EPF Mailing

Issue 6 (40)

22 November 2011

Dear EPF Members and Allies,

Welcome to the EPF mailing. In this issue we report on the Regional Advocacy Seminar in Bucharest that we co-organised in late October with our Romanian member organisation COPAC. The meeting focused on the importance of collaboration between patient organisations and health professionals' organisations. It was a very inspiring and productive 2 days and we are really pleased with the very concrete outcomes in the four countries directly involved in the seminar. Please go to our special feature section for more information.

The Commission has published a draft of the new Public Health Programme. EPF is working closely with the European Public Health Alliance on joint campaign work to ensure that the Programme reflects genuinely the needs and concerns of the public health and patient communities across the EU – please see section 9.

Since our last issue, the Commission has presented the Draft Directive on information to the General Public on Prescription Medicines. Please go to section 11 for an overview of the contents and EPF's initial reactions.

Another important development last month is the adoption of the Strategic Implementation Plan of the European Innovation Partnership on Active and Health Ageing, in which EPF and some of our members were actively involved. Please go to section 3 for more info, a link to the Plan and next steps.

We are also delighted to report on our work at the European Health Policy Forum Gastein where EPF board and staff were involved in several different sessions and organised a specific event on the needs and rights of older patients. Please go to section 4 for more details.

Readers will recall the EPF has set up a regular Dialogue with EUCOMED, the trade association representing the Medical Devices industry, where our respective members meet to discuss policy issues linked to medical devices. The second meeting took place on 13th October and a brief report is included in section 28.

At the beginning of November, EPF co-chaired an important meeting with the European Commission exploring the development of a Transparency and Ethics Charter. This meeting looked specifically at relations between the Pharmaceutical Industry and patient groups and the potential added value and contents of such a Charter - for more details go to section 8.

We also report on several other developments that have taken place over the last few weeks, regarding EPF's policy and programming work and planning in these areas for next year. Please do not hesitate to contact the secretariat should you wish further information on any of the sections.

The next EPF Mailing will be distributed at the end of January, and EPF will be sending out an interim update with our Christmas Greetings in mid-December.

With our warmest Greetings,
EPF President Anders Olauson
EPF Director Nicola Bedlington

TABLE OF CONTENTS

1. Regional Advocacy Seminar, Bucharest, 27-28 October 2011

The **fourth EPF Autumn Regional Advocacy Seminar**, organised in cooperation with the Coalition of Patients' Organisations with Chronic Diseases in Romania (COPAC), member of EPF, took place in Bucharest, Romania on 27-28 October 2011.

Annual EPF Regional Advocacy Seminars is the approach EPF is pursuing since 2008 in order to engage and work with national patient organisations and their national coalitions with a view to:

a) integrating national perspectives into the European debate to have a stronger patient voice;

b) feeding policy information and policy outcomes back into national realities and contexts;

c) developing and sustaining the advocacy capacity of patient leaders, particularly in new Member States.

While the core objective of strengthening patient leaders' advocacy skills is and will continue to remain the key feature of EPF's Regional Advocacy Seminars, these seminars represent also an opportunity to address specific issues which we identify in close consultation with our members on the basis of needs and challenges faced by the patient community. Issues such as promoting the establishment of national coalitions of patient organisations, health literacy, the meaningful involvement of patients in EU policies and projects, and the involvement of young patients in patient organisations were addressed in previous seminars.

The purpose of the EPF 2011 EPF Regional Advocacy Seminar was **to strengthen trust and mutual understanding between patient and health professional organisations** in order to foster their cooperation in the national health policy arena. Approximately **60 representatives of patients' and health professionals' organisations** (general practitioners, specialist doctors, nurses, and pharmacists) from **Bulgaria**, **Romania**, **Estonia** and **Hungary** attended this event.

We were particular pleased to welcome the Romanian Secretary of State for Health, Mr Cristian Irimie for Health, Mr Cristian Silviu Busoi, Member of the European Parliament, and Mrs Nathalie Chaze from the European Commission, DG SANCO.

During the two days the participants had the opportunity to build up new partnerships and explore new possibilities for enhancing patient-professional cooperation, especially in national health policy-making, while learning more about some major recent European health policy developments and understanding how to get involved and cooperate in the transposition and implementation of such policies.

The first day of the Seminar was dedicated to highlighting the importance of strengthening the cooperation between patient and health professional organisations as a way to foster better health policy and health outcomes at both European and national level. Various examples of good practice drawn from both the European and national levels were showcased and existing challenges and barriers were also highlighted and thoroughly discussed.

In the second part of the day the participants had the opportunity to explore in more depth how to advance patient-professional cooperation in areas such as Health Technology Assessment (HTA), eHealth, Health literacy, as well as in the context of the implementation and transposition of the Cross-border Healthcare and Pharmacovigilance Directives.

During the second day the participants had the opportunity to work in national working groups in order to develop short-medium term strategies and action plans for furthering patient-professional cooperation around some of the key health policy priorities in each of the four countries concerned.

EPF is delighted with the outcomes of this seminar. Although it was the fourth time that EPF organised a regional advocacy seminar, this was the very first opportunity for us to bring together patient and professional leaders from four different countries with the objective of reinforcing mutual dialogue and collaboration in health policy-making.

All this was confirmed, to a large extent, by the initial analysis of the responses to the evaluation form which shows that the participants were also extremely satisfied with the seminar in

Back to contents

all respects. It is important to underline, in this respect, that the participants indicated that their awareness about the opportunities for cooperation between patients' and healthcare professionals' organisations was raised considerably as a result of attending this seminar. Moreover, they felt that the seminar was very motivating and encouraged them to take immediate action in order to explore new ways of cooperating around key national health issues.

The full Seminar report will be available in December in the form of a toolkit. This report will be made available in the seminar's page within the EPF website Bucharest event section. Please visit our website for more news on the toolkit.

Meanwhile you can download all presentations given, including the key outcomes of the parallel sessions here.

EPF would like to acknowledge the contribution of the following organisations which supported us in the organisation and delivery of this Seminar: the Coalition of Patients' Organisations with Chronic Diseases in Romania, the European Federation of Nurses Associations, the EuroPharm Forum, the Pharmaceutical Group of the European Union, the Bulgarian National Patient Organisation, the Hungarian Osteoporosis Patient Association, the Estonian Chamber of Disabled People, the Confederation Health Protection of Bulgaria, and the Catalan Agency for Health Information, Assessment and Quality.

EPF would also like to acknowledge the kind support of the Medtronic Foundation and Sanofi in the form of unrestricted grants.

For more information on the Regional Advocacy Seminar please contact Walter Atzori.

2. Cross-border healthcare: European Commission consultation on the recognition of prescriptions across borders

Directive 2011/24/EU provides for the recognition of prescriptions issued in another Member States. Article 11 of the Directive states that the Commission shall adopt measures to enable health professionals to verify the authenticity of prescriptions through developing a non-exhaustive list of elements to be included in the prescriptions; to facilitate the correct identification of medicinal products or devices prescribed in one Member State and dispensed in another; and to facilitate the comprehensibility of information to patients concerning the prescription and the instructions included on the use of the product. The Commission's roadmap on the implementing measures stresses that regarding patient comprehensibility, input from the patient stakeholder group will be taken into specific consideration.

The measures are planned to be adopted by 25 October 2012. The Commission (DG SANCO) is currently conducting an impact assessment to evaluate various policy options under consideration, and is consulting stakeholders through an online questionnaire. The consultation closes on 8 January 2012.

Next steps:

- EPF will prepare an input into this consultation, and we would invite all interested members to review the consultation document and give their feedback. The EPF Secretariat will send out an email reminder and a briefing document to members in the next week.
- Deadline to send comments to the Commission via the online questionnaire is 8 January 2012.

Links:

- Directive 2011/24/EU on the application of patients' rights in cross-border healthcare.
- European Commission's public consultation documents and online questionnaire.

3. European Innovation Partnership on Healthy and Active Ageing

Readers will know from previous issues of this mailing of EPF's close involvement in this pilot Innovation Partnership, launched by the European Commission. EPF President Anders Olauson was represented on the high-level Steering Group of the Partnership, co-chaired by Vice President and Commissioner for the Digital Agenda, Neelie Kroes, and the Commissioner for Health and Consumer Policy, John Dalli. The EPF Secretariat participated in several "Sherpa" meetings, whose aim is to prepare the work of the Steering Group and refine the operational aspects of the Partnership. EPF's member organisations focusing on disease areas that were identified as priorities by the Commission's public consultation (diabetes, Alzheimer's disease/dementias, and Parkinson's disease) contributed actively to the relevant debates.

