



# EPF Mailing

Issue 3 (37)

10 June 2011

Dear EPF Members and Allies,

Welcome to the EPF Mailing – much has happened since our last EPF Mailing including our Annual General Meeting and Value + Seminar where we had the pleasure of working with over 60 leading patient delegates from throughout the EU. Read about these meetings in our [special feature](#).

The first meeting of the steering group of the European Innovation Partnership on Active and Healthy Ageing took place on 2 May, to which Anders Olauson was nominated - EPF has involved our members in important follow up from this meeting and the establishment of specific thematic working groups. [See section 4](#).

The eHealth Week also took place in Budapest, Hungary, and several EPF members were present. Anders Olauson represented EPF at a high level task force recently set up by the Commission to look at how to move forward on eHealth. [Go to section 20](#).

Several important EU health consultations took place over the last few weeks on crucial topics such as the clinical trials Directive, Research, eHealth and the Transparency Directive. Our [policy section](#) gives an overview of these and EPF's contribution.

Nicola Bedlington had the opportunity to meet with the board of the International Alliance of Patient Organizations on 15<sup>th</sup> May 2011 in Geneva. Our organisations are exploring ways of working together even more closely on common themes. Robert Johnstone, new EPF Board member is also a member of the IAPO board, ensuring optimal communications and synergy.

EPF submitted an application to the European Commission for operational funding through the Public Health Programme at the end of May and is also finalising a full project proposal to the Innovative Medicine Initiative on raising patient awareness of pharmaceutical research. We have joined a Consortium called SUSTAINS that will focus

on electronic health records, and will help us to substantiate our policy work in this key area. EPF is an associate partner in the EU Joint Action on Quality of Care and Patient Safety that was also submitted at the end of May. We will have more news on all these applications shortly after the summer, and specifically the involvement of our member organisations.

On 26 May, the first Patient / Medtech Dialogue meeting took place, to which several of our members were present. This was the launch of regular dialogue meetings with EUCOMED and their member organisations to discuss the patients' perspective on medical devices and policy issues in this arena. Read about this in [section 24](#).

We are looking forward very much to our forthcoming Conference under the Polish Presidency on 12-13 of July where we hope to see many of you. If you have not already registered, please do so before 15 June. Our first meeting of the new EPF board will take place on 11 July, where we do a mid-term review of the year and develop in greater detail our work plan for 2012. We are currently consulting our members on their ideas for the EPF thematic conference 2012.

Our next mailing in late July will give a snapshot of the Conference and the key outcomes and a brief overview of policy and project developments during the early summer.

Until then, we wish you all a very pleasant and productive lead up to the summer.

Warmest Greetings

EPF President Anders Olauson

EPF Director Nicola Bedlington

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## 1. Annual General Meeting

Over 60 patient representatives joined EPF's Annual General Meeting and Value + Seminar on 12-13 April 2011. Among those, a significant number of young patient representatives participated, as part of EPF's new youth strategy which was also adopted at the meeting.

The AGM adopted unanimously key governance documents including the annual report and audited accounts for 2010 and the work plan and budget for 2011 following presentations by Nicola Bedlington, Timo Nerkko, Treasurer and Johakym Laarousi EPF accountant. Please [click here](#) for a copy of these documents.

The AGM also endorsed membership applications, previously approved by board and presented to the AGM:

- The National Coalition of Patients in Slovakia
- Europso (approved by board)
- European headache alliance (approved by board)
- European Cleft association (associate member approved by the board)
- European Liver Patients Association (board approval recommended)
- Bulgarian national patient coalitions KZZ and NPA, following the signature of a Memorandum of Understanding.

Please go to [EPF website](#) for contact details for these new members.



This AGM decision has brought EPF membership to 50 umbrella organisations across the EU. We also have several organisations that are in the process of completing the application process.

Board elections were held as Vida Augustinienė, Guadalupe Morales, Maria Navarro, and Timo Nerkko had completed their two year mandate. Guadalupe Morales and Timo Nerkko (Treasurer) did not stand again and they were thanked very warmly for their strong contribution to the board. 6 candidates were nominated for 4 board positions and following a secret ballot the following representatives were elected:

[Vida Augustinienė](#) (Council of Representatives of Patients' Organisations of Lithuania), [Marco Greco](#) (European Federation of Crohn's and Ulcerative Colitis Associations - EFCCA), [Robert Johnstone](#) (National Voices) and [Maria Navarro](#) (Spanish Patients' Forum).

The EPF President congratulated warmly these new board members.

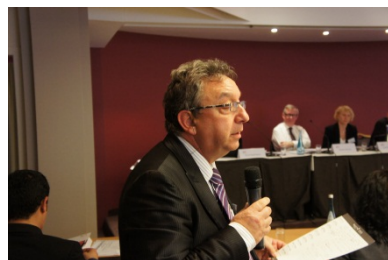
A discussion took place on EPF's funding and the board decision to apply for operational grant funding from the European Commission was supported, as was our coordinating role linked to the IMI application EUPATI (European Patients' Academy on Therapeutic Innovation).

In addition to the AGM, the meeting included an open space session where EPF's new youth group discussed next steps and the planning of their summer camp, and members came together to discuss possible joint projects and initiatives and to exchange membership information and know-how. A specific open space session was held on the follow up of VALUE + and the planning of a major capacity building programme from 2012 onwards.

