EPF Mailing

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STOP PRESS. On Tuesday 28th, the European Parliament Committee on Environment, Public Health and Food safety adopted the report on information to the general public on prescription medicines. The report, which EPF broadly welcomed made the focus of proposed legislation the right of patients to obtain quality information on medicines. We congratulate Christofer Fjellner, MEP, and author of the report for his significant work to date and we will continue to work with him and others during the next steps in the process to ensure the final dossier is as patient-focused as possible. A detailed analysis will be made available to EPF members in the coming days and in the next issue of this mailing.

Dear EPF Members and Allies,

Welcome to the first EPF mailing this autumn. As we go to press, we are delighted to learn that the Pharmacovigilance Directive has been adopted by the European Parliament. On 15 September, EPF together with PGEU representing pharmacists across Europe held an important event in the European Parliament that analysed a really critical aspect of the legislation – Direct Patient Reporting – Read about the event in our special feature section.

In our Policy Section you will find an update on the other legislative dossiers that are the focus of our policy work, specifically - Patients' Rights in Cross Border Healthcare, Information to the General Public on Prescription Medicines, Anti-counterfeiting - and the progress we have made in the European Parliament on these. On 1 September we held a meeting of our Policy Advisory Group where we also discussed a draft position on Third Country Clinical Trials and personalised medicines see section 23.

On 14th September the EPF board met to discuss our work plan for 2011 and review current activities please see section 22 for details. We also had the opportunity to celebrate Anders' 60th birthday. The meeting was followed by an annual briefing with EPF industry sponsors.

We are also very pleased to announce that our project "Chain of Trust" that explores how to build confidence and trust in telemedicine solutions among patients and health professionals will be co-funded by the European Commission in the framework of the European Public Health Programme. Scheduled to begin in early 2011, this project involves as associate partners our health professionals allies CPME representing doctors, EFN representing nurses and PGEU representing pharmacists and we are very much looking forward to our continued strong collaboration with these partners.

EPF, together with relevant members, will participate actively in the Commission's new Process on Corporate Responsibility launched at the Belgian Conference on Innovation and Solidarity at which we also presented a patients' perspective on stimulating innovation. See section 8 for details.

As we move into October, our energies turn to the European Health Policy Forum Gastein where for the first time we will co-host an event with our members, the European Men's Health Forum and the European Institute for Women's Health, and will also be speaking in sessions on health literacy, personalised medicine and transparency. And at the end of October our autumn regional advocacy seminar will take place in Budapest, which will focus on young patients and their role in patient organisations. This event will also be an important opportunity to discuss further health priorities under the forthcoming Hungarian Presidency (first semester 2011). It will be really great to meet many of our members' representatives from that region.

Warmest Greetings,
EPF President Anders Olauson
EPF Director Nicola Bedlington

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1. European Parliament Event on Direct Patient Reporting: Adverse Drug Reactions: Moving Forward Together on Patient Safety

On 15 September the European Patients' Forum (EPF), together with the Pharmaceutical Group of the European Union (PGEU), organised a lunch seminar entitled "Adverse Drug Reactions: Moving Forward Together on Patient Safety" that took a critical look at the Direct Patient Reporting, part of the Pharmacovigilance legislation. The seminar was hosted by Linda McAvan, Member of the European Parliament and Rapporteur on the draft directive on Pharmacovigilance within the European Parliament.

A wide range of stakeholders were invited to hear the views of pharmacists' and patients' representatives, regulators (including the European Medicines Agency and the MHRA1), academics (the Netherlands Pharmacovigilance Centre Lareb), the European Commission and the pharmaceutical industry. They discussed the new directive, which emphasizes a stronger reporting framework for pharmacists and health professionals, and a direct reporting by patients. The data gathered from such reports will be used to monitor eventual risks posed by medicines once they have been approved and become available to patients.

"The new pharmacovigilance legislation will contribute to better protection of public health by strengthening and rationalizing EU pharmacovigilance, (…) where better informed and involved (…) patients will be a result of more transparency", said Lenita Lindstrom from the European Commission.

A key message from Professor Kees van Grootheest who works at the University of Groningen in the Netherlands, was that in order to ensure accurate and necessary information is gathered, a co-operation and reports are needed from all people who are involved in the use of medicines, including patients and pharmacists.

During the lunch meeting, EPF president, Anders Olauson, warmly welcomed the proposal on direct patient reporting and a wider access to safety data, which “contributes to patients’ empowerment and greater patient safety.”

For more information please go to the EPF website.

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2. Pharmaceutical Package

Pharmacovigilance

EPF welcomes the Commission's legislative proposal to strengthen the European pharmacovigilance system and increase its transparency, which has been adopted by the European Parliament on 22 September by an overwhelming majority. Having worked intensively with the EP Rapporteur, Mrs Linda McAvan, and other key MEPs during the first reading, EPF was pleased that many of its concerns were reflected in the legislative text.

On 15 September, EPF co-organised a seminar with PGEU in the European Parliament to highlight the importance collaboration between stakeholders, such as patients and pharmacists, in medicines safety. The event was sponsored by Mrs McAvan and included speakers representing the patients, pharmacists, academia, regulators, the European Commission, and industry.

