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EPF Mailing

Issue 5 (39)
5 October 2011

Dear EPF Members and Allies,

Welcome to the EPF Mailing – once again, we have much to share with you in this issue.

During the summer break, EPF organised a retreat for our Youth Group to develop further our Youth Strategy and plan activities and a project for next year – please go to section 19 for more details.

In September, we held a funders' briefing dinner to review our work over the last few months and plans for 2012. The board also met on 14 September, to examine our preliminary work plan for 2012 and decide key activities.

In cooperation with CPME, EFPIA and PGEU, EPF organised a very successful event in the European Parliament on adherence/ concordance on 21 September in the European Parliament (see our special feature) We will be following up actively on the outcomes of this meeting in 2012 and beyond, notably through the European Innovation Partnership on Active and Healthy Ageing. Other key policy initiatives are reported in a policy section.

There have also been a number of external Conferences and events in September, where we have been able to put across the patients' perspective. Please see section for reports on these and sign-posting for further information.

Our programme team has been extremely active on both current projects and involvement as associate partners in selected Consortia applying for FP7 funds. Please see this section for an update on our project work.

Much energy has also gone into further preparations for the IMI project EUPATI, and a key Consortium meeting will take place on 19th October to finalise our proposal in the light of evaluators remarks and budgetary issues. The aim is to complete negotiations with IMI by mid-December in order to be able to kick off by early February. For more details go to section 18.

EPF has recently launched an equal opportunity recruitment process to employ a Communications Officer (Please click here for more information). We hope to have the successful candidate in post by the end of the year.

As we go to press, our focus is very much on the next major EPF event, scheduled to take place in Bucharest, Romania on 27, 28 October 2011. This EPF Regional Advocacy Seminar will focus in particular on the relationship between health professionals' organisations and patients' organisations and opportunities for closer collaboration and dialogue. The seminar has generated great interest and registration is now closed (see section 32). A detailed report on the outcomes of this meeting will feature on our next Mailing in mid-November.

EPF will also be very active in the European Health Policy Forum Gastein, where we hope to meet many of our colleagues and allies. We shall report on our learning and impressions from Gastein in our next EPF Mailing, in particular our own event focussing on older patients, taking forward conclusions from our Conference in Poland in July on Saturday 8 October.

Finally, we look forward to seeing several EPF members and EUCOMED colleagues at the next EPF/EUCOMED Dialogue meeting on 11 October 2011. For those EPF members, who are interested but have not yet registered, please contact the EPF secretariat.

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

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1. Adherence to therapies: EPF and allies call for concrete action at EU level

On September 2011, EPF co-organised in a lunch debate held at the European Parliament in Brussels with CPME, PGEU and EFPIA , to bring together the perspectives of patients, doctors, community pharmacists and the research-based pharmaceutical industry to explore the challenge of adherence to therapies. The event was hosted by MEPs **Linda Mc Avan** (S&D/IE), **Cristian Silviu Buşoi** (ALDE/RO) and **Christofer Fjellner** (EPP/SE).

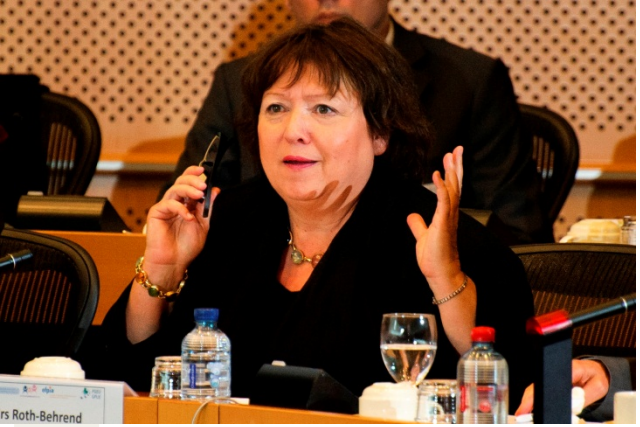
The key message that emerged clearly from the speeches and discussions is that a coordinated, multi-stakeholder and *patient-centred approach* – involving patients, their carers/families, health professionals, industry, and the public – is needed to address this major issue in order to improve patient safety and provide patients with high-quality healthcare which responds to their needs.

All stakeholders present, including the MEPs who represented the three biggest political groupings in the European Parliament, agreed that non-adherence is a major issue that calls for stepping up efforts and establishing a strong response at national and European level. Existing programmes and instruments, including the future EU Health Programme, the European Innovation Partnership on Active and Healthy Ageing, and the Research Framework, should be used in a coordinated approach to improve adherence. Structural Funds could also be used to channel most effective adherence interventions at national level.

Presentations and debates at the seminar also highlighted the *urgent need for an EU strategy for health literacy and information to patients*, which EPF has long been calling for. A European-wide campaign as part of such a strategy could significantly raise awareness on this issue among patients, the general public, healthcare professionals and decision-makers.