The following day, Kaisa Immonen-Charalambous, EPF Senior Policy Advisor gave a detailed presentation of the key policy dossiers on which EPF is working. Please go to [EPF website](#) for a copy of this presentation. Parallel sessions then took place on the future of the EU Public Health Programme, eHealth, opportunities for patient involvement in research, patient involvement in structural



funds and patient involvement in HTA, patient involvement in pharmacovigilance legislation and cross border healthcare – please go to [EPF website](#) for a copy of presentations. EPF is developing short internal briefings exclusively for our members.



## 2. Pharmaceutical Package

### *Information to Patients*

As announced in our previous issues, the European Commission is currently working on a revised legislative proposal regarding information to patients, following the first reading position adopted the European Parliament (See EPF's statement on the EP vote [here](#)). The Commission is required to present a revised proposal to take into account the views of the Parliament and those expressed by the Council.

The revised proposal is expected to be presented to the Council towards the end of June. This means that effectively most of the discussion and work on this dossier will take place in the second half of 2011 during the Polish Presidency, and is likely to continue into the Danish Presidency in 2012.

This dossier will be one of EPF's key priorities in the next months. Once the content of the revised proposal is known, EPF will brief the membership and seek their views on the proposal. We are committed to continuing our until now very close involvement with the EU Institutions to ensure that the final legislation is as patient-centred as possible and delivers real added value for European patients.

For further information please contact the [EPF Secretariat](#).

### *Falsified medicines*

The EU Directive on falsified medicines was formally adopted without a debate at a session of the Transport, Telecommunications and Energy Council, on 27 May 2011. It will now be published in the EU Official Journal. The Council press release can be read [here](#).

On 4 May, EPF Director, Nicola Bedlington, spoke at an event of the European Alliance for Access to Safe Medicines in London on the topic of falsified medicines – [see here](#).

On a global level, during the 64<sup>th</sup> session of the WHO World Health Assembly in Geneva held on 16-24 May, the International Alliance of Patients' Organizations (IAPO) delivered an intervention highlighting the need for urgent action to protect patients from falsified, counterfeit or substandard medical products. IAPO's press release is available [here](#).

The report of the WHO working group of Member States on Substandard/Spurious/Falsely-Labelled/Falsified/Counterfeit Medical Products, presented at the World Health Assembly, is available [here](#).

### 3. Commission Initiative on Corporate Responsibility in the Field of Pharmaceuticals, Second meeting of the Steering Group on Access to Medicines in Europe

We have covered the background of this initiative in [previous issues](#) of the Mailing. It encompasses three “platforms” of activity, of which the Platform on Access to Medicines in Europe was the first to be launched in late 2010.

EPF is participating in the Steering Group of the Platform together with Member States' representatives and other stakeholders. The overall aim of the 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.

The Steering Group held its second meeting on 4 May in Budapest, combined with coordination meetings of the project groups on managed entry agreements and biosimilars.

In addition, the Commission updated the SG on the progress of the two other Platforms within the Initiative.

#### Platform on Access to Medicines in Developing Countries

The Platform on Access to Medicines in Developing Countries (focusing on Africa) is currently being prepared by the relevant Commission DGs, ministries of member states, stakeholders and NGOs. This Platform is expected to hold its first Steering Group

meeting at the end of 2011 and start its work in 2012. The International Alliance of Patients' Organizations (IAPO) has been invited to represent patients on this Platform, and EPF will be working closely with IAPO to ensure the link between the Platform and the work done by the European Platform's WHO/prioritisation sub-group (see below).

## **Platform on Ethics and Deontology**

The third platform looks at ethics and adherence to rules and "duties". It will be focusing on work in three areas: relations (of industry) with patients, with health professionals, and with Member State competent authorities. EPF was invited to co-chair the first work group together with the Commission. The work groups are to be set up in the second half of 2011, during the Polish EU Presidency.

## **First meeting of the Prioritisation and Innovation sub-group**

Readers will remember that within the European Platform, a sixth project group was proposed to undertake a broader reflection process on prioritisation and innovation. This "sub-group" held its first meeting on 7 April in Brussels.

Its mandate is based on a proposal by the SG to look at this topic based on the WHO report "Priority Medicines for Europe and the World" (2004) and the Belgian Presidency report "Innovation and Solidarity" (2010); as well as a request from the Belgian EU Presidency to review and update the WHO report. The report, together with all its background reports, is available on the [WHO website](#).

At the first meeting, the WHO report was presented by WHO representatives and progress since 2004 (or lack of it) was discussed. It is clear that in some areas, such as orphan drugs and medicines for children, there have been significant developments, while in other areas less so.

The group also identified certain cross-cutting themes that will be addressed in the review: adherence to therapies; prevention; health systems issues; drugs delivery systems; needs of specific patient groups particularly older patients, women and children; and issues related to product stability, diagnostics/biomarkers, orphan drugs and safety. EPF presented clearly the patients'



perspective insisting that issues relevant to patients be taken into consideration, including quality of life; equity and solidarity; the need for patients' input into the chain of research, approval, prioritisation and reimbursement; empowerment and information.

### Next steps:

The Commission will now explore the practical means to undertake the update in collaboration with WHO, and will aim to complete the work by 2014 – the 10<sup>th</sup> anniversary of the WHO report. EPF will be closely involved in the process and we will invite our members' views and expertise wherever appropriate.

