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

Contribution of EuropaBio

EuropaBio welcomes the opportunity to provide inputs to the European authorities on the current Community system of pharmacovigilance. This process is of particular importance for the healthcare biotech industry due to the innovation of the products, the complexity of their production and the varying size of the industry.
We believe that the current EU pharmacovigilance system has important public health challenges where the industry is committed to deliver.
Duplication of efforts, insufficient transparency, new healthcare technologies to be delivered to patients and realisation of innovative European tools such as the EudraVigilance projects provide new opportunities to rethink the current system.

Inputs to the Commission sponsored study: Assessment of the European Community System of Pharmacovigilance, Fraunhofer Institute Systems and Innovation Research

1. Data Sources and safety issue detection

   Data collection is of major importance for European public health systems. Industry recognises its responsibility and involvement in this process.
   As advised in the study sponsored by the Commission, we do support the importance of having a centralised database, EudraVigilance, where all the events are collected. The biotech industry, made up of large and small size enterprises is particularly keen to have one single database, where reports from all over the EU are shared and that would include all the data sources from Member States. National databases, developed by some of the Member States, should be considered as supportive tools at the National level.
   Their impact should be considered in their national dimension and would therefore not have to be as exhaustive as the European EudraVigilance system.
   One of the main reasons of such interest for a centralised database is to limit the duplication of efforts in the reporting systems. This single interface would save financial resources, without losing any safety imperatives and allow industry and authorities to invest in other areas.

   Patients have the capabilities to report in certain Member states. Such reports provided by individuals have the potential to become more important due to the evolution of the society. For reason of efficiency and transparency, such patient reports should be standardised.

   ➔ To have a **European report** with single standards on quality, a single destination of notification and a single publication on EudraVigilance

2. Legal framework and new legal tools

EU pharmacovigilance regulatory framework is quiet unclear, developed into various format of documents and with National interpretations. It is based on a number of documents that have not always legal certainty.

In fact, even if for centralised products, a general legal framework exists; reporting can varies from one Member States to another one. Differences between countries are even more accurate when it comes to the evaluation process of a safety report. Those differences of process, of requirements and in the interpretation have a major cost for the private sector. It requires different actions regarding the Member States. It also requires allocation of resources for each individual country where the product is commercialised. This system is not appropriate for the industry, especially for start-ups who had obtained initially one single EU market authorisation.
On the public health side, actions further to a signal assessment should be similar for all European patients. Variation in interpretation of Regulations across Europe should not be European reality.

Therefore, EuropaBio is asking the Commission to develop one single framework for the pharmacovigilance system. Further to experiences we gain in the pharmacovigilance process and based on the success of the centralised system, the biotech industry is calling for the development one single report, the creation of a single European entry for each reporting – via EudraVigilance, the adoption of single pharmacovigilance standards and the sharing of experiences and resources.

To support such evolution, the Commission should propose to Member States and to the European Parliament a European Regulation on Pharmacovigilance.
Due to the time required for the success of such proposal, and considering the fact that interpretation on the actual legal framework is major, EuropaBio supports the proposal for harmonisation of the current pharmacovigilance requirements.

➔ To have an **harmonisation of the pharmacovigilance requirements** in the mid term
➔ To have a **EU Pharmacovigilance Regulation** in the long term

3. Decision making in pharmacovigilance

As reported in the study, the decision making can take long time. It also varies from one Member States to another one.

EuropaBio agrees with the study on the fact that a better use of the expertise existing in Member States should be developed in order to share the work and to limit duplication. Furthermore, such decision making processes should be homogeneous across Europe, based on transparent, objective and consistent evaluations.

➔ To design **framework for decision making process**
➔ To promote a **single evaluation** and **European decision** on pharmacovigilance signals

4. Impact of the communication and actions

EuropaBio stresses the importance of respecting an appropriate timing between the decision making on a signal and the action. The decision should also be taken in an adequate timing, but respecting all the requirements for an adapted evaluation of the signal.
Furthermore, the action should be taken by all the stakeholders. The results of such action are not today measured sufficiently. Pharmacovigilance system success does not only rely on the process but also on the results in the medical environment and in the understanding of the society.

