Conference Report

Pharmaceutical Forum Delivering for Patients

How to move from agreed principles to good practice and positive change across Europe

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Directorate-General for
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More information on the Pharmaceutical Forum and all the related documents are available on the internet: http://ec.europa.eu/pharmaforum/.

Pharmaceutical Forum – Delivering for Patients

“How to move from agreed principles to good practice and positive change across Europe”

Conference co-organised by the European Commission and the European Patients’ Forum

Brussels
25 March 2009

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Introduction

This Conference was co-organised by the Commission and the European Patients' Forum in order to facilitate the dissemination of the outcomes of the Pharmaceutical Forum initiative among European and national patients groups and the Health Community at large.

The Pharmaceutical Forum was set up for a 3 year period in 2005 with the objective of finding relevant solutions to public health considerations, while ensuring improvement of the performance of the pharmaceutical industry in terms of competitiveness and contribution to social and public health objectives. The final conclusions and recommendations of the Forum as well as all the information relating to the process are available at http://ec.europa.eu/pharmaforum/.

The conference provided patients' leaders and health stakeholders throughout the European Union an opportunity to share the knowledge gathered by the members of the Forum on information to patients, pricing and reimbursement and relative effectiveness, to explore the solutions proposed and to put forward proposals for actions to implement and follow up the recommendations in their respective organisations and constituencies.

In addition, concrete experiences were presented to illustrate how the Forum's conclusions and recommendations can be translated into reality by all health stakeholders and to ensure the momentum and energy underpinning the Pharmaceutical Forum can be maintained at all levels.

Summary of the discussions

WELCOME SPEECH

Karin Johansson, State Secretary to the Minister of Health and Social Affairs, Sweden

Key points:

- Sweden believes in the fundamental right of health care and thus aims to provide good access to health services for all.
- Two key achievements of the Forum were the work process in itself and the success in bringing together so many different stakeholders whose participation was highly appreciated.
- Patients' access to medicines and quality information about diseases and treatment options is key; the focus has to be on the needs and interests of patients; the pharmaceutical industry is a natural stakeholder in this dialogue.
- Handling increasing demands from an ageing society is a challenge; part of the solution is cooperation between all the players involved.
- The Forum showed that there is a real added value for cooperation at EU level that could lead to better access to medicines for patients.
- Some countries are further advanced than others in terms of investing in research.
- Conclusions drawn from the Forum by the Troika (France, Czech Republic, Sweden EU presidencies) were that research on anti-microbial resistance has to be a priority and that incentives for the development of new medicines have to be created. We count on the Member States' support for this work.
- An expert conference, "Assessing Drug Effectiveness – Common Opportunities and Challenges for Europe", will be held in Stockholm on 29 July 2009 during the Swedish EU-Presidency. The purpose of the conference is to find ways of cooperating systematically across Europe to assess drug effectiveness, i.e. how well the drug treatment works in everyday clinical use.

MORNING SESSION: SHARING THE OUTCOMES OF THE PHARMACEUTICAL FORUM

Patients' Empowerment, Equity of Access, Fostering Innovation, Cost Containment, Maintaining and Improving Healthcare Systems – Really a Bermuda Triangle?

Georgette Lalis, DG Enterprise and Industry, European Commission

Key points:

- The outcomes of the Pharmaceutical Forum are the result of a 3 years process involving key actors from the health sector and all the Member States, with experts working in three Working Groups: Information to Patients, Pricing and Reimbursement and Relative Effectiveness; the overall goal was to ensure patients' access to medicines based on sustainable health care budgets.
- This exercise has been a major achievement at the European level. The three-year process has strengthened the understanding of the positions and concerns of all parties.
- The Forum has also demonstrated the added value of working together in a consensus-based manner, leading to the adoption of strategic recommendations and priorities for future joint work. We reached a level of trust among the partners, built on mutual understanding among the interested parties and often on common diagnosis for the core issues.
- The Forum created a political momentum in the three themes that we want to anchor for the future. Indeed, it resulted in the development of and agreement on EU principles, methods of implementation and desired outcomes in the areas of information to patients, pricing and reimbursement and relative effectiveness, creating thereafter a common framework of reference and action.
- The dissemination of the final conclusions and recommendations of the Pharmaceutical Forum is crucial, as well as exploring how to apply the outcomes in a tangible way.
- The Conference was organised together with EPF with the aim to involve patients as drivers for change in their constituencies.
- There is a need to maintain the issues addressed in the Forum high on the political agenda; future success will rely on the dynamism of networks and implementation of actions inspired by the Forum's process and deliverables.

The outcomes of the three Working Groups were presented.

