europeanpatients'forum

EPF's POSITION ON THE LEGISLATIVE PROPOSAL ON INFORMATION TO THE GENERAL PUBLIC ABOUT PRESCRIPTION-ONLY MEDICINES[1] adopted by the Commission on 10 December 2008

Resume of EPF's base line position in previous consultations on information to patients:

- Article 88a introduced to Directive 2001/83/EC by Directive 2004/27/EC states that "*the Commission shall, if appropriate, put forward proposals setting out an information strategy to ensure good-quality, objective, reliable and non promotional information on medicinal products and other treatments"*. However the proposals put forward during the consultation ending in April 2008 were very limited to only a narrow, albeit important part of the larger 'information to patients' challenge.
- EPF, alongside other health NGOs, has pursued consistently discussions with the EU institutions on the need for a **comprehensive EU information to patients strategy,** including a political and programmatic commitment to health literacy.
- The ban on direct to consumer advertising (DTCA) should be maintained.
- Industry should be able to provide information only on a non- promotional basis.
- This information should meet stringent quality criteria, and robust monitoring systems should be set up, including appropriate sanctions, to secure this.
- In this regard, there is a key role at EU level to support the Member States in implementing appropriately legislation to ensure that there is a harmonised approach to patients' access to information across the EU Member States.
- We have argued that the necessary mechanism or process at EU level should be transparent, and involve stakeholders including patients.
- The key concepts from a patient's perspective are:
    - Acknowledgement of the empowerment[2] of patients and their need for comprehensive, comparable information, from a variety of sources;
    - Assurance of the quality of the information;
    - Objectivity of the information;
    - Maintenance of patients' trust;
    - Avoidance of unnecessary bureaucracy BUT a robust approach to monitoring.

[1] Proposal for a Directive of the European Parliament and the Council amending, as regards information to the general public on medicinal products for human use subject to medical prescription, Directive 2001/83/EC on the Community Code relating to medicinal products for human use

[2] Empowerment – a process through which people gain greater control over decisions and actions that affect their health (WHO, 1998)

Consultation process

Important issues regarding the "information to patients" proposal were outlined during an EPF policy workshop in January 2009. These formed the basis of a draft document for discussion by the EPF membership at our Annual General Meeting in March.

EPF members and allies were invited to provide additional views and comments to be incorporated in a final position paper by the end of April 2009.

This document includes the feedback from this process and constitutes EPF's final position, approved by the EPF board. EPF's sister organisation at international level, the International Alliance of Patients' Organizations (IAPO) has also supported this position.

EPF's POSITION ON THE CURRENT PROPOSAL ON INFORMATION TO GENERAL PUBLIC ON PRESCRIPTION MEDICINES, INTRODUCED WITHIN THE PHARMACEUTICAL PACKAGE AND ADOPTED BY THE COMMISSION ON 10 DECEMBER 2008

I. The need for a comprehensive information strategy on information to patients

A fundamental point, that EPF and its members have raised in previous consultations and will continue to do so is our disappointment in the limited scope of the proposal which focuses solely on the role of industry in providing information on prescription medicines to the general public, without the context of being part of a comprehensive EU information to patient strategy.

The need for such a strategy has been extensively discussed, recognised and endorsed during the Pharmaceutical Forum process and reiterated further during the Conference co-organised by the European Commission and EPF on the outcomes of the Pharmaceutical Forum – Delivering for Patients, 25 March 2009.

A good example of some of the broader information to patients challenges is the current Product Information Leaflet that does not respond to the needs of patients - this should be transformed into a genuine "PATIENT information leaflet". Another illustration is the EMEA database ' EUDRAPHARM' features information about the approved summaries of product characteristics and the package leaflet, but in reality patients face difficulties (in terms of time constraints, language, health literacy skills, etc) to access this information. This should be equally available in all Member States.

We need to see tangible and swift action by the European Commission advancing on a comprehensive EU information to patients strategy, in the form of a concrete proposal incorporating the considerable wealth of recommendations put forward by EPF and others.

This was articulated in a statement to the Commission prepared by a group of health NGOs, including EPF in November 2008. It was further addressed in the work of the Pharmaceutical Forum in the documents ' A framework for an information to patients' strategy- direct and logical follow-up', and 'Wider Health and information/ Health Literacy issues – By products of the key debates within the Information to patients working group of the Pharmaceutical

Forum'. It was also one of the key conclusions on the EPF Conference on Health Literacy, April 2008.