The overall goal of the Partnership is to add two healthy life years to the average healthy life span of European citizens by 2020. The wider objective of the EIP is to achieve a "triple win" for Europe: Improving the health status and quality of life of European citizens, particularly older people; supporting the long-term sustainability and efficiency of health and social care systems; and enhancing the competitiveness of European industry through business and expansion of new markets.

The EIP aims to facilitate new ways of working in partnership, by mobilising and linking up the different stakeholders, EU institutions, national authorities and the regional/local level actors. It will address a number of bottlenecks and barriers that have been shown to hinder the uptake and spread of innovations, such as fragmented evidence available on innovative solutions, lack of EU-wide standards and interoperability of systems, difficulties in scaling-up pilot projects, funding barriers, legal and other framework conditions, social and healthcare systems' complexity, organisational and budgetary "silos", and lack of integration.

Strategic Implementation Plan adopted

Following the final meeting of the High-Level Steering Group on 7 November 2011, the European Commission has published the Strategic Implementation Plan (SIP) which has been prepared by the Steering Group and sherpas in a collaborative process during the last months.

The SIP sets out the vision for a new paradigm of ageing, a vision for "healthy and active" ageing, and the key action areas that will be addressed by the Partnership. The SIP is available on the Commission website (http://ec.europa.eu/active-healthy-ageing)

The SIP content is structured on the basis of three "pillars", roughly corresponding to a life-stage approach for older persons. These are "prevention and early diagnosis", "care and cure", and "independent living". Within the three pillars there are 12 priority "action areas", where there is potential for innovation to achieve the objectives of the Partnership. Within those action

areas, five priority actions have been selected for implementation in the first instance. They focus on actions where there is potential to deliver quick results and where there was readiness on the part of all partners to start working immediately. In addition to the pillars, a number of horizontal issues were identified, and one horizontal action is selected for implementation, focusing on age-friendly environments.

EPF has been actively involved in the process, and we are pleased to see much of our input reflected in the SIP. We support the positive vision of ageing as an opportunity, highlighting the value of older people themselves and their contribution to society. We are also happy that the definition of "active and healthy ageing" centres around quality of life, physical, mental and social well-being of older people, and that "active" in this context refers to continuing participation in social, economic, cultural, spiritual and civic affairs – not only the ability to be physically active or participating in the labour force. In the "care and cure" pillar there is explicit recognition that new models for care need to be centred around the patient and their family/carers, and an explicit recognition of patient empowerment as a necessary factor in order to realise shared decision-making in healthcare"

Going forward, EPF will be involved at least in the selected actions on adherence and health literacy, and integrated care. An open call for participation and commitment to the six actions will be published in early 2012, and following this six action groups will be formed who will take forward the implementation of the actions. We would like to extend an invitation to all our members to become involved according to your interest and capacity to commit.

Next steps:

- 2 December: Commission will inform EPSCO Council on the Partnership
- 5 December: Commission will inform Competitiveness Council
- February 2012: Commission will publish a Communication that incorporates the Commission' response to the SIP with recommendations to the Council and EP
- February/March 2012: Commission planned event on the Partnership (Brussels)
- Early 2012: Open call for participation to the Action Groups (first 5 actions)

Links:

- Strategic Implementation Plan
- Innovation Partnership home page
- EPF's response to the public consultation

4. European Health Policy Forum Gastein – 5-8 0ctober 2011

EPF was again very active during this year's Health Policy Forum in Gastein. Our representatives attended a number of sessions over the four days, giving presentations, participating in panel discussions and as usual gathering information and insights.

EPF workshop: New perspectives on the needs and rights of older patients

On Saturday 8 October, EPF ran a specific workshop on **"Ageing in action: a renewed focus on the rights and needs of older patients".** The session was a very well attended despite being on the last day of the Forum, showing that there is great interest on this topic. The session explored this theme in the context of the European Innovation Partnership on Active and Health Ageing (see section 3), underlining the importance of issues related to the rights and needs of older patients from a variety of stakeholder perspectives – older patients themselves, health professionals, policy makers, older people's advocates and industry.

EPF was also represented in a plenary session panel on the Innovation Partnership, where we had the opportunity to express key thoughts on our vision of the Partnership and how we want to move forward on the various actions identified. For more on the Innovation Partnership on Active and Healthy Ageing, see section 3.

In addition to the EPF-led session, EPF representatives participated in other specific sessions. Kaisa Immonen-Charalambous, EPF Senior Policy Adviser, contributed to the session on "**The Future of Medicine – developing an infrastructure for personalised medicine**". This parallel session, organised by the Max Planck Institute for Molecular Genetics (Berlin) in cooperation with the FP7 flagship initiative project ITFoM and the Institute for the Public Health Genomics, Maastricht University, ran over two days and explored the implications for health policies and health infrastructures as PM enters clinical and public health practice. The first part focused on Information and Communication Technology (ICT) applications, with a keynote speech by former European Commissioner for Health, David Byrne and contributions by scientific experts and EPF (an overview of patient expectations and concerns regarding personalised medicine). The second part started with a digital agenda perspective given by the Director-General of DG INFSO, Robert Madelin, and continued with presentations including case studies from cancer and a panel discussion with all speakers.

Nicola Bedlington was involved as a rapporteur in a **workshop organised by the European Men's Health Forum** that explored the recommendations emerging from the research undertaken by EMHF on behalf of the European Commission on the status

of men's health across the European Union. Using the theme from the film 'Grease', and the analogy of the mechanics of a car, a very lively and reflective debate took place on the core determinants influencing men's health in different Member States of the European Union and how we could advance the men's health agenda in Europe. A Conference will take place in June during Men's Health Week, under the Danish EU Presidency, led by EMHF in which EPF and the European Institute on Women's Health will be involved, to look at health inequalities from a gender perspective. Further information will be available in future issues of the EPF Mailing. For a copy of the report on the status of men's health across the European Union and the recommendations from this session, please contact Ian Banks (ian.banks@emhf.org), President of the European Men's Health Forum, which is also a member organisation of EPF.

Robert Johnstone, EPF Board member, was also very active in a number of sessions, including a part-session on "New policies and strategies for health and wellbeing in Europe – towards Health 2020" on the theme of citizen and patient empowerment. Robert, in his feedback to EPF said: "The European Health Forum in Gastein is a fascinating opportunity to mix with high level policy makers from across the continent in an informal setting & a relaxed environment. This year there was much to interest us with good session topics, a higher proportion than usual attending from the patient community & younger attendees from all sectors."

EPF Treasurer, Tomasz Szelagowski, participated as a panellist in a session on the **Digital Agenda**, and the session led by the **World Health Organisation**. These sessions yielded interesting information and insights: Innovativeness is understood as a complex involving new technologies (ICT), drugs, medical devices but also new approaches to routine duties, new attitudes to partners and our everyday behaviours. Treatment of patients in their own environment is stressed; focus on shortening time hospitalisation time and shifting treatment of patients to the community environment (including home, family, residence area). An important role in this scenario is given to nurses, midwives and carers.

There is a need for new, effective channels of communication on health-related topics to a broad audience, as the current media channels can lack objectivity and quality of the information; Leaflets and folders are not as effective as they were before; electronic materials get lost in the mass of information available on the Internet; big social campaigns produce short lived results. One proposed solution was a partnership with patients' organisations, as defined together with WHO during the panel debate

with Robert Johnstone, Tomasz Szelagowski and WHO representatives. A wide co-operation and cross-sectoral partnership is needed involving the European and country regions and including corporate social responsibility (CSR).

More information:

- The programme, presentations from the various sessions, and photos from the EHFG 2011 will be available on the Forum website, www.ehfg.org, soon.
- For more information about the EPF contributions, including a full report of our workshop on the needs and rights of older patients, please contact the EPF Secretariat.

