Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel
Federal Institute for Vaccines and Biomedicines

Paul-Ehrlich-Institut

Directorate-General
for Health and Consumers,
Unit SANCO/D/3

sanco-pharmaceuticals@ec.europa.eu

Contact person: Dr. Katrin Völler
Phone: + 49 (0) 6103 77-3902
Fax: + 49 (0) 6103 77-1251
e-mail: eu-cooperation@pei.de

04 November 2011

PCIM/11/01 – Public Consultation on implementation measures for pharmacovigilance

Comments from the Paul-Ehrlich-Institut (PEI), Germany

A. Pharmacovigilance system master file:

Consultation item no. 1: Key aspects are covered.

Consultation item no. 2: Notification of significant changes of the PhV master file would be helpful for national competent authorities/ inspectors to fulfil the tasks. The date of the last review should also be provided.

Consultation item no. 3: Concerning potential delegation of pharmacovigilance tasks it is clearly stated that the MAH remains to be fully responsible for all aspects of pharmacovigilance. Therefore, it is not necessary to be more precise in the document.

Consultation item no. 4: It is not necessary to retain a copy of the audit report in the master file. Documentation about audit schedules is considered helpful.

Consultation item 5: Agreement as regards the content and maintenance of the pharmacovigilance master file.

B. Quality systems for the performance of pharmacovigilance by MAHs

Consultation item no. 6: There is no need for additional quality procedures.

Consultation item no. 7: Agreement with requirements as described in the document.

C. Quality systems for the performance of pharmacovigilance activities by national competent authorities and EMA

Consultation item no. 8: Agreement with requirements for competent authorities.

E. Signal detection

Consultation item no. 9: Work sharing is essential for efficiency reasons. However, signal detection should be performed by all MS. Signal detection will certainly benefit from parallel monitoring as it is assumed that signals may be more likely detected if all members are involved compared to one lead member state and EMA.

Consultation item no. 10: The proposed provisions with regard to signal detection are not sufficiently clear. Roles and responsibilities of stakeholders are and details of signal detection tools and methods are not described.

F. Terminology

Consultation items no 11/12: The implementation of terminology based on ISO EN has been already discussed in relevant working groups of EMA. The implementation of the terminology will require additional financial resources at least in same MSs.

G: Transition and submission requirements

Consultation item no 13: There may not be a need for a transitional period with regard to obligations stipulated in Articles 21a and 22 a

to Directive 2001/83/EC and Articles 10 and 10a to Regulation (EC) No 726/2004 as MAHs have the opportunity to start preparing for implementation on the basis of Annex IV of this document

Annex 1

Consultation item no 14: It needs to be emphasised that not for all case reports of biological medicinal products it will be possible (despite all efforts) to get the information about the batch number.

Annex 2

Consultation item no 15: Agreement

Annex 3

Consultation item no 16: The changed PSUR content is based on the prerequisite that EudraVigilance is fully functional and that descriptions of single case reports in the PSUR are no longer necessary. However, at present query options for Member States in EudraVigilance are rather limited. Due to the unsolved problem of duplicates in EudraVigilance validity of the query results are not ensured. As a minimum overview tables with all fatal and all serious unexpected case reports in the electronic PSUR may be necessary until EudraVigilance will be fully functional.
It is recommended that a transitional period may be considered until the PSUR repository and other database functions will be available and are considered functional.