I. Information to Patients

Presentation of the outcomes by Ivana Silva (PGEU) as a member of the Information to Patients Working Group

Key points:

- We are confronted with the urgent challenge to invest in high quality and accessible information on diseases and treatment options. We need to mobilise knowledge and resources of all parties involved while recognizing that health professionals and competent authorities are the primary sources of information to patients. The group strongly agreed that the ban on Direct to Consumer Advertising of medicinal products should remain.
- Our reflection on information included aspects related to sources, quality, dissemination and sustainability of information in order to respond to the following questions: What should be the core issues patients need to be informed about? Who produces the information? Who validates it? How can we ensure dissemination of information through electronic and non-electronic means? How can we improve the availability of and the access to information in specific healthcare settings?
- Recommendation 1: The quality of information should be enhanced by using the core quality principles developed in the Forum and their methodology, the identification of key elements for the provision of comprehensive information to patients on medical conditions and treatment options and the DARTS-principles to identify good quality websites.
- Recommendation 2: The accessibility and dissemination of information should be increased through effective communication taking account of local traditions and culture, healthcare systems and languages, through identification of best practices, cooperation among Member States and further development of the EMEA database.
- Recommendation 3: Information can be generated through the involvement of all actors concerned (taking into account ethical requirements), through raising the visibility of existing partnerships and increasing cooperation.
- Recommendation 4: The momentum on information to patients has to be continued with further cooperation and actions to be taken forward by all interested parties and a first review to be carried out by the Commission in two years.

Panel debate on Information to Patients

Susanna Palkonen, European Patients' Forum (EPF)

Key points:

- Ø EPF support the concrete tools and outcomes of the High Level Pharmaceutical Forum working group on information to patients, and was delighted to play an active part together with other stakeholders
- Ø The focus from now and always should be on information as a means to empower patients and build their knowledge; we need to have a patient-centred approach, despite any other interest.
- Ø We should work with all actors that have the expertise and follow the rules, without prejudice.
- Ø EPF has already started to apply the tools produced by the Forum and invites other stakeholders to make use of them as well.
- Ø The discussions in the working group very quickly moved towards the need for a comprehensive European Strategy on Information to Patients that also embraces health literacy, that is needed to empower patients everywhere in the EU. We now need now build on the momentum and move forward.
- Ø One concrete example of information as means of empowerment and need for comprehensive strategies is a patient with severe chronic obstructive pulmonary disease (COPD), who can be so breathless that even small daily tasks such as brushing teeth is very energy consuming. For him/her, practical tips such reserving enough time in mornings for routines to be able to follow own pace and just sitting down while brushing teeth to save energy is empowering patient information and can make huge difference. Not all patients should have to learn by own experience only

Jeremy Mean, Medicines and Healthcare Products Regulatory Agency (MHRA), UK

Key points:

- Ø The UK strongly supports the outcomes of the Pharmaceutical Forum. We firmly reject Direct to Consumer Advertising but welcome the idea of a framework providing quality information on health.
- Ø We see information as a means to an end and not an end in itself – people want and should be empowered by this information. Member States should integrate the quality principles elaborated by the Forum in their information provision strategies.
- Ø Nobody should per se be excluded from providing information – it is the quality of information that is decisive.
- Ø There should be a range of 'information to patient' options to patients – one size does not fit all.

- Ø The UK has started to integrate the quality principles into an accreditation scheme for providers: in order to assure both speed and quality, the information provider rather than the information should be accredited.
- Ø Our key message is that high quality information supports patients' concordance and rational and effective use of medicines.

Rita Kessler, Association Internationale de la Mutualité (AIM)

Key points:

- Ø AIM supports the empowerment of EU-citizens and patients through better access to patient-centred, comparative, evidence-based, independent and evaluated information, generated by official independent bodies within a validated process.
- Ø We need to focus on quality, not quantity: developing synergies at EU-level and reinforcing collaboration among existing national bodies involved in issuing independent patient information already represents a high added value for all.
- Ø For AIM, the main challenge regarding patient information is raising awareness and facilitating access to independent high-quality information sources. Since 2006, AIM has called for a specific EU-logo as a trust mark for citizens to identify trustworthy, reliable, evidence-based information, independent of commercial interests.
- Ø The source of information is an important aspect. It is therefore essential to not create confusion between public health mission and commercial interest. The pharmaceutical companies' role is clearly laid down in EU legislation. AIM insists on maintaining the current ban on DTCA (Direct to Customer Advertising) and resists any direct or indirect process aimed at relaxing it.

Hubertus Cranz, Association of the European Self-Medication Industry (AESGP)

Key points:

- Ø With increasing options for treatment it becomes crucial to help patients choose what is best for them; the role of health professionals is key.
- Ø Pharmacists play an important role as gatekeepers, but there are areas to be improved like communication skills and the understanding of the need for self care.
- Ø AESGP is participating in a project which aims at patients' empowerment by developing core self-care competencies for pharmacists within their professional development. This enables community pharmacists to provide the most appropriate guidance on self-care related areas including relatively new indications for self-medication, e.g. in the area of cardiovascular diseases.
- Ø This project is an example of a private public partnership with online training modules with self-assessment questions and training material, allowing a targeted learning process.

- Ø The project is transferable into all Member States, notwithstanding the challenges of translation and of different cultural attitudes.

