

EPF'S BASELINE POSITION ON THE LEGISLATIVE PROPOSAL ON PHARMACOVIGILANCE¹

November 2009

EPF welcomes the Commission's legislative proposals to strengthen rules for the authorization, supervision and pharmacovigilance of medicinal products within EU. Pharmacovigilance is a core public health key issue. The rate of patient deaths and harm caused by adverse drug events remains alarming, estimated as the fifth largest cause of death in hospital – yet the rates of reporting adverse drug reaction is approximated at between 10% and 25% of all cases. Therefore, EPF calls for an equal and timely implementation of these measures across EU so that all patients across EU, no matter their economic and social background, are protected against adverse events of medicinal products.

1. Broader legal basis and a patient-centered approach

The proposals should have a broader legal basis and highlight explicitly Art 152 of the Treaty of the European Union, which clearly states that the activities of the Community shall include “a contribution to the attainment of a high level of health protection”. EPF would further argue that in a European Union built on human rights and solidarity, pharmacovigilance has to be seen primarily from patients' rights' perspective rather than as industrial or economic perspective.

2. EPF strongly welcomes the direct patient reporting

EPF particularly welcomes the specific objective to involve stakeholders in pharmacovigilance, including through direct patient reporting of suspected adverse events and the inclusion of patients and health-care professionals in decision-making. Patients have a unique knowledge and experience of side effects and adverse effects of the medication they take and this knowledge should be valued and used in the benefits of other patients' as well.

For example, for patients with rare diseases, most of the drugs prescribed by their doctors do not have a specific marketing authorisation for their disease. Those drugs used off label may cause serious adverse effects, sometimes even death. Very often the dose needs to be adapted. Because they have prescribed the drug off label under their own responsibility, doctor can be very reluctant to declare adverse effects and death. If families and patients are given the possibility to report themselves, and several reports of serious adverse effects are received , this could lead to some beneficial modifications of the marketing authorizations

¹ *DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending, as regards pharmacovigilance, Directive 2001/83/EC on Community code related to medicinal products for human use;*

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

(source: Eurordis) Any further information and examples of patients' direct reporting or the need for direct patients' reporting, are welcome.)

Question for EPF members: the Directive provides for patients to report both to competent authorities and pharmaceutical companies. What are your views on this?

According to the Commission's proposals, the new European medicines safety web-portal that will be established provides for web-based structured forms for the reporting of adverse events by healthcare professionals and patients. It is important that patients are consulted and involved in setting-up the "web-based structured forms" for reporting of adverse events, so that these forms are tailored to the needs of patients. (Regulation, Art 25).

However, patients need to have further possibilities to report than only the European medicines safety web-portal. A variety of reporting options specific to patients (e.g help lines, health centres, etc) are necessary to enable patients to react rapidly and with confidence.

Patients and their families need to know where and whom they can address (in the community, close to their homes) when they notice adverse events of medicinal products or have further questions. This is a health literacy concern and there is a scope for EU action to further support it.

4. Public information and education campaigns

Patients' organisations can be particularly helpful in the development of public information campaigns, in cooperation with an identified regulatory body and national agencies, approved websites, health centres, public private partnerships and sister patient organisations at pan European and national levels. Contact and cooperation between regional and national pharmacovigilance centres and patients organizations should be fostered in order to allow patients to meaningfully report adverse effects of medicines. Patients organizations can be involved in raising awareness about the importance of reporting and in training of patient leaders and healthcare professionals . Partnerships should be established to ensure Pharmacovigilance bodies and patient organisations define and develop communication strategies and policies as to when, how and what to communicate in order to ensure the correct use of medicines. This would lead to a faster and effective response in case of drug safety alert. Such information should be shared at EU level and not only at a national level.

5. Further support to national and regional pharmacovigilance centres

Local and national pharmacovigilance systems need to be further supported in order to ensure that a quality transfer of data to Eudravigilance database. Reports from patients, health care professionals and companies should be collected by each national competent authority which will then be responsible for sending them to the Eudravigilance database.

6. Appropriate access for patients to Eudravigilance database

Regarding the Eudravigilance database, we welcome that the public and health-care professionals are granted appropriate level of access. (Regulation, Art 24). We call for consulting patients when defining the "appropriate level of access" to the database, so that this is genuinely patient oriented and responds to the real needs of information that patients have. A set of guidelines on how to interpret the data in the Eudravigilance database will also be necessary.

7. EPF welcomes the warnings for products under intensive monitoring

The proposal introduces some changes in the summary of the products characteristics and the package leaflet (Directive, Art 59). It includes for example warnings for products under intensive monitoring. We very much welcome this. It also provides for including a concise section on the key information about the medicinal product and information how to minimize risks and maximize its benefits. This information should be truly patient-centered and should respond to patients needs.

8. EPF supports the request of individual adverse reactions events

The proposal also acknowledges the possibility for the public (patients) to request individual adverse reaction reports. Those reports shall be provided by the EMEA or the national competent authority from which they are requested within 90 days. It is important that this is properly communicated to patients, in a transparent way, so that patients are aware of this new right. Patients will need clear and understandable information (including information accessible for people with disabilities) about the procedure to request these reports. As patients will need to discuss these reports with their health professionals, we think it is crucial that health professionals are involved in this process as well. (Regulation, Art 24)

The proposal provides that pharmaceutical companies may not refuse reports of suspected adverse reactions received electronically from patients and health-care professionals (Directive, Chapter 3, Art 107 2.) This needs however further clarification in terms of how this will be done in practice, monitored, etc. EPF has also a concern about patients with low health writing and IT literacy skills and about their difficulty to report in this case.

9. Further cooperation between the European Medicine Agency and the Member States

Finally, EPF strongly supports further cooperation between the European Medicine Agency and the Member States to continuously develop pharmacovigilance systems capable of achieving high standards of public health protection for all medicinal products.

The **European Patients' Forum** (EPF) is a European non-governmental organisation, based in Brussels, which was founded in 2003 to become the collective patients' voice at EU level, manifesting the solidarity, power and unity of the EU patients' movement.

EPF currently represents 40 member organisations - which are chronic disease specific patient organisations working at European level, and national coalitions of patients organizations. EPF therefore reflects the voice of an estimated 150 million patients affected by various diseases in the European Union.

EPF's vision for the future is high quality, patient-centred, equitable healthcare throughout the European Union.