Empowerment
Information
Sustainability

CONFERENCE REPORT

European Patients' Forum Spring Conference
Brussels, 20-21 March, 2007

www.eu-patient.eu

Introductory Remarks

Anders Olauson

Dear colleagues and friends,

It is my pleasure to present you with the report of the European Patients' Forum's Spring Conference, which took place on 20-21 March in Brussels. This third EPF conference brought together more than 120 participants, representing a wide range of patient organisations and other stakeholders involved in healthcare at European and national level.

We chose three specific themes for the conference to address – themes which are essential to patients and their organisations: empowerment, information and sustainability. Empowerment, information and sustainability can be considered conditions for patients to play an active role in healthcare decisions at an individual as well as an organisational level, leading to improved health and quality of life outcomes. Each of these themes however involve some fundamental principles which need to be considered:

- Empowerment should include choice, respect, participation and responsibility.
- Information should be of high quality, timely and accessible.
- Sustainability is important for both the patient's individual journey and patient organisations.

The conference themes and these principles were addressed by speakers representing different perspectives and were discussed in plenary sessions and in interactive breakout sessions. Although stakeholders expressed different views and concerns, there was general agreement on the importance of the themes and related principles and the need to firmly raise these on the EU agenda. The time is right to work on this and the call for action expressed during the conference was clear. Many patient organisations still struggle to make their voice heard; resources are still a major challenge and information to patients as the 'fundamental right to know' is a key concern for the EU patient community.

Many ideas were raised during the conference on how to address these challenges. A key question is always: what are the roles and responsibilities of the different stakeholders involved. The answer is simple: we all have a responsibility and a role to play.

Introductory Remarks

The following report aims to provide an overview of the key points raised in the presentations and discussions. Most importantly, we hope the recommendations and conclusions included offer inspiration for future action.

I am delighted to see so much progress since the first EPF conference in 2004. However, it is clear that much needs to be done to ensure that the interests of patients are appropriately represented in health policy at all levels. We therefore need to continue to move forward towards ensuring that the notion of patient-centred, equitable healthcare is truly implemented throughout Europe. We hope that the conference recommendations contribute to reaching this objective.

I would like to end by thanking you for your support. Conference participants have given EPF the mandate to take concrete actions in relation to the core themes of empowerment, information and sustainability. We value this and the responsibility this entails. And together we can make progress. After seeing so much enthusiasm and solidarity at the conference, I am confident that in partnership with all stakeholders, we will succeed.

With best wishes,

Anders Olauson
EPF President

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Executive Summary

Importance of partnership

The conference themes of patient empowerment, health information and the sustainability of patient organisations may be seen as objectives that can only be successfully achieved through a series of partnerships involving all of the relevant stakeholders, including the European Institutions.

A patient-centred vision is developing today that involves a drive towards enhanced information that leads to greater empowerment for patients. To be meaningful, the process must embrace all appropriate stakeholders.

Patient involvement in EU policy making

Patients who feel empowered are essential if we are to achieve improved quality of care and health outcomes leading to a better quality of life. It is an ongoing process that requires the active engagement of all stakeholders, not simply those who choose to be most vocal. Representation in healthcare decision-making and planning is an essential element of empowerment.

EU Institutions and Agencies are increasingly interacting with patient organisations. This development is to be applauded as the patient's voice is essential in all discussions surrounding EU health initiatives and policies.

Patients have a right to information

Information should be easily accessible to everyone, in a language of their choice, in a format with which they feel comfortable and that respects differing cultures and environments. Different stakeholders can each play an important part in the provision of such information. However, safeguards need to be in place with regard to such matters as who will control the information and guarantee its quality. Such questions have yet to be fully addressed. We need to appreciate that information on its own, however good, is only part of the answer. A number of interventions are required to be sure that the information is helpful and used appropriately. In this respect, health literacy is vital, and should be given the necessary priority, if patients are to make the right day to day decisions concerning their health and its management.

A strong evidence base on economic benefits is needed

Improved information and greater empowerment can lead to enhanced quality of life for patients and economic benefits for all citizens. However, at this moment of time, the evidence available to support such statements is scarce and far more research is needed. Additional evidence based research will undoubtedly strengthen the case for further progress in the areas of patient information and empowerment.

Sustainability as a challenge: demonstrating added value of patient organisations

For patient organisations to be viewed as stable and sustainable, it is essential for them to secure long-term funding. This is a major challenge in every disease and condition area. Hence, it is necessary to explore all possible funding avenues including the EU Institutions. Creativity and imagination will be essential. If, through research, the unique role and added value of patient organisations can be demonstrated, it would then be reasonable to assume that funding, coupled with its sustainability, will be more readily forthcoming than at present.

An important role for EPF

Whilst disease and condition specific issues need to be addressed by the relevant individual organisations, the European Patients' Forum could, and perhaps should, play a significant role in representing the key interests of patients at the EU level.

Recommendations: Moving forward together

At the end of the conference, participants endorsed recommendations for concrete actions for EPF to take forward at EU level in partnership with other stakeholders.

These actions around the core themes of the conference build on recommendations and outcomes of previous EPF and other patients' events and aim to contribute towards EPF's vision of patient-centred, equitable healthcare throughout Europe.

