RESPONSE TO: Commission Public Consultation: As Assessment of the Community System of Pharmacovigilance

Name: EFPIA

Type of stakeholder: Industry

Organisation: EFPIA

Your comments:

The EFPIA comments relate principally to three themes:

1. Industry-Authority partnership
2. Harmonisation of pharmacovigilance requirements
3. The Single Report

These, together with other considerations, are presented within annex 1 (Community PV System - EFPIA suggestions).

Taken together, the themes promote the following notions:

- One Pharmacovigilance system in one language
- One set of binding rules to all stakeholders
- One assessment (rapporteur/lead member state)
- One voice (in pharmacovigilance communication)

- **On the specific areas highlighted in the Commission sponsored study which can be summarised as follows:**

1. Data sources and safety issue detection

- Create medical European automated data bases to collect data on prescriptions and follow up on medical conditions either by GPs or specialists
- Promote use of these data bases with access to medical records for validation of the findings
- Put more efforts in the utilisation of Eudravigilance and make this database a unique powerful tool for data mining and signal detection in Europe

2. The legal framework and new legal tools

- Pharmacovigilance rules in the EU are found in a wide array of documents that are sometimes contradictory and often unclear. As such, the rules can be both complex and confusing
- The focus of pharmacovigilance activities should be on safety evaluation instead of on meeting duplicative, unclear and complex regulatory demands. This approach would be in the best interest of Public Health
- A single legally binding text with one single set of simple rules to be applied uniformly by all the EU countries is required that should contain clear and concise, unambiguous provisions that would simplify, strengthen and provide legal certainty to the EU legislative framework for pharmacovigilance
- One language (English) to be used for pharmacovigilance purposes and reporting to EudraVigilance

3. Decision making in pharmacovigilance

- Under the leadership of the Rapporteur/Lead Member State
- Define roles and responsibilities of the stakeholders that would involve for each product:
    i. The Rapporteur /Lead Member State
    ii. MAH(s)
    iii. CHMP (with PhVWP)

EC law requires that the MAH supplies the competent authority with any new information that might entail the amendment of various particulars or documents that comprise the dossier and marketing authorisation, including information, which might influence the risk-benefit evaluation of a medicinal product. This requirement is set out in Article 23 of Directive 2001/83/EC, as amended by Directive 2004/27/EC and in Article 16(2) of Regulation 726/2004.

"[The MAH] shall <u>forthwith inform</u> [the competent authorities] […] <u>of any other new information which might influence the evaluation of the benefits and risks</u> of [the medicinal product] concerned."

This provision, if not properly clarified in a revised version of Volume 9A, will leave the pharmaceutical industry no choice but to interpret the meaning and for some this

will mean reporting all new safety information to the regulatory authorities in an expedited manner. That will overburden the system and risk not responding in a timely fashion to serious safety concerns.

For this reason we believe it is critical to distinguish a 'safety concern' (*any new safety information which might [probably] influence the evaluation of the benefits and risks of the product*) from a 'signal' (*any new safety information [for which the impact on the risk-benefit of the product hasn't been analysed yet]*). Only safety concerns should qualify for regulatory reporting from the MAH to the authorities, and vice-versa as appropriate.

There is also a need to better define the terms '*forthwith'* or '*immediate'*, which occur in the legislation and on numerous occasions in Volume 9A. The categorisation, timing and method of notification of new safety information to the competent authorities should be governed by the clinical significance and potential public health impact of the safety concern. Important safety concerns should be submitted within a reasonable timeframe after initial analysis.

Annex 2 proposes a method by which this could be accomplished. It includes clear definitions for *'signal'* versus *'safety concern'* and a categorisation based on the level of risk-benefit impact linked to reasonable timeframes for and methods of notification The suggested approach will present regulators with all new safety information that is relevant to the evaluation of benefits and risks of a product within an appropriate timeframe and by means of an appropriate route.

4. Impact of communications and actions

Current negative opinion regarding pharmaceutical companies and regulatory agencies underlines the need for better communication with the media, patient organisations, professional interest groups and the public on topics associated with the safety of medicines. Specifically industry and regulators should:

- Develop and test training and education programmes for patients with a priority on understanding the benefit: risk of medicine
- Establish agreed definitions of when a "signal" becomes a "safety concern" and clarify the timing and method of notification of new safety information governed by the clinical significance and potential public health impact of the safety concern
- Develop innovative methods of risk communication to healthcare professionals and patients and measure the effectiveness of these
- Work with advisory boards of patient groups to educate in the area of the benefit: risk decision making and to seek their input in future decision making

- Communicate activities to enhance pharmacovigilance and risk management to the public

5. Facilitation and monitoring of compliance with pharmacovigilance requirements

Agree that there should be monitoring of compliance but essential that consistent standards are developed for inspections of company pharmacovigilance departments by the EMEA and EU Member State authorities and sharing of the results

6. The need for quality management and continuous quality improvement

Agreed and should apply equally to industry and the regulators based on:

- Training
- Set of SOPs
- Audits and Inspections

- **On your experiences of the Community system overall**

- **On any part of the Community system (section 1 of this consultation paper describes the system and those involved directly)**

- **On how you could better contribute to the Community pharmacovigilance system**
  - To make proposal for a better use of EudraVigilance and implement a robust signal detection system

- **On suggestions to strengthen the Community pharmacovigilance system**
  - EFPIA suggestions are described in annex 3

- **Any other comments**