PHARMACOVIGILANCE IMPLEMENTING MEASURES

BEUC response to the public consultation

Contact: Ilaria Passarani – health@beuc.eu
Ref.: X/2011/112 - 02/11/11

BEUC, the European Consumers' Organisation
80 rue d'Arlon, 1040 Bruxelles - +32 2 743 15 90 - www.beuc.eu
EC register for interest representatives: identification number 9505781573-45

Summary

BEUC strongly welcomed the adoption of the new pharmacovigilance legislation as an important step to strengthen the EU pharmacovigilance system and to increase consumers' trust in the safety of medicines.

For a proper implementation of the legislation it is necessary to guarantee that the European Medicines Agency and the national competent authorities have adequate resources to perform their tasks and are in the position to have a complete oversight on the safety profile of all medicines on the market.

In implementing the legislation it is important to bear in mind the new definition of adverse reaction that now includes also misuse, abuse and medication errors.

The technical requirements for the pharmacovigilance master file, the quality systems, the collection, processing and assessment of data, the formats and protocols should be designed as to ensure an efficient detection of signals and a proper management of risks.

BEUC, the European Consumers' Organisation
80 rue d'Arlon, 1040 Bruxelles - +32 2 743 15 90 - www.beuc.eu

This is the BEUC response to the European Commission public consultation on the concept paper[1] regarding implementing measures in order to harmonise the performance of pharmacovigilance activities provided for in Directive 2001/83/EC and Regulation 726/2004.

1. General remarks

BEUC strongly welcomed the adoption of the new pharmacovigilance legislation (Directive 2010/84/EU and the Regulation 1235/2010) as an important step to strengthen the EU pharmacovigilance system and to increase consumers' trust in the safety of the medicines on the market. We are particularly pleased that the new legislation gives all consumers around Europe the possibility to speak up and be heard if they are harmed by a treatment, reinforces their right to be informed about safety issues and increases transparency and accountability of regulators.

For a proper implementation of the legislation it is necessary to ensure that the European Medicines Agency (EMA) and the national competent authorities have adequate resources to perform the new tasks they are entrusted with. Taking into account that many pharmacovigilance tasks are delegated to marketing authorization holders, it is important that the competent authorities are in the position to have a complete oversight on the safety of all medicines on the market at all times and to conduct inspections.

In implementing the legislation it is necessary to bear in mind the new definition of adverse reaction that now includes also misuse, abuse and medication errors. Procedures should be defined as to make sure that information on the use outside the terms of the marketing authorization is collected, processed and taken into account in the risk assessment.

We support the proposals outlined in the concept paper. Below we provide some specific comments on the items which we consider most relevant from a consumer perspective.

2. Specific comments

A. Pharmacovigilance system master file

- Item 2. We consider appropriate to require the marketing authorisation holder to notify any significant changes/ modifications to the master file to the competent authorities in order to facilitate the supervision tasks. The master file should indicate the date of the last review. Any deviation from the pharmacovigilance procedures, their impact and management should be noted and retained in the master file also after the issue is resolved.

- Item 3. It is necessary to describe in details the delegation of pharmacovigilance tasks and the roles and responsibilities of third parties in addition to the copies of the signed agreement. It is also important to provide proofs that the third party has all the requirements and qualifications to correctly fulfill pharmacovigilance tasks.

[1] http://ec.europa.eu/health/files/pharmacovigilance/2011-09_concept-paper.pdf

BEUC, the European Consumers' Organisation
80 rue d'Arlon, 1040 Bruxelles - +32 2 743 15 90 - www.beuc.eu

- Item 4. A copy of the audit report should be retained in the master file and it is appropriate to require the documentation regarding the audit schedules to encourage their performance.

- Item 5. Overall, we agree with the requirements as regards the content and the maintenance of the pharmacovigilance master file.

B. Quality systems for the performance of pharmacovigilance activities – Common obligations

We would welcome the publication by the European Medicines Agency of a list of performance indicators following the consultation of the Pharmacovigilance Risk Assessment Committtee.