Empowerment

Active support for the genuine involvement and meaningful participation of patients in the entire EU health arena, specifically:

- The input and role of patient organisations in the EU Health Policy Strategy where involvement of patients should be a baseline performance indicator, and reflected in effective consultation processes.
- Patient representation in relevant health mainstreaming policy and programme work.
- EPF's major project proposal under the EU Public Health Programme on approaches and recommendations to how involve patients as researchers or partners through their representative organisations in EU funded health-related projects.
- In the longer term patient-involvement as a core eligibility criterion for funding of future EU-funded health related projects.

Information

Active support for EPF's continued strategic and valued input, from a patient's perspective on:

- The draft report on information to patients presented by the European Commission to the European Parliament and the European Council in April 2007.
- The High Level Pharmaceutical Forum's work on information to patients.

Sustainability

Commitment to, and support for, EPF's drive towards:

- A patient-centred approach throughout the patient's entire journey as demonstrated by future joint projects and initiatives.
- Patient organisations being able to access a wide and secure EU funding base, including adequate and ongoing core institutional funding to fulfil their role in participatory democracy.

The need to move forward, to implement these actions and to measure results was emphasised by all participants.

Summary of Presentations

KEYNOTE ADDRESS

Mr Bernard Merkel, Head of Unit Health Strategy, Health and Consumer Protection Directorate General, European Commission

Main points: The conference objectives of empowerment, information and sustainability can only be achieved through partnerships involving all stakeholders, including the EU Institutions. The European Commission has launched several initiatives of direct relevance to patients, for example, the new EU Health Strategy, the Pharmaceutical Forum, Health Services and Patient Safety. The new EU Health Programme (2007 – 2013) should offer new funding opportunities for patient organisations. Patient organisations should become actively involved in these initiatives and policies at the EU level, where the patient's voice is essential.

SUMMARY OF PRESENTATION

Partnerships

The conference themes can be seen as objectives for individual patients and patient organisations. However, empowered and informed patients and sustainable patient organisations can only be achieved by partnerships between all the health stakeholders. Patients should be central, but in partnership with other organisations.

The patients' movement in Europe

The patients' movement has made considerable progress. This is evidenced by the fact that EPF is represented on many of the European Commission's policy working groups and forums, such as the High Level Pharmaceutical Forum[1].

There are several EU initiatives with high relevance to the conference themes of empowerment, information and sustainability.

A new EU Health Strategy

A first important initiative is the new EU Health Strategy. There are many actions in the area of health at EU level, but a clear and comprehensive overview is missing. A new strategic approach is needed, setting out overall objectives, priorities and milestones for a European health policy. The European Commission is therefore in the process of drafting a new EU Health Strategy that will aim to guide European health initiatives for the decade to come.

Although the exact content is still being developed, the strategy will clearly recognise patients' needs, particularly in relation to empowerment and patients' right to information about their own health. The new Health Strategy will be adopted later in 2007.

Information to patients

The current situation with respect to information to patients is unsatisfactory and unbalanced. Patients need to have access to comprehensive, up-to-date, objective and understandable information that is based on evidence. Information on medicines has to be linked to information on health.

High Level Pharmaceutical Forum

The High Level Pharmaceutical Forum is an important EU initiative to address information to patients. The Forum was established by the EU Commissioners for Enterprise and Health in 2005 to examine the competitiveness of

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[1] *For more information on EU initiatives and developments referred to in this report, please see 'Glossary', p. 24*



the European-based pharmaceutical industry and related public health issues. The Forum has three Working Groups looking at three priority areas: Information to Patients, Relative Effectiveness and Pricing and Reimbursement. EPF is represented in each of the Working Groups.

With respect to information to patients, the Forum aims to identify ways forward to improve the quality of information patients receive in Europe about medicines and related diseases. Most recently, proposals have been developed to provide a model of information on one disease area: diabetes. In addition, a document setting out quality principles has been developed to provide guidance on what criteria should be followed when creating new information. Both these documents have been submitted to a public consultation.

Health services

Another priority of the European Commission is health services. Patients have been a driving force behind healthcare developments at European level. Important judgements of the European Court of Justice applying free movement rules to healthcare were driven by individual cases brought by patients seeking health services in other Member States. Without patients and these individual cases, the current EU debate on healthcare cooperation between Member States would still not take place.

An important issue in the discussion on health services is the lack of information on patient rights and quality of treatment and care abroad. The EU Health Services initiative aims to provide patients with clear rules about access to healthcare in other Member States and the basis on which this care will be provided. The Commission is developing the health services initiative in consultation with other stakeholders, including patient organisations and individual patients.

Patient safety

Patient safety has been identified by the European Commission as a key priority for 2008. Patient organisations have an important role to play in improving patient safety, by influencing policy and decision-makers and by sharing information on medical errors and their effect on patients. At the European level, work on patient safety is taken forward through the Commission's patient safety working group of which EPF is a member. The working group has developed recommendations aiming to provide a European framework for improving patient safety in all sectors of healthcare in Member States. Empowering citizens and patients is an important area for action.

Funding for patient organisations

A new EU Health Programme should come into effect in 2008. The Programme aims to improve health security, promote health and generate and disseminate health knowledge. Compared to the previous Programme, the new EU Health Programme will contain a number of financial instruments in addition to project grants. These include for the first time the possibility to provide operational grants for the work of public health and patient organisations.

Once the new Programme will come into force, there should be opportunities for patient organisations to bid for funding for projects and for operational needs. However, if patients are to benefit from these funding opportunities, patient organisations should familiarise themselves with the Programme and its opportunities.

Input of patient organisations

Input of patients and patient organisations in EU health initiatives is essential. This will ensure that the patients' voice is reflected in the EU's health agenda. For the first time, consultation with patients and patient organisations is done in a serious and sustained way. However, this also gives patient organisations a responsibility to be well organised, efficient and representative.

