert Borschette* (CCAB 1B), Rue Froissart 36, in 1040 Brussels.[3] The meeting will close at 18h at the latest.

The Commission reimburses travel expenses for one expert per Member State, as well as Croatia (economy flight or first class train). Subsistence expenses are not reimbursed.

[1] Article 10b of Regulation (EC) No 726/2004 and Article 22b of Directive 2001/83/EC.

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

[3] Access plan is here http://ec.europa.eu/oib/pdf/building-map_en.pdf.

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The meeting will focus on a discussion of situations where post-authorisation efficacy studies may be required as described in point 5 of the concept paper put out for public consultation[4] and the structure of the delegated act. To this end a further working document will be sent in advance of the meeting.

Experts from Croatia, as well as from the EEA Contracting States may participate at the meeting as observers.

For organisational and security purposes, please use the attached form to indicate if you intend to participate or not, and send it to sanco-pharmaceuticals-D5@ec.europa.eu by 21 May 2013.

If you have additional questions, please do not hesitate to contact the responsible desk-officers (email addresses below).

Yours sincerely,

Sabine Jülicher

Encl.: Registration form

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