All contributors agreed that a strong pharmacovigilance system based on a "no-blame" reporting principle is essential to ensure the confidence of patients, health professionals and regulators alike. For the first time, all adverse drug reactions, not just serious ones, will be collected in a centralised database at EU level (except for certain well-known drugs where it is no longer considered necessary to collect non-serious adverse reactions). More on the event in our special event section.

EPF particularly welcomes the commitment of the Commission and European Parliament to involve stakeholders in pharmacovigilance, including the possibility for direct patient reporting of suspected adverse events. Patients have a unique personal knowledge and experience of the effects of the medication they take; we hope that the measures included in the legislative proposal will facilitate the wider use of this knowledge for the benefit of patients as well as regulators.

Read More…

3. Patients' Rights in Cross border healthcare

Readers will recall that EPF worked extensively with the Rapporteurs on this proposal in 2008 and 2009, and a patients' perspective was well reflected in the text adopted by the European Parliament in the first reading in April 2009.

The common position adopted by the Council under the Spanish Presidency in June 2010 was unsatisfactory from a patients' perspective, and took several steps backwards on many important issues, such as equity of access, safety and quality.

The Secretariat continued its work with the new Rapporteur appointed for the second reading, Mrs Françoise Grossetête MEP, to whom we made several proposals for improvement of the text in order to make it more patient-centred.

EPF's key areas of concern were: that patients should not be expected to pay the costs of cross-border healthcare upfront; that the rationale and specific conditions for prior reimbursement should be clarified; that EU cooperation on improving safety and quality should be strengthened, and that same standards should be to eHealth and telemedicine; that patients with rare diseases should have special provisions; and that stakeholders should be involved in the implementation and evaluation of the Directive, notably in the provision of information to patients in cooperation with national (information) contact points and the proposed European HTA Network.

Mrs Grossetête has now prepared a Draft Recommendation for the second reading in the European Parliament. We are pleased to see that the Recommendation has taken on board EPF's arguments to a great extent, and from the perspective of patients the Draft Recommendation significantly improves on the Council's position.

Read More…

4. Clinical Trials in Third Countries

Since March 2009 EPF has participated in an EMA Working Group on Third Country Clinical Trials, whose aim is to discuss the challenges of meeting international ethical standards in clinical trials in countries outside the EU. The patients' perspective is represented in this working group by EPF, the International Alliance of Patients' Organizations (IAPO) and the European AIDS Treatment Group (EATG). Patients' organisations main concerns relate to the need for adequate information and education for patients, transparency of clinical trials procedures, preventive measures and sanctions to combat unethical research.

As a result of the discussions, the EMA launched a public consultation to invite comments on the "Reflection paper on ethical and GCP aspects of clinical trials conducted in third countries for evaluation in marketing authorisation applications for medicines for human use, submitted to the EMA" prepared by the working group.

The EPF Secretariat prepared a briefing paper for its members in consultation with IAPO and the EPF Policy Advisory Group. We also attended a workshop on the reflection paper on 6–7 September in London, where various aspects of third country clinical trials were discussed.

Comments and suggestions from all our member organisations are welcome **by Wednesday 29 September** in order to finalise EPF's response to EMA.

Note, however, that the Working Group will continue its task in the coming months, with a view to finalising the EMA guidance and proceeding to its practical implementation. EPF will be involved, and there will therefore be further opportunities to contribute to this work along the line, so if your organisation is not able to meet the current deadline, we will be pleased to receive your comments at a later date.

You can access the EMA reflection paper through this link.

You can access the EPF consultation paper through this link.

5. EPF Roundtable on "Cross Border Health Care – the patients' perspective", held under the auspices of the Belgian EU Presidency, 1 December 2010, Brussels (TO BE HELD)

EPF is establishing a tradition of holding high-level events under the patronage of the EU Presidency, as exemplified by the Value+ conference in 2009. This year, we will organise a High-Level Roundtable around the highly topical theme of Cross-Border Healthcare, focusing on inequalities in health, safety and quality aspects. The event will put forward a patients' perspective on the importance of the new Directive on Patients' Rights in Cross-Border Healthcare, on the eve of its Second Reading in the European Parliament. The implications of the Directive for patient safety, quality of care, and health inequalities will be explored.

The Spain-Belgium-Hungary Trio Presidency have identified "Health Inequalities" as an overarching theme, with Health Safety being among the specific priority areas of the Belgian Presidency. The Roundtable aims to raise awareness among key decision-makers regarding the legitimate and constructive role of stakeholders, such as patient groups, as part of the policy debate and as catalysts to ensure that EU instruments are taken forward in a national and regional context. Around 40 high-level participants, composed of policy-makers and stakeholders, including patient leaders, health professionals, insurers, industry, and health managers, will convene for a one-day debate. Speakers will include Mr John Dalli, the Commissioner for Health and Consumers, high-level representatives from the Commission and from the Belgian, Spanish and Hungarian Presidencies, the Rapporteur leading on the legislative dossier under discussion, and representatives of the key EU stakeholder groups. The event will end with conclusions and recommendations on the way forward, which will be extensively disseminated to stakeholders.

The official website of the Belgian Presidency is www.eutrio.be.
For more information please contact the EPF Secretariat.