THE EMPOWERED PATIENT: A BENEFIT OR A LIABILITY?

The Regulatory Perspective: What role should the EMEA perform with regard to the provision of information on medicines? - Mr Noël Wathion, The European Medicines Agency

Main points: The EMEA increasingly interacts with patient organisations and aims to empower patients and to promote partnerships between patients and healthcare professionals. This is done amongst others by providing information better adapted to the patients' needs. In order to improve the quality of information provided by the EMEA, patients are directly involved in the provision of information. For the achievement of its objectives, the Agency relies to a large extent on a network of excellence including all EU Regulatory Authorities.

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Interaction with patient organisations

With respect to interaction with patient organisations, the Agency aims to empower patients and to promote a true partnership between patients and healthcare professionals. This is done by:

- Providing information better adapted to the patients' needs.
- Developing appropriate communication tools.
- Increasing the awareness of patients in relation to the use of medicines.
- Promoting a rational use of medicines.

The achievement of these objectives will rely mainly on a network of excellence between all EU Regulatory Authorities and a network of patients and consumers. The Agency will focus primarily on patients' participation in its activities and the provision of information to patients.

Provision of information

Since its establishment, the EMEA has taken initiatives to increase transparency of operation. In addition, the Agency has improved the information provided to its stakeholders, patients in particular. Improved information is available on the EMEA website (www.emea.europa.eu), including European Public Assessment Reports (EPAR) in understandable language, information on products prior to marketing authorisation and patient friendly information on safety issues. In addition, EudraPharm (www.eudrapharm.eu) is a database which, once fully populated, will contain information on all medicines authorised in the EU, information on treatment of children and on clinical trials.

Involvement of patients

In order to improve the quality of the information provided by the EMEA, patients are involved in the provision of information, amongst others through review of the EPAR summaries and review of the package leaflet at the time of renewal of the marketing authorisation. The involvement of patients in reviewing product information will start in April 2007.

The patients involved are experts designated by patient and consumer organisations fulfilling the criteria for involvement in EMEA activities. Among the key criteria are legitimacy, representation, accountability and transparency.

Information to patients as a priority

Several high-level initiatives, such as the High Level Pharmaceutical Forum, have been taken at EU level to address information to patients and patient safety. These initiatives underline that information constitutes a priority at EU level.

Within the EU Regulatory System networking model, the EMEA will continue to develop and strengthen its interaction with patients and consumers to better inform patients and the general public and to promote a better use of medicines.

The Physician's Perspective: Should the healthcare professional be the gatekeeper of all information? – Dr Daniel Mart, President of the Standing Committee of European Doctors (CPME)

Main points: There is a strong development towards a patient centred vision. This development is supported by physicians. In addition, there is an information revolution that raises challenges with respect to the amount and quality of information. It is impossible for healthcare professionals to be the gatekeeper of all information. However, guidance is needed to distinguish information from advertising and to apply information appropriately. In a changing environment with changing roles, the patient-physician relationship remains essential and cannot be replaced by virtual consultations.

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A patient centred vision

There is an increasing focus on patient rights, patient safety, patient autonomy and patient information. This societal evolution is pushed by politicians and the general public and is supported by physicians.

Information revolution

Information has always existed. The real revolution is the amount of information, search engines, the price of information, access, availability and ubiquity. Information needs to be targeted and purpose related as patients have different education levels, language skills, needs and expectations. This involves a shift from the healthcare professional to the patient. It is also important to clarify whether information should address patients or citizens. Needs, lifestyle and educational issues are again different for citizens.

Information or advertising

In order to distinguish between advertising and information, it is essential to address some fundamental questions: who provides the information? For what purpose? Who validates the information? Who decides about priorities?

The creation of 'hypes' around certain diseases should be avoided and all disease and therapy areas should be equally covered by appropriate information and treatment guidelines.

Changing patient-physician relationship

The patient-physician relationship is changing but remains essential. There continues to be a strong need of a real-time and person to person consultation. The interaction between a patient and his/her physician is complex and involves much more than information exchanges. This complexity can never be obtained by virtual exchanges.

Role of the physician in a challenging environment

A resulting challenge of the empowered and informed patient is that the patient-physician consultation has become more time-consuming, as more explaining and feedback is necessary. However, this raises different issues, such as finances, defensive medicine and diagnostics.

Physicians cannot be eliminated in a cost cutting move to streamline the healthcare sector. The role of the physician remains important and needs to be adapted to the patient's new profile.

A new role and rights for patients

Patients have a new role including specific rights, such as a right to ask for person to person contact, a right to self-determination and a right to confidentiality. However, citizens seem to be suffering from information overload and may inverse diagnostic logic. Information alone does not automatically mean 'knowledge'. Guidance is needed to apply the information appropriately. The key question remains: who is the gatekeeper of all information?

The Economic Perspective: Is there a financial case to be made for an informed patient? – Mr David McDaid, London School of Economics

Main points: Enhanced information and choice can lead to quality of life and economic benefits. However, enhanced access to information alone is not sufficient, multiple interventions are needed. In addition, it is important to think about minimising negative consequences such as inappropriate demand. Unfortunately the evidence base on the economic value of empowerment and access to information is still limited. More research and evaluation is needed.