5. EU Clinical Trials Directive

In May 2011, the European Commission completed a second public consultation on the review of the Clinical Trials Directive. EPF submitted a response as we have done to previous consultations, focusing on the specific questions asked by the Commission but also reiterating the key principles of concern to all patients across disease-areas. To raise our concerns further with the Commission, in July EPF met with a European Commission representative to discuss the issues raised in our statement; a fruitful exchange of views took place regarding the concept paper, EPF's response, and other issues of interest such as wider issues around patients' involvement in research.

Based on this meeting, the issue was then discussed in the Policy Advisory Group that met on 8 September in Brussels; the group agreed that a meeting with EPF's members and Commission representatives would be a good idea to further explore the possibilities of a common patients' position, and to have an open exchange of views with the Commission.

The meeting, to which EPF members were invited to participate, will take place on 21 November in Brussels. We will update our members on the discussions and outcomes of the meeting. Moreover, we would also encourage all member organisations that are particularly interested in contributing to the discussions around clinical trials, whether or not they are able to join the meeting, to consider joining a specific task group of the EPF Policy Advisory Group (see article 15).

Next steps:

- The Commission's legislative proposal will be published in the second quarter of 2012 (by June 2012).

Links:

- EU Clinical Trials legislative framework
- Report of the Commission's public consultation 2009-2010
- Commission's concept paper and public consultation (2011)

EPF's position statements and previous responses to the consultations

6. Commission Green Paper on Modernising the Professional Qualifications Directive

The European Commission organised a public conference on 7 November to discuss the upcoming modernisation of the Professional Qualifications Directive. The Commissioner for internal market and services, Mr Barnier, presented conclusions from the Single Market Forum in Krakow on 3-4 October, where participants declared that a European professional card could give more certainty to professionals and enhancing trust among national authorities (see conclusions of the Forum here). As highlighted in our last mailing, EPF has expressed reservations on the card in our consultation response and calls for clarification of its features, added value and cost effectiveness.

The public health dimension in the Directive was the object of a panel discussion: the debate drew on a recent report on healthcare professionals' mobility and safety published by the House of Lords (UK) which highlights concerns regarding the language requirements in the directive and calls for allowing language testing by competent authorities. The report also recommends putting in place a proactive alert mechanism to enable authorities to share fitness to practice information and warn each other about practitioners who have been subject to disciplinary proceedings. Many speakers highlighted the need to make "the right proposal for patients". The conference was also the occasions to discuss linkage between the Directive and recent educational reforms, based on a recent study (available here).

The Internal Market and Consumer Protection committee of the European Parliament adopted on 27 October a draft motion for a resolution on the implementation of the Professional Qualifications Directive. Although non-binding, this report, once adopted in plenary can have political weight on the modernisation process. EPF has given input from the patients' perspective to MEPs in relevant committees, and had sent a strong message through a joint statement with EPHA, EWL and BEUC.

The report stresses that "protection of consumer and *patient safety is a vital objective* in the context of the revision of the directive". Below are some other key points addressed by the report:

- *Partial access* and partial recognition of training must not apply to these professions that have health and safety implications, as EPF and allies highlighted in the joint statement.
- *Continuing Professional Development*: the report stresses the need for patients to have better insurance that Healthcare Professionals have kept their skill and knowledge up to date and call on the Commission to do a comparability table of CPD requirements in Member States.
- The report also stresses the importance of healthcare professional's *communication skills* both with patients and within the healthcare team.
- *e-health services* should offer the same standards of quality and safety as non-electronic healthcare services- requirements of the directives should apply to e-health service providers.
- *Language requirements* need to be clarified, and the language requirement regime should be revised to allow National authorities to test if necessary technical and conversational language skills.

Next Steps:

- The European Parliament is expected to adopt its motion for a resolution on implementation of the professional qualifications directive in the plenary session on 15 November, the debate will be held on 14 November.
- The commission is expected to adopt the proposal for the modernisation of the Directive on 13 December 2011. EPF will then consult all members on our position for this directive.

For more information please contact Laurène Souchet.

7. Review of the EU Transparency Directive

As announced in our last mailing, the so-called "Transparency Directive" (Council Directive 89/105/EEC) relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems will be re-opened according to the latest new.

The latest update of the work plan of the European Commission indicates that the provisional date for the adoption of the legislative proposal for the review of the Directive is 30 November.

One key concern for patients which we have stressed in our input to the Commission is that the timeframe for making decisions regarding pricing and reimbursement should under no circumstances be extended. However several Member States have indicated in their response to the Commission's consultation that they considered the time limits for pricing and reimbursement decision are too tight, or indicated that they currently do not meet the time limit requirements in practice. EPF will continue to take a strong stance on this point to ensure that patients across Europe have timely access to the treatment they need.

Next Steps:

- EPF will consult its full membership once the details of the proposal are known

For more information or queries, please contact Kaisa Immonen-Charalambous.

8. Transparency Charter – Meeting on Patient and Industry Relations, 4 November 2011

As part of the overall European Commission Initiative on Access to Medicines, the Commission has set up a 'Transparency and Ethics' Platform. The primary aim of the Platform is to develop a Charter on Transparency and Ethics that reflects the relationships and modus operandi between industry and patient organisations, health professionals' organisations and public authorities at European level. A meeting of a sub –group on ' industry and patient groups' was held on 4th November, where we looked at a preliminary mapping exercise of some existing Codes of Conduct, and discussed the purpose, scope and possible content of a Charter. The next meeting focusing primarily on the relationship between industry and health professionals will take place on 23 November 2011. A progress report will be given on the occasion of the steering group on Access to Medicines in mid December in Warsaw.

See also article on Process on corporate responsibility.

For more information, please contact Nicola Bedlington.

9. EU Health Programme

On 9 November 2011 the European Commission adopted proposals for the new Health Programme, entitled "Health for Growth". The new programme will run from 2014 to 2020 with a budget of €446 million. The focus of the "Health for Growth" programme will be on fewer concrete actions which the Commission believes offer clearer "EU added-value".

The programme aims to support and complement the work of Member States to achieve the following four objectives:

1. *"To contribute to the creation of innovative and sustainable health systems".*
   Addressing shortages of resources (human and financial), promoting uptake of innovation through HTA and eHealth, expertise on healthcare reforms and support to the

   European Innovation Partnership on Active and Healthy Ageing.

2. *"To increase access to better and safer healthcare for all EU citizens".*
   Increasing access to medical expertise and information for specific conditions; solutions and guidelines to improve quality and patient safety – cross-border healthcare, rare

   diseases, prudent use of antibiotics and high standards of quality and safety for organs and substances of human origin.

3. *"To promote good health and prevent diseases"*
   Addressing key risk factors namely smoking, alcohol abuse and obesity, by identifying and disseminating best practices for cost-effective prevention and action on specific diseases such as cancer.

4. *"To protect people from cross-border health threats".*
   Focusing on developing common approaches for better preparedness coordination in health emergencies

The budget of the new Health Programme (€446 million) will be funded as previously through joint actions and grants to international organisations, grants to NGOs working in public health, and procurement contracts.

Next steps:

- EPF will engage with the EU Institutions on these proposals to ensure they are as patient-centred as possible. We will consult our membership shortly.

Links:

- European Commission proposals for Health Programme "Health for Growth"
- EPF's joint letter with EPHA

10. European Medicines Agency (EMA): Patients and Consumers Working Party meeting

On 13 September 2011, the EMA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) met in London. EPF Vice-President, Susanna Palkonen, participated as EPF's representative.

On the agenda were a number of topics, including the new EU pharmacovigilance legislation (update on direct patient reporting of suspected adverse reactions). As readers will know, the new legislation requires Member States to put in place appropriate methods facilitate reporting by patients, including a standardised web-based reporting forms. Patients will report to their country's competent authorities, who will forward reports to the EMA pharmacovigilance database, Eudravigilance.

The Agency has looked at some of the reporting forms already in use within Member States where direct patient reporting is established, and based on this it is preparing a draft standardised form. The core data will be harmonised for all EU countries, but the format will be flexible as there are already existing forms in several Member States. The draft form will be further discussed in the next meeting of the PCWP on 30 November.

The Agency presented an overview of the Eudravigilance Access Policy and demonstrated its use. The Access Policy foresees the publication of collated adverse reaction data related to spontaneous reports, with the objective to proactively disclose information which meets public needs, whilst maintaining personal data protection. The public will have access to data on centrally authorised products by the end of 2011, and data on all other medicinal products towards the end of 2012. The data will only relate to authorised product, not adverse reactions related to clinical trials.