6. New Eudravigilance Users' Group at European Medicines Agency

Eudravigilance is a centralised European database of adverse reactions related to medicinal products authorised in the EEA, and those subject to clinical trials. This database is the key EU resource to support the Agency's responsibility to evaluate and coordinate safety of medicines, including the collection, management and dissemination of information on adverse reaction to medicines (pharmacovigilance).

In line with current EU legislation, the EMA is in the process of implementing the EudraVigilance Access Policy with the aim to make adverse reactions related to spontaneous reports proactively available to healthcare professionals and patients. The draft Policy was subject to public consultation from December 2008 to March 2009, with further recommendations provided by the European Data Protection Supervisor in September 2009 and the European Ombudsman in April 2010. Based on the comments received, the Access Policy is now being finalised.

The European Medicines Agency has established an "EudraVigilance Users Group" with patients, consumers and healthcare professionals. The Group will hold its first meeting on 28 October. EPF has been invited as one of the stakeholder organisations to join this Group, which will prepare the practical implementation of the Access Policy. Its remit will be to define jointly with the Agency and the EudraVigilance Expert Working Group the requirements on how to best implement the Access Policy. EPF believes that it is important to ensure that access to Eurdravigilance will meet the real-life needs of patients, and that appropriate guidance will be made available to enable patients and their families to interpret the information in the database. If properly implemented, this will be a key resource for all patients' representatives.

For more information, please contact Kaisa Immonen Charalambous.

7. Plenary Vote Animal Research Directive

The long running revision of Directive 86/609, governing animal research in Europe has been passed at its second reading in the European Parliament. The text, which was passed without amendment, is essentially a compromise between the many divergent views on this issue in Europe.

European patient groups have been active in communicating the importance of the continuation of animal research to progress towards cures and treatments for currently unmet health needs, whilst also seeking viable alternatives to animal testing. Our voice has brought a valuable balance to the debate.

The issue is not closed, as the legislation now moves to transposition, and there are still issues regarding interpretation of certain sections of the Directive. Of particular concern to patients are the interpretation of restrictions on the use of Non-Human-Primates (NHPs - animals which are vital to the understanding of some complex health concerns such as neurological

conditions), which are intended to prevent trivial use, but could be misinterpreted to restrict use to a degree damaging to biomedical research.

It is important that nationally active patient groups continue to communicate to their governments the importance of animal research, and continue to provide a reasoned balance to this debate.

If any patient group would like advice on how they can contribute to this debate, please contact Nick Meade of the European Genetic Alliances' Network (EGAN) at nick@geneticalliance.org.uk

EPF would like to congratulate Nick and EGAN on their leadership of this campaign and will continue our cooperation with regard to translating the legislation into practice.

8. Corporate Responsibility Process

This process was launched on 23 September at the EU Ministerial Level conference on Innovation and Solidarity (see section 16). The background to this is a recognition that the pharmaceutical sector contributes significantly to the health and well-being of citizens, but also to economic growth and employment in Europe. Despite the many achievements over the past years, the European pharmaceutical sector is confronted today with major health, economic and scientific challenges.

Considering the contributions the pharmaceutical industry can provide to EU citizens, it is important to ensure that the strategies are in line with the societal needs and that all partners exercise their responsibilities. The Process on corporate responsibility in the field of pharmaceuticals has been set up to initiate a momentum among the Member States, industry and other relevant stakeholders by considering in a balanced approach of societal and industrial challenges.

Given the experiences of the G10 process and of the High Level Pharmaceutical Forum, the Process on corporate responsibility in the field of pharmaceuticals should facilitate discussions on ethics and transparency of the sector but also on non-regulatory conditions for better access to medicines after their marketing authorisation.

The Process will therefore comprise three independent platforms:

- Transparency and ethics in the sector
- Access to medicines in Europe, in the context of pricing and reimbursement
- Access to medicines in developing countries with a focus on Africa

EPF is represented in steering group, and we, together with our members will be actively involved in all three platforms and our international sister organisation IAPO (International Alliance of Patients' Organizations) will lead patient representation in the platform on access to medicines in developing countries.

The DG Enterprise and Industry will manage this process in consultation with other relevant services of the Commission for a period of two years.

For further information, please contact the Secretariat.

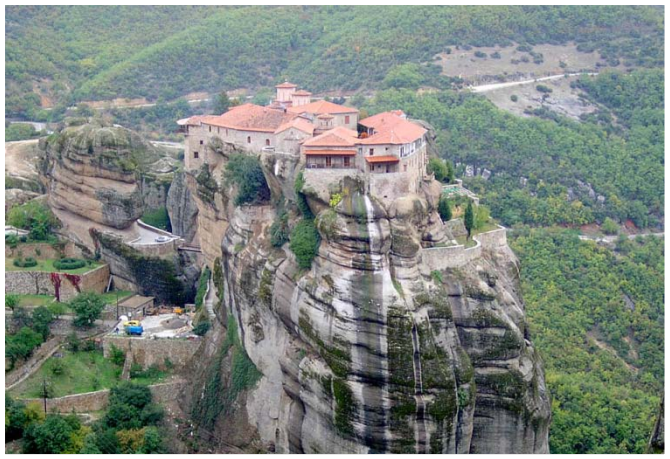
9. European Medicines Agency Patients' and Consumers' Working Party (PCWP) elects new co-chair

Lise Murphy

The PCWP provides recommendations to the Agency and its human scientific committees on all matters of interest to patients and consumers in relation to medicines.

