Draft Response from the European Patients' Forum to the
Public consultation on legislative proposals for
A Strategy to better protect public health by strengthening and rationalising EU Pharmacovigilance

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The European Patients' Forum (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 30 member organisations – which are chronic disease specific patient organisations operating at European level, and national coalitions of patients organisations. EPF reflects the voice of an estimated 100 million patients affected by various diseases in the European Union, and their families.

EPF facilitates exchange of good practice and challenging of bad practice on patients' rights, equitable access to treatment and care, and health-related quality of life between patient organisations at European level and at Member States level. EPF's vision for the future is patient-centred, equitable healthcare throughout the European level.

The European Patients' Forum considers pharmacovigilance as a major public health issue and welcomes the initiative of DG Enterprise and Industry to consult stakeholders on legislative proposals to strengthen and rationalise the EU system of pharmacovigilance.

The current legislation must be improved by taking into account the changes that have occurred in recent years: technological advances, scientific changes and

pharmaceutical innovations. Alongside this, there is a recognised need for patients to be empowered. We welcome the acknowledgement in current proposals that a key outcome of the last public consultation on pharmacovigilance was the importance of enabling patients to report adverse drug events – and the negative side effects they may experience in relation to their medicine.

Given the importance of this initiative, EPF is concerned about the consultation timeframe of only 8 weeks, including Christmas vacation period; this has limited the opportunity to consult effectively with our members, and their members at national level. It is in direct contradiction with a number of positive developments at EU level on EU health stakeholder involvement and transparency. This time barrier needs to be considered when analysing the outcome of the consultation, and where there is a lack of responses from particular health stakeholder groups, then further efforts should be made to glean their views.

EPF supports largely however the proposals as presented in the consultation document. Our response outlines additional provisions and clarity in relation to the role of patients and patients' organisations. We have focused our response on the key proposals presented in section 3 of the consultation; ie the legislative strategy and more specifically the key proposals for legislative change. We have not touched upon issues we consider to be more appropriately addressed by other stakeholders.

Pharmacovigilance as a core public health issue

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[1].

[1] UK National Audit Office, 16 January 2003: *Safety, Quality, Efficacy: regulating medicines in the UK*; The Lancet, Vol. 350, Issue 9296, 1 December 2001, p.1872-1873, E. Heeley.

It may be helpful to give the proposals a broader political context and highlight explicitly provisions within 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" (Article 3 (1)[2]. This is particularly relevant for patient safety.

EPF would further submit 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 and that this should also be reflected in the document.

Section 3.2 Key proposals for legislative change

- ***Patients' involvement***

The need for more effective patients' involvement in adverse drug reactions reporting was highlighted in previous consultations: patients should be directly involved in all aspects of the processes proposed within the consultation document. Clarity regarding reporting procedures and 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 are often in a central position to identify when and sometimes why adverse reactions occur but they need to know how they can report this effectively. Patients' organisations can also play a key role in this respect, if appropriately resourced. Where patients' organisations can be particularly helpful is 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. They could help to publicise the importance of reporting and in the training of

[2] *European Union - Consolidated Versions on the Treaty of the European Union and of the Treaty establishing the European Community* (OJ C 325, Volume 45, 24.12.2002), [on-line], Europa, EUR-Lex, Official Journal, last accessed 1 February 2008, http://europa.eu.int/eur-lex/lex/JOIndex.do?year=2002&serie=C&textfield2=325&Submit=Search&_submit=Search

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.

From a patients' perspective, the initiative to establish a committee with clear responsibility for coordinating pharmacovigilance within the European Medicines Agency (EMEA) and making recommendations on the safety of medicines to the existing Committee on Human Medicinal Products is a welcome development. However we would urge an explicit link between this committee and the EMEA Working Party on patients and consumers. We also urge a link with the work of the Patient Safety Working Group of the High Level Group on Health Services and Medical care on identifying key areas where patients' safety action is most effective and should be promoted at national and European levels across EU Member States.

We also welcome that the outcomes of the Committee will be binding Commission decisions to ensure that for important safety issues appropriate action is taken in **all** Member States to protect the health of European patients.

The continued development of the Eudravigilance database is an important dimension of an overall pharmacovigilance strategy. Giving patients and health professionals access to this database will help to promote a shared understanding, knowledge and trust.

- ***Equity and access to safe medicines concerns***

Guaranteeing safe medicines to all is the ultimate aim of pharmacovigilance system. Equity is not only about cost and availability of treatments but also about medicines' safety once they are on the market and ultimately health outcomes.

Starting with the premise that no individual or organisation sets out to develop and promote bad medicine, it does not alter the fact that when drugs and medicines come to market, comparatively little is known about their safety profile until they have been exposed to a much wider range of patients over a longer time period. This is not possible in clinical trials. Particular emphasis should be placed on appropriate surveillance of medicines that have gone through a fast track authorisation procedure, with thorough audit and quality management systems. This surveillance should happen in all health care provision settings, hospital settings but also in primary health care clinics, nursing homes, pharmacies and patients' homes.

Safety should also be guaranteed equally across all EU Member States by ensuring legally binding provisions. Innovation and pharmacovigilance should not be polarised: A patients' life may depend on medicines. EPF outlined very clearly in our response to the future of pharmaceuticals for human use[3] the fact that authorities and stakeholders generally under-estimate the degree of risk which patients are prepare to take in relation to new medicines; however this must always be balanced by patient safety issues.

The proposal refers to 'Good Vigilance' practices. EPF suggests that the potential role of patients' organisations is also made explicit here – and offers our support in terms of identifying good practice in terms of involvement in pharmacovigilance procedures across our member organisations.

The proposal also advocates codifying guiding principles of non-interventional post-authorization safety studies and 'light oversight' of non-interventional post-authorisation studies to ensure that they have health rather than promotional objectives. This "light oversight" has to be clearly defined so that it does not become

[3] *Final Response from the European Patients' Forum to the European Commission's Consultation on the future of pharmaceuticals for human use in Europe: making Europe a hub for safe and innovative Medicines*, Brussels 12 October 2007, [on-line], European Patients' Forum, last accessed 31 January 2008 http://www.eu-patient.eu/doclibrary/newsletter/2007_10/epf_response_future_pharmaceuticals.pdf

a rubber-stamping exercise. Such post-authorisation studies should be structured from a patient's perspective.

- ***Information to Patients***

EPF is of the view that pharmacovigilance is intrinsically linked with the current developments in relation to information to patients – and the work of the Pharmaceutical Forum in relation to the provision of information based on a series of quality principles, and proposed legislation that will clarify the role of the pharmaceutical industry in providing non – promotional information on their products, *including information on possible side effects.* This transparency is important for patients in relation to their awareness on adverse effects[4].

Conclusions

EPF welcomes the opportunity to be involved in ongoing debates at EU level on the improvement of pharmacovigilance systems. As the European umbrella body representing a wide spectrum of disease areas and patients' groups, EPF would like to use this opportunity to highlight the importance of taking into account patients' voice - and their highly relevant experience and expertise - in the debate not only as a consumers of medicines but also as victims of the current system deficiencies.

[4] *Information to Patients – the fundamental right to know,* [on-line], European Patients' Forum, last accessed 31 January 2008, http://www.eu-patient.eu/news/2007_05_16_information_to_patients.php