The PCWP co-chair, Lise Murphy, recently gave a presentation about the EMA model of patient involvement at a meeting of the heads of national medicines agencies. Feedback indicated that there are varying levels of patients' and consumers' involvement within the different agencies. The Agency is currently surveying the activities of NCAs with patients and consumers, and a similar short online survey was prepared and disseminated to patient organisations recently to gather their feedback. The results of both surveys will be discussed at the 30 November meeting.

For a full description of these and other topics discussed on 13 September, and the presentations given at the meeting, see the EMA website (link below).

Links:

- The full minutes of this meeting as well as presentations are available on the EMA website here.
- Eudravigilance Access Policy.
- Eudravigilance dedicated website.

11. Information to patients: European Commission publishes revised proposals

On 11 October 2011, the European Commission presented its modified proposals for a Directive and a Regulation on information to the general public on medicinal products subject to medical prescription ("information to patients").

Readers will recall EPF's extensive involvement on this topic since the original legislative proposals were adopted by the Commission on 10 December 2008, as part of the so-called "pharmaceutical package". The two other components of this package – legislation on pharmacovigilance and on falsified medicines – have already been adopted and moved on to the implementation stage. It is the 'information to patients dossier 'that has proved most controversial and difficult of all.

The Commission's proposals aim to amend the current legislation (Directive 2001/83/EC and Regulation (EC) No. 726/2004 respectively) with regard to information to the general public on prescription medicines. The Commission wants to create a clearer framework for the provision of non-promotional information to the general public by the pharmaceutical industry, while maintaining the ban on direct-to-consumer advertising of prescription medicines.

On 24 November 2010, the European Parliament adopted a legislative resolution at its first reading, with a large majority endorsing the report of Mr Christofer Fjellner MEP. EPF worked closely with the key MEPs in the Parliament, and our input was reflected in the Parliament's position which achieved above all an important political shift from a narrow focus on the rights of industry, to the right of patients to access high-quality, non-promotional information about the medicines they take.

The revised proposals will now be debated by Member States in the EPSCO Council meeting of 1-2 December 2011, having already been subject to a preliminary discussion. Once the Council adopts a common position, the European Parliament will have its second reading on the proposals. Unlike the first reading, which had no time limit, the second reading has a time limit of three

months, which may be extended to four. There are also restrictions as to the type of amendments that can be tabled, and who can table them.

The EPF secretariat has analysed the proposals and formulated a preliminary position, which has been circulated to our membership for a consultation.

The proposals are narrow in scope, addressing only prescription medicinal products. They do not, therefore, address the wider information needs of patients and citizens on health-related issues, including information on diseases and conditions, wider therapy options, prevention and healthy lifestyles, etc. This wider information need was a crucial part of the rationale behind the European Parliament's position: in his report, the rapporteur called for a wider information strategy, including health literacy. The Commission has indeed recognised that there is a need for broader information, but stated that it cannot be addressed within the scope of the current proposals.

While national competent authorities and healthcare professionals should remain the main sources of information on medicinal products for the general public, the proposals reaffirm the "pull" principle for information to the general public – that information should not be disseminated actively by industry ("push"), but that it should be available to those who actively seek it.

On the whole, the proposals are welcome as they take on board, fully or in part, most of the 78 amendments adopted by the European Parliament. There are still some points of concern and uncertainty, but overall the revised proposals are a great improvement on the original 2008 ones.

EPF will share an official position on the proposals once our internal consultation process is completed.

Next steps:

- EPF member consultation: ongoing
- EPSCO Council debate on the modified proposals: 1-2 December 2011

Links:

- Commission modified proposals, including Q&A and press statement in all EU languages
- EPF statement – reaction to the new proposals
- EPF previous position statements and responses to consultations

12. Access to Medicines –Process on Corporate Responsibility in the Field of Pharmaceuticals

This process, the so-called "Tajani initiative" after the Commission Vice-President who initiated it, encompasses three "platforms" of activity: the Platform on Access to Medicines in Europe, which was the first to be launched in late 2010; the Platform on Ethics and Transparency; and the Platform on Access to Medicines in Developing Countries. The background on this initiative has been extensively described in previous issues of this mailing.

EPF is represented on the Steering Group of the Platform of Access to Medicines in Europe and the Platform on Ethics and Transparency, together with Member States' representatives and other stakeholders. The patient perspective on the Platform on Access to Medicines in Developing Countries is provided by IAPO.

Platform on Access to Medicines in Europe

The overall aim of this platform is to facilitate fair and timely access to medicines following their market authorisation through a non-legislative approach focusing on collaboration between different parties. All five project groups have now started their work, and an update will be given to the Steering Group on 14 December in a meeting to be held in Warsaw.

Platform on Ethics and Transparency

A first meeting of the Platform on ethics and transparency took place in Brussels on 1 September. This platform will look at ethics issues, focusing on relations between industry and three other parties: patients, health professionals, and Member States' competent authorities. EPF was invited to co-chair the working group on industry relations with patients, together with the Commission DG Enterprise. A first meeting of the working group took place on 7 November.

The working group will aim to produce a comprehensive transparency charter that will identify the roles and responsibilities of industry and patients, in order to create the highest possible standards in the sector. EPF as co-chair of the working group has conducted a preliminary mapping exercise, collecting existing codes that patient groups use in their relations with industry. An analysis of the main components, commonalities and gaps was presented at the meeting on 7 November. following this, a framework of potential content will be developed which will be submitted for review by EPF's membership.

Next steps:

- The Steering Group will meet on 14 December in Warsaw, where SG members will be updated on the progress of the project groups.
- The project groups will submit their final reports and recommendations by the end of 2012.
- For more information on this process see the DG Enterprise website or contact the EPF Secretariat.

13. Medical Devices

The future proposal to recast the Directive was one of the topics discussed by EPF members and the MedTech industry at the second MedTech dialogue organised with Eucomed on 11 October (see event section). Eucomed Chief Executive Director John Wilkinson presented the current state of play and priorities for the industry on this dossier. EPF Director Nicola Bedlington presented areas within the recast that had been identified by the Policy Advisory Group in previous consultations with the membership.

One key area identified at the last Policy Advisory Group meeting and again stressed by member organisations who participated at the MedTech dialogue is the importance of meaningful patient involvement: The European Medicines Agency was highlighted has having developed a very good model in this area for medicinal products, which needs to be transferred for medical devices, regardless of which authority or body is designed in the proposal to improve existing system and coordination on medical devices.

Other good practices which were established by the Agency were identified as model to follow by the policy advisory group, such as the system of direct reporting for pharmacovigilance which could be adapted for the vigilance system and reporting of serious incident for medical devices, and methods for communication on safety issues.

Next Steps:

- The Commission is expected to adopt a legislative proposal in the first quarter of 2012. Our membership will be consulted to form EPF position.

14. Anti-Discrimination - Health Inequalities

The European Union Agency for Fundamental Rights (FRA) recently published two reports in the field of fundamental rights and health.

On 11 October the Agency published the report "Migrants in an irregular situation: access to healthcare in 10 European Union Member States"). The report highlights that irregular migrants have limited access to healthcare due to legal, economic or practical barriers, though they face increased health risks due to living and working conditions. Irregular migrants have rights to healthcare according to international conventions, though often vaguely defined and with limited enforceability. The FRA research highlights that inn six out of the ten countries studied, access is limited to emergency care, and for other countries, healthcare may be subject to conditions (e.g. proof of residence). The report contains opinions from the FRA on actions to take to improve the situation of irregular migrants as regards healthcare. The complete report is available here.

On 24 October the FRA published a report on "legal protection of persons with mental health problems under non-discrimination law". It highlights that definition of disability encompasses people with mental health problems in almost all EU Member States. They are also covered in most but not all EU Member States by reasonable accommodations measures in the field of employment, that is to say modifications and adjustments to allow persons with mental health problems to enjoy exercise of their fundamental right on an equal basis.

These findings offer new elements in relation to the EU anti-discrimination legislation framework. Different definitions of disability currently apply across Member States; and patients with chronic diseases are not always comprised in the definition, depending on their disease-area and the Member State they live in. As a result they are not always included in the scope of EU anti-discrimination legislation in the workplace.