### Links:

- [DG ENTERPRISE website – information on the Platform on Access to Medicines in Europe](#). The agendas and minutes of the Steering Group are published on this website.

## 4. European Innovation Partnership on Active and Healthy Ageing

EPF President Anders Olauson attended the first high-level Steering Group meeting of the European Innovation Partnership on 2 May 2011. The minutes of this meeting and a guidance paper are available to read on [the Commission's website](#).

The high-level SG meeting was co-chaired by Vice President and Commissioner for the Digital Agenda, Neelie Kroes, and the Commissioner for Health and Consumer Policy, John Dalli. Members of the SG identified key priorities, including better use of existing technologies, early screening and prevention, chronic disease management. It was also proposed to build work around a "lifecycle approach" centred around issues of (1) awareness & education; (2) early diagnosis, screening & prevention; (3) secondary & tertiary treatment, including chronic disease management; and (4) independent living at home.

The EPF secretariat has participated in several "Sherpa" meetings, whose aim is to prepare the work of the Steering Group and refine the operational aspects. The minutes of these meetings will also be available on the Partnership's website. Several EPF member organisations focused on older patients, who had contributed to the EPF response to the Commission's public consultation ([available here](#)) have given their input to the preparation of our input to the meetings.

## Next Steps:

- A number of workshops will be organised in Brussels during the second half of June to identify specific, concrete actions that can be proposed for inclusion in the Partnership's Strategic Implementation Plan. EPF member organisations active in the relevant areas will be invited to the workshops.
- The next meeting of the Steering Group will be held on 7 July 2011. The Steering Group is expected to select those priority areas it wishes to take forward.
- EPF will be involved at Secretariat level in those work areas that tie in with the priorities of our work plan, notably "Health literacy/information" (co-leader), "Adherence to therapies" and "Health Technology Assessment". We will invite our members' input into these topics where appropriate.
- A "horizontal task force" composed of SG members will set to work on identifying appropriate indicators to measure the progress and impact of the activities, as well as tackle the issues of funding, reimbursement, social and economic impact and mapping.
- We will report in more detail about the progress of this Partnership and the specific work areas in our special July/August issue, which will be dedicated to older patients – including the outcomes of the EPF/FPP conference in Warsaw (12-13 July).

For further information please [contact the EPF Secretariat](#).

### *EPF/FPP Conference on "The Rights and Needs of Older Patients" – Reminder!*

We would like to remind EPF member organisations that the online registration for the EPF/FPP conference on "The rights and needs of older patients", which will take place in Warsaw, Poland on 12-13 July, will be open **until 15 June 2011**. Don't miss it!

For more information about the conference and to register please go [to the EPF website](#).

## *2012 theme year on “Active Ageing and Solidarity between Generations”*

On 10 May, the European Parliament and the Council decided to name the 2012 theme year as the “European Year on Active Ageing and Solidarity between Generations”. The agreement is expected to be formally endorsed by the Council on 6 June and by the Parliament in plenary on 23 June 2011.

### **Links:**

- [European Parliament](#)
- [European Commission](#)

## **5. European Medicines Agency – First Stakeholder Seminar on Pharmacovigilance**

On 15 April EPF attended the first of two stakeholder seminars on the new EU Pharmacovigilance legislation. The objective of the seminar was to raise awareness of the requirements of the new legislation, and promote the exchange of ideas, concerns and opinions. Participants included Member State representatives, organisations of health professionals, patients and consumers, and industry. The perspectives of all stakeholders were heard. Most of the full-day seminar focused on the EMA/Member States technical contribution to draft European Commission implementing measures.

Several key aspects of the new legislation were discussed, including:

- changes to inspections and pharmacovigilance systems, including the introduction of Pharmacovigilance System Master Files;
- use of internationally agreed terminology, formats and standards;
- minimum requirements for monitoring data in EudraVigilance;
- changes to Periodic Safety Update Reports;
- format and content of risk management plans;
- new measures for transparency and communication, including the creation of websites to highlight safety issues with medicines and the introduction of a public hearing process.

The agenda and all presentations of the first stakeholder seminar are available for downloading from the EMA website [here](#).

A second seminar will take place on 17 June in conjunction with a joint meeting of the Patients' and Consumers' Working Party and the Healthcare Professionals Working Group. This event will concentrate more on practical aspects, including direct patient reporting. EPF will be attending and contributing to this event. A key point from our perspective is ensuring that patients are appropriately informed about the new provisions and how this will be set up at Member State level.

## 6. Clinical Trials – EPF responds to the Commission consultation

The European Commission recently published a [concept paper](#) to outline its preferred options for revising the [Clinical Trials Directive](#), and launched a second public consultation focusing on the concept paper, which closed on 13 May 2011. After consulting our membership, EPF submitted a response. Our response reflects as much as possible the common position of our members, given that there are diverging views within our membership on certain aspects of the Directive. The EPF response was circulated to all members by email on 17 May.

EPF also submitted a separate “EPF statement” to raise again certain fundamental issues around patient involvement, information and access that we had highlighted in the first round of consultation in 2009/2010 (see our response [here](#)), but which were not addressed in the Commission’s concept paper.

The statement elaborates on the previous response and urges the Commission to listen to the patients’ voice. We firmly believe that the current review process should aim for a better functioning, more proportionate, and more patient-centred approach to the design and regulation of clinical trials. In particular, this review is an opportunity for reform towards more patients’ involvement throughout the research process, greater trust and confidence in medical research, and improved participation rates.

