PGEU Response

The Concept Paper on Implementing Measures in Order to harmonise the Performance of the Pharmacovigilance Activities Provided in Directive 2001/83/EC and Regulation (EC) No 726/2004

PGEU

PGEU: *The Pharmaceutical Group of the European Union (PGEU) is the association representing community pharmacists in 32 European countries. In Europe over 400.000 community pharmacists provide services throughout a network of more than 160.000 pharmacies, to an estimated 46 million European citizens daily.*

PGEU's objective is to promote the role of pharmacists as key players in healthcare systems throughout Europe and to ensure that the views of the pharmacy profession are taken into account in the EU decision-making process.

Preliminary Remarks

PGEU welcome the Concept paper on Implementing Measures in Order to harmonise the Performance of the Pharmacovigilance Activities Provided in Directive 2001/83/EC and Regulation (EC) No 726/2004. Over all, we find the Concept Paper and proposed implementing measures constructive and balanced. We believe that at the same time when laying down principles of the new pharmacovigilance system it clarifies roles and responsibilities of MAH, national authorities and EMA. We believe that proposed measures well address principles of an effective system of pharmacovigilance:

- Effective collection of data on adverse drug reactions.
- Effective analysis and follow up of collected data.
- Coordination between national and EU authorities.
- Pro-active and pre-emptive approaches to risk management on the part of market authorisation holders.
- Effective post-marketing authorization safety analysis.
- The scope for rapid and effective action by competent authorities acting in the public interest.

The current Community rules on pharmacovigilance that are replaced by the new legislation were drafted in very general terms and lacked detailed and specific procedures and obligations. Therefore we very much welcome the separation of the pharmacovigilance master file from the marketing authorisation documentation and introducing minimum requirements for the quality system for the performance of pharmacovigilance activities. However we believe it should be made obligatory for MAH to notify significant changes/modifications to the master file to the competent authority as soon as they occur. We welcome the fact that risk management becomes a strict requirement of a marketing authorisation and we believe it will strengthen medicines safety in Europe over all. We encourage MAH and competent authorities to recognise healthcare professionals as important actors in risk management plans as we believe many safety concerns can be addressed when effectively engaging prescribers and pharmacists in the process. Therefore effective communication by MAH and competent authorities to healthcare professionals becomes crucial.

We believe that maintaining competence throughout a career during which new and challenging professional responsibilities will be encountered is a fundamental ethical obligation for all those working in the pharmaceutical industry[1]. This is particularly important for the *Qualified Persons* and we very much welcome the fact that EC recognises role of training and continuing professional development as part of quality assurance for the performance of pharmacovigilance activities.

We very much welcome internationally agreed terminology and standards as well as proposed format and content of the electronic transmission of suspected ADRs and electronic periodic safety update. However with regard to reporting of ADRs we would strongly suggest developing separate forms for patient and healthcare professional reporting as we believe that patient-friendly language and terminology should be used in order to facilitate understanding and capture personal experiences. We strongly believe that implementation of the new Directive will increase ADR reporting in Europe and will help to detect safety concerns at earlier stage.

Analysis and follow up where EMA and national competent authorities have clearly defined roles and will support each other will be more effective and transparent. Here we very much welcome provision that

[1] *EIPG* ***Guidance on CPD for QUALIFIED PERSONS***
http://www.eipg.eu/records/EIPG%20Guidance%20on%20CPD%20for%20QP%20Rev%20Apr%2007.pdf

Member State where new risk is identified in relation to specific product or substance should actively inform other Member States and the EMA.

Finally, please note that we responded to those questions that are relevant to community pharmacist and are in the scope of our expertise.

Consultation item no. 2

The aim of pharmacovigilance master file is two-fold: to concentrate information in one global document and to facilitate maintenance by uncoupling it from the market authorisation. Therefore changes to the content of the master file will be no longer subject to variation obligations. Would it be nevertheless appropriate to require the marketing authorisation holder to notify significant changes/modifications to the master file to the competent authorities in order to facilitate supervision task? If so, how should this be done? Should the master file contain a date when it was last reviewed?