In early September, PCWP elected a new co-chair, Lise Murphy who will be replacing Nikos Dedes who's mandate has come to an end. Ms. Murphy has been a member of PCWP since 2007, representing EURODIS (the European Organisation for Rare Diseases). She will co-chair the party along with Isabelle Moulon, Head of the Information Sector at the European Medicines Agency.

10. RENEWING HEALTH 2nd PSC Meeting and User Advisory Board's last developments



A view of the famous "Meteora" (Μετέωρα, "suspended rocks"), the second largest and most important complexes of Eastern Orthodox monasteries in Greece, located 15 Km North of Trikala.

There have been new developments in the RENEWING HEALTH project since our last Mailing. RENEWING HEALTH, is a project implementing large-scale real-life pilots in nine European regions for the validation and subsequent evaluation of innovative telemedicine services for patients suffering from diabetes, cardiovascular diseases (CVD), and chronic obstructive pulmonary disease (COPD) using a patient-centred approach and a common rigorous assessment methodology.

The second Project's Steering Committee (PSC) and the second clinical meeting were held on September 9 and 10 respectively in Trikala (Greece). The meetings were an opportunity for project partners to update each other on recent work done and activities planned for the next four months. This is a crucial period for the project, particularly for the various pilot sites which have now to finalise their Scientific Clinical Protocols, i.e. the documents outlining the methodology and quality standards of the trials and also the application of evaluation methods. The Protocols will also be used for the applications to the local Ethics Committees and for trial registration.

The actual implementation of pilots is set to start in February 2011 after the final approval of the Protocols and will be carried out in the form of pragmatic randomised controlled trials.

The next PSC and clinical meetings will take place in Carinthia (Austria), on January 26-27, 2011.

EPF is involved together with EHTEL (European Health Telematics Association) in the management of the User Advisory Board (UAB), which was set up to ensure that the interest and needs of the users of the piloted telemedicine services, i.e. patients and

their formal and informal carers, health professionals and payers are properly taken into account throughout the stages of design and deployment.

In Trikala the UAB held a joint-meeting with the Work Package 3 (WP3) responsible for Evaluation Methodology and Pilot Evaluation. The purpose of this meeting:

a) to explore concrete ways for UAB and WP3 cooperation, specifically in selecting questionnaires to measure end users' satisfaction
b) to strengthen the links between the UAB and the various pilot sites
c) to illustrate the rationale and the scope of the first deliverable of the UAB, i.e. "User Requirements".

The User Requirements is a comprehensive analysis of needs, requirements and expectations of end-users of telemedicine services which is currently being produced by the UAB through an extensive literature review and set to be presented during the next UAB meeting scheduled on November 2nd in Brussels. A representative from one of the pilot sites in Veneto (Italy) testing telemedicine applications for remote monitoring of patients with CVD will be also invited to the UAB meeting to present the pilot and get feedback from UAB members.

For more information about RENEWING HEALTH contact Liuska Sanna or Walter Atzori.

11. CALLIOPE

On 3 September, partners of the CALLIOPE network met for the last project meeting in Athens, Greece. The purpose of the meeting was to discuss and review the second draft of the **eHealth Interoperability Roadmap,** one of the key deliverables expected of CALLIOPE.

There was much convergence of views at the meeting, which made it possible to set a clear process, action plan and milestones for improving the structure and optimizing the content of the circulated draft for arriving successfully at a final deliverable by the project end date in November.

In terms of content, the main blocks of the roadmap agreed upon are:

- Setting the context: this part will describe the health policy needs; the personal needs and vision of each key stakeholder and the role of eHealth as an enabler to support the changes in health.
- Enabling eHealth deployment: will address what concretely needs to be done; the interoperability aims; the technical framework and standardisation; the personal electronic identification, authentication and signatures; semantics; the legal framework (ethics and regulatory issues, privacy and data protection) and the governance and organisational issues.
- Addressing open issues: resources and monitoring; and finally Recommendations focusing on processes.

CALLIOPE Closing Session November 16th

The CALLIOPE plenary meeting will take place on 16 November from 9:30 – 13:00 at the European Parliament, in Brussels supported by MEP Milan Cabrnoch. The title of the event is "**Crossing boundaries in eHealth: the CALLIOPE think-tank and collaborative platform**".

The event will focus on presenting the project's result and their added value and will look at the next phase when much of the work done through CALLIOPE will be translated into the High Level eHealth Governance Initiative. Thus, there will be a clear focus on the perspective of different stakeholders and on the future use of the Roadmap.

For more information please go to CALLIOPE's website or contact Liuska Sanna.

12. Regenerative medicine project and the importance of involving the patient's view

The topic of stem cells and regenerative medicine has been featured in past issues of EPF's Mailings. The EU-funded FP7 project REMEDiE (Regenerative medicine in Europe),is a social science project examining the global changes in the field of stem cells and regenerative medicine especially in regards to issues around innovation, translational medicine, and the regulation of new products and treatments. The project will hold its final, international conference in Bilbao next year to which EPF members

will be invited. On November 10-11 in Brussels a meeting has been organised with MEPS where feedback on the interim results of the project will be presented.