Ivana Silva, Pharmaceutical Group of the European Union (PGEU)

Key points:

- Ø It is important to ask the question: "What does it mean to be an informed patient?" An informed patient is not just a person who has or is given access to information. So the discussion should not be limited to the dissemination and accessibility of information.
- Ø Information must be relevant and meaningful for the particular patient at the particular time of his/her life and evolution of his/her condition. Such tailored information sometimes has to comprise therapeutic patient education and is best achieved through dialogue between the patient and a health professional, such as for example the community pharmacist.
- Ø The possibility to discuss information not only provides an opportunity for patients to become more involved in their treatment but also allows knowledge to develop and evolve.
- Ø PGEU supports the idea of an EU strategy on information to patients that is based on developing health literacy, improving communication skills of health professionals as well as patients and exploring the full potential of ICT in facilitating information to patients without disregarding the traditional, non-electronic means of information.

Comments and Discussion

- Ø Patients with chronic diseases need not only information about medicines, but especially about how to manage the challenge of their disease in every-day life.
- Ø Patients need to be empowered to play an active role in their care; they should be partners with doctors in the decision of the appropriate treatment and its management.
- Ø There is not one single patient, but a plurality of experiences and expertise:
    - o Information should be written in simple language that everyone can understand. However, access to more complex information should also be made available.
    - o Factors linked to lifestyle do not apply to all patients. Patients with multiple sclerosis, for example, do not contract the condition because of unhealthy behaviour.
- Ø More EU action is needed on promoting education and training on communication with patients for all health professionals including doctors, nurses, pharmacists.
- Ø Health literacy needs of patients should be addressed.
- Ø For life threatening disease, both the speed and quality of the information are essential; we should not divide these two aspects.

- Ø We should not exclude per se any provider of information, but we have to recognize that information can be biased.
- Ø It is of extreme importance now to bring forward the debate at national and local levels.

II. Pricing and Reimbursement

Presentation of the outcomes by Stefan van der Spiegel (European Commission) on behalf of the Pricing and Reimbursement Working Group

Key points:

- Ø Pricing and reimbursement decisions need to find agreement between three types of very different expectations :
    - o The patients' need to access to the best health solutions available, at an affordable cost.
    - o Manufactures' expectations for a reward for their long and risky investment in research and development.
    - o The funding authorities' need to optimally use their limited resources available. They need to invest national budgets in cost effective health solutions.

  Patients will only get access to medicines when these last 2 expectations are met within a pricing and reimbursement decision that is acceptable for manufacturers and for funding authorities.
- Ø Recommendation 5: The EU should accelerate the access to medicines for all EU citizens, improve their availability in small markets and ensure equal access to orphan medicines.
- Ø Recommendation 6: Valuable innovation should be encouraged, identified and rewarded. We should set common and clear expectations, consistent with recognition and reward of innovation, and align all elements in national pricing and reimbursement systems.
- Ø Recommendation 7: Limited resources are to be optimally used. To do so we need to keep the focus on patients, align all elements of pricing and reimbursement practices, further develop knowledge and exchange experiences between Member States.
- Ø Recommendation 8: The momentum on pricing and reimbursement is to be maintained with further cooperation and exchange of experiences at EU level; the Commission in cooperation with relevant stakeholders is to undertake a first review of progress on pricing and reimbursement within the next 2 years.

Panel debate on Pricing and Reimbursement

Christoph Talheim, European Patients' Forum (EPF) and European Multiple Sclerosis Platform (EMSP)

Key points:

- Ø This Conference in itself shows recognition of the importance of patients.
- Ø While advanced at EU level, the concept of patients' involvement is rather static at national level, which is extremely disappointing from the patients' point of view.
- Ø Equal access – we are very far from that; access is higher in countries where decisions are made by patients and doctors together (28-30% in the case of multiple sclerosis) and very low where doctors decide on their own (2-3%). We have to achieve an equal level of commitment on the payers' side in all Member States.
- Ø In the set up of budgets we need to consider investments in early stages of chronic diseases. This will help patients to remain in the labour market and helps saving costs for society on the long run.
- Ø How many of the Member States are regularly involving patients in pricing and reimbursement processes? According to the feedback in the Working Group on P&R apparently only one does.
- Ø We have to fight prejudices towards patients' organisations that are funded by industry. We have an unequivocal commitment to transparency and independence.

Thomas B. Cueni, European Federation of Pharmaceutical Industries and Associations (EFPIA)

Key points:

- Ø Finding a balance between reward for innovation, improved patient access to innovative medicines and controlling budgets remains a challenge. Companies need to gain back the money that they have invested into innovation. If we want to lower the costs of new medicines, we need to find a different system of rewarding innovation.
- Ø Health care spending should be seen as an investment and not a cost. Currently, Europe sees health care innovation too much as a burden rather than an asset.
- Ø We have to limit the extraterritorial impact of national price controls: A similar price-level across Europe leads to very different levels of affordability in the different Member States, depending on their economic situation. Adding to the pre-existing huge differences in purchase power across the EU, the financial market crisis and the resulting currency fluctuations make it even more important that national price controls are limited to the territory of the respective Member State.
- Ø Patients' access to new medicines has to be improved. Patients in Europe are faced with long delays in access to new innovative medicines, including medicines for life-threatening diseases. This is unacceptable.

Greg Perry, European Generic Medicines Association (EGA)

Key points:

- We had some difficult discussions in the Working Group. Nevertheless, we achieved consensus on a number of common approaches and best practices.
- Generics seem to hold the promise of great savings in Europe's health care sector. We need concrete measures to make generics available on the market soon after their authorization.
- It is crucial to maintain the principles of equal access and solidarity. But how long will we be able to maintain such a society?
- The industry benefits from lower manufacturing prices today, but is this benefit being delivered to the patients?