We very much welcome separation of pharmacovigilance master file from marketing authorisation, however it is important to ensure that information in the master file is accurate and reflects the latest system used by MAH. We would strongly support a provision that the pharmacovigilance master file contains the date of the last review and that there is notification to the national competent authority once there are significant changes/modifications.

Consultation item no. 4

Overall, do you agree with the requirements as regards the content and maintenance of the pharmacovigilance master file? Please comment.

We would agree with the proposed provision that the audit report should be retained in the master file. We believe that not only it is appropriate, but rather it would be desirable to require documentation of audit schedules.

Consultation item no. 6

Is there a need for additional quality procedures, e.g. in relation to study reporting in accordance with Article 107p of the Directive, in relation to communication on pahramacovigilance between the marketing authorisation holder and patient/health professionals; in relation to processes for taking corrective and improvement actions or in relation to the detection of duplicates of suspected adverse reaction reports in the Eudrovigilance database?

We believe that additional quality procedures in relation to communication on pharmacovigilance between MAH and patient/healthcare professionals is crucial. It is important to ensure that follow-up procedures are in place and that it respects confidentiality of personal data. As we have suggested in the introductory note we believe that communication to healthcare professionals should be integral part of risk minimisation plan.

Consultation item no. 7

Do you agree with the requirements for marketing authorisation holders? Please comment.

In principle we agree with proposed provision and timelines for retaining pharmacovigilance related documents.

Consultation item no. 8

Do you agree with the quality system requirements? Please comment, if appropriate separately as regards requieremts for marketing authorisation holders, national authorities and EMA.

In relation to *Compliance management (point (d))* we suggest that competent authorities and EMA not only inform each other and the EC prior to public announcements relating to information on pharmacovigilance concerns, but also tries to inform healthcare professionals and their professional organisations prior to announcement so that healthcare professionals can play an active role in risk minimisation action as well as be in the position to respond to patient concerns and advise suitable action. In case of community pharmacies, dispensing support systems are available in majority of the Member States and early announcement would allow integrating safety message in the system, so that pharmacists can take a proactive role in risk management.

Consultation item no. 9

For efficiency reasons a 'work sharing' procedure could be appropriate for the monitoring of medicinal products or active substances contained in several medicinal product. However, do you see a risk in cumulating all tasks (for the authorisation, PSUR scrutiny and Eudravigilance monitoring) in one Member State, as thereby the benefits of parallel monitoring may be lost ("peer review" system)? Additionally, it may be envisaged to extend 'work sharing' to all medicinal products (including all centrally approved products) and to appoint a lead Member State in addition to EMA (Article 28a(1)(c) of Regulation (EC) No 726/2004). Please comment.

Recognising the financial implications when implementing the new pharmacovigilance Directive as well as different capacity and resources available in Member States, we would very much support 'work sharing' between national competent authorities and the idea of appointing a lead country for active substance, provided that other member states still have an obligation monitor national data to some extent. In addition we would welcome to extend this provision and have a lead country appointed along with EMA for all medicinal products. This would enable 'real work sharing' between the Agency and national competent authorities.

Consultation item no. 10

In the Commission's view the aim of this part is to establish common triggers for signal detection; to clarify the respective monitoring roles of marketing authorisation holders, national competent authorities and EMA; and to identify how signals are picked up? Are the proposed provision sufficiently clear and transparent or should they be more detailed? If so, which aspects require additional considerations and what should be required? Please comment.

Yes.

Consultation item no. 11

Do you agree with the proposed terminology? Please comment.

Yes.

Consultation item no. 12

Do you agree with the list of internationally agreed formats and standards? Please comment.

Yes.

Consultation item no. 13

Is there additionally a need for transitional provisions as regards certain aspects of this implementing measure, especially in relation to the specifications on format and content? Please comment.

Yes.

Consultation item no. 14

Do you agree with the proposed format and content? Please comment.

Yes.

Consultation item no. 15

Do you agree with the proposed format and content? Please comment.

Yes.

Consultation item no. 16

Do you agree with the proposed format and content? Please comment.

Yes.

Consultation item no. 17

Do you agree with the proposed format? Please comment.

Yes.

END