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Empowerment and economics

The economic impact of poor health is far-reaching. Costs go beyond direct healthcare costs and relate to areas such as employment, carers and social exclusion. Empowerment of patients can play an important role in limiting these costs. Empowerment however has many dimensions, such as enhanced access to and use of health related information, greater say over choice of treatments, greater financial control over healthcare budgets and increased involvement in determining (cost-) effectiveness of interventions.

Enhanced information and choice

Enhanced information and choice can lead to significant quality of life and economic benefits and can help to encourage the use of interventions that best meet patient needs. In addition, better information and choice can improve concordance with treatment leading to better long term outcomes. Other positive effects are a reduced chance of harmful events and reduced waste from unused medications and interventions.

However, enhanced information needs to be linked to a capacity to assess the information (health literacy). In addition, it is important to determine who funds the information and to make a distinction between information and advertising and between 'good' and 'bad' information.

Cost effectiveness of ‘decision-aids’

Certain ‘decision aids’ guiding the information and choice process, such as leaflets, DVDs, decision boards, websites and phone support, could be used. However, there is only limited evidence showing cost effectiveness in using these aids. Some studies indicate cost effectiveness, whereas others indicate that for example information provided before a first consultation has no impact on costs or outcomes.

Concordance

Concordance, i.e. involving the patient in the treatment process to improve compliance, has health and economic consequences. In some cases, treatment may need to be adapted in order to fit better with a patient’s individual lifestyle. As a consequence, there may be costs of additional treatment and/or diagnosis. However, these may be offset by under-use of some other treatments. Unfortunately and surprisingly, the evidence on (cost-) effectiveness of interventions to improve concordance is limited.

Reforms to financing and empowerment

Reforms to financing can promote patient empowerment. Models of consumer directed healthcare in which patients receive individual budgets to buy services that best meet their needs, promote independence and inclusion and offers opportunities for education, leisure and employment. However, consumers may need support to make choices.

There are some experiments with budgets across Europe for a range of client groups, such as older people and people with disabilities. The general satisfaction levels are good, but there is little known about long term outcomes and costs.

Equal allocation of resources?

Important questions such as inappropriate demand for some interventions and only limited focus on and access to some other interventions, need to be addressed. Some groups are more vocal than others and some issues are more ‘attractive’ than others. Media stories play an important role in this respect, often focusing on ‘popular’ health issues. These issues may lead to an inefficient and inequitable allocation of resources.

Role of patient organisations

The role of the doctor and pharmacist remains vital. However, patient organisations also have an important role to play by focusing on the following actions:

- Providing information on how to make best use of existing healthcare treatments.
- Helping to increase the understanding of risks and benefits of alternative drug and non-drug treatment options.
- Looking at impacts and consequences beyond healthcare systems.
- Making careful use of evidence when presenting a case.

For all actions, there should be awareness that decisions are not made in a vacuum: all decisions have consequences for the rest of the health service.

Limited evidence base

There is a substantial information deficit. The evidence base on the economic value of empowerment and access to information is limited. There is a strong need for careful controlled prospective and long term monitoring of different interventions. This should include an analysis of resource use and consequences both within and outside the health sector.

The Politician's Perspective: Can information be controlled by legislation nationally or internationally? – Ms Dagmar Roth-Behrendt MEP

Main points: Patients and citizens have a right to information. This should be the central point in the EU debate on information to patients. There should be democracy in relation to information with equal access to information provided in different settings. The quality of information should be ensured. Different stakeholders have a role to play in providing information. There should be no monopoly.

SUMMARY OF PRESENTATION

Unequal access

There are many differences in healthcare across Europe. EU citizens currently do not have equal access to information and care which is an unacceptable situation: there should be a minimum healthcare standard in the EU. Differences can be overcome by including healthcare in the EU Treaty. However, this has been difficult to achieve until now.

Patients' right to information

Patients have a right to information and informed patients are a benefit to society. These should be the central points in the EU debate on information to patients. Other issues are less important. Information should be consistent with the Patient Information Leaflet, but should be much more. Information should be comprehensive and include a full range of patient information, such as information on diseases, treatment options and quality of doctors.

Need to ensure quality

'Neutrality' and 'objectivity' are difficult criteria, as there will always be interests involved in information provision. However, the quality of information should be ensured. A key question is: who will be responsible for controlling the quality of the information provided? Should and can the EMEA play a role, i.e. will the Agency have the resources to check all information?

A democracy of information

Healthcare professionals play an important role, but are not the only providers of information. Other stakeholders such as patient organisations and the industry play a role as well. Currently, information is not available for all. There should be a democracy of information with equal access to information provided in different settings. There should be no monopoly.

The Commission's Perspective: By whom and to whom should information be provided? – Mr Martin Terberger, Head of Unit Pharmaceuticals, Enterprise and Industry Directorate General, European Commission

Main points: A new EU framework for information to patients is needed. However, before this new framework is established, key questions such as who controls the information and who enforces a governance system need to be addressed. As an important next step, the European Commission will present a report on current information practices and proposals for a new information strategy to the European Parliament and Council by April 2007.

SUMMARY OF PRESENTATION

Unequal access

EU citizens currently have unequal access to information. The access and information depend on a number of factors, such as geographical location, technical skills, income and age. The lack of a proper EU framework, including quality standards, hampers patients' and consumers' right to equal access to quality information.

Need for a new EU framework

The current EU regulatory framework for information to patients is no longer satisfactory. A new EU framework for information to patients is needed. However, before this new framework is established, some key questions need to be addressed, such as who controls the information and when and who enforces any governance system. These difficult political choices have not yet been made. It is clear however that any future framework will not allow for advertising of medicinal products.

