



europeanpatients'forum

EPF AND PATIENT GROUP ALLIES' RESPONSE TO THE COMMISSION CONSULTATION ON A LEGISLATIVE PROPOSAL ON INFORMATION TO PATIENTS

Key words: fundamental right to information, quality, equity, holistic approach, patient-centred, patient perspective, monitoring and trust

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 31 member organizations – which are chronic disease specific patient organizations operating at European level, and national coalitions of patients organisations. EPF reflects the voice of an estimated 150 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 organizations at European level and at Member States level.

Developing knowledge on the needs and interests of patients, from a patient perspective is only possible with the active involvement of patients and/or patient representatives. The European Patients' Forum (EPF) therefore welcomes the Commission's initiative to consult on the key ideas for a proposal on Information to Patients.

EPF's vision for the future is patient-centred, equitable healthcare throughout the European Union. We believe strongly that health equity is a major pillar in building Europe's future. This is not only about achieving the Lisbon agenda but also crucially about commitment to a European Social Model – Health, wealth **and** equity. It is in this spirit that our response to this consultation has been formulated and endorsed.

Methodology around EPF's consultation with its membership and patient group allies in agreeing this response

European Patients' Forum, Rue Belliard 65, B-1040 Brussels
Phone : +32 (2) 401 68 11 Fax: +32 (2) 401 68 68
Email: info@eu-patient.eu Web: www.eu-patient.eu

A draft response was prepared on the basis of previous extensive consultation with the EPF membership and other patient group allies. This was then circulated to EPF Board Members for their comments and circulated to the wider EPF membership and patient group allies (see the list at the end of this document) for their further input and endorsement.

A final response was submitted to the Commission on 7 April 2008.

This response deals explicitly with the patients' perspective. It should be read in conjunction with the Commission's consultative document.

We would also like to refer readers to the following documents on Information to Patients available on the EPF website:

- EPF's Position Statement on Information to Patients;
- A Reference Paper for EPF's Input to the Pharmaceutical Forum's Information to Patients' Working Group
- EPF's Response to the European Commission Consultation on Quality Principles in Relation to Information to Patients;
- EPF's Response to the European Commission Consultation on the Diabetes Information Package.
- EPF's Response to the European Commission Consultation to Draft Report on Current Practice with Regard to Provision of Information to Patients on Medicinal Products

These documents provide additional background and details regarding patients' organisations' reflection and rationale for the way forward on information to patients in Europe.

EPF's response to the current consultation focuses on 4 fundamental areas

- The distinction between quality information and direct- to – consumer advertising
- The distinction between 'push' and 'pull' information mechanisms
- Quality Criteria
- The proposed Structure for Monitoring

Introduction

EPF, our members and our patient group allies consider that all patients, no matter their disease, condition, background or nationality, have a fundamental and legitimate human right to access quality information about their health, medical conditions and treatments and their availability, including knowledge on the best available management of their disease. **It is a question of solidarity, equity and patients' rights.**

EPF, its membership and patient group allies believe that a legislative proposal focusing on prescription medicines, **in concert** with other developments within the Pharmaceutical Forum Working Group on Information to Patients, and the new EU health strategy 'Together for Health' can make a significant contribution towards achieving this goal, when implemented and resourced effectively, with the best interests of patients in mind, and driven by the fundamental right to know

We would therefore urge the Commission to proceed with minimal delay in presenting the legislative proposal to the European Parliament and Council.

We would wish however to repeat specific comments from our members that pharmacological information is one part of a much bigger picture. It should be clear that on its own this proposal is not the information strategy called for by stakeholders responding to the Report on Current Practice with Regard to Provision of Information to Patients on Medicinal Products. EPF and our patient group allies reiterate the importance of also ensuring a strong political focus on this issue. We believe this information strategy should be patient- centred and driven by DG SANCO as it is integral to taking forward the overall White Paper ' Together for Health'.

EPF would like to highlight that we have been interviewed as part of the Commission impact assessment process for the forthcoming legislative proposal, and this was an opportunity to reiterate many of the comments outlined in this and previous responses.

Main Policy Objectives

EPF, our members and our patient group allies endorse the vision behind the proposal, namely;

'to put the interests of patients first and.....to aim at reducing differences in access to information and ensure the availability of good-quality, objective, reliable and non-promotional information on medicinal products'.

We also support the main policy objectives i.e

1. Establishing a framework which provides citizens of EU Member States with understandable, objective, high-quality and non-promotional information about the

benefits and the risks of their medicines, and which maintains the confidence of citizens, regulators and healthcare professionals.

2. Maintaining the ban on direct-to-consumer advertising of prescription medicines, making sure that there is a clear distinction between advertising and non-promotional information.

3. Avoiding unnecessary bureaucracy, in line with the principles of Better Regulation. This reflects very much our commentary in previous consultations.

It is of crucial importance that the final proposal remains true to these objectives and they are not in any sense diluted.

The distinction between quality information and direct- to – consumer advertising

This distinction is absolutely fundamental to ensuring patient confidence in the legislative proposal. Although this is explained implicitly in the text and the table of proposed action, using the agreed quality criteria and only information included in the medicine authorisation documents (patient information leaflets PILs and summaries of product characteristics SPCs) as a frame, we believe that greater clarity regarding this distinction is essential to make the proposal workable.

During our consultation it was highlighted once again that PILS and SPCs tend not to be patient friendly and accessible.

In EPF's view, it would be extremely useful to develop hypothetical, example 'communications' for print, radio, television and other media and illustrate by use of such examples what are the key differences between "quality information" and "advertising". This should then be piloted and approved by the European Advisory body (see below) to act as a basic guideline for both industry and regulators and form part of the code of practice (See below under proposed structure for monitoring).