The latest progress report on the discussion at the Council regarding the so-called horizontal "anti-discrimination directive" which aims to set a framework the prohibition of discrimination on the grounds of religion of belief, disability, age or sexual orientation outside of the workplace (see previous issues of the mailing) was issued in June, and highlighted progress on the provisions related to reasonable accommodations. However essential disagreements by some Member States on the scope of the Directive still remain which hampers adoption of the directive.

Next step:

- The Council is expected to re-examine the proposal for a horizontal anti-discrimination directive in January 2012.
-

15. EPF Policy Advisory Group– call for interest to participate in task groups

As announced in the last mailing the Policy Advisory Group's structure is changing, to adapt to the increasing role that the group is playing within the policy consultation process and because the work load of the Members of the PAG has become increasingly complex and demanding.

The renewed PAG will encompass a number of smaller task groups that will provide expertise in specific policy areas. The whole PAG group will still be involved in the process, but preparatory work and background information will be more focused on the task groups. Organisations who are already participating are asked to indicate their priority areas of interest/expertise. Other EPF member organisations, which are not yet member of the PAG, are invited to join and participate in task groups of their choices.

The EPF Secretariat as set up an online poll which will be circulated in the coming days to EPF Members: This survey is a call for interest to all EPF member organisations to indicate whether they would like to participate in one or more task groups. This survey is a first step in forming the task groups. We expect that some areas will be more popular than others, but will aim to have a balanced representation across the groups. All interested parties will be contacted with more information.

Should you wish to participate, please indicate areas that your organisation would like to actively participate in according to your interest but also your organisation's realistic capacity to contribute - the members of task groups will be expected to give input regularly, and sometimes at short notice.

All EPF member organisations will still have an equal chance to give input through the full member consultation procedures.

For More information please contact EPF Senior Policy Adviser Kaisa Immonen Charalambous.

Back to contents

16. Magnetic Resonance Imaging (MRI) Directive Update

The Alliance for MRI held a meeting on 8 November to update its members on the state of play for the proposal to revise Directive 2004/40/EC on electromagnetic fields (EMF), which would introduce an exemption for Magnetic Resonance Imaging (MRI) from the binding exposure limits proposed in the new directive. For more information on the alliance, please refer to our July issue.

The absence of exemption for MRI would limit the use of this technology in several ways: it would be an obstacle for healthcare professionals to accompany patients who need it through the process, it would also limit research on MRI, and MRI guided surgery.

MRI poses no known risks to workers, and its safety is ensured by international standards in place. In addition guidelines for the safe use of MRI would be developed once the directive adopted to further protect healthcare professionals and other workers.

At the European Parliament, MEP Isabelle Morin-Chartier (EPP, France) is rapporteur for the committee on Employment and Social affairs which is responsible for this proposal. The Environment, Public Health and Food Safety committee will also give its opinion: rapporteur for the ENVI committee is MEP Philippe Juvin (EPP, France).

Current discussions in the Council of Ministers on the proposal indicate that several Member States do not support the exemption: this may result in a compromise whereby each Member State will decide whether they will put in place exemption, creating an uneven situation for patients across Europe.

The Alliance, of which EPF is a member, calls for the exemption proposed by the European Commission to be adopted without delay, as limits set by the 2004 Directive may otherwise enter into force in April 2012.

Next Steps:

- Vote on opinion of ENVI committee is scheduled for January 2012,
- Vote in the Employment and Social Affairs committee of the European Parliament is scheduled for the 13 February
- Vote in the European Parliament will then take place in March 2012 (to be confirmed).
- EPF encourages its members who have a particular interest for that issue to contact the Secretariat.

For more information or queries please contact EPF Policy Officer Laurène Souchet.

17. Particular nutrition regulation

In June 2011 the European Commission adopted a proposal for a regulation on food for special medical purpose**.** This regulation partially repeals the current framework for particular nutrition and aims to take out the concept of dietetic food from EU legislation, to replace it by a limited number of well-established categories of specialised foods. Many stakeholders now consider the concept of dietetic food is irrelevant and may be misleading for consumers, and the current framework for dietetic food often conflicts with new EU legislation, causing different interpretations of rules across Member States.

Food for special medical purposes is intended for the dietary management of patients, to be used under medical supervision, for the "exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients contained therein, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet." The Commission takes the example of patients with cancer or renal failure, which may have specific nutrition need.

The proposal establishes a ***single EU list of substances***, instead of the existing three, that can be added to these foods. It maintains **the existing compositional and labelling rules.** Other food law applies for specialised food. The labelling, presentation and advertising of food, shall provide adequate consumer information and must not be misleading This food shall only be allowed on the retail market in the form of pre-packaged food.

Under the proposal *gluten free* and *low-gluten products* will not be comprised under the particular nutrition framework, and the specific regulation on these products will be repealed by this regulation. These products will instead come under the regime of the health& nutrition claims regulation (Regulation (EC) No 1924/2006), with the necessary technical adaptations.

The dissemination of any useful *information* or *recommendations* with reference to this category of food may be made exclusively by persons having qualifications in medicine, nutrition and pharmacy.

The Commission will be empowered to adopt delegated act on some specific requirements (composition of the food, labelling, presentation, health claims and advertising) and the notification procedure for the placing on the market of this food.

The rapporteur for the committee responsible in the European Parliament(Environment Public Health and Food Safety) is MEP Frederique Ries (ALDE, Belgium).

Next Steps:

- European Parliament the adoption of report scheduled for adoption in committee on 29 February 2012, and plenary sitting (first or single reading) is expected to take place on 17 April 2012.

Projects & Initiatives

18. Chain of Trust: progress update and implementation of the National Workshops

As the reader may recall from previous EPF Mailing issues EPF is leading, since January 2011, a EU project co-funded under the Public Health Programme called Chain of TRUST. This project, which is implemented together with other six partners, aims at assessing the perspective of the main end users of telehealth services across the EU to see whether and how views have evolved since the initial deployment of telehealth and what barriers there still are to building confidence in and acceptance of this innovative type of services.

To achieve this objective during the first half of 2011 the Chain of TRUST consortium conducted a **literature review and an online survey** to gather knowledge on patients' and health professionals' views, needs and barriers regarding telehealth. See www.chainoftrust.eu/news.

In early October the consortium started implementing the third core project activity, the six **National Workshops**. The ultimate objective of these workshops is to assess through a qualitative approach the views, needs, benefits as well as the barriers related to telehealth from the perspective of patients and health professionals in six European countries in order to enable the Chain of Trust consortium to validate and further complement the findings of the literature review and the online survey.

At the time of writing five out of six national workshops have been successfully delivered: in **Nieuwegein** (the Netherlands) on October 11th; **Oslo** (Norway) on October 17th; **Coimbra** (Portugal) on October 26th; **Riga** (Latvia) on November 2nd; and **Warsaw** (Poland) on November 10th. The last workshop will take place in **Thessaloniki** (Greece) on December 5th.

"All four groups, the doctors, patients, nurses and pharmacists were very active during the focus group sessions, learning from each other and exchanging experiences and opinions", said Undine Knarvik, organiser of the Norwegian workshop.

"The workshop led to a profound discussion, some new ideas and solutions for Telehealth development", commented the organisers of the Dutch workshop.

The reports of the five national workshops are currently been prepared and the outcomes will be included in an intermediate public deliverable that will be published in early 2012. EPF would like to take this opportunity to also acknowledge the great effort made by all national patient and health professional organisations who have been involved in organising and delivering the Chain of Trust National Workshops.

The six National Workshops will be further complemented by four **European focus groups**, one with patients, one with doctors, one with nurses and one with pharmacists, which will take place in Brussels between December 2011 and early February 2012. The first focus group to be organised will be the one with patients on December 10th which will be led by EPF.

For more information on the Chain of TRUST project please contact Walter Atzori or visit the project website at www.chainoftrust.eu.

Chain of TRUST National Workshop in Nieuwegein

19. RENEWING HeALTH: Project status update and Mid-term workshop

RENEWING HeALTH, "**REgioNs of Europe WorkINg toGether for HEALTH"**, is a three-year project co-funded under the EU Competitiveness and Innovation Programme, which started in February 2010 with the objective of implementing large-scale real-life test-beds for the validation and subsequent evaluation of innovative telemedicine services for patients with chronic conditions in nine European regions.