The EPF statement can be accessed [here](#).



### Next steps

- EPF will work closely with the European Institutions and stakeholders throughout the review process to ensure that the vision and the core issues outlined in our statement are translated into effective, patient-centred EU legislation on clinical trials. We will seek our members' views on specific issues as the review progresses.
- EPF has taken the initiative to organise a meeting in early July, involving the Commission and several members of the EOF Policy Advisory Group and Brussels-based member organisations, to discuss further the issues outlined in our statement as well as those areas where there are diverging views among patient groups.

For more information please [contact the EPF Secretariat](#).

## 7. Adherence to therapies – a new joint initiative by EFP, PGEU, CPME and EFPIA

EPF together with CPME, PGEU and EFPIA (the European umbrella organisations representing doctors, community pharmacists and industry, respectively) have joined forces in order to raise awareness on the vital topic of adherence. We will organise a joint lunch seminar at the European Parliament on 21 September 2011, titled “Improving the sustainability of healthcare systems through better adherence to therapies: a multi-stakeholder approach”.

Adherence to therapies is an issue of primary importance that touches on all aspects of European healthcare and health policy. Poor adherence is a worldwide public health problem of dramatic proportions, particularly in chronic disease. In the EU alone 194,500 deaths each year are due to misdose of and non-adherence to prescribed medication. Non-adherence carries a huge cost, both to patients and to health systems: it is estimated to cost the European Union €1.25bn annually. Reduced productivity is among its impacts on wider society.

Improving adherence has great potential for improving the financial sustainability, as well as the quality of European health systems through improved health outcomes and significant cost savings.

Adherence is closely linked to other EU-level policy dossiers and initiatives, including Pharmacovigilance; Information to Patients/Health Literacy; Patient safety and quality of care; eHealth; and the Innovation Partnership on Healthy and Active Ageing. Tackling the problem effectively requires a coordinated, multi-stakeholder, and most importantly patient-centred approach – involving patients, their carers/families, health professionals, industry, and the wider public.

The seminar aims to raise awareness of the vital importance of adherence, and underline the value of a dialogue and collaboration within a multi-stakeholder approach. We will explore the challenge from multiple perspectives, present examples of successful existing good practices from different contexts, and examine how these may be replicated.

More details will be available in the next mailing.

## 8. European Commission public consultations on research and innovation, the Transparency Directive, and the PROGRESS programme

The European Commission launched several important public consultations on health-related themes recently, with their deadlines falling in the same two-week period in May. While it was not possible within the deadlines imposed by the Commission, to consult the views of our full membership, nevertheless we considered that patient input into some of these areas is crucial as they have potential consequences for patients with chronic diseases.

EPF has therefore liaised with the Commission on the following consultations, stating that the issues are of importance and relevance to patients and expressing our interest in contributing. There should be further opportunities to engage in the process at a later stage, when we hope the time frames will allow enough time for a full member consultation.

- *DG Research and Innovation – [Green Paper](#) “From Challenges to Opportunities: Towards a Common Strategic Framework for EU Research and Innovation Funding”*. EPF submitted a brief statement prepared with the input and approval of the Board,

drawing upon our work to date regarding the meaningful involvement of patients in research, as well as members' input into past consultations. We will develop a full response at a later stage with members' input.

- *DG Enterprise and Industry – public consultation on the review of the [EU Transparency Directive](#).* EPF has requested a meeting with the Commission to discuss this topic and has prepared some preliminary input within the Board and Policy Advisory Group. Following the outcome of the public consultation the Commission will decide whether to reopen the Directive; if that is the case we will consult our members on this dossier.
- *Commission public consultation on the possible successor instrument to the EU's Employment and Social Solidarity Programme ([PROGRESS](#)).* Although we had to prioritise other issues and could not give written input, we have indicated EPF's interest in this issue to the Commission and will arrange a meeting with the Commission to discuss next steps. EPF believes that this instrument plays a role in tackling discrimination towards patients and in implementing the "Health in all policies" principle.

#### Next steps:

- The Commission is expected to issue legislative proposals at the end of 2011 regarding future EU funding framework for research and the successor instrument to PROGRESS. EPF will therefore consult its membership to give input into the process as appropriate. We will also continue to liaise closely with the Commission regarding the 8<sup>th</sup> Framework Programme.
- The Commission will decide whether to review the Transparency Directive once the results of the public consultation are known. If so the Commission is expected to present a legislative proposal in December 2011. If that is the case EPF will seek its membership's views in order to formulate an official position on the legislative proposal.

#### Links

- [More information on the EU research and innovation](#)
- [More information on the EU Transparency Directive](#)

- [More information on PROGRESS](#)

## 9. The European Union Health Policy Forum Meeting

Nicola Bedlington represented EPF at the European Union Health Policy Forum Meeting on 19 May 2011 in Brussels. The main focus of this third meeting of the renewed group of the EUHPF was:

- Follow-up on current and future work of the EUHPF
- Follow-up on the work of the Council Working Group on Public Health at Senior Level and activities with the European Innovation Partnership on Active and Healthy Ageing
- New Health Programme; mid-term evaluation of the current health programme and the health strategy
- Health Security

For a copy of presentations and the minutes of this meeting please contact the EPF secretariat.