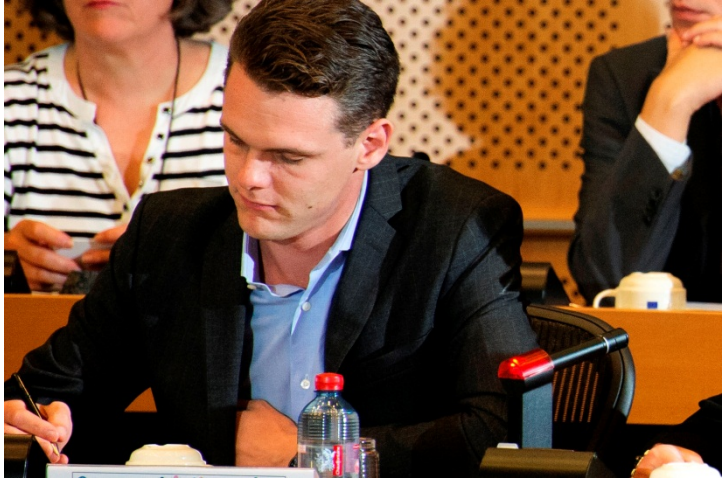
The full meeting room demonstrated that this is an issue of considerable interest and importance. The strong commitment of all the stakeholders to address it together was very clear. A joint press release was circulated immediately after the event to stakeholders and media at EU level. EPF will keep you informed on further follow-up actions with partners through this mailing and our website.

Below, you will find a summary of the key points raised by the speakers and the audience during the seminar.

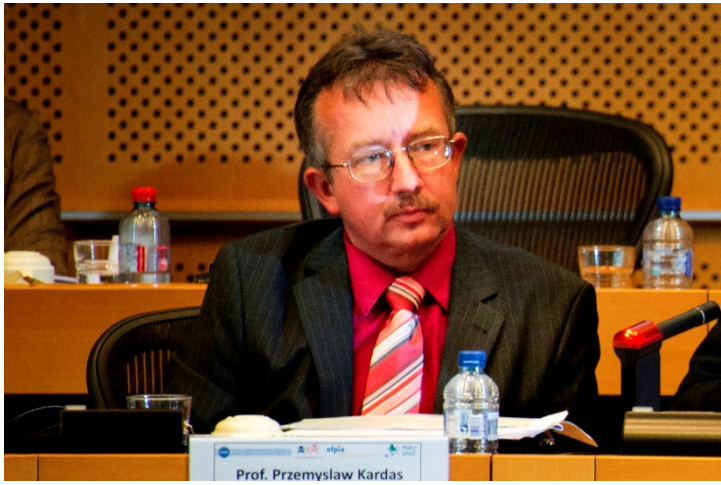


In the opening statement, **Dagmar Roth-Behrendt (S&D/DE)** standing in for Linda McAvan who was unable to attend for family reasons, said: "Improving the effectiveness of adherence interventions could have a far greater impact on health than any improvement in specific medical treatments" echoing a statement made by the World Health Organization. She acknowledged adherence as a major issue: studies estimate that 20–30% of patients do not take their medication as prescribed. With long-term therapies the figure goes up to 50%. She highlighted the *enormous impact on patient outcomes, patient safety, and healthcare expenditure*: In the EU alone, an estimated 194,500 deaths each year are due to misdose and non-adherence of prescribed medication, which costs the Union around €1.25 billion annually.

Ms Roth-Behrend stressed that an appropriate balance between health, social, and economic policies, as well as multidisciplinary and inter-institutional efforts at the national and EU level is critical for a successful approach. In her view, the crucial point is the patient-healthcare team relationship: appropriate communication, information and follow-up are core components for adherence. More time is needed between doctor and patient – but are health systems willing to pay for this? She then handed the floor to **Christopher Fjellner** (EPP/SE), moderator of the seminar, who pointed out the exceptionally high level of attendance at the event. Mr Fjellner then introduced the speakers.

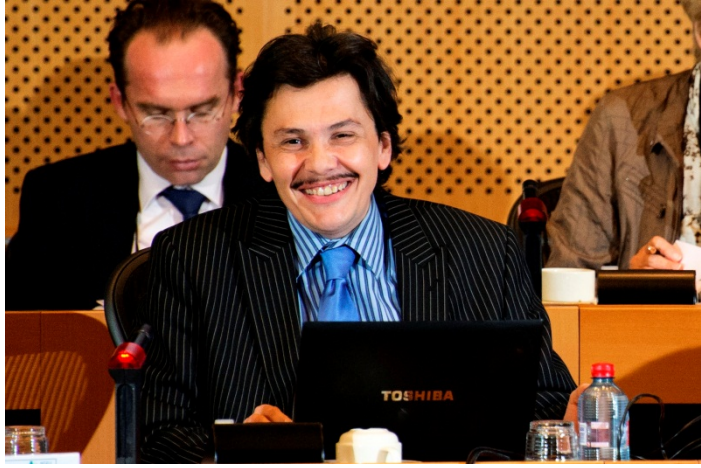


An overview of the facts and figures of non-adherence was presented by **Professor Przemyslaw Kardas** from the Medical University of Lodz, Poland**.** He explained that in reality non-adherence is more frequent than the statistics show, as it can take a variety of shapes: patients may not purchase the prescribed treatment at all, they may delay starting the treatment but take it well, or initiate the treatment well but then stop; or they may take it only if they feel symptoms. Adherence is not a recent problem, as it was already mentioned by Hippocrates (ca. 460 BC – ca. 370 BC).