René Jenny, European Association of Pharmaceutical Full-line Wholesalers (GIRP)

Key points:

- Full-line wholesalers play a key role in the sustainable, safe and efficient delivery of the full range of medicines to all pharmacies, including the more profitable medicines as well as the less profitable medicines. As the more-profitable medicines contribute for the less profitable medicines, full-line wholesalers can commit to supply all medicines that the patients need.
- However, this sound model of "sustainable availability and delivery" of medicines is under threat from new distribution arrangements. New distributors focus exclusively on products that generate profits and leave the non profitable medicines to the traditional full-line wholesaling system. As a consequence full-line wholesaling is thrown off balance and it becomes impossible to supply only the less profitable medicines. Regardless of the needs of the patient, costs will go up and supply will be incomplete.
- Possible solutions have been discussed in the Working Group Pricing where an excellent paper on "Ensuring access to medicines in small markets in Europe" has been developed.

Comments and Discussion

- The individual patient with a chronic disease is a real expert and should absolutely be included in pricing and reimbursement decisions. It is crucial to have an open process in involving patients in decision making bodies.
- Patients' organisations should make their policies on independence and transparency more visible.
- Patients' organisations are important, but there is poor support for them from an institutional and legal point of view. We have to demonstrate the importance of patients' organisations to politicians and other stakeholders.

- Ø The Forum has created a basis for further cooperation; an example is the newly founded Network on Pricing and Reimbursement that involves all Member States, but interestingly no other stakeholders.
- Ø For national budgets to be sustainable the prices of medicines need to decrease; this can be achieved by lowering the costs of innovative drug development and by shifting to cheaper alternative medicines where this is possible, e.g. when a generic medicine is available.
- Ø There is a trend towards more personalized, specialized drugs, but they are also more expensive and may not be affordable in the long run. Fundamental ethical and societal debate is needed on the way forward.

III. Relative Effectiveness

Presentation of the outcomes by Anna Bucsics (ESIP) as a member of the Relative Effectiveness Working Group

Key points:

- Ø Relative effectiveness can be defined as the extent to which an intervention does more good than harm compared to one or more intervention alternatives for achieving the desired results when provided under the usual circumstances of health care practice.
- Ø Recommendation 9: Agreed good practice principles for relative effectiveness assessments should be implemented: Member States and stakeholders – the pharmaceutical industry, social insurers, health care professionals and patients' organisations – have to be encouraged to adopt the agreed working definitions on efficacy, relative efficacy, effectiveness and relative effectiveness and implement the agreed best practice principles for relative effectiveness assessments as well as to regularly communicate and exchange information on their adoption.
- Ø Recommendation 10: The exchange of information on relative effectiveness assessments should be promoted in order to improve data availability and transferability. Further cooperation should focus on strengthening the methodological quality and rigour of relative effectiveness assessments and on consolidating scientific evidence. Listen to the views of stakeholders, engage early dialogue between Market Authorization holders and decision makers during the drug development process, and make best use of the EPAR (European Public Assessment Report) and NPAR (National Public Assessment Report).

Panel debate on Relative Effectiveness

Albert J. Jovell, European Patients' Forum (EPF) and Spanish Patients' Forum

Key points:

- Only patients can provide information on how diseases affect their lives.
- Patients should be on the same footing as other stakeholders: they provide unique information on side effects and effectiveness of treatments – we live and breathe it.
- Independent bodies involving all stakeholders should be responsible for relative effectiveness assessment of medicines; the current health economic approach is too limited.
- It is crucial to increase health literacy skills for patients and citizens.
- Efficiency of the system has to be combined with quality of care.
- The universal free access to quality health care in the European Union has to be maintained – health is a human right.

Stanislav Primoži•, Agency for Medicinal Products and Medical Devices of the Republic of Slovenia

Key points:

- Drug regulation now falls into EU jurisdiction while pricing and reimbursement is still decided at national level and calls for networking and cooperation. Some Member States do not have specialized networks and structures at national level for the assessment of relative effectiveness.
- The deliverables of the Pharmaceutical Forum can be instrumental for Member State authorities, regardless of the stage of their development and the size of their human or financial resources, and can help them to cope with the advent of new technologies and the pressures exerted by different stakeholders.
- At the current stage, EU level cooperation should be non-binding, but involving a high degree of professional standards and information exchange. A high degree of transparency towards different groups of health professionals as well as patient groups should be maintained.

Anna Bucsics, European Social Insurance Platform (ESIP)

Key points:

- The WG on Relative Effectiveness showed just how useful international information exchange can be and identified networks for this purpose such as the EUnetHTA project, and MEDEV (the informal Medicines Evaluation Committee).
- Relative effectiveness is a difficult process because of the scarcity of data. All stakeholders need to think about how to generate more and better scientific evidence

on relative effectiveness for decision-making, profiting from Europe-wide resources and economies of scale.