Regarding the new public health programme, it was agreed that the EUHPF should create a working group to develop the members' collective position on the vision, direction and scope of the new programme. EPF has joined this group and will be consulting our membership on a draft document in the early summer. Those EPF members who have a particular interest in this area, who are not directly represented on the EUHPF are invited to contact Nicola Bedlington as soon as possible.

## 10. Proposed priorities for innovative health research FP7 Health 2012 Work Programme



The European Commission's Seventh Framework Programme for Research and Development – Health Research (FP7) aims at “improving the health of European citizens and increasing competitiveness of European health-related industries and services, as well as addressing the socio-economic dimension of healthcare and global health issues.” A draft orientation paper outlining the priority areas for health research in 2012 was published in early May. This document will inform the 2012 FP7 Health Work Programme which is expected to be published after the European Info Day which will take place in Brussels on June 9<sup>th</sup> 2011. EPF will report on the main outcomes of this event in the next Mailing Issue.



The orientation paper foresees major efforts in the following areas: **health systems, medical technologies** and **rare diseases** which are followed by complementary areas mainly concerning “**active and healthy ageing**” – such as developing personalised medicines approaches, improving availability of organs for replacement, medical technologies, gaining a better understanding of ageing, tackling chronic diseases linked to ageing, adapting healthcare systems to meet specific needs. As in 2011, **Clinical Trials** will continue to be a cross-cutting priority for FP7 Health Research.

The meaningful involvement of patients and patient organisations in future FP7 Health projects is strongly encouraged by the Commission, especially in clinical studies. For this reason we would like to encourage all patients’ organisations to consider invitations they may receive from project coordinators wishing to involve them in their projects.

As in previous years, EPF will closely monitor the implementation of the FP7 Health 2012 Work Programme and the upcoming call for proposals, expected to be launched in July, to ensure that the principle of patient involvement is reflected in future research projects through the meaningful participation of patients and patient organisations in future consortia.

Detailed information can be found at: <http://cordis.europa.eu/fp7/health/>

Alternatively you can contact [Walter Atzori](#).

## PROJECTS

### 11. Joint Action on Patient Safety and Quality of Care

In [previous issues](#) of this Mailing we have described in detail the progress of the new proposal for a Joint Action on Patient Safety and Quality of Care.

We are pleased to say that after many months of hard work on the part of all partners, this Joint Action was successfully submitted to the Executive Agency on Health and Consumers by the deadline of 27 May. If successful, the Joint Action will start work at the end of 2011 or in early 2012.

The overall aim of the 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 the implementation of the Council Recommendation on patient safety;
- Initiate Member State cooperation on quality of healthcare;
- 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.

#### Useful links:

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

## 12. EPF Health Technology Assessment Research Initiative

In November 2010 EPF started conducting primary research on patient involvement in Health Technology Assessment (HTA) with the aim of better understanding the involvement of lay patients, informal carers and patient organisations in all the EU Member States and to contribute this knowledge to inform HTA research, policy, and practice. This initiative is the follow up of [EPF HTA Seminar held in May 2010](#) where patient organisations clearly called for support to be meaningfully involved in HTA processes. The outcome of this research work will be a good practice toolkit to be shared with HTA agencies, patient organisations and decision making bodies in the EU.

The HTA research is broken down in three stages. The first stage, which was completed in February 2011, consisted of a survey conducted with 40 HTA agencies and/or national bodies responsible for HTA from 22 European countries. A detailed report based on the 1st stage is now available at our website at: <http://www.eu-patient.eu/Initiatives-Policy/Initiatives>

In late winter 2011 EPF commenced the second stage of the HTA research by launching a survey for healthcare decision-makers who use evidence from HTA reports on Monday, 16<sup>th</sup> May 2011. The aim of the survey is to understand the involvement of lay patients, informal carers and patient organisations in decision-making processes for health technologies informed by HTA in European countries. The profile of decision makers we propose does not include only civil servants and public officials, but it includes also other stakeholders that are/can be involved in decision-making.

The foreseen expiration of the online survey is by mid-June 2011. The third phase of the HTA research, which will involve a consultation with patient organisations, is expected to be launched soon. We will report on the outcomes of the second stage of the HTA research and plans for the third stage in the next Mailings.

For more information you can contact [Liuska Sanna](#) or [Abi Rajan](#).

### 13. Towards EPF Youth Strategy

As anticipated in the previous Mailing issue, in order to better align our work with the needs and expectations of the young patient to support the implementation of the Youth Strategy, we set up a Youth Group made up of young patient representatives from within our membership aged 15 to 25. The first nine members of the group participated as second delegates to the AGM and held an exploratory meeting on April 12 to discuss the EPF Youth Strategy and agree on further steps, including the first official meeting of the Youth Group. Such meeting, which is scheduled to take place in end August in Brussels, will represent the “official” start of the implementation of the EPF Youth Strategy with the adoption of the first two-year work plan.

More information on this meeting will be provided in the next Mailing Issue.

For more information on the EPF Youth Strategy you should contact [Walter Atzori](#).



## 14. Chain of Trust - Completion of the literature review and launch of online survey



Over the last two months there have been some important developments in the Chain of Trust project. As announced in the previous EPF Mailings, this project, led by EPF and co-financed by the EU Public Health Programme, started off in January 2011 with the overall objective of 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. Throughout 2011 Chain of Trust's main focus is on gathering knowledge of the needs and perceptions of telehealth among patients and health professionals. In order to do this, in 2011 the Chain of Trust consortium will undertake a literature review on telehealth users' perspective, conduct an online survey and implement six national workshops with the support of local organisations in six different European countries, namely Greece, Latvia, the Netherlands, Norway, Poland and Portugal.