The role of patients

Some of the key questions for patients include how the scale-up of allogeneic-based therapies will ensure long-term safety of transplanted cells and how some websites offering stem cell treatments (costing up to 80,000 euros) exploit vulnerable patients and their families.

The REMEDiE project has explored this issue in its work within Europe and more recently China and while recognising the crucial importance of ensuring that all treatments, wherever they are given, meet proper ethical and regulatory standards, is interested in the role that informed patients, through the networks and the choices they make, can play in providing information and feedback on treatment. REMEDiE's most recent conference also showed how the stem cell-tourism question needs to address the equally important issue of post-treatment monitoring, the protection of patient rights and what role if any European-based GPs have in this regard. These issues link to the project's related work on clinical trials which will be reported to the EPF in the near future.

The International Society for Stem Cell Research has recently provided guidance looking at concerns surrounding stem cell tourism via the website: www.closerlookatstemcells.org .

Further details of the project can be found at www.york.ac.uk/res/remedie or contact Andrew.

13. Healthcare: the demographic crisis" Stakeholder Workshop

Kaisa Immonen-Charalambous participated in a panel discussion on 14 July at an event organised by Fondation EurActiv, with the support of Intel, to address the twin challenges of falling fertility and rising life expectancy, which have fostered dramatic demographic shifts for developed countries and pose a challenge to European already heavily burdened health systems. Increasing numbers of older people will require higher investment in the healthcare sector, more health professionals, and greater public spending on pensions and social security.

Ehealth and telemedicine promise to offer new prospects for both cost savings and improved quality of care. However, the benefits of new technologies may not always be distributed equally. Some of the questions discussed included, "Will spending in health technology save money in the long run?", "Will healthcare continue to shift away from hospitals and towards community care?", "What are the barriers to change?", and "What do patients want?"

Participants included Antonyia Parvanova, MEP; Constantijn can Oranje-Nassau from the Cabinet of the Commissioner for the Digital Agenda; Pascal Garel, Chief Executive of HOPE; and Mário ROMÃO, Senior Policy Manager for Digital Health. The debate was moderated by Gary Finnegan, Editor of EurActiv.com and chaired by Rick Zednik, its CEO.

EPF addressed particularly the patients' perspective. It was highlghted that good health is a right of all citizens, and that it also has economic benefits in terms of increased productivity and full participation of citizens in society. Technologies may provide part of the answer, and it is possible that spending in health technology may save money in the long run; but the development and implementation of new technologies in healthcare should be driven by their potential to improve the quality and safety of care, and by patients' needs and preferences. For patients, it is important to build the necessary skills and confidence in new technologies.

Overall, the challenges faced by European health systems are multi-faceted and touch upon all policy areas, not just health. These issues need to be addressed through open, public discussion, with the participation of all stakeholders. Health literacy is essential in this context. Patient organisations should be involved as a partner in a two-way dialogue – both in the provision of

information to patients and citizens, and in feeding patients' needs and preference to the policy-making level to ensure policy and programmes are developed with the "patient at the centre".

14. EFAPH (European Federation of Associations of Patients with Haemochromatosis) AGM

Kaisa Immonen-Charalambous was invited to give a presentation about EPF at the EFAPH Annual General Meeting, held in Nijmegen, The Netherlands on 18 September. EFAPH members heard about EPF's vision and mission, main activities, as well as the rationale and benefits of uniting at EU level. Disease-specific federations such as EFAPH have a crucial role to play in uniting their national members at European level and providing a channel for collaboration with EU-level actors – patients' umbrella groups like EPF, but also EU institutions and other bodies. EPF would like to congratulate EFAPH, a relatively young federation, for its dedication and commitment in channelling the voice of patients with haemochromatosis so it is heard in Brussels and in the Member States.

15. EFPIA Patients' Think Tank 22 September

Kaisa Immonen- Charalambous and Nicola Bedlington represented EPF at the EFPIA Patients' Think Tank. Key items on the agenda included the EU Corporate Responsibility Process, The EMA Road Map and an update on current EU health legislative dossiers from the industry and patient perspective respectively.

For further information please contact Nicola Bedlington.

16. EU Ministerial Level Conference on Innovation and Solidarity

Nicola Bedlington represented EPF at the EU Ministerial Level Conference on Innovation and Solidarity, that brought together high level representation from 25 member states to address stimulating, measuring and valuing innovation. EPF presented the patients' perspective in the session devoted to "stimulating innovation".

The conference discussed a background prepared by the Belgian Presidency entitled ' A Call to Make Innovative Medicines Accessible in The European Union' Including recommendations for a coordinated action to stimulate, measure and value pharmaceutical innovation.

For a copy of this report and further information on the conference please visit www.eutrio.be.

For a copy of Nicola's presentation, please contact the secretariat. It is based on EPF's policy work on and post the Pharmaceutical Forum our input in relation to the impact assessment on the Clinical Trials Directive and our work on meaningful patient involvement in the framework of the EPF Value + project.