These documents made a compelling case for a comprehensive EU information to patients strategy that would

1. Develop and maintain a sound evidence base on ITP delivery across the EU
2. Coordinate work on the ITP dimension of e-health
3. Advance health literacy as a political and programmatic priority at EU and member state level, including concerted work on the education and communication skills of patients and professionals
4. Provide continuous support for health mainstreaming (Health in all policies) and information to patients
5. Maintain the momentum of the work undertaken by the Pharmaceutical Forum on quality principles on information to patients, approaches to enhance ITP delivery in specific healthcare settings, ethics around public private partnerships on ITP, and key elements of a comprehensive and comparative ITP provision to patients.

II. EPF's perspective on the details of current proposal and proposals for change

Regarding the current proposal on information to the general public on prescription medicines, EPF members can welcome its objectives, as we believe that information should from a wide range of sources, including industry but are concerned about a number of details therein which contradict with EPF's positioning to date.

The following **issues of particular concern** were raised during the consultation:

1. There is a contradiction between the objective to address the inequalities across the EU in relation to patients' and the public at large's access to information (Recital, (3)) and the referral to Member States to decide on core aspects of the proposal.
    - For example, it is for Member States to decide on what constitute "health–related publications" (Art 100c (a)). This is likely to differ considerably from country to country, thus the problem of unequal access will remain.
    - Also, it is for Member States to ensure that there are adequate and effective methods of monitoring to avoid misuse of information disseminated by marketing authorisation holders (page 16, Art 100g, 1.)

    EPF would like the proposal to ensure that the EU Institutions playing a stronger role in monitoring. Linked to this, the "authority" of the European Code of Practice and Guidelines is not made clear in the current proposal (Art 100g, (2)).

    Will these become obligatory, as has been implied in dialogue with EU officials? EPF stresses the importance of this, given the difficulties that certain MS are likely to encounter in establishing and implementing an appropriate monitoring system. We would further argue that it is of critical importance that patients, health professionals and other stakeholders are involved in the drafting of the Code and Guidelines.

2. Although the proposal recognises that "boundaries between advertising and information are not interpreted consistently across the Community" *(*Explanatory memorandum, *1.2)*, the proposal provides no clear definition of and distinction between what represents "information" and what represents "advertising".

3. The proposal states that prohibition on advertising shall not apply to vaccination campaigns and “other campaigns in the interest of public health” carried out by the industry and approved by the competent authorities of the Member States (Art 84 (4)). This requires further clarification to avoid a perception that this might be used for advertising.
4. The proposal highlights that the market authorisation holders can refer to non-interventional scientific studies or accompanying measures to prevention and medical treatment or material that present the product in the context of the disease. (Art 100b (d)). This requires further clarification as well, to avoid a perception that this might be used for advertising.
5. The contribution that patient organisations can make in provision of information needs to be more widely acknowledged and recognised in the proposal – also in the context of the transposition of the eventual legislation. Patient organisations need to be involved at various levels, including the actual information provided to contribute towards ensuring that it is of high quality in patients’ terms and responds to real needs of patients.

EPF and its members and allies **welcome that:**

1. The proposal’s goal is to address the issue of unequal patients’ and public at large’s access to information across the EU Member States, where there is very different interpretation of the current EU legislation.
2. The proposal highlights that national competent authorities and health care professionals should remain important sources of information, while industry may be a valuable source of non promotional information on medicinal products. (Recital, (8))
3. The proposal maintains the current ban on Direct to Consumer Advertising (DTCA) and focuses exclusively on ‘ pull ‘ rather than ‘ push’ information (Art 100d, (b))
4. The quality principles on ‘information to patients’ adopted by the Pharmaceutical Forum are the mainstay of the proposal (Art 100d).
5. The emphasis in the proposal is on the quality and purpose of the information, not the source.
6. The proposal introduces a requirement that information is accessible to people with disabilities. (Art 100f, (1))
7. The importance of the patient/ doctor relationship is stressed and the proposal stipulates that a health professional should be contacted if the patient requires clarification on the information provided (Art 100d, (b)).
8. The proposal stipulates that the source of information (ie industry) should also be highlighted in the information provided, indicating its author and giving references to any documentation that the information is based on (Art 100d, (g)).
9. There is reference to a European Code of Practice and Guidelines but this needs clarification (see above).

III. Conclusion

Subject to appropriate redrafting, in consultation with EPF, in accordance with the comments and proposals outlined above, EPF supports this legislative proposal, providing there is an assurance that it will become part of a broader, comprehensive

information to patients strategy outlined earlier in this document, and an affirmation that a proposal for such a strategy will be drafted at the earliest opportunity.

EPF and its membership will follow closely the legislative pathway of the proposal and will be providing input on an on-going basis to all three Institutions

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 39 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.