Professor Kardas then went on to present some of the key findings of the "Ascertaining Barriers for Compliance" (ABC) project funded by the Seventh Framework Programme (FP7): "When long-term medication is prescribed, 50% of patients fail to adhere to the prescribed regimen" he stated. Though adherence is far more frequent in long term treatments, it is also widespread in shorter-term treatments, including antibiotics. This results in avoidable mortality and unnecessary costs for healthcare. "The better the adherence, the better the financial effect" he said, adding that adherence interventions are "*win-win strategies*" for patients, industries, healthcare professionals and healthcare systems. "*Adherence-enhancing interventions should be adopted as a routine part of normal care, and provided to every patient*" he concluded.

Bringing *the patients' perspective on medical adherence* into the discussion, **Christos Sotirelis** from the UK Thalassaemia Society spoke on behalf of EPF. He gave an overview of the evolution in terminology, which reflects the changing role of patients from passive recipients of healthcare services to health literate patients who are responsible and empowered actors in the management of their health: the word "compliance" implies that the patient does what the doctor tells him/her to, and patient acceptance is based on the doctors' status. "Adherence", a more acceptable term, implies that the patient in collaboration with the physician seeks to optimise the disease management process, the relationship is here based on trust.



He then explained that adherence is a multifactorial issue: it can be intentional or involuntary, and may relate to information needs, impact of the regimen on daily life, physical or mental incapacity, or social isolation of the patient, their self-image, and their ability to absorb the burden of uncertainty of the treatment and symptoms. Such a complex problem needs a multi-stakeholder response *with the patient at the centre*. This is why we should move towards a new concept: "*concordance"***.** Unlike the former terms used, concordance does not refer to patients' drug taking behaviour or doctors' prescribing policies, but to the interaction between patient and clinician. They are considered equal partners in a "therapeutic alliance", where the beliefs of both parties carry equal value. However, *the most important choices are those made by the patient.* It is a more patient-centred model of shared decision making. The implications of concordance to adherence are that concordant prescribing processes are likely to result in higher adherence by patients.

Mr Sotirelis then discussed how to achieve concordance in clinical practice. It is necessary to improve the consultation skills of doctors so they can communicate on patients' terms, share understandings and consider possible alternative

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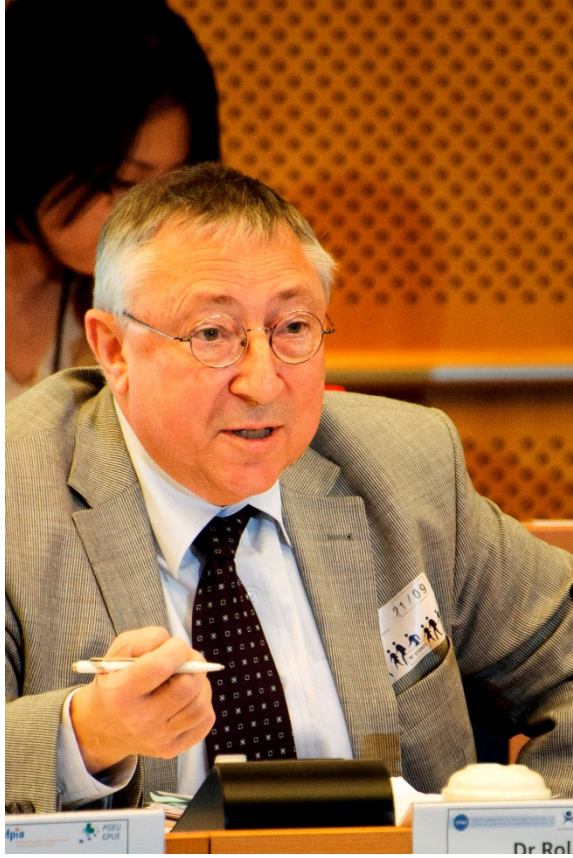
solutions together. Involving other healthcare professionals who are under less time constraints – such as nurses or pharmacists – can also help to support patients' adherence. Achieving concordance also implies *empowering patients* including through health literacy and greater involvement of patient organisations (e.g in formulating and dissemination of educational and scientific Guidelines, Standards and Options for treatment within a medical consensus).

"Adherence support and concordance are key components of good quality care. We believe that concordance in healthcare decision-making will lead to higher adherence by the patient. Health professionals should engage with patients as equal partners in the prescribing process, really listening to and taking account of their views. We need to empower patients and educate health professionals in order to create such an environment and promote meaningful dialogue," he stressed.

Dr Roland Lemye, Vice-President of CPME, presented *the role of doctors in a health care team with patients and pharmacists*. He affirmed the commitment of doctors to solve this widespread problem, which is costly for the healthcare system, as illustrated by piles of boxes of unclaimed medicines in pharmacies. "Doctors believe that much can be done from the communication point of view in order to improve medical adherence. eHealth tools could be used on a more regular basis in order to facilitate easy and fast communication, particularly between doctors and pharmacists, under the condition that data protection and privacy is safeguarded" he said.



