Reference Paper for European Patients' Forum Input to the Pharmaceutical Forum's Information to Patients' Working Group Commentary on the Development of a European Health Information & Governance Model

Final version following consultation with the members
22 February 2007

1. Background

There is now 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 states in provision, quality and accessibility to such information. As a result, promoting better health outcomes at a time when Europe faces unprecedented health challenges is limited.

The main existing sources of information on medicines in an EU context are the Product Information Leaflet (PIL) and the European Public Assessment Report (EPAR) www.emea.europa.eu, both of which are difficult to understand and fall short of delivering the range of information that patients and citizens desire.

To fill the information void on various aspects of health, Europeans are increasingly turning to the Internet where information is abundant, but uncontrolled, often of low or unknown quality, generally available in English only and may not correspond to European approved treatment guidelines.

The resulting situation is **not only one of restriction but of profound inequalities between citizens of different European nationalities, socio-economic levels,**

educational background, languages and cultures. It is a contradiction to European solidarity and integration.

> *"Information to patients is not about money, or innovation, or competitiveness, it is rather a matter of life and death, and goes to the heart of a human rights agenda".*
> EPF President, Anders Olauson at the High Level Pharmaceutical Forum in Brussels, 29 September 2006.

a. The Opportunity for Positive European Reform

The European Commission has been mandated to review EU legislation regarding information on authorized medicines and, if deemed necessary, to submit proposals for reform by mid-2007 on ways to improve the quality of health information in general in Europe.

The European Patients' Forum is concerned, however, that conflicting views and lack of trust between stakeholders may result in little or no progress on this issue, and may further delay improvements to a patient-centred healthcare framework in Europe.

b. Purpose of this paper

EPF wishes to contribute towards an agreement:

- on reforming the current legislation to include better access to treatment information;
- providing a framework on information to patients/health information in general through multiple sources,

through the development of a collective proposal by the Information to Patients Working Group for:

- a credible European health and treatment information model, that is accessible at national level in respective languages and cultures;
- an efficient, equitable and cost-effective governance structure.

This paper identifies some of the potentially contentious issues linked to such a proposal, and presents the patients' perspective on these, in an attempt to move the debate forward.

c. Shared Principles on information provision by all members of the Pharmaceutical Forum.

For many of these principles we have included a single example from patients' organizations by way of illustration that was submitted to us following consultation with the membership.

A) Europeans want and have a right to **better access to high-quality, reliable and validated information** in their native language about diseases, prevention, treatments and medicines in order to be more actively involved in decisions about their health.

CASE IN POINT: FIGHTING FOR BREATH – EUROPEAN PATIENT PERSPECTIVE ON SEVERE ASTHMA[1]

This report outlines the outcome of the biggest survey ever of people with severe asthma in 5 European countries including 1300 patients by the European Federation of Allergy and Airways Diseases Patients' Associations (EFA) 2004-2005. It reveals that respondents did not have many expectations for improvement of their asthma management in the future as they felt powerless over their disease. Such powerlessness could clearly be helped with improved information to help them to take control over their disease.

In another European EFA survey PATIENT VOICE IN ALLERGY[2] for members of allergy patient groups in 11 countries in 2005 including 3562 people with allergic rhinitis, two thirds of the patients said they had made changes in their home (allergen avoidance) and spent a lot of money but almost all of them found these ineffective and most of them were suffering persistent symptoms despite their medication. This points unequivocally to the need for better information provision on both preventive measures and other treatment.

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[1] Dockrell, M. Partridge, M. R. Valovirta, E. Limitations in Severe Asthma – results of a European Survey. Allergy. 62(2):134-141, February 2007, http://www.efanet.org/activities/documents/Fighting_For_Breath1.pdf

[2] E Valovirta, SE Myrseth, S Palkonen, Allergic Rhinitis is not a Trivial Disease. Ahead of publication in Current Opinion of Allergy and Clinical Immunology April 2007, http://www.efanet.org/enews/documents/AllergysummaryreportFINALdata220605-onsitea.doc

B) More and better quality Information **strengthens the patient-health professional relationship** as **informed patients** have more productive discussions with their health professional given that they are more likely to understand their own individual health profile, treatment options and the importance of treatment compliance/concordance/adherence.

