COMMISSION PUBLIC CONSULTATION: AN ASSESSMENT OF THE COMMUNITY SYSTEM OF PHARMACOVIGILANCE

EFPIA Priorities

EFPIA has identified the following themes as priorities for better protection of European public health in the future.

1. Industry-Authority partnership

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

- Involve MAH early as a key stakeholder in communicating safety information
- Single contact for the MAH to discuss communication of safety information with, representing all 25 Member States
  - Facilitates co-ordination of a consistent message across Europe
  - Applies to discussions on individual product or product class
  - Single European web site for communication of safety information?
- Improved objectivity, transparency & consistency of decision making e.g.:
  - Consistency in understanding of ‘safety signal’ vs. ‘safety concern’
  - Clarify the timing and method of notification of new safety information
    - Should be determined by the clinical significance and potential public health impact of the safety concern
    - Define threshold for “forthwith” notification of a safety concern

In addition:

- Develop and test training and education programmes for patients with a priority on understanding the benefit:risk of medicine
- Develop innovative methods of risk communication to healthcare professionals and patients; measure the effectiveness of these
- Work with advisory boards of patient groups to educate in the area of the benefit:risk decision making; seek their input in future decision making
- Communicate activities to enhance pharmacovigilance and risk management to the public

2. Harmonisation of pharmacovigilance requirements

EU pharmacovigilance rules are found in a wide array of documents that are sometimes contradictory and often unclear

- 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

Better regulation in the area of pharmacovigilance is required: a single legally binding text is required that should contain unambiguous and concise provisions that would simplify, strengthen and provide legal certainty to the EU legislative framework for pharmacovigilance.

- The legislation must
  - Not allow variation in interpretation of regulations across Member States
  - Encourages Member States to seriously consider a single standard for protecting European public health
  - Releases significant resource, currently used in managing diverse pharmacovigilance requirements, for value-added safety surveillance activities
- National legislators need to be better in touch with European legislators
  - Allow time for national legislators to provide input into and preparation for implementation of new EC regulations.

3. The single report

- The ‘single report’ is required, to replace multiple reporting standards that currently waste significant resource across industry and regulatory authorities
  - Single standard for quality and language of report
  - Single destination for notification of report
- Promote the use of EudraVigilance by the Member States
- Centralisation of report collection still allows for national evaluation and surveillance of safety data

4. Further considerations

In addition, EFPIA invites the European Commission to consider broader aspects with regards to future pharmacovigilance legislation:

- Tools for conduct of pharmacovigilance and patient risk management, e.g.:
  - Cohesive European pharmacoepidemiology system
  - Use of patient registries
- Consistent standards for monitoring of compliance

- To include co-ordination of inspections across Member States
- Mutual recognition of inspections & findings?

- Impact on/of Data Privacy and Financial legislation