Dr Roland Lemye illustrated this by presenting a good practice example, the introduction of the 'medication records' in pharmacies in France. Through this system the pharmacist can monitor all the medications the patient is taking, allowing for the identification and avoidance of redundant treatments. The pharmacist then informs the respective doctor of their patient's medication, contributing to a possible review of the medication by the doctor.

Informing the patients is a key part of the process, especially as for older patients with multiple conditions the treatments tend to become very complex. Dr Lemye highlighted the importance of coordination between healthcare practitioners. The information given to patients should be complementary, never contradictory. He stressed that the collaboration with the patient is fundamental, concluding that *"good medical adherence cannot be obtained without patient empowerment".*

Raj Patel from the British National Pharmacy Association, a member of PGEU, spoke of *the role of pharmacists' services in improving adherence*. He illustrated the importance of adherence for patients and health systems through examples from the United Kingdom: Unused drugs cost £300 million annually to the National Health Service and account for 6.5% of emergency hospital admissions. Researchers have estimated that £500 million could be saved if medicines were used optimally in five major therapeutic categories of chronic disease: asthma, diabetes, hypertension, vascular disease and schizophrenia.

Mr Patel explained that community pharmacists can intervene at several stages, from initial patient counselling when collecting new prescriptions, to discussions when repeat prescriptions are collected. *They have a key role to play in tailoring medicines adherence interventions to patients' needs*. He presented three initiatives implemented in the UK:

- The Medicines Use Reviews, now provided by 86% of pharmacists. These services are aimed at helping patients to understand their therapy, identify issues and solutions. They are usually provided to certain target groups: patients on high-risk medicines, patients discharged from hospital, or patients with respiratory diseases;
- New Medicines Services, which will be introduced in October 2011 for patients starting to take medicines in specific diseases: counselling and information leaflets will be provided on prescription delivery, and the pharmacist will then have two consultations with the patient and liaise where necessary with their GP;
- The Chronic Medicines Service, which will be introduced in Scotland. Patients will register will their pharmacy and a care plan will be agreed upon with the pharmacist that will consider various factors related to the individual patient and the medicine. Pharmacists will then liaise with the GP to produce a serial prescription for up to 48 weeks and will provide them with relevant information.

Mr Patel concluded: "Pharmacists´ interventions to improve adherence – such as medicine use reviews – have been shown to be effective, both in terms of patient outcomes and cost efficiency. The need for new approaches to counselling patients on medicine use will only grow as our population ages, and more of our fellow citizens take a number of different medicines at the same time. But to really make an

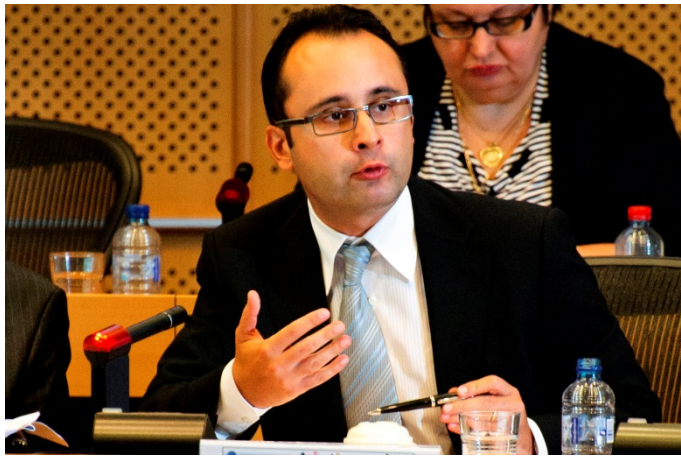
impact we need to develop such initiatives on a large scale. Partnership with patients and other health professionals is crucial for this."

The last speaker was **Richard Bergström**, Director-General of EFPIA, who explained *how the pharmaceutical industry can contribute to improve adherence*.

"EFPIA and its member companies are committed to improve adherence to therapies. This will contribute to better health outcomes and support sustainable healthcare systems in times of economic constraints. EFPIA wishes to encourage more data gathering and evaluation, encourage best-practice sharing, and involve all relevant stakeholders. A medicine that is sold but not taken is a waste for everyone – only cost, and no benefit," he asserted.

He presented several examples of initiatives aimed at improving adherence where the pharmaceutical industry was involved. These included the 2008 "Master your medicines" campaign in Ireland to help older people to take their medicine appropriately and make them knowledgeable about their treatment; a good use of medicines campaign conducted in Belgium; a free self-education course developed in Sweden under the fass.se database on how medicines work, common interactions and problems; and a pilot study in the Netherlands launched to study the role of the pharmacist in consulting patients with polypharmacy in their homes. Beyond projects, EFPIA provides recommendations on how adherence can be improved through encouraging research and providing platforms to share best practice, and prioritising adherence within relevant EU programmes.

A question-and-answer session then followed. Participants raised important questions, including how medicines packaging can be improved to provide *better information for patients*. A patient speaking from the audience stressed that "*it has never been so complicated to be a patient*" as patients with chronic conditions face ageing while coping with multiple diseases and therapies; high- as well as low technologies can play a part in the solution. Another audience member stressed the role that patients can play in helping other patients, as is done through the "Expert Patient Initiative" in the UK.