CASE IN POINT: THE GUIDE TO TREATMENT AND MANAGEMENT OF MULTIPLE SCLEROSIS

The book “Multiple Sclerosis – the Guide to Treatment and Management” was reviewed by members of the International Medical & Scientific Board of the Multiple Sclerosis International Federation, all of whom are neurologists in active practice who treat patients with MS on a daily basis.

Their opinions are based not only on published data but also on their daily experiences and information from trusted colleagues.

"By focusing on alternative medicines, the book helps increase awareness of the uses of these treatments for the physician. This may help open a dialogue between physician and patient (...)"(*Archives of Neurology,* March 2001).

Information about multiple sclerosis (MS) has never been more widely available. The Internet has enabled people affected by MS and health professionals in every part of the world to share their knowledge about effective treatments and has created a real opportunity for truly international cooperation in finding a cure and ending the devastating effects of this disease. However, this rich source of facts, advice, and support is tempered by misinformation and opinion that has also been disseminated. Therefore it becomes increasingly important to deliver up-to-date and accurate information in order to distinguish valid treatments from those that are ineffective or even dangerous.

The sixth edition of “Multiple Sclerosis: The Guide to Treatment and Management” is the result of meticulous work by the International Medical and Scientific Board of the MSIF to establish authoritative guidance on a wide range of therapies currently being used in the management of MS. The book has been completely revised to reflect the latest available information about this disease.

Feedback reveals that people with MS, their friends and caregivers, and health care professionals have found great value in the Guide.

C) Providing health information to the public should be a **holistic communications process** that informs, educates and empowers citizens and patients and carers to make better lifestyle and healthcare choices.

CASE IN POINT: THE DIABETES UK WEBSITE
www.diabetes.org.uk/Guide-to-diabetes/

The Diabetes Website in an excellent example of a holistic communication process in practice. It provides a guide to diabetes with facts about Diabetes and the information one needs for managing the condition from diagnosis to everyday living.

The main menu covers the following areas:
- Introduction to diabetes
- Treatment and your health
- Living with diabetes
- What care to expect
- Complications
- Food and recipes.

Under *treatment and your health*, there are sections on:
- Eating well
- Keeping active
- Smoking
- Managing your weight
- Treatments
- Structured Education (patient education courses) and
- Monitoring your health.

Under *Living with diabetes* there is a specific section called *Teenzone*; this includes sections on:
-It's off to work we go (employment opportunities and discrimination)
-Going back after diagnosis (how to tell friends and colleagues)
-Moving on (lifestyle management, independence from parents etc) and
-Your problems sorted (a personalised helpline and problem-page).

D) Access and ability to provide health and treatment information should be based on **the quality of the information and not the source**.

CASE IN POINT: THE MENINGITIS TRUST UK

Meningitis is a rare but devastating disease; the fact that it is rare in Europe should not be an excuse for the dearth of information that is available. Especially as we know that early recognition and thus early diagnosis and treatment saves lives. We have a number of case studies where the recognition of symptoms through our pocket card has saved a life.
The Meningitis Trust has shown over the years that raising awareness in the general public must go hand in hand with awareness in the healthcare profession. Meningococcal disease can develop in an apparently health child with frightening speed. An empowered parent will take a child with flu-like symptoms to the community physician and an empowered physician will know that the child requires parental monitoring and a return to the surgery if conditions change. The Meningitis Trust has thus developed a number of tools and educational resources for healthcare professionals, teachers and the public, examples of which can be found on the websites:
www.meningitis-trust.org
www.inmedonline.com
www.meningitis-learning.org.

Patient organisations play a strong role in the provision of information precisely because they are seen by the public as reliable and independent. The development of the whole concept of patient groups providing information and education to the public and to healthcare providers is an area which requires a great deal of attention. There must be a credible path between governments on the one hand who are legitimately concerned with the economics of healthcare within their countries, and the pharmaceutical industry where the legitimate business is to make a profit. This path should be trodden by independent patient organisations who are respected by all stakeholders.

The Meningitis Trust believes that everyone should be aware of the signs and symptoms of meningitis and the action to take so that they can protect themselves and their families. This is particularly important with respect to a rare disease where knowledge of signs and symptoms may be the only means of protection. The Meningitis Trust uses a range of methodologies to disseminate messages including a helpline, targeted websites and a range of specific information for different stakeholders including the public, healthcare professionals and business.