Today, there is a clear problem in terms of communicating pharmacovigilance concern to the general public and to the media. A partnership between authorities and industry could be created to engage a reflection on better communication. Industry has an important role to play in that sense. Companies also need single contacts in the National agencies to build up consistent safety information communication in all the Member States.

- ➔ To have an **evaluation of the outcome** of pharmacovigilance actions
- ➔ To create an **Industry-Authority partnership** to work on better communication

EuropaBio experiences of the Community system overall

The problems mentioned above reflect EuropaBio experiences within the Community system.

Comments on any Part of the Community system

We welcome the efforts of the EMEA to ease the access to SMEs for reporting to the EudraVigilance system.

How biotech industry could better contribute to the Community system

EuropaBio is ready to engage its efforts together with authorities and other stakeholders for a simplification, harmonisation, and transparency of the Community system. Those challenges have to be tackled in order to contribute to the efficiency of the systems, maintaining the safety of products in the market. The unique objective is to contribute safety of patients in the EU community system. Biotech companies recognise in terms of pharmacovigilance their public health responsibilities especially because they develop complex products.

The Biotech industry has extensive experience with manufacturing processes specific to Biotech products and potential safety issues related to changing of production systems. It is interested to share such experiences and develop the knowledge and tools for managing risks related to adverse events emerging from specific conditions of the manufacturing of biotech products or the specific nature of such products.

The Biotech industry is interested to contribute to establish and maintain an international living database and/or library containing pooled safety datasets specific for biotech products or of specific relevance to such products. Such data sets can be very useful to Regulators and individual companies to support investigation of potential specific safety signals with individual products or groups of products. Since Biotech industry is characterised by a significant proportion of small and medium sized companies, direct access to such pooled data sets may be of particular interest to the Biotech sector. It enables smaller and middle sized companies to better fulfil their signal detection responsibilities.

Suggestions to strengthen the Community Pharmacovigilance system

Further to EuropaBio contributions to the study sponsored by the Commission, we would like to extend our suggested solutions to participate with concrete proposals for the review of the Community pharmacovigilance system.

EuropaBio suggestions:

An EU Pharmacovigilance Regulation would allow EU Institutions to redesign the entire system and to shape it in accordance to the current needs of the population, healthcare professionals and stakeholders.

Such legislative framework would comprise a set of European tools; relying on existing National mechanisms.

EuropaBio is asking for:

- Single European Pharmacovigilance Database of Reference
- Single electronic Reporting: European Safety Report
- Single evaluation of the European Safety Report
- One European Communication by European Safety Report: on its evaluation and actions decided

Understanding that such proposal would need time to be put in place, EuropaBio is calling for a better implementation of the pharmacovigilance requirements by Member States with all efforts made towards harmonization. Such harmonisation is needed for better processing of the evaluation and decision on safety issues. It is also required for marketing authorisation holder to have a consistent legal framework, engaging binding but certain requirements.
The differences between European legislations and National implementation texts should be gathered and published at the European level in English. Specific requirements developed by Member States should be listed in a unique European table and updated by National authorities.

EuropaBio is also in parallel to an immediate action to harmonize the system for a better use of the existing elements in place. Therefore, we would recommend the authorities to promote the sharing of Member States experiences and to create a list of pharmacovigilance experts available at the community level that would help smaller Member States to complete their limited national resources.

Finally, EuropaBio agrees on the need to develop with other stakeholders a partnership on Communication. A reflection process on the risk communication, the education on risk management should be encouraged with all the stakeholders concerned.

EuropaBio recommends the Commission to work closely with the Head of Medicines Agencies on the proposed objectives for harmonisation. The recently published strategy paper of the Heads of Medicines Agency explores interesting possibilities to improve the actual system.

About EuropaBio

EuropaBio has 69 corporate members operating worldwide, 9 associate member organisations, 6 bioregions and 24 national biotechnology associations representing some 1500 SMEs involved in research and development, testing, manufacturing and distribution of biotechnology products.
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