Finally, in his *closing speech*, **Cristian Silviu Buşoi MEP** noted that the Steering Group of the European Innovation Partnership on Active and Healthy

Ageing, which is a pilot flagship initiative within the EU "Innovation Union", has recognised the importance of addressing treatment adherence and polypharmacy. He stated that "the Partnership will be an excellent opportunity to explore potential innovative solutions that can support individual patients and carers, improve data sharing and communication between health professionals, and improve the integration of care."
He also affirmed that adherence should be a priority in the future Health Programme, and that the ABC project outcomes should be built upon in the future Research Framework Programmes and other ongoing EU initiatives that are directly or indirectly linked to adherence topic – such as eHealth and the development of interoperable, ICT-based solutions in healthcare; strategies to combat anti-microbial resistance; information to patients and health literacy; pharmacovigilance; the reflection process on chronic diseases; and ongoing EU actions on patient safety and quality of care.

2. European Innovation Paternership on Healthy and Active Ageing

Readers will know from previous issues of this mailing that EPF is very closely involved in this pilot Innovation Partnership launched by the European Commission. EPF President Anders Olauson is represented on the high-level Steering Group of the Partnership, which is co-chaired by Vice President and Commissioner for the Digital Agenda, Neelie Kroes, and the Commissioner for Health and Consumer Policy, John Dalli. The EPF Secretariat has participated in several "Sherpa" meetings, whose aim is to prepare the work of the Steering Group and refine the operational aspects of the Partnership.

The preparation of the Partnership has proceeded at a remarkable speed: the Steering Group in its first deliberations identified three broad work areas: "Prevention/early diagnosis", "Care/cure", and "Independent living", and workshops were organised on these topics before the summer. Despite the time restraints imposed by the process, the EPF Secretariat ensured that key EPF member organisations focused on disease areas identified as priorities by the SG (dementias/Alzheimer's disease, Parkinson's disease and diabetes) were included in the workshops, while the Secretariat retained an overview on the progress. EPF's views

and key principles on the theme of healthy and active ageing can be found in our response to the Commission's public consultation (February 2011).

The Commission received over 100 "fiches" or proposals for a specific action within the three broad areas, and has been working to narrow these down into a limited number of feasible projects involving that maximum number of relevant partners. The Steering Committee will ultimately decide in its meeting in November which actions will be included in the Strategic Implementation Plan (SIP) of the Partnership.

EPF has put forward a fiche concerning patient empowerment, with a focus on health literacy. This is increasingly recognised by the stakeholders as a key cross-cutting element in prevention as well as care, and we continue to promote this as a horizontal action. Other action areas that are being put forward to the Steering Group include: adherence to therapies; innovation-enabled personal guidance systems for older persons; disease prevention, vaccination and early diagnosis of functional/cognitive decline and malnutrition; capacity-building and replicability of successful integrated care systems; interoperable ICT solutions for independent living.

A drafting group has been set up to work on a final version of the SIP. EPF is taking a reviewing role in this, in order to ensure actions are patient-centred, with consideration to the "human factor" in addition to technology, and address issues of equity and inclusiveness.

Next steps:

- 7 November 2011 – Steering Group meeting
- The Commission will publish the finalised SIP in the form of a Communication – it will then need approval from the Council and the European Parliament.

Links for more information:

- Innovation Partnership: http://ec.europa.eu/research/innovation-union/index_en.cfm?section=active-healthy-ageing

- The Steering Group: http://ec.europa.eu/research/innovation-union/index_en.cfm?section=active-healthy-ageing&pg=steering-group
- The Sherpa group: http://ec.europa.eu/research/innovation-union/index_en.cfm?section=active-healthy-ageing&pg=sherpa-group
- Commission guidance paper for the Steering Group: http://ec.europa.eu/research/innovation-union/pdf/active-healthy-ageing/steering-group/guidance_paper.pdf#view=fit&pagemode=none
- Reports from workshops: http://ec.europa.eu/research/innovation-union/index_en.cfm?section=active-healthy-ageing&pg=workshops
- Frequently asked questions: http://ec.europa.eu/research/innovation-union/pdf/eip_faq.pdf#view=fit&pagemode=none

See also Conferences and events section.

3. Review of the EU Clinical Trials Directive

The Commission will present its legislative proposal for the review of the Clinical Trials Directive (2001/20/EC) during the second quarter of 2012. A second public consultation on the review of the Directive closed on 13 May 2011. The responses can be accessed here.

EPF submitted a response on the specific questions asked by the Commission, with the caveat that there were some divergences in views between some member organisations on certain details of the Commission's proposals. In addition, EPF submitted a formal statement, reiterating and expanding on the key principles that had already been voiced in our response to the first public consultation. These centred around patient involvement; access to high quality information; and access to treatment. EPF's response can be accessed here and here.

On 7 July 2011 EPF met with the European Commission to exchange views on the issues raised in our response, and how to best address patient involvement in the framework of the review of the CT Directive.

Next steps

- The Secretariat will organise a roundtable meeting in November in Brussels to offer an opportunity for our members to engage in further discussion and dialogue towards consensus on specific issues. A European Commission representative has confirmed his availability to participate in the meeting. An invitation to the meeting will be sent out to members as soon as a date has been confirmed.
- The Commission's legislative proposal for the revision of Directive 2001/20/EC is due to be published between March and June 2011.