The Meningitis Trust is currently preparing its own model of information to patients within the European context and it will shortly be made available.

A form of **governance is required** to guarantee the quality and reliability of health and treatment information from multiple sources.

2. Content of Patient-Centered Information Model

a. EPF and its allies believe a patient-centred health information model should address the following elements:

- Public and Patient Needs (chronic, acute, rare and lifestyle illnesses);
- Sources of Health Information (role of patient groups, and other stakeholders, including health professionals, industry, insurers, academia and governments);
- Delivery of Information Channels;
- Audiences (General Public, patient, family, carers);
- Content:
    - Diseases (symptoms, life-cycle/development of the disease, risk factors, health related quality of life)
    - European treatment guidelines
    - Prevention information (diet, exercise, environment and treatments)
    - Diagnosis information (questions to ask your doctor)
    - Treatment information (choices, risks, benefits, side-effects, cost, written self-management plan, follow up, emergencies and compliance information)
    - Patient resources throughout the patient's journey (government, patient groups, services)

A model is being developed by the Information to Patients Working Group drawing on the example of diabetes. The Diabetes UK website is also a very good model where all of these elements are included (see above). We have drawn on one example from Finland to demonstrate an information model from another arena.

CASE IN POINT: ASTHMA INFORMATION LEAFLET AND WEBSITE

A Patient information leaflet by the patient organisation Finnish Allergy and Asthma Federation in collaboration with professionals: the Helsinki University Skin and Allergy Hospital contains the following issues and is written in clear plain understandable language:
http://www.allergia.com/chapter_images/1300_ASTMA_OPAS.pdf

Background
- prevalence

Diagnosis
- methods

Disease information
- disease mechanisms;
- symptoms;
- causes of symptoms;
- occurrence of symptoms;

- exercise induced asthma;
- hereditarity;
- chances of cure;
- co-morbidities;
- psychological factors;
- asthma as occupational disease;
- primary prevention.

Treatment
- medicines (class, name of active ingredient and commercial name in brackets);
- medicine mechanisms on how they act;
- compliance;
- safety;
- self management and empowerment;
- misconceptions about medication;
- medications which may worsen asthma;
- advice for emergencies;

Other treatment/lifestyle
- diet;
- smoking;
- exercise;
- climate treatment;
- air humidifiers and cleaners;
- cold air and asthma;
- breathing masks;
- acupuncture.

Environmental factors
- outdoor air pollution;
- indoor air pollution.

Support services
- government;
- reimbursement;
- patient organisation (helpline, education, rehabilitation, peer support, patient information)

Where to find more information

The leaflet is available in printed form; freely to order by the public, health care centers, hospitals and pharmacies to hand out to patients, in the internet as pdf, as text only http://www.allergia.com/index.phtml?menu_id=170&lang=1 and by topic http://www.allergia.com/index.phtml?menu_id=39&lang=1.

This is the basic leaflet on asthma, in addition the following specific related leaflets are available in all 3 formats mentioned: Allergy; Allergy Renovation and Cleaning at Home; Allergic Rhinitis and Child; Atopic Eczema; Atopic Eczema and Child, Hypersensitivity to Fragrances, Allergy to Cosmetics, Children's Food Allergies; Exercise and Child; Where to get Help in Allergy and Asthma; Where to Get Help to Indoor Air Quality and Mould Problems; Food Allergy and Hypersensitivity; Pollen Allergy and Indoor Air Quality. http://www.allergia.com/index.phtml?menu_id=2.

The information is in Finnish, but some also in Swedish: http://www.allergia.com/index.phtml?menu_id=11&lang=1

b. Potential contentious issues and EPF’s position on behalf of its members and allies

A) Distrust around the distinction between information to patients, and Direct to Consumer Advertising.

The European Patients’ Forum and our patient allies **do not** support direct to consumer advertising on prescription medicines (DTCA). There is however increased consensus on the line between access to quality information and DTCA with the distinction between “pull” mechanisms whereby the patient is actively seeking out information and needs to know where and how to access it, and push mechanisms where it is thrust indiscriminately upon the patient through media advertising.