C. Quality systems for the performance of pharmacovigilance activities by marketing authorisation holders

- Item 6.There is an urgent need to develop guidelines for educational programs in the context of the risk management plans, including web based programmes, patient support programs and programs for compassionate use. Specific protocols should be in place for such programs to ensure that the information provided is of high quality and non promotional and that they are complying with the data protection legislation.

The report and the summary of the non interventional post authorisation safety studies, and more generally comunication on pharmacovigilance between the marketing authorisation holders and the general public should not be used to promote, directly or indirectly, the use of a medicinal product.

In the protocols for non interventional post authorisation safety studies particular attention must be paid to the information provided to the patient, ensuring an informed consent.

- Item 7. The wording " *a sufficient number of competent and appropriately qualified personnel"* is not sufficient. Specific requirements should be introduced in relation to a minimum number of staff dedicated to pharmacovigilance activities defined in proportion to given criteria such as the number of products to be monitored. Specific requirements should also be foreseen in relation to the qualification of the personnel entrusted with pharmacovigilance tasks, including the educational background (e.g. medicine, pharmacology, biochemestry etc) and the minimum level of experience.

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

- Item 8. As for marketing authorisation holders, also for EMA and for the national competent authorities there should be specific requirements with regard to the minimum number of staff dedicated to pharmacovigilance activities and to their professional qualifications and experience. All members of staff of the national competent authorities and of EMA should be asked to sign a declaration of conflict of interests. The declaration of conflict of interests of staff in management position should be publicly available on the competent authority web site.

BEUC, the European Consumers' Organisation
80 rue d'Arlon, 1040 Bruxelles - +32 2 743 15 90 - www.beuc.eu

In order to be effective, the communication with patients and with the general public should be understandable,accessible,reliable and timely.
In relation to the quality system, it is worth stressing also in the document, that as stated in article 105 of Directive 2010/84/EU the management of funds intended for activities linked with pharmacovigilance should be under the permanent control of the competent authorities in order to guarantee their independence.

E. Signal detection and risk identification

- Item 9. While we understand the need to optimize the use of resources, we see a risk in cumulating all tasks in one Member State. Not only this prevent the safeguards ensured by a “peer review” system where the parallel monitoring can facilitate the detection of signals, but also it can create imbalances in the monitoring of certain products depending on the lead Member State.

It should also be clarified according to which criteria the lead Member State would be appointed.

- Item 10. For the detection of signals quantitative statistical analysis should be complemented with some forms of qualitative analysis. A series of few adverse drug reports could be sufficient to detect a relevant signal.

F. Use of terminology

- Item 11. With the introduction of direct consumer reporting it is worth considering that consumers will do so in lay-man’s terms and that the addition of other terms might be necessary. For example, when patients report “electric shock sensations” in the withdrawal of antidepressants, this has been "translated" as "paraesthesia", which communicates little of the disabling impact of withdrawal symptoms on users.

- Item 12. Overall we agree with the list of internationally agreed formats and standards.

Annex I - Electronic Submission of suspected adverse reactions

- Item 14. The indication of the batch number can be useful for all products and not just for biosimilars. The identification number should be available on all medicines following the implementation of the legislation to combat falsified medicines 2011/62/EU. It could be introduced at least on an optional basis and could help detect duplicates of suspected adverse reactions.

We would also suggest introducing a causality assessment part performed according to common defined standards.

BEUC, the European Consumers’ Organisation
80 rue d’Arlon, 1040 Bruxelles - +32 2 743 15 90 - www.beuc.eu

Annex II – Risk Management plans

Item 15. The risk management plan should include an assessment of the effectiveness of the interventions and details about these evaluations, including indications on the procedures in place in case of a negative evaluation.

As mentioned above we consider the definition of guidelines for educational programmes including risk minimization plans for patients to be necessary as they can be misused for promotional purposes.

Annex III -Electronic Periodic Safety Update Reports

It is important to ensure that the competent authorities have access to all information which is used by the marketing authorization holders to make the evaluation of the benefit-risk balance.

END

BEUC, the European Consumers' Organisation
80 rue d'Arlon, 1040 Bruxelles - +32 2 743 15 90 - www.beuc.eu