EPF FINAL VERSION APPROVED BY THE EPF BOARD, 3 May 2007, FOLLOWING CONSULTATION WITH THE MEMBERS

The EPF response to the Commission Consultation on Quality Principles in relation to Information to Patients

1. *Is a set of principles on good quality information on health-related information and treatments for patients and citizens useful at the EU level*?

Yes, such a set of principles agreed by all Member States and stakeholders should provide the backdrop for current and future EU level developments on information to patients. Such a set of principles should and could serve as a model for the Member States.

2. Do these principles provide a clear basis on which to judge the quality of information at a European level?

Yes, but a clear introduction to the set of principles is essential to give it appropriate context, and gravitas.

This may include reference to the universal recognition by all players involved in the Pharmaceutical Forum that citizens and patients across the European Union need to have **better access to high-quality, reliable, and balanced information about diseases, prevention methods, healthcare services, and treatment options, including medicines.** Currently there are differences in and between the member

European Patients' Forum, "Park Leopold" Rue Wiertz 50/28, B1050 Brussels
Phone : +32 (2) 401 68 11 Fax: +32 (2) 401 68 68
Email: info@eu-patient.eu Web: www.eu-patient.eu

states in provision, quality and accessibility to such information.

The title of the document should be ‘ Quality Principles on Information to Patients on Diseases, and Disease Management’

From EPF ‘s perspective, we wish to see included some revisions in this set of principles to facilitate clarity and access. It is important, we believe, that these principles both in their content and their form reflect best practice in relation to information to patients.

See proposals outlined below.

3. Should any of these principles be revised and if so, how? Are there any important principles missing?

EPF considers that two important principles are missing:

That relevant reliable information should also be based on the patients’ direct experience, as evidenced by individual patients and patients’ organisations.

That information to patients should be two-way process and include contact information to enable feedback and obtain additional details / pose further questions.

In addition to these additions and an introduction as outlined above, we propose the following revision to the original text as a result of consultation with the EPF members.

We would suggest that the existing text should now read:

To make informed choices, patients need accurate, objective and comprehensive information as reflected in the principles outlined below. A regulatory system is required to ensure these principles are upheld in relation to information on

prescription medicines from any sources.

The European Commission and Member States have a responsibility to provide information, alongside other health stakeholders, and to set in place an appropriate system to regulate information on prescription medicines.

Evidence -based

The evidence base for any information resource needs to be stated, and where this does not exist, it needs to be highlighted. Information should be verifiable, based on comparisons, which may be quantitative, qualitative and or anecdotal, and backed up by scientific peer review where possible.

Up- to- date

Information should be kept up – to – date and the date of publication/ references, and revisions should be included

Reliable

Information should be factually correct and not misleading. It should reflect the latest knowledge and wherever possible be validated by independent scientists (where possible be scientifically valid).

Understandable

Without prejudice, all patients and citizens should be able to understand the information

Accessible

Information should be accessible via different media and different distribution channels. Information should be accessible to disabled people and other potentially marginalised groups.

Transparency

Current principles concerning transparency (for instance with regard to disclosure of

funding sources) at EU level are equally applicable in the context of information to patients.

Relevant and appropriate

Information should be comprehensive and include issues of relevance to patients' decision-making in all aspects of disease and disease management and their likely impact on quality of life and participation in society.

It is important to stress that information should not be alarmist. It is extremely important to find the right balance between information that may raise anxiety, promote denial and hide the benefits provided by a given treatment or therapy, and information that supports the patient throughout the entire patient journey.

Consistent with statutory information

Information not regulated by statute should be consistent with legal requirements and developments in relation to European law, particular with regard to the prohibition of direct to consumer advertising. This should be established through a regulatory process.