EPF and our patient allies do not object to pharmaceutical companies, as a legitimate source of information on their products, providing validated information on their websites and other ‘”pull” mechanisms for people actively seeking out further information on their conditions and available medicines. Pharmaceutical companies have vital information on the drugs they produce which would be of interest to patients and carers alike.
Additionally, EPF shares the view of its members and allies that the pharmaceutical industry can have a role to play in disease awareness and other educational activities targeted at educating the public throughout the European Union. These should include information about the symptoms, mention the existence of available treatments (without mentioning specific products) and support services.

We believe that by working together in multiple public private partnerships we will achieve the trust and respect of the public by sharing the responsibility for providing information, sharing the vigilance and monitoring of product lifecycles and working together when the system is violated to ensure appropriate redress. History tells us that it is paramount that an EU level regulatory system provides the vigilance to ensure the highest public trust.

B) The focus on the “diabetes model”

While the EPF and its allies applaud the decision to develop a model focused on diabetes, we would like to reiterate that one size clearly does not fit all. Whilst there are universal principles linked to information to patients, information also needs to be disease specific, very often age, gender group specific and most importantly, accessible to the individual patient, in his or her cultural context.

C) Clarifying the scope of information to patients

EPF and its allies would wish to reiterate that information to patients can never be exclusively about information on medicines in isolation, but rather an all-embracing approach to information including a variety of health related quality of life, prevention, lifestyle, treatment, therapies, disease management, social and peer support, patient education and reimbursement options.

D) The limitations and potential of the Internet

It should be remembered that only 50 % of EU citizens have access to the Internet, and many sites are in the English language only.

The Internet, although challenged because of the very nature of the medium (any doubtful and uncontrolled information can be posted on the Internet), is nevertheless a recognised tool by patient organisations (websites of European or national patient organisations), health professionals, the media (websites with medical dossiers on diseases), the medical publications and the pharmaceutical industry.

EPF believes there are strengths and indeed weaknesses linked to the use of the Internet as the only source of information and supports strongly development for **e-health quality criteria** on the quality, accessibility and objectivity of information linked to health information available on the Internet dealing with prevention, diagnosis, disease management and alternative sources of medicine. Such criteria must include information sources and their accuracy, and could provide a "quality label" for health websites. This should clearly be linked to the governance model as described below.

A key principle for EPF is that the Internet is not perceived as a sole information source for patients but rather in concert with other information resources and support as part of an overall self help education programme.

An essential component of such a programme is training to empower patients and carers to pose the appropriate critical, reflective questions in relation to information provided, in accordance with his or her own individual situation and circumstances, and to develop the confidence to challenge and query this as necessary.

3. Development of a proposal for a governance structure/framework and process to guarantee the quality of information from multiple sources at the:

- European level
- National level

Potential Contentious Issues and EPF's position on behalf of its members and allies

A) An effective governance structure – who should be responsible?
EPF and its allies believe that such a crucial initiative, key to establishing public trust and confidence, needs to be funded both publicly and privately. We believe that a refocusing of resources will not mean an increase in expenditure, but a realignment of priorities in both public and advertising expenditures respectively.

We need to create an EU governance framework supported by Member States that is transparent and fulfils the obligation to provide high quality, reliable information in a holistic perspective, to the citizens they serve.

We believe that validation needs to be undertaken initially at a EU level with Member States responsible for a standardised implementation and enforcement.

We would also identify a clear role for representative patient organisations within a European governance structure.

B) Why European and national governance systems?

The European Patients' Forum and its allies recommend strongly governance systems at both levels, and these are not mutually exclusive.

The European dimension of medicines and health product development, and current reflection on patient mobility and cross border health services point to the need for a European approach to information to patients, and thus a European governance system that would work in concert with national governance systems.

National governance systems are crucial to validate national initiatives on information to patients and to ensure the linguistic and cultural appropriateness of trans-national or European information.

Although several national governance systems across the Member States are highly developed and rigorous, others are at a formative stage, and would benefit strongly from a European structure for guidance, support and some coordination.

C) Are existing structures not adequate?

The European Medicines Agency (EMEA)'s database and website Eudrapharm, which when completed will contain information about all medicines authorised for sale throughout Europe, is not the panacea but rather a good first step towards the robust governance model that we are seeking.

The recently launched EU Health Portal will also play an important role in relation to information to patients, particularly when it becomes available in all EU languages. Its remit however is not to provide detailed information on disease specific areas, treatments and medicines, but rather a resource to provide information on information and data on health-related issues and activities at both European and international level.