Lisette Tiddens-Engwirda, Standing Committee of European Doctors (CPME)

Key points:

- Ø CPME is in favour of a common tool to assess the relative effectiveness of treatments. The assessment of cost-effectiveness can be integrated, but the main focus should be on scientific evidence rather than reimbursement issues. Doctors need to rely on objective data; transparency, quality and patients' rights are key concepts here.
- Ø By improving the availability of data, networks and cooperation, the development and safety of drugs will be improved as well.

Andrea Rappagliosi, EuropaBio

Key points:

- Ø One key principle developed in the Working Groups is the definition of the need for stakeholders' involvement in the Relative Effectiveness assessment. The next challenge is to set up systems in order to put this involvement of different stakeholders into practice.
- Ø The European Medicine Evaluation Agency (EMEA) plays a significant benchmark role in the EU. In particular, the Orphan Drug Designation is granted by the Committee for Orphan Medicinal Products – a committee in which patient representatives are full members and participate in the scientific and value assessment.
- Ø There is a need to establish a linear process in the evaluation of new therapies. What has been assessed and decided at one step should not be reopened for evaluation at a following step. Therefore, it is important that the EMEA is involved in the Relative Effectiveness assessment in order to avoid repetition of processes that delay patient access.
- Ø We need to further consolidate the patients' contribution to the assessments of Relative Effectiveness; patients should have voting rights in decision-making processes on Relative Effectiveness.

Comments and Discussion

- Ø Patients make a plea for a European approach to relative effectiveness; everyone should have access to the best treatment options, no matter what country he lives in!
- Ø The assessment of relative effectiveness is based on recognized science and could be carried out at EU level (European Network for Health Technology Assessment).
- Ø On the other hand, cost-efficiency assessment should be handled at national level, depending on country-based values and behaviour

AFTERNOON SESSION: BUILDING ON THE PHARMACEUTICAL FORUM OUTCOMES

European Momentum, European Principles, Trust in all Partners – Key pillars to advance actions at EU level?

Introduction:
Anders Olauson, European Patients' Forum (EPF)

Key points:

- Ø EPF and its representatives have been very committed to the entire Pharmaceutical Forum Process and have contributed actively to all of the work areas from a patient's perspective.
- Ø Why – because we believe strongly that the empowerment and independence of patients can only be achieved through equal access to quality information and equal access to affordable therapies and treatments. This was our starting point.
- Ø Our contribution is largely reflected in the conclusions and the recommendations of the Forum and the final report which we have supported wholeheartedly.
- Ø We have gained a greater insight and understanding, and the recognition of the importance and value of working in partnership – Member States and stakeholders together. We can all be proud of this legacy.
- Ø The wide range of tools and reference documents produced in each of the working groups are of lasting value on a number of levels. We know from talking to patient group allies at national level that these tools could be widely used in patient communities across Europe.
- Ø We welcome the clear sign posting towards health literacy and a comprehensive and coherent information to patients strategy at EU level and how this could be taken forward in practice – this is one of the key 'by-products' of the Pharmaceutical Forum in our view. One that will help to ensure that all patients throughout the EU access the information they need, when they need it and in a format they can make use of in their daily lives.
- Ø So, how do we move forward, maximise the impact of the Pharmaceutical Forum and do even better?
- Ø We would urge all those involved to maintain the political momentum for sustained and tangible cooperation, achieved through the Pharmaceutical Forum.
- Ø The conclusions and recommendations cannot be purely a 'statement of intent' but must be translated into real actions and real policies. As the voice of patients across the European Union, we call on continued leadership, vision and ambition in both the political and practical follow-up to the Pharmaceutical Forum.
- Ø And we, as the umbrella body representing patients' organisations across the European Union, are fully committed to taking our responsibilities in this process.

- Three underlying questions to participants for reflection and discussion:
    - Do the principles from the Pharmaceutical Forum bring added value?
    - Do you want to work with all partners?
    - What can you do, in your environment, to ensure the implementation of the Forum's conclusions and recommendations?

FOCUS: Information to Patients

Case study Translating the quality principles at EU and local level

Susanna Palkonen, European Federation of Allergy and Airways Diseases Patients Association (EFA)

Example of a workshop for EFA members, held in 2008 as part of their involvement as patient representatives in the Network of Excellence 'Global Allergy and Asthma European Network GA²LEN'.

Key points:

- The participants in the project agreed that one package would be the development of a European fact sheet on "Aspirin induced asthma", needed to give one message all over Europe about the latest evidence based information on aspirin induced asthma.
- The researchers within the project developed an excellent first draft.
- EFA used the quality principles developed by the Pharmaceutical Forum to check whether all aspects of quality were covered in the information provided in the fact sheet.
- As a result, rather than focusing only on the content, also the date of publication (principle Up-to-date), detailed references (principle Transparency) and contact information (principle Accessible) were indicated in the fact sheet.
- The fact sheet was written for patients and the public in general, in easily understandable language, medical terms were explained and the content was chosen according to its direct relevance for patients. Included were, for example, an explanation on common fears and misunderstandings about aspirin-induced asthma.
- Some recommendations regarding taking forward the Quality Principles:
    - Translate the Quality Principles into national languages.
    - Integrate the Quality Principles into a quality checklist to be used by patients.
    - Use the Quality Principles and give feedback about their effectiveness.
    - Collate practical tools from the Forum into a "tool box".