EPF would like to inform its readership that the Project is organising a mid-Term Workshop in Brussels on November 30th afternoon attached to EHTEL 2011 Symposium "Seamless Integration for Personal Health Services – Evidence and Sustainability". This workshop, which is kindly hosted by the European Economic and Social Committee (EESC), the voice of the voice of organised civil society in the EU's decision-making process, will be a key opportunity for you to learn more about the project, its objectives as well as its potential for promoting new patient-centered care models for patients with chronic diseases.

You can register to the RENEWING HeALTH Mid-term workshop here.

The project's User Advisory Board (UAB), which EPF is co-managing together with EHTEL (the European Health Telematics Association), will meet in early December for the fifth time in Brussels. As mentioned in previous Mailing issues the primary mission of the UAB, is to operate as a standing advisory committee to advise and provide on-going feed-back to the project team on the needs of users (patients, carers, health professionals, health managers) of the piloted telemedicine services. The objective of the next UAB meeting will be to approve the revised version of the User Requirements Deliverable - a document designed to serve as a reference framework for the representation of user needs, requirements and expectations in relation to telemedicine.

The project Steering Committee will meet in Treviso (Italy) on February 8-10 2012.

For further information please contact Walter Atzori or visit the project's website at: www.renewinghealth.eu

20. e-Health Governance Initiative – eID Workshop and Work Package Trust and Acceptability Meeting

We presented in the previous Mailing issue an update on the EU eHealth Governance Initiative (eHGI), a political initiative set up in 2009 aimed to establish an efficient, appropriately governed and sustainable platform to enable EU Member States and stakeholders to further develop cooperation on eHealth issues to help implement and deploy interoperable eHealth services across Europe.

The reader may recall that the first priority of the eHGI is the deliver by spring 2012 of a proposal of recommendations for a common **EU framework on eID** (electronic Identity) Management that should make possible cross-border eHealth services within the framework of the Directive 2011/24/EU on the application of patients' rights in cross-border healthcare.

To this end the eHGI organised an **exploratory seminar** on this topic in **Athens on November 9th 2011**, in the context of a major event marking the launch of the epSOS project pilots (epSOS is the main eHealth interoperability project focused on improving medical treatment of citizens while abroad by providing health professionals with the necessary patient data).

The eID workshop was characterised by productive, intensive discussions revolving around a number of key eID-related issues including: which conditions need to be met in order to guarantee the possibility to verify and validate the information?; which information and communication strategies should be used in order to inform users and enforce trust on this specific topic?; what successful measures/strategies in countries which have already deployed e-ID have been taken in order to secure trust from the users and what have been the main barriers?; which aspects/solutions need to be considered in order to make an eID framework "usable" in the context of healthcare?; what will be the necessary architecture to cover the e-ID (including authentication and authorisation) requirements for these services?; what kind of security is needed to minimise risks at legal, organisational and technical level?.

We would also like to take this opportunity to remind you that the **eHGI has recently launched a call for expert(s) who will support the various eHGI work packages on (eID) Management**. The initial set of issues identified by the project can be classified

under three components, Trust and Acceptability (Users' Perspective), Interoperability, Standards and Market, and Legal Privacy and Data Protection.

The call is open to all individuals with proved experience and expertise in the domain. Application will include an **application letter** and **CV** and shall be sent to Walter Atzori. For a more detailed description of the call, components, time line, and project structure please click here.

This eHGI seminar was also an opportunity for the project partners to hold separate Work Package meetings to agree on short term operational priorities.

EPF is co-leader of the **Work Package dedicated to Trust and Acceptability** whose general objective is to provide stakeholders' representatives with the means and the opportunities to discuss and identify possible ways to enhance eHealth users' trust and acceptability and make proposals to EU Member States, representatives as well as to the European Commission, as appropriate, on how the needs of users should be best taken into account in the development of European and national eHealth strategies.

In early 2012 this Work Package will publish a deliverable which will provide an overview of the impact of different eHealth operational solutions on trust and acceptability in relation to a number of domains identified in close consultation with different groups of eHealth users.

More information on this item will be provided in next Mailing issues.

For more information on the eHGI please contact Walter Atzori.

21. Interquality

The project InterQuality, officially started in December 2010, held its second meeting in Madrid on 7th November 2011.
The rationale behind InterQuality is the acknowledgement that increasing health care spending often does not improve quality, efficiency or availability of medical services. It is therefore very much needed today to develop scientifically proven tools to help make decisions regarding the selection of appropriate financing mechanisms in different areas of the health care system.

The meeting held in Madrid was organized to discuss and comment on the first interim results. EPF presented the project Dissemination Strategy which was approved by the project Executive Board.

Dr. Berenson (Urban Institute, Washington) and Prof. Hermanowski (University of Warsaw) presented the first interim results from WP1 and WP2. WP1 produced a report on the effect on quality, cost and access in four areas of payment: physician, hospital, integrated care, non-hospital facilities. WP1 also produced an articulate typology/model of payment systems for physicians, hospitals, and integrated care systems

WP2 report presents guidelines on common terminology and conceptual framework for outcomes, cost and economic efficiency measurement with review of methods of measuring quality and equity of healthcare. The aim is to solve methodological challenges raised by analysis of patient-level data in international comparative research of payment systems in four types of healthcare that it specifies: (i) outpatient care, (ii) inpatient care, (iii) integrated care, and (iv) pharmaceutical care.

All partners are now developing procedure to produce papers based on collaborative work.
For more information please send an e-mail to Liuska Sanna or to Gaya Ducceschi.

22. Joint Action on Patient Safety and Quality of Care

In previous issues of this Mailing we have described in detail the progress of the proposal for a Joint Action on Patient Safety and Quality of Care, which was submitted to the Executive Agency on Health and Consumers on 27 May 2011. We are pleased to announce that the application was successful, and the Joint Action consortium is currently in the negotiation phase with the

European Commission to finalise the contract. The Joint Action kick-off is envisaged for March 2012, and the action will last three years.

The overall aim of this Joint Action is to create a permanent platform for future cooperation between Member States in the area of patient safety and quality of care. Three specific objectives are to support Member States in the implementation of the Council Recommendation on patient safety; to initiate cooperation on the quality of healthcare; and to facilitate the sharing of good practices in patient involvement and empowerment.

The Joint Action is led by the French health authority, the Haute Autorité de Santé (HAS). EPF is an EU-level stakeholder organisation representing patients, together with other organisations representing doctors, nurses, dentists, health and hospital managers as well as international organisations. EPF will be actively involved in several key work packages of the Joint Action. We will update members in more detail in the next issue of this mailing.

Links:

- Commission Communication on patient safety
- Council Recommendation on patient safety and healthcare associated infections
- EUNetPas (European network on patient safety) project website

23. New Projects to Start in 2012

EUPATI – meeting of the Consortium

In the previous Mailing issue we announced the imminent start of a major patient-led project coordinated by EPF named EUPATI, "**European Patients' Academy on Therapeutic Innovation**", a five-year project supported by the **Innovative Medicines Initiative Joint Undertaking** aimed at creating better education and information tools for patients on pharmaceutical research.

From 2012, the academy will educate patient representatives and the lay public on personalised and predictive medicine, design and conduct of clinical trials, drug safety and risk/benefit assessment, pharmaco-economics as well as patient involvement in drug development.

You can read more about this project in the temporary project webpage within the EPF website at:

www.eu-patient.eu/Initatives-Policy/Projects/EPF-led-EU-Projects/EUPATI/

The EUPATI Consortium, consisting of 26 leading pan-European patient organisations, academic and not-for-profit organisations as well as EFPIA member companies, gathered in Brussels on October 19th 2011 to agree on important steps towards the finalisation of the project description. This meeting was chaired by Anders Olauson, EPF President and facilitated by Jan Geissler, consultant to the Project.

Major outcomes of this meeting were the clarification of the project's governance structure and further specification of roles and responsibilities of the two main advisory bodies, the **Project Advisory Board**, composed of high level representatives with long standing experience and credibility in relation to patient involvement and/or pharmaceutical R&D who will provide on-going advice to the EUPATI consortium, and the **Regulatory Advisory Panel**, set up to help provide for objectivity, transparency and independence and ensure that output generated within the project is unbiased and free from commercial interests.
At that meeting a "EUPATI Ethical Framework" was also agreed. This framework defines the responsibilities of the project to its participants as well as the ground rules on anonymity, confidentiality, informed consent, social research, ethical review,

professional integrity and publication ethics. An *ad-hoc* **EUPATI Ethics Panel** will ensure compliance with the EUPATI Ethical Framework throughout the project life-cycle.

