European Commission's modified legislative proposals on pharmacovigilance

EPF position statement

February 2012

The European Patients' Forum (EPF) welcomes the opportunity to comment on the European Commission's modified proposals concerning "information to patients" concerning pharmacovigilance.[1]

EPF 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 50 member organisations; disease-specific patient organisations active at European level, and national coalitions of patients' organisations. EPF reflects the voice of an estimated 150 million patients affected by various chronic diseases in the European Union, and their families. EPF facilitates the exchange of good practice, and challenges bad practice on patients' rights, equitable access to treatment and care, and health-related quality of life. Our vision is high quality, patient-centred, equitable healthcare for all patients in the EU.

Methodology of the EPF position statement

EPF contributed to the development of the new EU legislation on pharmacovigilance, drawing upon a consultation of our European-wide membership. All previous contributions are available on EPF's website.[2] The current paper is based on a renewed consultation of the membership, together with input from EPF's Policy Advisory Group, and has been endorsed by the EPF Board. A full list of EPF's member organisations can be found on our website.[3]

New provisions on pharmacovigilance

The European Commission parallel to the amended proposals on information to patients, presented certain new provisions with the aim to complement and further strengthen the EU pharmacovigilance system introduced by Directive 2010/84/EU and Regulation (EU) No. 1345/2010. This was seen as necessary following recent safety issues in the EU, notably the French Mediator case.

[1] Proposal for a Directive Of The European Parliament and of the Council amending Directive 2001/83/EC as regards pharmacovigilance (COM(2012) 52 final); Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 726/2004 as regards pharmacovigilance (COM(2012) 51 final).
[2] http://www.eu-patient.eu/Initatives-Policy/Policy/Pharmaceutical-Package/Pharmacovigiliance/
[3] http://www.eu-patient.eu/Members/The-EPF-Members/

The new proposals provide for an *automatic procedure* in cases of specific serious safety issues with nationally authorised products[4], to ensure the matter is assessed in all Member States where the product is authorised. (Art. 107i) The relevant cases are:

- where a MS considers suspending or revoking a marketing authorisation, or refusing its renewal;
- where a MS considers prohibiting the supply of a product;
- where a MS is informed by the MAH that they have interrupted the supply based on a safety concern or have asked for the marketing authorisation to be withdrawn or have not applied to renew it;
- where the MS considers that a new contraindication, a reduction in recommended dose or a restriction of the indications is necessary.

Furthermore, in cases of *voluntarily revocation or non-renewal* of a product's marketing authorisation, or its withdrawal or interruption from being placed in the market, the marketing authorisation holder is obliged to inform the competent authorities of the reasons for taking such action. The Member State concerned is then obliged to inform the EMA. (Art. 23a, 123; Regulation Art. 13-14)

The new pharmacovigilance rules provide for a publicly available list at EU level of those medicinal *products that are subject to additional safety monitoring* following their authorisation. The revised proposal for a Regulation on information to patients clarifies this by specifying that the list will include all medicinal products that are subject to conditions or safety requirements as part of their marketing authorisation. (amended Article 23 of the Regulation). The proposal also clarifies that the EU medicines portal should allow searches in all official EU languages and that the database shall be actively promoted to EU citizens.

EPF position

EPF and our members wholeheartedly welcome the new provisions on medicines safety, as they will serve to further strengthen the regulatory framework for medicines safety monitoring provided by Directive 2010/84/EU and Regulation (EU) No. 1235/2010.

EPF would like to stress the role played by patients in reporting adverse or unexpected reactions to medicines, as provided for in the above legislation ("direct patient reporting"). EPF works closely with the European Medicines Agency in the implementation of the legislation. Our member organisations are very interested to contribute to the development of the reporting system at national level, and to providing information to the grassroots patient communities and the public. But many of them feel they lack a continuous working relationship with the national authorities.

EPF calls on Member States' authorities to specifically involve patient organisations to ensure that the rules are implemented in a way that improves patient safety and empowers the citizens.

[4] Where the scope of the procedure concerns a range of products, or a therapeutic class, then all products belonging to the range or class will be included in the assessment, including products authorised centrally.

The information gap
At a workshop organised at EPF's Annual General Meeting in April 2011, patient representatives highlighted the low awareness within patient communities about pharmacovigilance. They stressed that in order to have an effective implementation of the EU legislation, that fully benefits from the added value of patient reporting, it is crucial that patient communities are given informed about:

- What Pharmacovigilance is and why it is important;
- How the new Directive will help improve medicines safety;
- Why it is important that patients report suspected adverse reactions, and what avenues are available to do it.

EPF has prepared guidance for patient organisations on the new legislation. We recommend that national authorities and the European Commission should organise information and awareness campaigns to raise awareness. In the long term, patient groups can effectively support awareness, as they are in regular contact with the grass-roots patient communities.

Systems for reporting should capture the special richness of patient reports
The benefits and added value of direct patient reporting are clear; patients understand their condition and the effect of treatment on their body, as well as their daily lives. They are in the best position to report a reaction.

Reporting systems should capture this richness of patient reports, and it should be considered in the way reports are processed. Feedback is important, and should at the minimum include something about how the information will be used, and about the public health and patient safety benefits of the report, which would add motivation. Patients should ideally be involved in setting up and user testing the system to make sure it is fit for purpose and user-friendly.

Reinforcing the health professional-patient relationship
EPF believes that the EU legislation represents an opportunity for patients' and health care professionals' organisations to work together to promote best practices in shared decision-making and patient empowerment in order to implement patient-centred healthcare.

Reasons cited by patients for wanting to report reactions directly include a perception that their doctor "did not seem interested" in the patient's problem, or was "unwilling" to report. Building patients' health literacy is important – but the necessary counterpart to the empowered, health literate patient is the health professional who *welcomes* this, and creates an enabling environment for dialogue and partnership approach.

EPF calls for exchange of best practices and experiences in the training and education of health professionals concerning how to listen and involve the patient and progress towards concordance in prescribing decisions, inter alia in the framework of modernising the EU Professional Qualifications Directive.