Case study Learning from existing partnerships? The Swedish experience:
Lars-Olof Hensjö, Healthcare Direct

Examples of two different channels in Sweden providing quality information for the public:

- www.1177.se is a website on diseases, investigations, treatments and medicines – owned and run by the 21 county councils of Sweden.
- 1177 Sjukvårdsrådgivningen is a free nursing advice line (the phone number is 1177 all over Sweden).

Key points:

- Ø Although there is much medicines-related information for the public on the internet and elsewhere (for example the Product Information Leaflets), this information is often difficult to evaluate for lay people and hard to understand. Furthermore, isolated drug information lacks the context of information on the disease or symptom treated, which is necessary to understand the purpose of the treatment.
- Ø The information on the website www.1177.se is produced following a strict quality process in cooperation with pharmacists and clinical experts in different fields. The texts are edited by journalists in order to make them easy to read, easy to understand, relevant to and reflecting the perspective of the reader. All texts are revised once a year or on demand.
- Ø Questions that are answered are: What is the benefit of the drug? How does the drug work? What are the most common adverse drug reactions or important ones to know?
- Ø Links to useful and reliable sources like FASS (PDR), SPCs etc. are presented.
- Ø The information on diseases as well as their symptoms and treatments is also used as a quality assured source in a professional electronic counselling support used by nurses giving telephone advice.

Case study The Swedish Medicines Information Engine - a matter of trust
Per Manell, Swedish Association of the Pharmaceutical Industry (LIF)

"FASS" is a medicines information portal developed by the Swedish Association of the Pharmaceutical Industry (LIF), which uses XML (Extensible Markup Language) format to offer access to information on medicinal products approved in Sweden.

Key points:

- Ø FASS provides up-to-date information on medicinal products (more than 140 pharmaceutical companies are online with the database and update it daily) and alerts the user about important changes.

- Ø FASS is a product of several Private Public Partnerships (PPPs), although an essential part of the development has been the active participation of health-care professionals and patient organisations.
- Ø With the "My FASS"-function, the user can follow and better understand his/her medications. After storing a personal medicine information log, he/she can request dosage intake reminders to the mobile phone (via instant messaging) or via e-mail.
- Ø FASS is adapted for users with disabilities, and an automated dictionary has been added for reader assistance.
- Ø FASS registers more than 4 million visitors every month.

Audience-led debate Opportunities for a European Virtual Library on Information to Patients – What will be the critical success factors?

The Members of the Pharmaceutical Forum invited participants to consider the launch of a European information library of existing high quality information to patients.

Key points:

- Ø This information library should be a Portal of portals.
- Ø The EU Health Portal could be used for this purpose.
- Ø It is important to sign-post the information about the existence of the portal on websites that people usually visit (e.g. My Space, You Tube, etc.).
- Ø The library should be seen as a quality standard for EU countries.
- Ø The library should include information about patients' experiences.
- Ø It is important to promote it among students and educators from an early stage on.
- Ø More thoughts are needed to map out: 1) How to get started? 2) What is the most relevant host-portal? 3) Who will do the quality-check and approval of the portals visible as links? etc.

FOCUS: Pricing and Reimbursement

Case study Swift access to the patients with new pricing practices: Risk sharing and conditional pricing.

Hildrun Sundseth, European Cancer Patient Coalition

Example of a risk sharing approach for patients with cancer: Following the NICE decision that Velcade is not cost-effective for the treatment of multiple myeloma, the NHS and the company who developed the drug (J&J), agreed to a "risk-sharing scheme" and a "money back guarantee". The Department of Health and NICE agreed to fund the project under certain conditions. The scheme was developed with the involvement of haematologists, pharmacists and Primary Care Trusts.

Key points:

- Ø Flexible approaches of risk-sharing or conditional pricing are welcomed by patients as they provide an opportunity for early access. They offer an early reward for companies while they give funding authorities the certainty of control over the spending and at the same time collect valuable experience about how the innovative medicine works in real life settings.
- Ø But if the approach outlined in the example had been agreed before the NICE evaluation, it would have avoided more than one year delay and enabled data collection on clinical experience and therapeutic value in controlled settings while the patient still had access.
- Ø Access to innovative medicines is especially critical for patients with a life-threatening disease or a disease where there exist currently few treatment options and time is of the essence.
- Ø Conditional pricing mechanisms should be set for all cancers/diseases with currently no treatment options.
- Ø Cancer patients are faced with a painful dilemma: wanting access to innovative medicines and wishing investment in further research on one hand, and understanding governments' pressure to maintain sustainable financing of healthcare for all patients on the other hand. All the more reason why we need new thinking and more flexible approaches.

Case Study Improving Access to Orphan Drugs - From agreed principles to good practices: France & EU Pharma Forum.

Yann Le Cam, European Organisation for Rare Diseases (EURORDIS)

All orphan medicines are designated and authorized through EU centralised regulatory procedures.

In France, for the period 2000-2003, orphan medicines costs were paid from individual hospital pharmacy budgets, which meant penalizing hospitals that developed Centres of Reference for Rare Diseases, and generating inequalities for patient access to orphan medicines from one hospital to another.