The last key item that was agreed upon was the development of a **EUPATI Evaluation Plan**. This Plan provides for a framework for systematically and objectively assessing the relevance, performance, impact, relevance and sustainability of EUPATI and is complemented by **Quality Assurance** measures designed to ensure that excellence is inherent in all EUPATI educational and informational content and that such content meets the requirements of the different target audiences and remains relevant throughout project implementation and beyond.

The project is expected to start in the first quarter of 2012.

For more information on the EUPATI project please contact Nicola Bedlington.

SUSTAINS - a new EU project

EPF is pleased to announce the imminent start of a new project called SUSTAINS - ***Support USers To Access INformation and Services*** on **patient access to Electronic Health Records (EHR)**. The project will contribute directly to the implementation of Key Action 13 of the Digital Agenda for Europe, "Undertake pilot actions to equip Europeans with secure online access to their medical health data by 2015 and to achieve by 2020 widespread deployment of telemedicine services".

The project proposal was submitted in June 2011 under the EU Competitiveness and Innovation Programme – ICT strand – Pilot Type B. SUSTAINS was recommended for funding in early September and, at the time of writing, it is undergoing the final stage of the negotiation phase. The project should officially kick-off in January 2012.

SUSTAINS will provide a rich basket of services based on giving citizens online access to their EHR. The services proposed have been distilled from the experience of European regions which have already pioneered such access.

Although each of these services has a specific objective, all the services contribute to the achievement of a new paradigm in healthcare in which the citizen/patient is not any longer a passive subject, but he/she becomes an active player in the

management of his/her own health. Fostering patient empowerment through supporting the widespread deployment of patient-centered eHealth services is indeed the primary objective of SUSTAINS.

The background to the SUSTAINS project has three drivers that SUSTAINS contributes to. These can be summarised as:

1. **Empowerment of patients,** there is a growing tendency by patients and the public to question information from the health system, ask for a second opinion, demand respect and dignity in their treatment, expect convenience, etc.
2. **Medical results.** Progress in treatment especially of chronic diseases need efficient and continuous contact between the patient and the professionals in order to achieve optimal medical result
3. **Efficiency and economy,** with the new treatments available, and the growing demand from patients/public, there is a need for improved efficiency and economy.

EPF has lots for expectations from this project for two main reasons:

a) The project represents an excellent opportunity to explore and gather evidence-based information on patients' access to EHR and assess whether and how patient empowerment can be effectively strengthened as a result of such access

b) EPF will play a key role in this project, especially in two Work Packages (WP), notably WP3 "Evaluation and Deployment Planning" and WP 4 "User Requirements". In the context of WP4, which is led by EPF, EPF will lead the work on patient requirements identification which will inform the use cases specification of the piloted services. In the context of WP3 EPF will lead the work on patient empowerment evaluation aimed at assessing the change in patient empowerment before and after the trials.

The kick-off meeting will be held in Uppsala (Sweden) in mid-January 2012.

For more information on SUSTAINS please contact Walter Atzori.

24. Other Initiatives

HTA Survey with Patient Organizations

The third phase of the HTA research was launched on 19th September. This survey targeted patient organisations that give patient perspectives/evidence to HTA and those that have tried to contribute to HTA processes but for whatever reason were not successful.

We will report on the outcomes of the third stage of the HTA research in the next mailings. For more information please contact Gaya Ducceschi or Abinaya Rajan.

Conferences and Events

25. National Conference on quality registers Stockholm, Sweden, 5 October 2011

EPF President Anders Olauson addressed a large national conference addressing the issue of quality registers. Please go to www.kvalitetsregister.se/om_kvalitetsregister/quality_registries for a copy of the programme.

In his speech , Anders highlighted that the the EU Directive on cross-border healthcare, adopted earlier this year, explicitly refers to the principle of high quality of healthcare – and contains important provisions concerning quality and safety. It requires Member States to have in place standards and guidelines on quality and safety, and to give this information to patients on request. Member States will also need to cooperate with each other on the standards and guidelines on quality and safety.

In order to achieve this, Quality Registries are a key tool for the collection of reliable data and its comparative analysis.

In Sweden, the registries and competence centres together form a “comprehensive knowledge system” for continuous learning, quality improvement, and management of healthcare services at all levels.

EPF wholeheartedly supports this spirit of continuous learning and improvement: effective registries benefit both health professionals and patients. Furthermore, in order to raise the overall quality standards in the EU, it is crucial that data is made available and can be meaningfully compared across different Member States.

Patient feedback plays a key role in developing good quality systems in healthcare. Do patients – for example – perceive "quality" in the same way as health professionals of hospital managers do?

Listening to their input, and integrating it in policy, helps ensure that services are developed in a way that meets patients' real-life needs and preferences.

EPF recommends that patients should be meaningfully involved both at the individual and the collective level, in developing, implementing and evaluating quality and safety-related policies and programmes.

To watch full video of Anders' Presentation, please visit the following link: www.kvalitetsregister.se/konferenser_5/konferens-2011/film

For more information on the outcomes of the meeting and next steps, please contact the EPF Secretariat.

26. Alzheimer Europe lunch debate in the European Parliament, 11 October 2011.

On 11 October, EPF member Alzheimer Europe organised a lunch debate entitled debate "The £20 billion question: Improving the lives of people with dementia and their carers through cost effective dementia services" in the European Parliament, Brussels. It was co-hosted by MEPs Marina Yannakoudakis (ECR, UK) and Keith Taylor (Green/EFA, UK).

Louise Lakey, Policy Manager of the Alzheimer's Society (UK) gave an overview of the findings and recommendations of the inquiry launched in December 2010 to identify barriers to cost-effective dementia services, which led to the publication in July 2011 of the report "The £20 Billion question" (available here) , which highlights in the UK live with dementia, and the cost of dementia care

amount to 20 billion pounds for 750,000 people with dementia, but it is often spent on inadequate care. The report identified opportunities to deliver better care, including through shifting resources away from hospital into community based services which would improve quality of life of patients and bring savings for social and health care.

Baroness Sally Greengross, chair of the All-party parliamentary group on Dementia (UK) explained that dementia is one of the biggest health and social care challenge Europe is currently facing, and the recommendations, which focus on saving money by providing adequate dementia care, are of interest for other EU Member States.

Links:

- Article on the event on Alzheimer Europe's news section.

27. European Health Policy Forum, Brussels 12 October 2011

Nicola Bedlington represented EPF at the last European Health Policy Forum in October. Key items on the agenda included follow-up on the European Innovation Partnership on Active and Healthy Ageing within the EU 2020 strategy**;** Information on the EC anti-smoking campaign "EX-SMOKERS ARE UNSTOPPABLE" ; a report on the EU Health Strategy from the meeting of the Council Working Party on Public Health at Senior Level by Polish Presidency and follow-up on the mid-term evaluation; an update on the future of the Health Programme post-2013 and mid-term evaluation of the current Health Programme. Professor Mark McCarthy presented the STEPS project exploring health research and innovation and a presentation by the European Health Management Association and the European Society for Quality of Care on patient safety in hospitals.

For more information and a copy of the report from the meeting please contact Nicola Bedlington.

28. EPF EUCOMED Dialogue Meeting, 13 October 2011

Readers will recall the EPF has set up a regular Dialogue with EUCOMED, the Trade Association representing the Medical Devices industry , where our respective members meet to discuss policy issues linked to medical devices. The second such Dialogue Meeting took place on 13 October. Issues on the agenda were an exchange of views on the revision of the Medical Devices Directive, HTA and medical devices, and exploring patient centred healthcare in the context of medical devices.

For a copy of the report of the meeting, please contact Nicola Bedlington. EPF members will be contacted in due course regarding the date of the next Dialogue meeting in early spring.

In our next issue, we will report back on a meeting on 23 November with Ms Jacqueline Minor, Director of Consumer Policy, DG SANCO to discuss EPF's position on the Medical Devices Directive and an effective patient focused governance model for MD regulation.