The literature review of the project was completed in late April. The analysis of the literature sources investigated provided an overview of the state of the art knowledge on user perspectives on telehealth and highlighted a number of under-researched areas and knowledge gaps requiring further investigation. With a view to validating the findings and knowledge gaps identified in the literature review the consortium prepared two online questionnaires, one for patients and one for health professionals that are aimed at collecting additional information on experience of telehealth among those who have used these services as well as perception of benefits and challenges of these services among non-users of telehealth.

The on-line survey was launched in early June and is available in 11 languages: English, French, German, Polish, Norwegian, Latvian, Greek, Portuguese, Dutch, Spanish and Italian. EPF will particularly value the support of its members and broader readership to disseminate this on-line survey across national patient and health professional groups.

You can find the questionnaires both for patients and professionals in the eleven languages at the project website: [www.chainoftrust.eu](http://www.chainoftrust.eu)

For more information on the Chain of Trust project please contact [Walter Atzori](#).



### 15. 27-29 March, Lyon, BioVision, the World Life Sciences Forum

Anders Olauson represented EPF at the BIO VISION Forum in March. He was involved in a Panel –Would Pasteur and Fleming survived the precautionary principle? This session was video streamed – Please go to: [www.biovision.org/bv2011/BioVision-TV.html](http://www.biovision.org/bv2011/BioVision-TV.html)

Please contact [the EPF secretariat](#) for a copy of Anders' presentation.

### 16. 30-31 March – Brussels Innovation in Healthcare

Anders Olauson was involved as a speaker in the second conference on Innovation in Healthcare, held in Brussels at the end of March. For more details on the conference, please go to: [http://ec.europa.eu/research/health/events-04\\_en.html](http://ec.europa.eu/research/health/events-04_en.html)

For a copy of Anders' speech, please contact [the EPF secretariat](#).

### 17. 07 April – Brussels, EFPIA Think Tank

On 7 April 2011, Nicola Bedlington joined other representatives of European patient groups and pharmaceutical industry representatives met for a meeting of the EFPIA Think-Tank. The following topics have been discussed:

#### Review Transparency Directive

A representative from DG Enterprise presented the Commission's views on reviewing the Directive 89/105/EEC relating to the Transparency of measures regulating the pricing of medicinal products. The current directive provides a set of procedural rules for national decision-making in terms of time limits (obligation to make pricing and reimbursement decisions within 90/180 days), motivation of decisions and judicial appeal. Reasons for the review are, inter alia, significant disparities in time to market

medicinal products (with delays linked to pricing and reimbursement procedures) and medical developments (e.g. personalised medicines).

### **Revision Clinical Trials Directive**

With a view to the expected revision of the Clinical Trials Directive in 2012, an industry representative presented her views on the current situation, namely a substantial lack of homogeneity in terms of administrative requirements, leading to a bottleneck that limits the number of new clinical trials in Europe. Through a new legislative approach with administrative simplification and standardisation, the trend of clinical trials rarefaction in the EU should be reversed, fostering and facilitating access by sponsors, centres of medical excellence and patients.

### **Pharmaceutical Package**

An up-date was given on recent developments on the falsified medicines directive (final publication expected by July 2011) and information to patients (awaiting the Commission's modified proposal in May 2011).

### **Water Framework Directive**

A presentation was given on the Water Framework Directive which, inter alia, aims to eliminate pollution of surface water by establishing a priority list with substances to be limited or removed. The list is currently being reviewed and for the first time included pharmaceutical substances. The Commission is expected to adopt a proposal in September 2011.

### **Revision EFPIA Patient Organisations Code**

An update was given on the current review of the EFPIA Patient Organisations Code, aiming to improve transparency. The revised EFPIA code is scheduled for adoption in June 2011.

## 18. 08 April 2011 - Amsterdam – International Meeting on Quality of Care

Nicola Bedlington represented EPF at a major International Meeting on Quality of Care and gave a presentation on EPF's policy and programme work on patient safety and quality of care.

For more information on the meeting, please go to:

<http://internationalforum.bmj.com/2011-forum/programme/tuesday-session-details>

For a copy of Nicola's presentation, please contact the [EPF secretariat](#).

## 19. 11-12 April, Brussels, European Patients' Rights Day

The European Patients' Forum has enjoyed a strong collaboration with Active Citizenship Network, responsible for the organisation of the European Patients' Rights Day and we were delighted to be involved at their event in the Economic and Social Committee on 11 April 2011.

For more about the Day, and the follow up envisaged by Active Citizenship Network, please go to:

<http://www.activecitizenship.net/content/blogcategory/72/179/>

For a copy on Nicola's presentation, please contact [the EPF Secretariat](#).

## 20. 10-12 May 2011 - eHealth Week 2011 – Budapest, Hungary

The eHealth Week 2011 in Budapest, Hungary, co-organised by the Hungarian Presidency of the European Union and by the European Commission was a joint initiative that combined two major events of the eHealth sector in Europe: the "*High Level eHealth Conference*" and the "*World of Health IT Conference & Exhibition*". It attracted over 2.500 participants, among key representatives from the various stakeholder groups in the eHealth arena. Opening ceremony was conducted by 12 Health Ministers from EU Member States showing the importance of the subject to European community.