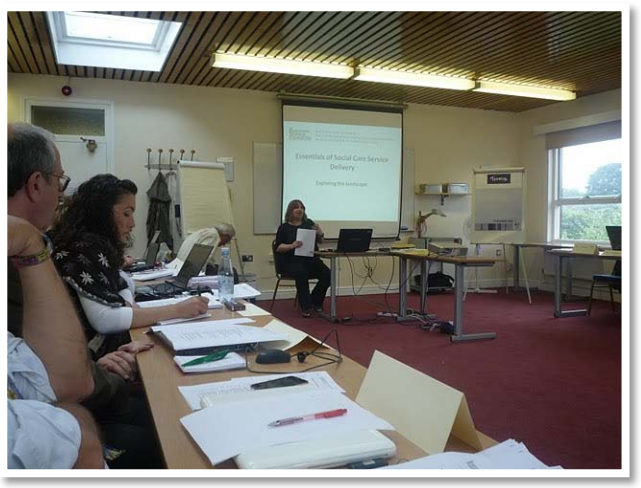
17. ESF Exploratory Workshop on Health and Social Care Informatics

On 21 – 23 July, Walter Atzori represented EPF at the Exploratory Workshop on Health and Social Care Informatics organised by the Keele University (United Kingdom) with the support of the European Science Foundation.

What was this Workshop about?

The premise of this workshop was to explore and discuss need and opportunities for integrated approaches to delivering care to the individuals through Information and Communication Technologies (ICT).

While social care is increasingly being regarded as an essential part of maintaining health and wellbeing of individuals, eHealth continues to narrowly limit itself to health organisation related activities. Health involves far more than the services provided by health agencies. Particularly when we are to deal with a patient with a particular chronic condition or where aspects of impaired daily living affect health, social care services are needed to complement health agencies in providing effective care to the patient.



While recognising that health and social care records present very different characteristics, the workshop recognised the need for reconsidering the role of ICT more holistically in supporting health. However in most European countries responsibility for managing and providing health and social care services lays with different authorities often acting at different levels. The key challenge to developing such integrated ICT systems is therefore to ensure effective coordination of services provided by the various actors involved in providing care to the patient.

What kind of benefits can integrated social and health care informatics bring about?

Some advantages of integrated social and health care informatics can be straightforwardly expressed in terms of for instance avoiding clashing scheduling of activities of health and social service providers. Others are perhaps less obvious but equally important such as the possibility for health and social care providers to interchange information and jointly access shared records as and when appropriate, and hence the possibility for the patient to receive more individualized care more in line with his/her needs and preferences.

There are, however, some key challenges associated to integrated social and health informatics as “e-social” records are potentially even more sensitive than ordinary eHealth records. Unlike eHealth records “e-social” records include data not only on the patient but also on patient’s relatives and other informal carers. Issues like protecting the privacy and confidentiality, ensuring accuracy, quality and secure holding of records and *content access* permission are therefore even more critical when it comes to e-social records.

Follow up

A Declaration was produced on the basis of the outcomes of the workshop. A detailed workshop report to which EPF will also contribute will be also prepared.

EPF recognises that while setting up effective and interoperable ICT solutions for health should continue to be prioritised, delivering effective care to the patient requires action supporting more holistic approaches to care whereby the development of health informatics is undertaken in partnership with social care informatics. EPF will therefore continue to monitor developments in this area and may consider more concrete engagements in the future.

For further information please contact Walter Atzori.

18. Meeting with Valencia Representation

The Minister for Health of the Valencian region in Spain, Mr Manuel Cervera, and the President of the Valencian Government, Mr Francisco Camps, visited the office of EPF on 19 July for a meeting with EPF's Director, Mrs Nicola Bedlington, to present the health system of Valencia and learn about EPF and its work at European level. They were accompanied by the Presidents of the three professional associations of pharmacists of the Comunitat Valenciana.

Mr Cervera presented the policies of the Valencian Regional Government to provide quality healthcare to the people of the region. Valencia is particularly focusing on new information and communication technologies in hospitals and health centres, and paying attention to home care. Such technologies include electronic prescriptions, clinical consultation via phone, and appointment requests online.

Nicola Bedlington presented EPF's work and key priorities, including the new area of Structural Funds and Cohesion Policy where EPF recently organised a workshop at the EU Open Health Forum (covered in the previous issue of this Mailing).

Mr Cervera also referred to a cooperative project which he presented to the representatives of the Walloon Region in Belgium, concerning biobanks. The project envisages the creation of an area within the Centre for Advanced Research in Public Health to collaborate on diseases that transcend national boundaries. The Valencian region is the first to have a regulatory framework for biobanks in Spain, and it has a network of 25 biobanks, major hospitals and research centres.

19. Women's Health – Seminar on Gender and Health

Nicola Bedlington represented EPF at a Commission organised seminar on Gender and Health on 7 July in order to review the various activities currently underway in this area and to exchange good practice. Our member organisation European Institute for Women's Health played a key role in the meeting.

Gender issues are high on the political agenda and this meeting was also an opportunity to gather information and data to improve and promote equity between genders. The European Commission is currently discussing a Strategy towards Equality between Women and Men for 2010-2015. The conclusions of the Seminar will feed the health chapter, helping to establish priorities and actions.

The basic premise of the meeting was that achieving gender equity in health implies eliminating unnecessary, avoidable and unjust health inequities which exist as a result of the social construction of gender. It means that women and men have the same opportunity to enjoy living conditions and services that enable them to stay in good health and/or manage their diseases. Please click here for a copy of the conclusions.