29. MEDTECH FORUM 14 October 2011

Nicola Bedlington represented EPF at the MEDTECH FORUM, 12-14 October 2011, focussing on medical devices and innovation in Europe. She was a speaker in a session on regulation and market access in Europe and described the patients' perspective on regulation and access to medical devices. For a copy of Nicola's presentation please contact the EPF Secretariat. For more details of the event and a report on outcomes please visit www.medtechforum.eu/conference-material/post-event-report

30. Launch of the ENGENDER policy Briefings, 18 October 2011

EPF Participated to the roundtable discussion to launch the ENGENDER policy briefing which took place on 18 October at The European Parliament.

The event was chaired by MEP Edite Estrela (S&D, Portugal), and highlighted the specific health needs according to gender, and the need to apply a gender sensitive approach to treatment and care.

Dr Anna Mansdotter from the Karolinska Institute, Sweden, presented The ENGENDER project which focuses on gender inequalities in health. The 3 objectives of the project are

The promotion and support of gender equity in health by developing an **online database of good practices** in Europe, (which include any good practice from legislations, to guidelines or research projects, at all levels) Participants highlighted that this database is a key outcome and need to be used and kept up to date.

The creation of a sustainable "**European network on policies and interventions tackling gender based inequalities in health**", a forum to exchange information and good practices between the 27 EU Member States on gender and health,

Promoting **action and research on gender inequities in health through topic-specific policy briefings,** which are other key outcomes of the project. They focus on structural gender inequalities, gender stereotypes, gender exposure and vulnerabilities, gendered politics of health systems, gender imbalances in health Research, and Gender mainstreaming. Each of this brief bring forward examples of good practices from the database and make recommendations for policy actions.

Link:

- The complete report on the event
- Presentations at the meeting are available here.

31. Bringing Cross-Border Healthcare in Europe Closer to Reality, 20 October 2011

On 20 October EPF Policy Officer Laurène Souchet attended the event "Clarity and Quality: Bringing Cross-Border Healthcare in Europe Closer to Reality" organised by Public Policy Exchange. Speakers including healthcare professionals' and European Commission's representatives highlighted that many practical problems will need to be solved in the implementation period for the Directive on Patients' Right in Cross-Border Healthcare.

Speakers indicated that the implementation process is ongoing with Member States.

Information to patients provided to National Contact points, and by healthcare providers will be one key area in the implementation: Guidelines may be needed for adequate information to patients by healthcare providers, social security systems will also need to give information on the basket of benefits patients are entitled to and levels of reimbursement.

Some points regarding timeframe will need to be clarified: for example Member States shall set out "reasonable periods of time" within which requests for cross-border healthcare must be dealt with and make them public in advance and patients should receive reimbursement "without undue delay."

One essential part of the implementation is the application of **chapter 4 of the Directive on cooperation**: there are barriers to **recognition of prescription between Member States** to allow pharmacists to provide medicines when patients come with a prescription delivered in another Member State. The Commission is currently holding a consultation on this point.

Clarity and quality on continuity of care will also be a fundamental issue for patients and healthcare professionals alike. The European Federation of Nurses Association as recently published a statement on continuity of care in the framework of this Directive.

Next Steps:

- EPF will circulate shortly to its membership toolkits to help patients' organisations to engage with their Member States in the implementation process for this directive
- The European Commission has opened its consultation on recognition of prescription (deadline 8th January) here.

32. Addressing non communicable diseases, Brussels, 7 November 2011

EPF Policy Officer Laurène Souchet participated to the roundtable organised by Hill and Knowlton on "Addressing Non-Communicable diseases in Europe: the patient and professional experience". The event focused on the adoption of a UN political declaration on non-communicable diseases following the High level meeting on prevention and control of non-communicable diseases held on 19 September 2011 in New York.

The President of Gamian Europe, Dolores Gauci presented the patients' perspective, with a focus on mental illness, and presented the link between mental illness and co-morbidities, as patients with mental illness are at higher risk to experience other non-communicable diseases, and patients with non-communicable diseases may also experience mental illness (depression, anxiety).

Though non-binding, the declaration recognizes the increasing burden of NCDs worldwide and acknowledges a range of issues related to their prevention and control. Participants and speakers reflected on how to move forward with the political declaration, as it does not contain specific target or objective.

33. Conference on "Excellence in Healthcare: Comparability of Quality, Patient Safety, Competences and International Accreditation", Ljubljana, Slovenia, 10-11 November 2011

On 10-11 November, the Ministry of Health of Slovenia organised a European conference in Ljubljana on the theme "Excellence in Healthcare: Comparability of Quality, Patient Safety, Competences and International Accreditation". Kaisa Immonen-Charalambous attended as EPF's representative.

Among the speakers were Mr Dorijan Marušič, MD, Minister for Health of the Republic of Slovenia; Mr Martin Seychell, Deputy Director General of European Commission DG SANCO, Mr Zlatko FRAS, President of the European Union of Medical Specialists (UEMS), Ms Barbara Kutryba of the European Society for Quality in Healthcare, and a large number of other academic and medical experts, representatives of healthcare professionals and other stakeholders.

The event aimed to raise awareness on the tools to assure the highest quality of health care in Europe, including accreditation; highlight the purpose and added value of various tools for measuring quality and safety; explore the implications of the EU cross-border healthcare Directive on quality and safety; and to discuss the role of professional qualifications in the context of the review of the EU Professional Qualifications Directive. EPF's presentation focused on the cross-border healthcare Directive and particularly on the information that patients want and need in the cross-border context.

For more information about this event please contact Kaisa Immonen-Charalambous.

34. Diary

Date	Event	Attendance
November 18	Polish Presidency Expert Conference on New Quality Developments in Healthcare, Warsaw	Tomasz Szelagowski
November 21	EPF meeting on the Clinical Trials Directive, Brussels	Kaisa Immonen Charalambous
November 21	European Commission Patient Safety & Quality of Care working group, Brussels	Laurène Souchet
November 21	WHO EURO conference "Modern Health care delivery systems and the role of hospitals"; Brussels	Nicola Bedlington
November 22	Health Literacy Conference, Brussels	Nicola Bedlington
November 22	Launch event of the EFA Awareness Project on Respiratory Allergies, Brussels	Susanna Palkonnen
November 22	EPPOSI conference on chronic conditions, Brussels	Robert Johnstone
November 22	Chronic Conditions in an Ageing Population – a Spotlight on Parkinson's disease, Brussels	Kaisa Immonen Charalambous
November 23	European Federation of Nurses 50th Anniversary, Brussels	Nicola Bedlington
November 24,25	CPME meeting Warsaw	Nicola Bedlington
November 28	EPF Board meeting	Board members, Nicola Bedlington
November 29-30	Microsoft Health User Group	EPF Board members
November 29	HTA Conference « Improving patient care and value-for-money ?" Brussels	TBC
November 29	EFPIA Think Tank, Brussels	Nicola Bedlington
November 30	RENEWING HEALTH Mid-Term Workshop, Brussels	Walter Atzori
November 30	GSK Health Advisory Board London	Nicola Bedlington
November 30	European Heart Network patient seminar, Brussels	Kaisa Immonen Charalambous
November 30	GSMA Breakfast Meeting on Care without borders? Improving access and advancing the reach of healthcare via mobile technologies	Walter Atzori
December 01	EUROPABIO workshop in the European Parliament on clinical trials regulation, Brussels	Kaisa Immonen Charalambous

December 01	HTA Conference, London	Nicola Bedlington
December 01	ETHEL Symposium "Seamless Integration fro Personal Health Services-Evidence and Sustainability",EESC, Brussels	Walter Atzori
December 05	Pan-European Workshop on Medical uptake of Mobile Health solutions, Brussels	Walter Atzori
December 07	5th Meeting of the RENEWING HEALTH User Advisory Board	Walter Atzori
December 08	ABC Project European Forum on Patient Adherence to Medication, Brussels	Kaisa Immonen-Charalambous
December 08-09	EUnetHTA Conference, Gdansk , Poland	Anders Olauson
December 10	Chain of Trust European-level patient focus group on telehealth	Walter Atzori
December 14	Meeting of the Steering Group on Access to Medicines in Europe, Warsaw (tbc)	Kaisa Immonen-Charalambous
December 15	Meeting on "eHealth and Equity in the Global Health Communities", Brussels	TBC
December 15	EHealth High Level Task Force, Lisbon, Portugal	Anders Olauson