EPF was strongly present at the eHealth Week 2011 meetings in Budapest, Hungary. Anders Olauson is a member of the high level expert group presided by the President of Estonia, set up to explore ..... In this capacity he also attended a Ministerial meeting and reception.

[www.worldofhealthit.org/education/Details.aspx?ID=MET3](http://www.worldofhealthit.org/education/Details.aspx?ID=MET3)

Tomasz Szelagowski, Director of the Federation of Polish Patients received an invitation to present patients' involvement in development and implementation of originally design Web base applications for integrated Internet Patients' Account

He said "the whole event showed that implementation of Internet Communication Technologies (ICT) into healthcare services is not a temporary trend. It is actually fantastic solution to cope with high hospitalisation costs and bigger demand for diagnosis and various medical services. Implementation of telemedicine solutions and mobile technology will eventually lead to shift a numbers of medical procedures from hospital care to homecare with better quality and comfort for patients. To achieve such ambitious goals will require smooth communication processes established among all participants. Therefore it was important to use our collective patients' voice to make sure that our opinions are taken for an account and to highlight involvement of patients organisations as very important partner in this scenario."

Nicola Bedlington participated in an eHealth Forum organised by the Assembly of the European Regions (AER) , ' European Regions at the forefront of telemedicine'.

Following the invitation of the European Commission, the AER e-he@lth network organised this forum to showcase regional expertise in the e-health field. The forum's participants emphasised the major role played by regions in the deployment of personal e-health solutions by highlighting the progress achieved for chronic diseases such as diabetes, cardio-vascular and obstructive pulmonary diseases.

In order to respond to the challenges currently faced by our society, the European regions have to develop inventive and simple tools to satisfy the patients' needs.

Auvergne's (F) "Tele-Diabètes" project allows for example people with diabetes, for example, to calculate their insulin dose by themselves, thanks to an electronic device, after recording personal data such as their glucose ratio before and after each meal.



Syddanmark (DK) presented its project “ePatch”, aiming to answer the needs of policy, makers, health professionals, as well as those of the patients – financial constraints, patients’ desire to remain in their home environment, lack of health professionals. Easy to use, this patch will enable continuous control of the patient’s cardiac activity and will set up an alarm system based on several clinical research studies.

## Work for the recognition of e-health

“Whereas the amount of people suffering from chronic diseases keeps increasing, our knowledge has allowed us to make important technologic advances. Our goal is to make sure that e-health is integrated in public health policies. In order to do so, we need to put forward the issue of change management” said Agneta GRANSTRÖM, President of AER’s e-he@lth Network and regional councillor of Norrbotten (S).

A debate between regional politicians, patients’ organisations and industries sought to identify solutions, allowing the replication of the success of regional projects to the whole of Europe. It was recognised that even if the use of telemedicine is becoming more widespread in the European continent, some obstacles still prevent its full deployment. The absence of a reimbursement scheme for e-health solutions, the lack of awareness regarding existing solutions or the dilemma of the development of an e-health market have thus been identified as the main problems.

The Assembly of European Regions (AER – aer.eu) is the largest independent network of regions in wider Europe. Bringing together 270 regions from 34 countries and 16 interregional organisations, AER is the political voice of its members and a forum for interregional co-operation.

EPF also collaborated closely with AER in the framework of Cohesion Policy and structural funds.

Photo session: [www.stillwords.com/ehealthweek2011/110511\\_01/index.html](http://www.stillwords.com/ehealthweek2011/110511_01/index.html)



commonality of purpose of both organisations, notwithstanding our different geographic remits. A joint actions plan will be developed before the summer to be agreed by our respective boards. EPF will also participate in the next International Congress of IAPO in London in March 2012.

### **23. 25 May 2011 - European Wounds Management Association meeting**

Nicola Bedlington was honoured to speak at the plenary session of the European Wounds Management Association (EWMA) in the Bozar, Brussels on 25 May 2011. The meeting was also an opportunity to explore enhanced collaboration between EPF and EWMA, which represents a whole range of health professionals, academics and industry in the sphere of wound management.

For more information on EWMA, please go to [www.ewma.org](http://www.ewma.org)

To obtain a copy of Nicola's speech, please contact the [EPF Secretariat](#)

### **24. 26 May 2011 - EUCOMED –EPF DIALOGUE**

On 26 May 2011, EPF and EUCOMED organised jointly the first ever structured get-together of the Medical Technology industry with different patient organisations representing disease specific organisations and national coalitions. 10 member organisations of EPF participated and 7 representatives of EUCMED and its member companies were present. It was a very constructive, open and strategic first exchange of views, which started with the different priorities and expectations of each organisation in relation to the role of medical technology, and concluded with the identification of potential areas of common interest and agreed next steps.

It was recognised that both partners - the medical technology industry as well as the patient organisations are very diverse and have therefore varying priorities related to disease areas, country situation or subsectors within MedTech. There was however broad agreement about the overarching challenges of the current healthcare system and the potential and growing role of medical technology.

On that basis, a substantial list of potential topics of joint interest have has been identified, where it would be useful to exchange view and perspectives. One critical factor identified for building trust between patients and industry was the language used by industry when talking with or about patient groups and this will be addressed in the framework of this Dialogue.