20. Investing in Europe's health workforce of tomorrow: scope for innovation and collaboration

The Belgian Presidency of the EU Council drew political attention regarding the need to invest in sufficient, motivated and well-skilled health professionals at the conference "Investing in Europe's health workforce of tomorrow: scope for innovation and collaboration", on 9 and 10 September in La Hulpe, Belgium.

The purpose of the conference was to raise awareness on the health workforce of tomorrow and to support the European Commission's efforts in developing a coordinated approach in supporting national and regional policies in this area. These national and EU policies need to reflect the changing needs of patients and the overall health system in order to ensure the system is supplied with adequate, skilled health professionals.

Evidence shows that 80% of adverse events in healthcare happen due to lack of effective communication. For this reason trainings at all levels need to address patient safety issues in everyday life. This is of a great interest to EPF, where training and education skills provided to patients and health professionals are vital, to ensure high quality and safe healthcare.

A clear call for EU institutions has been formulated by relevant stakeholders, to provide training programmes for healthcare professionals.

For more information, please contact the EPF Secretariat.

21. 16th Congress of the EAHP (European Association of Hospital Pharmacists)

EAHP's annual congress is the largest congress for hospital pharmacy in Europe and is attended by professionals from over 50 countries. Approximately 3000 hospital pharmacists are expected to attend the 16th Congress of the EAHP next 30 March –1 April 2011 at the Austria Centre Vienna, Austria.

"Hospital Pharmacists in a changing world - opportunities and challenges" will be the theme for the presentations at the Vienna 2011 EAHP Congress. A scientific programme including **three keynote presentations**, **13 seminars** open for interactions with the speakers and **two interactive workshops** will offer participants the unique opportunity to meet, network and share expertise. EAHP's industry partners have also committed to conducting **satellite symposia** highlighting important new developments important to hospital pharmacy.

REGISTRATION IS NOW OPEN: Register online to attend the EAHP 16th Congress.

CALL FOR ABSTRACTS: Deadline for submission is 15 October 2010. Original contributions from all fields of hospital pharmacy are welcomed for poster presentation. Please visit the EAHP website for further details and the new abstract/poster guidelines.

For further information: Please visit the website, where you will also be able to find more details on our scientific programme.

22. EPF board meeting outcomes

On 14 September the new EPF board met for the second time since the Annual General Meeting in May 2010. The meeting was an important opportunity to review various EU project proposals, look at EMA' new conflict of interest policy, plan for 2011 on the basis of a draft plan, in particular in relation to the Hungarian and Polish EU Presidencies and to review finances to the end of August 2010.

For more information please contact Nicola Bedlington.

23. EPF Policy Advisory Group meeting

The EPF Policy Advisory Group met for the third time on the first day of September. The group was set up to advise the EPF's Board and Secretariat on policy topics prioritised by EPF's annual general meeting and which, because of their complex, controversial and/or highly political nature, required a more detailed and in-depth discussion. The group is made up of elected representatives or staff of EPF members - both European patient organisations and national patient coalitions - who have a particular interest in the policy areas EPF is working on.

At the meeting on 1 September, the group exchanged views and advised on several topics of crucial interest for EPF and our members: the Ethics of Clinical Trials in Third Countries – reviewing a draft position paper prepared by the Secretariat which is currently undergoing member consultation until 28 September; the EPF consultation on eHealth; Structural Funds and Cohesion Policy; and Personalised medicine. They also looked forward to a number of upcoming key issues for 2011 and 2012.

24. Membership Survey

During the summer, EPF sent out a membership survey to all its members, as agreed at the Annual General Meeting in May. The purpose of this survey is to identify how to improve EPF's communications and services to our members and how to engage them even more in EU policy and programme work. The Secretariat will analyse the results of the survey and report these to the EPF board, in order to integrate these into our future activities.

For those members who have not yet responded, you are strongly encouraged to do so by 15 October 2010. Should you have any questions, please contact Nicola Bedlington.

25. EPF Gearing Up for Autumn Regional Seminar

EPF is busy planning this year's Regional Advocacy seminar which will take place in Budapest, Hungary on 25-27 October.

In line with previous seminars, the purpose of this event is to increase the understanding among patient groups about the role and functioning of EU institutions and to strengthen their capacity to interact with policy-making at the European level.

There is also another focus, which is the involvement of young patients as advocates in patient organisations. For this reason we are inviting patient organisations to register two representatives – an "adult" and a young representative aged 15-25. Countries eligible to participate are Hungary, Slovakia, Germany, Austria and now also Italy, Bulgaria, Portugal, the Czech Republic and Romania due to the high interest the seminar raised.

The draft programme is available at: www.eu-patient.eu/Initatives-Policy/Events/EPF-Autumn-Regional-Advocacy-Seminar-for-Patient-Leaders/

Patient groups from the eligible countries can register their two representatives at: www.eu-patient.eu/Initatives-Policy/Events/EPF-Autumn-Regional-Advocacy-Seminar-for-Patient-Leaders---Registration-Form

For more information please contact Veronique Tarasovici or Liuska Sanna.