A Commission report and proposals

As an important next step, the European Commission has a legal obligation to present a report on current information practices followed by proposals setting out a future information strategy, to the European Parliament and Council by April 2007.

Differences across Europe

The European Commission has conducted a survey on experiences and practices with respect to the current legislative provisions on information to patients (Directive 2001 / 83) in the Member States. The survey shows that there are significant initiatives, including public private partnerships, to provide health information to all stakeholders across Europe. The type of information and the context however differs per Member State. EU legislation provides for a number of information mechanisms, but in general approaches and application are different for each Member State.

Former EU initiatives and achievements

The European Commission's "High Level Group on Innovation and the Provision of Medicines" (the so-called "G10 Medicines" initiative involving a range of stakeholders including Member States, industry and patients) put forward recommendations addressing a wide range of issues in 2002. Responding to these recommendations, the Commission created the High Level Pharmaceutical Forum in 2005. Information to patients is one of the Forum's priorities, together with relative effectiveness and pricing and reimbursement.

In addition, a number of provisions were included in the "New Medicines Legislation" to improve direct product related information such as readability of packages and transparency. More far reaching measures were not included in the new legislation, because of lack of a proper framework and a clear distinction between information and advertising.

Benefits of an informed patient

The role of the doctor and his or her relationship of trust with the patient should not be undermined. However, the role of patients and consumers has changed as they seek information proactively and have more own responsibility. This is a positive development as an informed patient can lead to rational use and improved health outcomes. However, an important question is whether more patient information will lead to an increase in healthcare costs. This is a concern of some.

No one clear answer, but harmonisation one option?

European Commissioner for Enterprise and Industry, Günther Verheugen has stated that patients and consumers have a legitimate right to information and that the current legal framework is not fully appropriate anymore. Industry would be a potential source of information. There is no one clear answer on how to improve patients' access to information, but harmonisation is one objective. The Commission has a legal base to regulate what information industry can provide.

The Patients' Perspective –
Ms Susanna Palkonen, Board Member European Patients' Forum

Main points: Patient empowerment is an essential precondition to improve quality of care, health outcomes and quality of life. It is an ongoing process, involving all stakeholders. Empowerment includes different aspects, at different levels: individual and organisational. From an organisational perspective, meaningful patient representation in healthcare decision-making and planning at the very onset is an essential element of empowerment.

SUMMARY OF PRESENTATION

Empowerment

Empowerment is key and is an ongoing process involving all stakeholders, helping people to gain control over their lives and act on issues they define as important. Patient empowerment is an essential precondition to improve quality of healthcare, health outcomes and quality of life, particularly with respect to chronically ill patients. Empowerment activities include participation (design, management, evaluation of livelihood activities and policies), individual and organisational capacity building and economic improvement and increased access to resources.

Individual level

Empowerment at an individual level includes:

- Access to early diagnosis.
- Access to comprehensive and reliable information.
- Freedom of choice.
- Access to quality, safe, evidence based care and flexible health services.
- True and meaningful partnerships with healthcare professionals.

- Access to written personal self-management and emergency plans.
- Continuity of care, regular review and follow-up.
- Access to patient education and peer support.
- Empowerment of carers and family, through education and peer support.

Organisational level

Empowerment at an organisational level includes:

- Capacity building leading to representative, inclusive, effective and sustainable patient organisations, operating in transparency and with accountability.
- Equal access to information on health policy developments.
- Meaningful patients' representation in healthcare decision-making and planning.
- Patient organisations as catalysts for multidisciplinary collaboration.

Outcomes of empowerment

Among the main outcomes of empowerment are increased ability of patients to manage their disease, overall healthier behaviours, enhanced self-education and improved mental health. Empowerment should also lead to better access to health services, more efficient use of health services and enhanced satisfaction with service providers.

Empowerment of carers

Empowerment of carers should not be forgotten. For carers, empowerment means increased efficacy and coping skills, reduced anxiety and depression, leading to an overall better quality of life.

Therefore, patient empowerment should be seen as an opportunity, not a threat as the beneficiaries are not only the patients, but the whole healthcare system.

HOW DO WE MANAGE THE FUTURE?

How can we ensure sustainability of patient organisations and who will be funding them in 2017? What part will corporate social responsibility play? – Mr Richard Bergström, Director of the Swedish Association of the Pharmaceutical Industry

Main points: Patient information, motivation and support are important to improve effective use of knowledge and medicinal products. The industry can play a positive role in providing information. The Swedish self-regulatory model has proven beneficial and satisfactory to all stakeholders involved. In order to remain credible and independent, patient organisations should not rely on one single source of funding, but should use funding from multiple sources, in full transparency.

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Effective use of knowledge and products

There are many challenges in moving from research to products to the benefit of the patient. Many products do not actually reach the patients. Looking at diabetes for example: the products and knowledge are there, but are not used properly. In the US, only 5% of people with diabetes receive and use appropriate care. This situation could be improved through patient information, motivation and support.

Industry and patient information

‘Consumer pressure’ is needed to move towards high performing health systems. Patients need to be informed, so that they can make informed choices. The industry can play a positive role in providing information to patients. ‘Fass.se’ is a website created by the Swedish Association of the Pharmaceutical Industry and contains information on all medicinal products on the market, diseases, research, environmental classifications and educational programmes. The website has more than 4 million visits per month. In addition, a quality seal is used in Sweden for company websites. Additional support for patients is provided through leaflets, compliance programmes and disease awareness websites.