The National Plan for Rare Diseases (2004-2008) introduced two new principles: (1) national decision making process for pricing & reimbursement on all orphan medicines and (2) national payment for orphan medicines for all patients treated from social security budget.

New practices are being proposed at national level for the next National Plan on Rare Diseases (2009-2014), in the light of the agreed principles in the EU Pharmaceutical Forum as well as in the Commission Communication on Rare Diseases (Dec 2008):

- commitment of France to take part in a new EU collaboration to prepare a European Common Scientific Assessment Report of the Clinical Added Value of Orphan Drugs;
- commitment to use this European Common Assessment Report to speed up national health assessment and to appraise pricing & reimbursement;
- promotion of conditional pricing & reimbursement with regular reviews, based on revised & updated reports;
- maintenance of national payment and
- better access to better targeted patients based on data generated by clinical research, performed after marketing authorisation.

At EU level, EURORDIS surveys from 2001, 2003, 2005, and 2007 on the availability of orphan medicines across all EU Member States, showed major inequalities of patient access between Member States, between regions inside a Member State, and between hospitals.

Key points:

Ø The new agreed EU principle that "Member States, stakeholders and the Commission should strengthen their efforts to ensure access to orphan medicines in all EU Member States", led to EU Exchange of Knowledge on the Scientific Assessment of the Clinical Added Value of Orphan Medicines, specific pricing & reimbursement mechanisms and an early dialogue on research & development, as well as an increased awareness on rare/orphan diseases.

- Ø New practices are recommended at EU level: a European Collaboration for the Scientific Assessment of the Clinical Added Value of Orphan Medicines, a Working Party to produce a European Scientific Common Assessment Report on this Clinical Added Value and regular revision and update of clinical added value reports based on post-MA data from real life studies.
- Ø France seems to be willing to implement these new principles and new practices because:
    - o it took part in their development within the EU Pharmaceutical Forum and agreed to them formally;
    - o they will lead to more consistent assessment and comparison with other Member States: scientific and medical date on which clinical added value is assessed are valid across the EU;
    - o they will help to coordinate post marketing requirements with other Member States, through EU level studies and registries, and thus create higher chances of obtaining more reliable data more rapidly for further reassessment and better targeting of patients with right treatment regimens and doses;
    - o they will lead to better value for money.

Case Study Evidence based Funding of 'Expensive Hospital Drugs' in the Netherlands
Huib Kooijman, Ministry of Health, the Netherlands

Key points:

- Ø Health Authorities look for high-quality, accessible and affordable health care which implies:
    - o rapid patient access to new therapies for diseases with high medical need;
    - o value for money;
    - o further research on 'real life value' of new drugs after market authorisation;
    - o appropriate and rational use of new therapies by doctors;

- Ø Expensive hospital drugs are paid out of hospital's lump sum budget; but their costs are growing dramatically and limited hospital budgets may affect the introduction of new drugs into the hospitals' portfolio and therefore patient access; access to new drugs in hospitals is not regulated, but rather controlled by professional standards. In order to compensate hospitals for growing expenditure on new hospital drugs, a policy rule was introduced:
- Ø Expensive Hospital Drug List I:
    - o Hospitals entitled to additional funding (on top of the hospital's regular budget) to compensate for rising costs of listed 'expensive drugs'; additional funding reflects 80% of net purchase costs and 100% for orphan drugs.

- Temporary listing for 3 years: definite listing subject to 'real life assessment' of cost-effectiveness and assessment of therapeutic value; a Final Assessment and Appraisal is carried out by the Healthcare Insurance Board.

Ø Expensive Hospital Drug List II:

- allows for swift market access of new high potential drugs while real life therapeutic and economic value is still uncertain;
- enforces further research on real life therapeutic value after market authorisation;
- first decisions are expected for the end of 2009;
- stakeholder involvement is built in;

Audience-led debate More convergence in the systems of Pricing and Reimbursement – Is it possible?

Key points:

Ø We do not need to achieve a convergence of prices, but a convergence of the way prices are set up and work (some Member States pay 10 times more than others for medicines).

Ø Each Member State's system functions quite well individually, but when put together systems clash.

Ø Pricing and reimbursement decisions are an expression of the country's wealth as well as a political and societal choice. However, in some cases, access does not depend on the system: not all countries can afford the same prices right now, given the huge differences in wealth (GDP/capita) between individual Member States. Furthermore, the unregulated monopoly of companies has to be addressed.

Ø When we move to more personalized medicines, the current pricing and reimbursement models are outdated.

Ø Other examples for risk-sharing schemes for patients were reported; while one can argue that this is not an ideal situation, this also means giving some people a chance – which is crucial for patients with life threatening diseases.

Ø More cooperation at EU level is crucial to combine data (on clinical control trials, registries) gathered from various sources to get solid evidence of the effectiveness of medicines.

Ø Patients' organisations should direct their constituencies towards evidence-based medicines.

FOCUS: Relative Effectiveness

Case study Patients' involvement in Health Technology Assessment decision making process?