4. EU Clinical Trials Register recognised as primary registry of WHO's International Clinical Trials Registry Platform

The World Health Organization (WHO) has recognised the European Union Clinical Trials Register (EU-CTR) as one of the primary registries for its International Clinical Trials Registry Platform (ICTRP). ICTRP is a web-based portal that allows access to a wide range of information from different clinical-trial registers from across the world. EU-CTR's recognition means that its information will be available through this portal by the end of the year, once the technical processes to allow transfer of the information are complete. It is also an endorsement of EU-CTR's importance for potential clinical-trial participants as well as sponsors, researchers, ethics committees and policymakers.

EU-CTR, which is managed and hosted by the European Medicines Agency, contains information on clinical trials in the European Economic Area (EEA), as well as information on clinical trials conducted outside the EEA that form part of a paediatric investigation plan (PIP). The Agency made the register public on 22 March 2011.

- For more information on the EU-CTR visit www.clinicaltrialsregister.eu
- For more information on the ICTRP visit www.who.int/ictrp/en

5. Commission Green Paper on the Professional Qualifications Directive

Following a consultation of our members and a discussion at the latest policy advisory group meeting, EPF submitted its contribution to the European Commission's public consultation on the Green Paper Modernising the Professional Qualifications Directive on 20th of September.

EPF also issued a second joint statement on 29 September with the European Public Health Alliance (EPHA), the European Women's Lobby (EWL) and the European Consumers' Organisation (BEUC), to send a strong message to the Commission and Member States. This statement is available on our respective websites and was disseminated to key actors of this dossier, including the Commission's Directorate General for Internal Market and Services, and the Directorate General for Health and Consumers.

As in our previous consultation response in March, and our joint Statement with EPHA, we reaffirmed that patient safety and quality of care must remain the highest priorities when considering requirements for healthcare professionals who migrate around Europe. We also stressed some other key elements:

EPF welcomed the proposal for *increased cooperation* through the Internal Market Information System (IMI), and through a proactive alert mechanism between competent authorities for migrating healthcare professionals who are under sanction. We however highlighted some reservations concerning the proposed *voluntary European Professional Card* which aims at accelerating and simplifying the recognition procedure.

We supported the proposal to *modernise training requirements* progressively, but urged all stakeholders and decision makers to take into account the views of patients and their representative organisations on healthcare professionals' training. We highlighted this is fundamental to ensure professionals have the appropriate skills to meet patients' needs.

We called for clearer and stronger provisions on language competences in the Directive and the accompanying code of conduct. Our response also stressed that *language skills* are important for all healthcare professionals, not exclusively these in contact with patients.

We opposed the application of the principle of *partial access* to healthcare professions, as this would lead to an unacceptable downgrading of minimum education and migration requirements.

Next Steps:

- A Steering Group was established to discuss the features of a possible European Professional Card. The group is composed of representatives from Member States, competent authorities and professional organisations. Its conclusions will be made public in early October.
- The European Parliament is preparing an own-initiative report on the implementation of the Professional Qualification Directive. The vote in the Internal Market and Consumer Protection Committee (IMCO) is scheduled for 17 October, and the draft report prepared by MEP Emma McClarkin (ECR/UK) will then be proposed to the plenary in November.
- A legislative proposal to review the Directive is planned for the end of 2011. EPF will again consult its membership once the content of the proposal is known.

For more information please visit this section of the EPF website or contact Laurène Souchet.

6. Review of the EU Transparency Directive

According to the latest information the European Commission will reopen the so-called EU Transparency Directive 'Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems). The Commission will present a legislative proposal before the end of 2011.

EPF will therefore be seeking its membership's views in order to formulate an official position on the legislative proposal. As outlined in the June issue of this mailing, EPF has given informal input to the Commission on a number of key messages highlighted by the Board and the Policy Advisory Group, based on EPF's existing positions and priorities. A meeting was held with Commission representatives in June to exchange views on the topic.

A key concern for patients is that the current time frames for making decisions regarding prising and reimbursement should under no circumstances be extended. This would worsen the already existing inequalities and delays in access to patients across Europe.

Secondly, effective means of enforcing the time limits are needed as Member States currently do not comply. Reopening of the Directive may result in some Member States asking for greater flexibility to the time frames, which will need to be strongly resisted.

EPF also believes that the goal of the review should be to strengthen good governance, accountability, timeliness and transparency in decision-making. The concept of transparency should be modernised, and include transparency to patients and the public regarding the procedures and criteria on which decisions are taken, the bodies responsible; and more transparency on pricing. Stakeholder involvement in the process should be improved.

Next steps:

- Commission legislative proposal expected before end of 2011.
- EPF will consult members on the proposal.
- For more information about the Directive and the proposed review, see here.

7. EU health programme

EPF has been active in the context of the EU Health Policy Forum in the preparation of input to the Commission regarding their proposals for a future Health Programme. The document prepared by EUHPF was submitted to the Commission for use in the internal lobbying ahead of the launch of the Commission's proposal for the multi-annual financial framework 2014-2020. Already prior to the EUHPF input, EPF had prepared a joint letter with EPHA addressed to President Barroso, strongly highlighting the achievements of the Health Programme and its key role in achieving the goals of EU 2020 as well as tackling the social challenges facing the Union.