The Swedish self-regulation model

An evaluation by the Swedish authorities in November 2006 has shown that the Swedish self-regulation model, in conjunction with regulation, adds value. Self-regulation can go further than legislation and can provide for additional sanctions. It can also include preventive measures and pre-vetting. Many countries have positive experiences with self-regulatory systems. Most often, the problem does not relate to overseeing the systems and the sanctions, but to the ethical rules not going far enough.

Relationship between industry and patient organisations

Patient organisations are increasingly important as advocates for patients. It is essential that patient organisations remain independent and credible. Patient organisations should not be funded only by industry or only by government, but should receive funding from multiple sources. As a result, Swedish industry only sponsors projects of common interests, rather than providing unconditional grants. This should be done in full transparency. Some companies have taken a leading role in providing full transparency on their relations with patient organisations. Other companies are expected to follow soon.

2017? Enabling choices for health in modern societies – Prof Dr Ilona Kickbusch

Main points: Patients increasingly act as active healthcare consumers seeking increased value of care. Investing in health literacy will help putting patients and citizens in the centre. Health literacy is a key dimension of a citizen’s right to health and has major consequences for society and healthcare systems. As a critical empowerment strategy in modern society, health literacy must become a priority in the health policy action arena.

Dimensions of a ‘health society’

A ‘health society’ includes different dimensions, such as a high life expectancy and ageing populations, an expansive health and medical care system and a rapidly growing private health market. In addition, health is a dominant theme in social and political discourse and is a right of citizenship

Forces of change

We are living in a changing environment. Driving forces of change include medical and technological progress and demographic change. Health behaviours and an evolving understanding of health, together with social trends, economic orientation and political factors also stimulate change.

These changes lead to an increasing relevance of the health market, market-driven innovation and a shift in orientation towards cost and added value. Most importantly, the patient moves to the centre.

Unsustainable health developments

Four unsustainable health developments can be identified:

1) An ageing society without health gains, leading to a breakdown of systems and solidarities.
2) The generation of children born at the turn of the 21st century could be the first to have a lower health and life expectancy than their parents.
3) Our health systems are not sustainable without major reorientation: high cost, low quality, unequal access.
4) Global infectious disease pandemic.

Health and economics

Ensuring good health is good economics as a healthy population stimulates economic growth and social productivity. In order to create health, resources need to be based on a new orientation: value for patients. There should be clear criteria and mandatory measurement of results and transparency for patients.

Health literacy

Health literacy plays an important role in addressing inequality and promoting patient-centred care. Health literacy is the capacity to make sound health decisions in the context of everyday life, at home, in the community, at the work place, in the healthcare system, the market place and the political arena.

Patients as active healthcare consumers

Patients increasingly act as active healthcare consumers seeking increased value of care. This important development includes three key conditions. Firstly, patients should have the competencies to navigate the health system and act as a partner to professionals. As a second and third condition, healthcare providers should be supportive and systems should be readable.

In addition, patients can and should:

- Actively participate in increasing choices in products and treatments, end of life care.
- Expect relevant information and seek advice.
- Make treatment and provider choices based on results.
- Choose health plans based on added value.
- Demand new professional roles.
- Demand a more health promoting health service.

Health literacy as a priority in health policy

Investing in health literacy will help putting patients and citizens in the centre. Health literacy is a key dimension of a citizen's right to health and has major consequences for society and healthcare systems. In addition, health literacy is of high relevance for equity, quality and efficiency of health systems. As a critical empowerment strategy in modern society, health literacy must become a priority in the health policy action arena.

Summary of Breakout Sessions

The breakout sessions aimed to address three questions related to the conference themes: Who really presents patients? (1); Is ignorance bliss or is an informed patient a sound economic investment? (2); Are patient organisations viable and sustainable? If so, by whom? (3). This is a summary of the main points discussed, including recommendations for further action identified in some of the sessions.

BREAKOUT GROUP 1: WHO REALLY REPRESENTS PATIENTS?

Facilitator: Ms Mel Read, President European Cervical Cancer Association, Honorary Chair Health First Europe
Rapporteur: Mr Mike O'Donnovan, Treasurer European Patients' Forum

KEY POINTS

Representation

Membership should not be the only criteria to determine whether a patient organisation is representative. More important factors include actual contact with a wide group of patients, a large number of patients accessing the patient organisation's services and democratic and consultative processes.

Who validates information provided by patient organisations?

Medical and treatment information should be checked and validated by experts. Information on patient experience should be validated by those who receive the information. However, it is impossible to control all information accessed by patients. "Best efforts" can be made to ensure quality sources. Patient organisations can in some cases offer "advice" rather than "information".

Solidarity

Solidarity across the European patients' movement is essential and needs to be increased. An essential condition is that individual organisations should be able to lobby on issues specific to their condition. On the other hand, organisations should be willing to identify issues common to several conditions and allow a single organisation such as EPF to lead. Finally, organisations should understand large generic issues where an umbrella organisation can be most effective.

Can other organisations represent patients?

Consumer organisations have been involved with health issues for many years and play a valuable role, particularly in relation to prevention and health promotion for citizens across the European Union. However, patient organisations are the best representatives of patient interests, as they can advance the interests of patients presenting a uniquely patients' perspective, based on the patients' own experience and expertise in disease management.

BREAKOUT GROUP 2: IS IGNORANCE BLISS OR IS AN INFORMED PATIENT A SOUND ECONOMIC INVESTMENT?