Vicki Combe, Alzheimer's Society, UK

Example of Alzheimer's Society UK – involvement in a technology appraisal for dementia drugs: The assessment took place from 2004-2007 in the UK. The Alzheimer's Society gathered evidence from over 4,000 people with dementia and carers to offer an expert patient view on the benefits of treatment, to complement the submissions made by others to the UK National Institute for Health and Clinical Excellence (NICE). 73% of survey respondents reported that the received drug treatment worked. Despite of this, NICE's first draft guidance stated that Alzheimer's drugs are clinically effective but not cost effective and that they should not be available on the NHS. To keep up pressure on government, Alzheimer's Society formed Action on Alzheimer's drugs – an alliance of over 30 leading professional and charitable organisations. In January 2006, NICE draft guidance made concessions (Aricept, Exelon and Reminyl would be available on NHS for people in moderate stages of dementia, but Ebixa, the only drug licensed for the later stages of dementia, should only be prescribed as a clinical trial).

Key points:

- Despite some concessions, the judgment means that people in the early stages of Alzheimer will continue to be denied access to Alzheimer's drugs.
- Patients' organisations have a vital role to play in ensuring that the patient voice is heard in health technology assessment.
- Patient groups need to engage in the technology appraisal process, but be ready to launch public and political campaigns where views of patients are not reflected in the decision making process.
- Patient groups might also need to explore legal routes.
- Length of process: The appraisal process took a significant amount of time and patient groups need to be prepared for this.

Case Study Patients' involvement in Health Technology Assessment Process
Francois Meyer, Health Authority France (HAS)

Key points:

- Ø Health Technology Assessment is the evaluation of health care technology (drug, procedure, medical device) aiming at providing objective information to support health care decisions.
- Ø Two main steps have to be followed when introducing a new drug in Europe: market authorisation and introduction into national healthcare systems.
- Ø HTA is performed within a given context varying from country to country (France: price negotiation based on assessment of clinical and relative effectiveness of the drug, UK: cost-effectiveness assessment based on the price set by the company).
- Ø There are centralised vs. decentralised decision making and/or financial and different other judgment values: e.g. 'lifestyle drugs'.
- Ø Participation of patient associations in HTA process within HAS: Patient representatives in 2 out of 4 HTA Committees (Medical Devices, Economic and Public Health).
- Ø Obstacles to patient representatives' participation: regulatory definition of composition of some committees and availability and willingness to participate (more than 1,500 products assessed every year, with 1 to 2 full-day meetings per month for each committee).
- Ø Other forms of patients' participation: on specific topics (e.g. review of anti Alzheimer's Drugs) and systematic participation for public health recommendations (e.g. Neonatal Hearing Deficiency Screening).
- Ø The way forward – HAS Plan 2009-2011: Development of patients and users associations' participation – ongoing dialogue with the Collectif Interassociatif sur la Santé, definition and implementation of a standardised and transparent procedure for patients associations' representatives' recruitment and involvement.

Discussion:

Key points:

- Ø Patients' involvement in HTA is very important.
- Ø HTA procedures should be transparent for stakeholders and the public to have confidence in them.
- Ø There is a need to set up a glossary of terms used in the HTA process, in a lay version, that is accessible to patients.
- Ø We need to explore the idea of training patients' organisations to take part in the HTA process.

CLOSING REMARKS

Anders Olauson, European Patients' Forum

Response to the three initial underlying questions to participants - Key points:

- Ø The principles from the Pharmaceutical Forum have shown already their added value; we should continue using them and apply the examples shared today.
- Ø The importance of involving all partners in moving forward has been reiterated on many occasions today and should become 'the norm'.
- Ø The presentations and debates have illustrated that much can be done at different levels and in different contexts to ensure the implementation of the Forum's conclusions and recommendations.

The discussion has led to a number of further 'take-home messages'.

With regard to Information to Patients:

- o More sustainable work is needed – there is clearly unfinished business from the Forum that needs to be addressed;
- o A comprehensive strategy on information to patients – of which health literacy should be a component – should be developed;
- o A quality label balancing speed of access and quality of information should be established;
- o European Library: we need to think seriously about the next steps, linked to the importance of a comprehensive information to patients strategy and the Commission should prepare a terms of reference document taking on board the key elements of today's discussion to move forward.

With regard to Pricing & Reimbursement, dialogue and transparency are key and we need to continue to work on convergence of pricing systems at EU level.

With regard to Relative Effectiveness, a key message is to involve the various stakeholders. European vs. national relative effectiveness processes need further debate and reflection.

Martin Benes, State Institute for Drug Control, Czech Republic

Key points:

- Ø The Czech Republic acknowledges the huge effort that has been made within the three-year process of the Pharmaceutical Forum. In line with the conclusions and recommendations, one of the Czech Republic's priorities is to improve patients´ access to relevant health information.
- Ø Member States should therefore ensure that they provide their citizens with high quality and accurate information.
- Ø The State Institute for Drug Control has recently launched a web site aimed at patients, comprising relevant data about medicinal products and health. Furthermore it is also important to provide healthcare professionals and decision makers with reliable information in respect of the sustainability of healthcare systems.
- Ø The Czech Republic welcomes the extension of the topic of relative effectiveness. A network and regular exchange of information among Member States will continue to be highly valuable.

http://ec.europa.eu/pharmaforum/