All participants saw huge merit in continuing the dialogue in order to increase mutual trust and knowledge. This Dialogue would be in line with EPF's code of ethics on transparency and independence and appropriate Terms of Reference, endorsed by the European Patients' Forum's board will be developed in advance of the next meeting on 14 October 2011 in Brussels.

For a copy of the summary minutes of this meeting, please contact [the EPF secretariat](#).

**SECRETARIAT**

## 25. Welcome Özgün



**Özgün Ünver** began her internship as EPF Assistant Programme Manager in April 2011. She holds a BA in International Relations from Istanbul Bilgi University and an MA in Social and Cultural Anthropology from Catholic University of Leuven. Currently she pursues an MA in Quantitative Analysis in the Social Sciences in College-University Brussels.

Prior to joining EPF, she volunteered in a number of NGOs in Turkey and wrote columns and articles for websites and magazines.

She is supporting EPF Programme Manager and Officer in research projects.

## 26. Members' corner

On 10<sup>th</sup> May, Nicola Bedlington was invited to a meeting hosted by the Hungarian Health Ministry to discuss the setting up of a Hungarian Patients Coalition. Several patient leaders joined the discussion and the outcome looks very promising. There is a clear

commitment to move forward on setting up a NGO that represents the collective views of patients in Hungary. More information on this exciting development will be available in early autumn.

## 27. Website updates

Many various sections of our website have been updated recently.

Section	Update
<b>Publications</b>	<ul style="list-style-type: none"><li>• <a href="#">EPF Annual Report 2010</a></li><li>• <a href="#">EPF Work Plan 2011</a></li></ul>
<b>Events</b>	<ul style="list-style-type: none"><li>• <a href="#">Annual General Meeting Presentations</a></li><li>• <a href="#">Details about the Conference on Rights and Needs for Older Patients</a></li></ul>
<b>Membership</b>	<ul style="list-style-type: none"><li>• <a href="#">Members section</a></li></ul>
<b>About EPF</b>	<ul style="list-style-type: none"><li>• <a href="#">Finances</a></li><li>• <a href="#">Secretariat</a></li><li>• <a href="#">The Board</a></li></ul>
<b>External Tools</b>	<ul style="list-style-type: none"><li>• <a href="#">European Directory of Patients' Organisations</a> is up and running.</li></ul>

## 28. Diary

Date	Event, Location, Representatives
<b>9 June 2011</b>	FP7 Health Info Day – Brussels Özgün Ünver and Walter Atzori
<b>14 June 2011</b>	Carers Interest Group in the European Parliament – special session on the European Innovation Partnership on Active and Healthy Ageing Nicola Bedlington (speaker)
<b>15-16 June 2011</b>	RENEWING HEALTH Steering Committee Meeting – Tromsø, Norway Walter Atzori
<b>16-17 June 2011</b>	EMA PCWP meeting and 2 <sup>nd</sup> stakeholder meeting on the new Pharmacovigilance legislation – London Kaisa Immonen-Charalambous
<b>17-18 June 2011</b>	NPO Youth Meeting “Youth patients for brighter future” - Velingrad, Bulgaria Laurène Souchet
<b>20-21 June 2011</b>	Prevention and early intervention workshops as part of the European Innovation Partnership on Active and Healthy Ageing – Co-organiser Nicola Bedlington
<b>22 June 2011</b>	Lunch debate on the reopening of the Clinical Trials Directive – Brussels Kaisa Immonen-Charalambous (speaker)
<b>29 June 2011</b>	RENEWING HEALTH 4 <sup>th</sup> Meeting of the User Advisory Board Özgün Ünver and Walter Atzori



<b>4 July 2011</b>	EFGCP workshop on the Clinical Trials Directive – Brussels Kaisa Immonen-Charalambous (speaker)
<b>7 July 2011</b>	European Innovation Partnership on Active & Healthy Ageing - Sherpas' meeting – Brussels Nicola Bedlington
<b>7 July 2011</b>	Meeting with European Commission on the Clinical Trials Directive Kaisa Immonen-Charalambous, Nicola Bedlington and EPF members based in Brussels
<b>8 July 2011</b>	IMI Evaluation of the EUPATI proposal
<b>11 July 2011</b>	EPF board meeting – Warsaw
<b>12-13 July 2011</b>	Conference on the Needs and Rights of Older Patients – Warsaw (more information <a href="#">available here</a> ).
<b>21-22 August 2011</b>	1 <sup>st</sup> Meeting of the EPF Youth Group Özgün Ünver and Walter Atzori
<b>6-7 September 2011</b>	Commission High Level Conference on EU Health Programmes – Brussels Representative to be confirmed
<b>8 September 2011</b>	AGM - European federation of associations of patients with haemochromatosis – Brussels Walter Atzori (speaker)
<b>14-15 September '11</b>	Chain of Trust project 2 <sup>nd</sup> Steering Committee Meeting – Riga Walter Atzori
<b>16 September 2011</b>	European Innovation Partnership on Active & Healthy Ageing - Steering Group – Brussels Anders Olauson

<b>21 September 2011</b>	Lunch debate on Adherence to Therapies – organised jointly by EPF, PGEU, CPME and EFPIA – Brussels - Representative to be confirmed
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<b>26-27 September '11</b>	RENEWING HEALTH Steering Committee Meeting – Barcelona Walter Atzori
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<b>27-28 October 2011</b>	EPF Regional Advocacy Seminar- Bucharest Walter Atzori, Nicola Bedlington and Kaisa Immonen-Charalambous
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