Facilitator: Mr Jorgo Chatzimarkakis MEP
Rapporteur: Mr Jean Georges, Board Member European Patients' Forum

KEY POINTS

A right to quality information

In the current European regulatory environment, the main existing sources of information on medicines are the Product Information Leaflet (PIL) and the European Public Assessment Report (EPAR) both of which are difficult to understand and fall short of delivering the range of information that patients and citizens desire. This situation needs to change: patients have the right to quality information. Additional information can have a positive impact on general health awareness and prevention.

Governance system

A key question is how to recognise reliable and valid information. A problem is that there currently is no 'quality seal' for information, no liability and no validation. A European governance system is needed, where public-private partnerships could play an important role.

The cost-impact of information

Expenditure is an important barrier in the European debate on information to patients, as Member States and health insurers fear that more information will lead to increased costs. However, better information and better access to treatment does not automatically lead to increased drug consumption and costs. Cost effectiveness should not be limited to healthcare costs, but should also include 'societal costs', such as costs of carers and unemployment costs.

EU developments

The European Commission has a mandate (article 88a of Directive 2001/83 EC) to present a report on current practices with regard to information provision and (if appropriate) to put forward proposals setting out an information strategy to ensure good quality, objective reliable and non-promotional information on medicinal products and other treatments. The Commission's report is expected to be presented to the European Parliament in April 2007, followed possibly by a legislative proposal, and impact assessment in 2008. Potential complicating factors for the debate will be the European elections in June 2009 and the appointment of a new European Commission in November 2009.

The current situation

The quality of package information leaflets remains poor and difficult to access and understand for many patients. Information should be improved, particularly for visually impaired patients, for example through audio-tapes, CDs and use of Braille. In addition, there still is a poor understanding of safety data. Information on risks and side effects needs to be improved.

Nationalise information to patients debate

The discussion on information to patients does not attract the same attention at national level as at EU level. Whereas the EU debate raises many serious issues related to national healthcare systems, these issues are not reported by the national media. Given the important role of the Member States and national authorities in improving the current situation with respect to information to patients, the debate urgently needs to be stimulated at national level.

Consensus recommendations

The following consensus recommendations resulted from the session:

- No direct to patient advertising.
- Information should be easily accessible for all EU citizens, in all EU languages in different forms.
- Information should include a comparison of existing treatments and alternative therapies, including lifestyle changes. Clinical trials should be considered as well.
- Information provision should be based on a strong collaboration, including patient organisations.
- Patients actively seeking information should be able to access information provided by the pharmaceutical industry.
- A future EU Directive should include clear quality criteria for information provided by the industry.
- An efficient system should be in place for penalising offending companies.
- The EU information to patients debate needs to be nationalised.

BREAKOUT GROUP 3: ARE PATIENT ORGANISATIONS VIABLE AND SUSTAINABLE? IF SO, BY WHOM?

Facilitator: Ms Celine van Doosselaere / Ms Jeni Bremner,
European Health Management Association
Rapporteur: Mr Rodney Elgie, GAMIAN Europe

Scope of the session

Key questions raised during the session were: how to fund EU organisations and how to ensure that small disease areas are appropriately represented? How do patient organisations become sustainable?

Out of the 26 patient organisations participating in the breakout session, only one organisation had a professional fundraiser and only one organisation had a fundraising committee. In general, organisations felt that funding is essential for their (long term) existence, but that a meaningful fundraising strategy is missing.

Critical success factors in fundraising

- Patient organisations should collaborate and not compete. There is a danger of creating bad press through ‘wastage of funds’.
- Duplication should be avoided. The organisation’s position has to be unique.
- The organisation needs to be seen as reliable to its members and to the outside world.
- Transparency and variation in funding are essential.
- Patient organisations need to be professional, in order to maintain credibility.

Sustainability

In general, it is feasible to obtain ‘start-up money’, but it is more difficult to obtain long term funding in order to make the organisation sustainable. Also, funding at national level for national organisations seems more easily accessible than EU funding for pan-European organisations. EPF can play an important role in providing guidelines for fundraising and principles of funding.

Profile raising

In order to be more successful in fundraising and obtain funding from different and new sources, the profile of patient organisations and the value they bring to society should be raised amongst others through the media.

Ideas for new, alternative sources of funding

- Offer tax relief linked to funding of patient organisations across all EU Member States.
- Use links with and to universities.
- Think about different actors, such as employers.
- Use individuality of patient organisations as these will appeal to different people.
- Work with healthcare professionals’ / specialists’ organisations.
- Be active in research.
- Quantify the value of volunteers: what are the costs of not offering voluntary services to the community?

Recommendations

The following recommendations resulted from the session:

- Organise a workshop involving a variety of stakeholders and potential funders from different sectors.
- Create an overarching European foundation with an independent board of trustees.
- Create an EPF platform for the development of an extensive media campaign incorporating the views of stakeholders and demonstrating the role and added value of patient organisations in Europe.

Glossary

High Level Pharmaceutical Forum:
The Pharmaceutical Forum was established by the European Commission in 2005 as a high-level platform for discussion. The aim of the Forum is to improve the performance of the pharmaceutical industry in terms of its competitiveness and contribution to social and public health objectives. The Forum brings together Ministers from all European Member States, representatives of the European Parliament, the pharmaceutical industry, healthcare professionals, patients and insurance funds. The Forum is supported by a Steering Committee and three expert Working Groups focusing on three priority issues: information to patients, pricing policies and relative effectiveness assessments.