In effect, the budget for the Health Programme foreseen in the Multiannual Financial Framework was not cut, but slightly increased. It is, however, still rather low considering the importance of health to achieving the Union's goals. The Commission's first proposals on the priorities of the programme, titled "Health for Growth", appear to tie the objectives of the programme rather closely to the financial objectives of EU2020.

EPF has prepared a contribution to the development of the Health for Growth programme, to which members are invited to give feedback – a consultation email was sent to members on 29 September. The key points of EPF's contribution are:

- Health is a fundamental right in itself, in addition to being a key strategy for achieving the objectives of EU2020. The HP should reflect the fundamental European values of equity and solidarity, particularly in the current financial climate. Health investment is needed to avoid severe human and economic costs for society in the long term;
- Sustainability of health systems must be ensured while upholding the principles of universality, safety, high quality, equity of access and solidarity. A multi-pronged approach is needed to tackle the twin challenge posed by ageing and chronic diseases – encompassing primary and secondary prevention, and patient-centred chronic disease management. Innovation should be focused on people rather than technology;
- Health inequalities are an urgent priority – for patients with chronic diseases, health equity implies equity of access to high-quality medical care and other necessary supports. Patient empowerment is a crucial strategy for tackling health inequalities, and health literacy a key empowerment tool for patients as well as citizens;
- "European added value" should focus on key social objectives such as equity and solidarity and the reduction of health inequalities, as well as users' involvement in policy and projects. Broad involvement of civil society organisations including patients' organisations in policy and programmes.
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Next steps:

- Comments from EPF's members on the draft contribution should be sent to the EPF Secretariat by 24 October.
- EPF continues to liaise with other stakeholders such as EPHA in order to identify points of commonality and advocate with a strong voice, while ensuring that the patient community's views are clearly heard in this process.
- The Commission will publish a proposal for the new Health Programme by the end of 2011.

8. Information to patients: Commission revised proposal to be published early October

Early Ocotber the Commission will publish its revised legislative proposals for information to the public on prescription only medicines. The discussion on this dossier will therefore take place during the Polish and Danish presidencies. The Polish Presidency has indicated its willingness to prioritise the topic in Council discussions.

The revised proposal is expected to follow the European Parliament's commitment to patients' needs, while probably having a somewhat narrower scope than the Parliament's first reading report. EPF is in favour of a comprehensive EU strategy on high-quality information to patients, including a programmatic commitment to health literacy. We worked closely with the EP rapporteur on this dossier, and we will continue this in the second reading.

EPF has also continued to address these concerns proactively in the context of other policy areas, including the future Health Programme and the Innovation Partnership on Healthy and Active Ageing, and will reassess the issue following the publication of the Commission legislative proposal.

Next steps:

- The information to patients dossier will be a key priority for EPF in the next months, with a member consultation on the revised proposal and active engagement with all the EU Institutions and stakeholders.
- The European Parliament's first reading reports on information to patients can be accessed here and here.

9. Pharmacovigilance: Concept paper on implementing measures released for consultation

The European Commission has published a concept paper on the implementing measures related to the new pharmacovigilance legislation. The paper is open for public consultation until 7 November 2011. It provides technical details that the European Medicines Agency (AM), regulatory authorities in EU Member States and pharmaceutical companies will need to apply when implementing the new rulers.

Next steps:

- On 20 October 2011, EPF will participate in the third stakeholder forum on the implementation of the pharmacovigilance legislation. Presentations from the first and second EMA stakeholder forums on the pharmacovigilance legislation can be accessed here and here.

EPF will provide feedback on the Commission's concept paper and would invite members to send any comments to the Secretariat as soon as possible. To access the concept paper click here.

10. European Medicines Agency

EPF participation in the Patients' and Consumers' Working Party

A meeting of the EMA-PCWP took place on 13 September 2011 in London, with EPF Vice-President Susanna Palkonen in attendance. Items on the agenda included updates on the pharmacovigilange legislation, interaction with the Health Care Professionals' Working Group, EMA training for PCOs (in follow-up from the brainstorming workshop held at the previous meeting) and the role of patients in scientific committees. The agenda of the meeting is available here. The minutes of the previous PCWP meeting (16 June 2011) are available here.

For more information contact the EPF Secretariat.

EPF participation in the third country clinical trials working group

A teleconference of this working group was held on 5 July to review the latest version of the EMA reflection paper on third country clinical trials. EPF has been an active participant in this working group. Our input is well incorporated in the revised version of the paper, and attempts have been made to address the issues raised by patients' representatives

The scope of the guidance EMA can provide is limited to the scope of current EU legislation regarding clinical trials and good clinical practice. Given these restrictions, the working group has decided to submit a parallel paper to the European Commission, which is to include some of the issues raised within the working group that go beyond the scope of the guidance. This paper is currently in preparation.

The Agency has recently published an extensive report of the international stakeholder workshop on third country clinical trials, held in September 2010 in London. The report can be accessed here. The presentations from the workshop can be found here.

For more information please contact the EPF Secretariat.