The distinction between 'push' and 'pull' information mechanisms

Regarding 'push' information, or information received passively by citizens through printed material, TV, radio and other media, there was some discussion among the membership with regard to whether this is appropriate, however the consensus is that documentary style broadcasting and 'rapportage' with quality non-promotional information may be useful for those patients who are unable to access internet and who may not for various reasons wish to actively seek information directly (pull information mechanisms).

EPF would insist however that that this material be subject to ex ante verification, to ensure that it does not fall within the definition of advertising.(See below under proposed structure for monitoring).

Regarding 'pull' information, or information actively sought by patients through registered websites, or through written or oral requests to pharmaceutical companies, EPF would support strongly that the latter be monitored on the basis of a transparent and effective complaints procedure that is accessible and patient friendly.

Regarding websites and use of internet, EPF has, in other consultations, called for a 'quality label' for all sites providing health information to ensure its quality and integrity. In addition to this, in relation to the provision information on pharmaceutical products companies should be obliged to notify the co-regulatory body in advance regarding the development of a new webpage/section together with a brief concept note on the nature of the information.

The Quality Criteria

EPF, its members and patient group allies welcomes the proposed use and application of the quality criteria developed and adopted in the framework of the Pharmaceutical Forum to underpin the different forms of information to patients. Given that these quality criteria will be used and implemented in other EU and national developments on information to patients, this ensures that the legislative proposal should be seen as one part of a broader patient-centred overall strategy on the provision of comprehensive and holistic information to patients to support them in the management of their disease and their daily life. The necessity of this has been explored earlier in this response.

The importance of ensuring barrier-free information was highlighted in particular during the consultation process with our members – particularly in relation to disabled people who may be patients.

Proposed Structure for Validation and Monitoring

EPF, its members and patient group allies can, in general, support the approach proposed for the overall monitoring structure and systems, We underline the importance of transparency of all aspects of the monitoring system to further build patient and public confidence.

We believe it is important for the proposed European Advisory Body also to be composed of key stakeholders, including in particular the representatives of the target users themselves -patients. This also reflects the structure of the proposed national co-regulatory bodies. We stress the importance of a transparent and inclusive procedure in forming the Advisory Body.

We would also suggest that the European Advisory Body should provide a model code of conduct using the quality criteria, upon which national models should be

based, clear guidance as described above based on scenario examples regarding what constitutes quality information and what is advertising, and also very clear guidance with regard to sanctions and penalties to ensure parity across the Member States.

With regard to the identified role of the competent authorities, we are concerned by the phrase '*in the case of repeated and severe cases of non-compliance*', as this is too vague and insufficiently rigorous, undermining the entire proposal. EPF would call for a phrase such as '*in all cases of non-compliance*' action should be taken by the competent authorities.

The actions of the competent authorities, sanctions and penalties should reflect the intent (deliberate, knowing) of the violation, potential severity of the consequences; target audience and repeated offence.

With regard to the tasks identified for the national co-regulatory bodies, 'monitoring information providers' is redundant, as goes beyond the scope of the legislative proposal. We are also of the view that it is not the role of co-regulatory bodies to 'name and shame' or insist providers change illegal information. Their focus should remain on ex ante evaluation in relation to push information as described above, reviewing the notification of new website materials from companies, managing the complaints procedure linked to monitoring and reporting non-compliance to the competent authorities to take action and on responding to requests for support and guidance from companies on any 'grey' areas.

Conclusions

'Information to patients' is a key driver for patient-centred high quality healthcare. Supported by health literacy, information to patients will ensure that an empowered patient and his or her family is able to manage more effectively the disease and its consequences and achieve better quality of life.

EPF and its patient group allies feel strongly that the final legislative proposal should reflect this premise in relation to prescription medicines. At the same time, we urge the Commission to move forward on a coherent and ambitious patient-centred overall strategy on information to patients and optimise the political momentum to achieve important change in this area.

Endorsement

The EPF members listed below have supported this response. **The International Alliance of Patient Organizations** has also given comments to the response and has endorsed the final version.

EPF Members that have supported the response

- Collectif inter associatif Sur la Santé (CISS)
- Council of Representatives of Patients' organizations of Lithuania (LPOAT)
- Euro Ataxia - European Federation of Hereditary Ataxias
- EUROPA DONNA - The European Breast Cancer Coalition
- European Alliance of neuro-Muscular Disorders Association - EAMDA
- European Federation of Association of Families of Mentally Ill People - EUFAMI
- European Federation of Allergy and Airways Diseases Patients' Associations - EFA
- European Federation of Crohn's and Ulcerative Colitis Associations - EFCCA
- European Federation of Homeopathic Patients' Associations
- European Genetic Alliances Network - EGAN
- European Heart and Lung Transplant Federation
- European Infertility Alliance
- European Kidney Patients' Federation - CEAPIR
- European Men's Health Forum
- European Multiple Sclerosis Platform
- European Network of (ex)users and survivors of psychiatry
- Foro Español de Pacientes
- GAMIAN Europe
- International Diabetes Federation - Region Europe
- International Patient Organisation for Primary Immunodeficiencies IPOPI
- Retina Europe
- Associazione Patologie Autoimmuni Internazionale - APAI
- European Coalition of Positive People - ECPP
- Debra Europe
- European Alliance of Genetic Support Groups
- European Forum for Psoriasis Patients's Associations in Europe
- AMD Alliance International
- Federation of Polish Patients
- European Federation of Associations of Patients with Haemochromatosis
- Movimento Consumatori