26. EPF Sponsors Meeting

On 14 September, EPF organised a sponsors' dinner meeting at Rouge Tomate in Brussels. The purpose of the meeting is to give our funding partners and potential partners the opportunity to learn more from us about EPF's key achievements and their impact over the last year, and our particular goals for 2011 and beyond, framed around our strategic plan and the broader EU health agenda. The evening also provided the opportunity to share ideas and thoughts with new EPF board members and staff during an informal dinner afterwards.

For more information, please contact Nicola Bedlington.

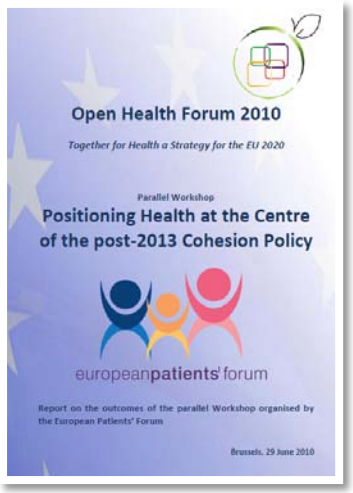
27. Translations of Value+ toolkits

EPF is delighted to announce that the Value+ toolkit, one of the key deliverables of the Value+ project has been translated into German and French. The toolkit has been translated in an effort to ensure that a wide group of European patient organisations will have access to this information.

The Value+ toolkit supports patients and patient organisations and shows them how to become involved as equal partners in European projects and political processes. EPF expects the toolkit translations into Spanish, Lithuanian and Bulgarian will be completed by mid-October.

To download the French and German translations please visit our website: www.eu-patient.eu/Initatives-Policy/Projects/EPF-led-EU-Projects/ValuePlus/Resources/Value-Resources

28. Report on Health and Cohesion Policy published



As you may recall from the previous Mailing Issue, EPF organised a Workshop on Health and Cohesion Policy which was held in Brussels in the context of the 2010 Open Health Forum on June 29, 2010. To follow up on the results of the workshop EPF decided to produce a detailed report to which you can now have access by clicking on the picture on the right-hand side of this page.

This report, which builds upon the short feed-back report presented by EPF President Anders Olauson during the second plenary session of the Open Health Forum, summarises the main issues raised by the various speakers as well as the outcomes of the debate structured in the form of panel discussion around the theme "Positioning Health at the Centre of the post-2013 Cohesion Policy?".

Through this report EPF wants to provide evidence and raise awareness of the importance of integrating health priorities in the next strategy for Cohesion Policy.

The goal of this report is threefold:

- to be used as a basis for future action EPF is considering undertaking in this area
- to call for concerted action involving all relevant stakeholders to advocate for positioning health at the very centre of the post 2013 Cohesion Policy
- to raise awareness among patient organisations about the importance to get involved in Cohesion Policy at both European and national/regional level.

For more information please contact Walter Atzori.

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29. Diary

October 6-9	13th European Health Forum Gasteinn Austria Attendance: Speakers Anders Olauson, Nicola Bedlington, Kaisa Immonen
October 12-14	Eucomed MedTech Forum 2010 Brussels Speaker: Nicola Bedlington
October 12	eHealth Event in the European Parliament Brussels Speaker: Nicola Bedlington
October 18-19	Post H1N1 Media Workshop, Paris Speaker: Nicola Bedlington
October 19-20	EU Presidency Meeting on Chronic Diseases Brussels Speaker and chair: Anders Olauson
October 21	ENRICH Conference Brussels Speaker: Kaisa Immonen
October 21	European Union Health Policy Brussels Attendance: Nicola Bedlington
October 25 - 27	EPF Regional Advocacy Seminar Budapest Attendance: Anders Olauson, Nicola Bedlington, Liuska Sanna, Kaisa Immonen
October 27	IVD Public Health Conference "Management of Chronic Diseases: A Major EU Challenge" Brussels Speaker: Kaisa Immonen
October 27-28	Empowerment in Mental Health Leadership Meeting Leuven Attendance: Magdalena Machalska

October 28	EMA Eurdravigilance Users' Group (first meeting) London Attendance: Kaisa Immonen
November 2	Renewing Health: Meeting of User Advisory Board Brussels Attendance: Walter Atziori, Liuska Sanna
November 4	Microsoft Leaders' Summit London Attendance: Anders Olauson
November 8-9	Reducing Health Inequalities from a regional perspective – What works, what does not? Genk Attendance: Walter Atzori
November 10-12	Patient link workshop Brussels Attendance: Kaisa Immonen
November 11 – 12	Careum Congress Zurich Attendance: Anders Olauson
November 16	CALLIOPE closing session Brussels Attendance: Liuska Sanna
November 17	EPPOSI Workshop "Patients' Engagement in HTA" Brussels Attendance: Liuska Sanna
November 18	EFPIA Think Tank Attendance Nicola Bedlington
November 29	WHO Europe Meeting on Patient Safety Copenhagen Attendance: Kaisa Immonen
November 30	Microsoft Users' Board
December 1	EPF High Level Roundtable on the Draft Directive on Cross border healthcare Brussels Attendance: Board and Secretariat

December 2	EPF Board Meeting Brussels
December 3	Conference: 21st Century Healthcare for Europe Brussels Speaker: Anders Olauson
December 7-8	InterQuality Project Kick-off Meeting Warsaw Attendance: Liuska Sanna
December 15	EMA Scientific Conference London Attendance: Anders Olauson and Nicola Bedlington