▶ http://ec.europa.eu/enterprise/phabiocom/comp_pf_en.htm

The Forum launched a public consultation on health-related information to patients in March 2007. The consultation focused on a diabetes information package and a set of principles on good quality information.

▶ http://ec.europa.eu/health/ph_overview/other_policies/pharmaceutical/pharma_consultation_en.htm

EU Health Strategy:
The European Commission is currently developing a new Health Strategy which it aims to adopt in 2007. Building on current work, this Strategy aims to provide, for the first time, an overarching strategic framework spanning core issues in health as well as health in all policies and global health issues. The Strategy aims to set clear objectives to guide future work on health at the European level, and to put in place implementation mechanisms to achieve those objectives, working in partnership with Member States.

▶ http://ec.europa.eu/health/ph_overview/strategy/health_strategy_en.htm

EU Health Services initiative:
Health systems and health policies across the EU are becoming increasingly interconnected. This is due to many factors, including movement of patients and professionals, common public expectations across Europe, dissemination of new medical technologies and techniques through information technology, and the forthcoming enlargement of the Union. This increased interconnection raises many health policy issues. The Commission therefore undertook in its 2007 Annual Policy Strategy to develop a Community framework for safe, high quality and efficient health services, by reinforcing cooperation between Member States and providing certainty over the application of Community law to health services and healthcare. The Commission launched a consultation regarding Community action on healthcare services in September 2006.

▶ http://ec.europa.eu/health/ph_overview/co_operation/mobility/patient_mobility_en.htm

EU Public Health Programme:
a new Programme for “Community Action in the field of Health” will come into effect in 2008 and will set the framework for the Commission's funding of projects relating to health between 2007-2013. The Programme will be part of a strategy bringing together the broad range of Community health action to define goals and priorities to help improve the health of European citizens. The Programme has three broad objectives: improve citizens' health security; promote health for prosperity and solidarity; generate and disseminate health knowledge.

▶ http://ec.europa.eu/health/ph_overview/pgm2007_2013_en.htm

European Medicines Agency (EMEA):

The EMEA is a decentralised body of the European Union with its headquarters in London. Its main responsibility is the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use. The EMEA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (more commonly known as the Patients' and Consumers' Working Party, or PCWP) was established to provide recommendations to the EMEA and its human scientific committees on all matters of interest to patients in relation to medicinal products. The PCWP is composed of representatives of patient and consumer organisations that fulfil certain eligibility criteria.

- www.emea.europa.eu/htms/general/contacts/CHMP/CHMP_PCWP.html

European Commission report on current information practices:

According to Directive Directive 2001/83/EC, article 88, the European Commission has an obligation to present a report to the European Parliament and the Council in 2007 on “current practice with regard to information provision – particularly on the Internet – and its risks and benefits for patients”. The same article also provides 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 and shall address the question of the information source's liability”. The European Commission launched a consultation on a draft report on current information practices in April 2007.

- http://ec.europa.eu/enterprise/pharmaceuticals/index_en.htm

G10 Medicines:

Refers to a ‘High Level Group on Innovation and the Provision of Medicines’ establishes by the European Commission in order to “take a fresh look at the problems facing the pharmaceutical sector and to come up with creative solutions”. The G10 group included Ministers for health and industry of some Member States, the industry, insurers and a patient representative. In July 2003, the European Commission put forward proposals for action based on recommendations developed by the G10 group. The recommendations and follow up actions cover a wide range of issues, e.g. relative effectiveness, pricing and information to patients. The High Level Pharmaceutical Forum was created as a response to the G10 recommendations.

- http://ec.europa.eu/enterprise/phabiocom/g10home.htm

New Medicines Legislation:

An EU Regulation (on the authorisation and supervision of medicinal products for human and veterinary products and the establishment of a European Medicines Agency) and a EU Directive (on a Community Code for medicinal products for human use) were adopted in March 2004. These pieces of EU legislation cover a wide range of issues in relation to medicinal products, e.g.: market authorisation, quality and safety, patient information.

- http://ec.europa.eu/enterprise/pharmaceuticals/review/index.htm

About the European Patients' Forum

The European Patients' Forum:

- Was set up in 2003 to become the collective patients' voice at EU level, manifesting the solidarity, power and unity of an emerging EU patients' movement.
- Reflects the patients' unique and direct experience and expertise in healthcare through member organisations' links with representative national, regional and local patient organisations in all 27 EU Member States.
- Adopts a holistic interpretation of healthcare, to include prevention, and the social, economic, environmental, cultural and psychological aspects of health.
- Acts as both a catalyst for positive change in EU healthcare systems and a watchdog (proactive and reactive).
- Is a credible and professional partner for cooperation, dialogue and negotiation with a broad range of EU level health stakeholders.
- 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 organisations at European level and at Member State level.
- Offers a resource for member organisations on EU healthcare intelligence, information dissemination, baseline patient-rights policy responses to the EU Institutions to enable them to focus on disease specific responses.
- Is open to European patients' organisations and national umbrella organisations that fulfil criteria relating to legitimacy, representation, democracy, accountability and transparency. EPF has currently 23 member organisations.

For more information on the European Patients' Forum: www.eu-patient.eu

About the presentations

The conference programme, presentations and conference report are posted on the EPF website: www.eu-patient.eu

About sponsorship

The Conference and the report were made possible thanks to unrestricted grants from GSK and Pfizer Public Affairs Europe

www.eu-patient.eu