EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
Medicinal products – authorisations, EMA

PHARM 611

PHARMACEUTICAL COMMITTEE
22 October 2012

Subject: **Enforcement of pharmacovigilance obligations**

Agenda item 2. b)

The new pharmacovigilance legislation puts a particular emphasis on the quality and reliability of the pharmacovigilance system implemented by pharmaceutical companies in order to support a continuous life-cycle management that produces the desired results or quality objectives for the fulfilment of pharmacovigilance tasks.

Pharmaceutical companies are therefore asked to establish robust systems the functioning of which is described in the new pharmacovigilance system master file. Such master file is not part of the marketing authorisation, instead it must be kept available at the site in the Union where the main pharmacovigilance activities of the marketing authorisation holder are performed or at the site in the Union where the qualified person responsible for pharmacovigilance operates.

Past experience has shown however, that for the purpose of monitoring compliance of marketing authorisation holders with pharmacovigilance obligations it is not sufficient to rely on written documentation, even if the new underlying quality systems will certainly improve the situation. Instead, it is additionally necessary that competent authorities inspect the premises, records and documents of the marketing authorisation holder.

In accordance with the amended Article 111 of Directive 2001/83/EC, if the outcome of the inspection is that the marketing authorisation holder does not comply, the Member States, where appropriate, shall take the necessary measures to ensure that a marketing authorisation holder is subject to effective, proportionate and dissuasive penalties.

The Commission services would be interested to know to what extent penalty proceedings are used as an enforcement instrument in the field of pharmacovigilance. To this end, the Commission services would like to ask delegates to provide replies to the following questions:

1. What is the average number of infringement procedures in the field of pharmacovigilance per calendar year in your Member State?

2. In view of the reinforced wording of Article 111 of Directive 2001/83/EC, do you consider to make more often recourse to that instrument?

Additionally, the Commission takes the opportunity to remind Member States that **Article 101(2) of Directive 2001/83/EC** requires Member States to perform a regular audit of their pharmacovigilance system and to report the results to the Commission on **21 September 2013** at the latest and every two years thereafter.

Action to be taken:

For discussion / follow-up