Final Response from the European Patients' Forum to the European Commission's Draft Report on Current Practice with Regard to Provision of Information to Patients on Medicinal Products

Key words: fundamental right to information, quality, equity, holistic approach, patient centred, patient perspective.

The **European Patients' Forum (EPF)** welcomes the Commission's initiative to consult stakeholders on the *Draft Report on Current Practice with Regard to Provision of Information to Patients on medicinal Products.*

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 EU patients' movement. EPF currently represents 27 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 more than 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 organizations at European level and at Member States level. EPF's vision for the future is patient-centred, equitable healthcare throughout the European Union.

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

A draft response was formulated on the basis of extensive consultation with the EPF membership and other patient group allies. This was then circulated to EPF Board 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. A final response was submitted to the Commission on 29 June 2007.

This response deals explicitly with the **patients' perspective.** We have also annexed

- EPF's Position Statement on Information to Patients;
- The 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.

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

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 the availability of treatments, including knowledge of the best available management of their disease. It is a question of solidarity, equity and patients' rights. This right implies that the same information that is available to doctors should also be available to patients.

The report as it stands

I. EPF considers the draft report to be a good overview of the current state of play across the EU Member States with regards to information to patients on medicinal products.

II. As a general principle, however, we would wish to stress that information to patients covers a much broader spectrum, beyond medicinal products per se, and that this should be addressed in future Community actions.

III. We regret that the report is purely descriptive and it does not present any proposals for the way forward.

IV. We also regret there is a lack of acknowledgement to documents supplied by patient organisations in the development of this report and that all sources of references are not mentioned.

V. EPF considers there is an insufficient recognition within the report of the significant role played by patient organisations as providers of information, information conduits and their potential role in future governance structures on information provision to patients in the Member States and at EU level.

VI. Although referred to in the report, we feel there is an under-estimation of the inequities in relation to the use of the Internet, and access to information by underrepresented and marginalised patients. Many European patients do not use the Internet; and even when they do, the Internet should never be considered as the sole source of information.

The barriers, limits and potential regarding current information provision across the EU

EPF and our patient group allies argue strongly that **high quality, timely and accessible information is essential** to support patient-centred disease management throughout the entire patient journey. Information is also integral to the therapy process. There is a strong evidence base that well informed patients enjoy

better health outcomes that uninformed patients[1]. Information on medicinal products, their effects, side-effects and alternative and supplementary treatments is also an essential pre-requisite for informed consent to treatment.

I. The current medicine information sources as referred to in the report: Product Information Leaflet (PIL), EPAR, EudraPharm are important information tools, but they fall short of responding to the whole spectrum of information needs of patients.

II. There are significant inequities with regard to the information that is currently available for patients in different Member States. Such disparities are intolerable in a European Union built on fundamental rights and solidarity.

III. Information should come from multiple sources to ensure equal access to healthcare and an informed choice. In several EU Member States, patients' organisations themselves can and do make a major contribution in producing and disseminating information in patient friendly language and formats effectively at regional, national and European level. We believe there is great potential to enhance and extend this role, if adequate and on-going resources are made available. We also believe that patients' own experiences should be a key source in the provision any medical information.

The current legislation framework does not permit pharmaceutical companies to respond to enquiries from patients regarding their medicines. EPF and our patient allies resist strongly direct to consumer advertising on prescription medicines (DTCA). There is however increased consensus on the line between access to quality information and DTCA. Pharmaceutical companies should be able to be a source of non-promotional information alongside other sources, on their products. They should be able to provide validated information for people actively seeking out further information on available medicines. However, it is crucial to ensure that when patients seek information from pharmaceutical companies, they get full information, including, for example, negative side effects. Ideally, empowered patients should be able to have meaningful

[1] Angelmar R., Berman Philip C - *Financing sustainable healthcare in Europe - Patient empowerment and health outcome*, *Motivated empowered patients to improve efficient health outcomes,* p.154-156, (2007) [on-line], http://www.sustainhealthcare.org/Report_3.pdf, last accessed 29 June 2007.

discussion and partnership with their treating health care professionals on individual self-management plans for their disease, including the choice of medicines among all those available.

IV. EPF and its allies are of the view that there is a need to emphasise the importance of a holistic approach, as should be demonstrated by the work within the Pharmaceutical Forum on: (a) quality principles and a comprehensive information model, (b) access to information in specific health care settings, and (c) on a toolbox on facilitating access to information for potentially vulnerable patients. It is crucial to go beyond the area of information on medicines per se, however, in the words on one of our members "it is inconceivable in today's society that information may be available on needles, the use of the injection system etc. but without any information on the medicine in those needles".

V. It is vital that Community action continues to support the development of health literacy for patients to ensure that patients are not only informed, but are also empowered. Health literacy, accompanied by patient education programmes will enable patients to use better information provision effectively, in their disease management decisions and choices and concordance, in a spirit of trust and cooperation with their health professionals. This in turn will make a significant impact on their quality of life. It should not be forgotten however, that while promoting health literacy, adjusted patient information for different groups of patients will always be needed.

VI. The limitations and potential of the Internet from a patients' perspective should be a key focus point in the future. We encourage the development of search engines that identify health websites that are validated for quality health information and would welcome Community action that would ensure further rigour in this arena.

VII. Printed material in accessible format (including requirements for blind and visually impaired patients and other groups with specific needs), in all EU languages will continue to be important and valued information tools for

patients. Any Community action that encourages and supports the implementation of the quality principles in this regard would be welcomed.

The way forward

EPF and our patient group allies believe that change of current legislation at EU level is required to enable a more effective "information strategy" for patients on high quality, validated, reliable, and balanced information about diseases, prevention methods, healthcare services, and treatment options, including medicines. All European citizens should have access to the same type of information to avoid misinterpretation, to promote equal treatment and equity. Under the current legislation, for example, the same company, in different countries provides different elements of information. In Belgium for example one is not allowed to refer to the name of the medicinal product, while in the Netherlands the name of the product and the summary of characteristics are mentioned.

A transparent and accountable private-public partnership between patients' organisations, health care professionals, private sector and government is the way forward, where patients' organisations are involved in a meaningful way, in conveying the needs, experiences and expertise of their respective constituencies, whilst maintaining independence. Examples of such partnerships already exist:

- The GAVI Alliance[2] is an example of a unique partnership that combines public and private sector resources to bring the benefits of immunisation to children in greatest need. It is focused on increasing children's access to vaccines in poor countries. Partners include the GAVI Fund, national governments, UNICEF, WHO, The World Bank, the Bill & Melinda Gates Foundation, the vaccine industry, public health institutions and non-governmental organisations.

[2]The GAVI Alliance (formerly known as the Global Alliance for Vaccines and Immunisation), [on-line], http://www.gavialliance.org/General_Information/About_alliance/index.php, last accessed 29 June 2007.

- In the *Declaration of the eHealth Conference 2007*[3], Member States and the European Commission committed to work together with eHealth related industry and carefully plan pilot activities to implement eHealth related services. The document clearly underlines that patients organisations, health professionals organizations and health service providers are crucial in the design, adoption, implementation and validation of these services.

I. Such a partnership should comprise a framework for information to patients from multiple sources including:
    - Quality Principles;
    - A credible European health information model for different disease areas, that is accessible/ transferable at national level in respective languages and cultures; that will also facilitate comparative analysis in the longer- term.
    - An efficient, equitable and cost-effective regulatory system.

II. Among the three governance or regulatory system options that have been suggested, in relation to the quality principles in the framework of the Pharmaceutical Forum,
    1) *Ex anteriori validation mechanism which could provide a system for national authorities to assess and validate information to patients on diseases and treatment*
    2) *Co-regulation which includes a review process which would be built on a posteriori controls including sanctions. This mechanism could be based on an obligation for those providing information to allow the information to be reviewed by national authorities and relevant stakeholders*
    3) *Self-regulation according to an agreed code of practice.*

EPF, its members and patient group allies would favour a way forward that builds in robust safeguards with appropriate sanctions, but is workable, effective and non bureaucratic to avoid delays to patients in receiving crucial information, and where representative patient organisations are represented.

[3] *Better health care in Europe - Renewed commitment for co-operation on cross-border electronic health services,* Berlin, 2007, [on-line], http://ec.europa.eu/information_society/newsroom/cf/itemlongdetail.cfm?item_id=3370, last accessed 29 June.

III. EPF would like to stress its commitment to move forward together with all stakeholders in achieving better access to high-quality, validated, reliable, and balanced information about diseases, prevention methods, healthcare services, and treatment options, including medicines, and looks forward to continuing dialogue on the basis of all of the responses to the Commission Consultation.

EPF's members supporting EPF's response

Alzheimer Europe

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 Multiple Sclerosis Platform

European Network of (ex)users and Survivors of Psychiatry

EURORDIS

Foro Español de Pacientes

GAMIAN Europe

International Diabetes Federation - Region Europe

International Patient Organisation for Primary Immunodeficiencies IPOPI

Retina Europe

Associazone Patologie Autoimmuni Internazionale – APAI

European Coalition of Positive People – ECPP

Debra Europe

European Alliance of Genetic Support Groups

Other allies that support this response:

International Alliance of Patient Organizations (IAPO)

Dutch National Council