EMA news: Improvements to the package leaflet template

The European Medicines Agency's Working Group on Quality Review of Documents recently revised the human product information templates for the package leaflets of medicines to make the information easier for patients to understand. There are

also new sections added on medicines' benefits and their uses in children. These changes are the result of five years of user testing and feedback from a range of stakeholders, including patients and consumer groups, national regulatory agencies, industry and academics. It has been an ongoing concern for patients that the information needed to be more user-friendly, with better balance of information on benefits as well as risks, and concerning the uses of medicines in children. They reflect the conclusions of a report on the expectations of patients, consumers and healthcare professionals regarding benefit-risk information and the requirements of the paediatric regulation. In addition to the package leaflet, the revision also included changes to the templates for the summary of product characteristics (SPC), labelling, and the 'annex II' – the section of the product information covering the conditions imposed on marketing authorisations.

11. Access to Medicines - Process on corporate responsibility in the field of pharmaceuticals

The process on corporate responsibility in the field of pharmaceuticals ("the Tajani initiative") encompasses three "platforms" of activity, of which the Platform on Access to Medicines in Europe was the first to be launched in late 2010. Please see previous issues of this Mailing for the background on this initiative.

EPF sits on the Steering Group of the Platform of Access to medicines in Europe and the Platform on ethics and transparency, together with Member States' representatives and other stakeholders.

Platform on access to medicines in Europe

The overall aim of this platform is to facilitate fair and timely access to medicines following their market authorisation through a non-legislative approach focusing on collaboration between different parties. While EPF Secretariat is represented in the Steering Group, we published a call for interest from member organisations to nominate expert representatives for the project groups focusing on specific areas, and we are pleased to say there are patient representatives active in all five groups:

1. Mechanism of coordinated access to orphan medicinal products (Eurordis)
2. Capacity building on managed entry agreements for innovative medicines (Spanish Patients' Forum)
3. Facilitating supply in small countries (Cyprus national patients organisation)

4. Promoting a good governance for non-prescription drugs (EMHF)
5. Market access for biosimilars (National Voices)

Platform on ethics and transparency

A first meeting of the Platform on ethics and transparency took place in Brussels on 1 September. This platform will look at ethics issues and adherence to rules and duties; it will be focusing on work in three areas: relations between industry and patients; industry and health professionals; and industry and Member States' competent authorities. EPF has been invited to co-chair the working group on "industry relations with patients" together with the Commission (DG Enterprise). A first meeting for this working group will take place towards the end of October 2011. (see also Conferences and Events section).

Platform on Access to Medicines in Developing Countries

The Platform on Access to Medicines in Developing Countries (focusing on Africa) will hold its first Steering Group meeting at the end of 2011 and start its work in 2012. The International Alliance of Patients' Organisations (IAPO) will represent patients on this Platform, and EPF will be working closely with IAPO to ensure coordination and coherence across all the platforms.

Next steps

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

12. EPF survey on patient safety

The European Commission is currently surveying Member States on their progress in implementing the Council Recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections. The Commission is

obliged to produce report by 9 June 2012 assessing impact of the Recommendation, the extent to which the proposed measures are working effectively, and to consider the need for further action.

In order to bring the patient perspective on the progress made in implementing these recommendations, EPF is preparing a survey for member organisations, which will be launched in the coming weeks.

EPF had given input to the Council recommendation as well as on the Commission communication of 2008 on patient safety, and continues to be an active member of the patient safety and quality of care working group.

The recommendation contains specific provisions to improve patient information and empowerment, and to involve patient organisations in the development of policies and programmes. It is therefore important to give the patient perspective on measures taken by Member States and possible obstacles in the implementation of these provisions.

Other areas addressed in the recommendations include measures to establish comprehensive blame-free reporting and learning systems, and to embed patient safety in healthcare professionals' training. It also enjoins Member States to take actions to support the establishment and development of national policies and programmes on patient safety, and advises on actions to prevent and control healthcare associated infections, including though improving patient information by healthcare institutions.

Next steps:

- EPF will circulate a survey in October, to which members will have ample time to respond.
- The information collected will also be a useful resource for EPF's future work in the area of patient safety, including in the upcoming Joint Action on Patient Safety and Quality of Care.

13. Medical devices

The Council of the European Union adopted Conclusions on innovation in the medical device sector in June 2011. The Council stresses that patient safety must be a core priority in EU regulation for medical devices. EPF gave input into the process, which was well reflected in the final conclusions. Below are some of the key recommendations:

- Innovation should be patient- and user-centred – increased involvement of patients, families and other users in research and development
- Innovation should be based on a holistic approach considering all the patient's medical, social, psychological etc. needs
- Research is needed to identify public health priorities and to define patients' medical needs
- Patients and healthcare professionals should be involved in vigilance on adverse incidents relating to the use of medical devices.

The Commission is also planning a recast of the three medical devices directive(Directive 90/385/EEC regarding active implantable medical devices, Directive 93/42/EEC regarding medical devices, and Directive 98/79/EC regarding in vitro diagnostic medical devices) The recast aims at merging the 3 directives and to strengthen the current framework.

EPF is currently identifying key issues and areas to bring the patients perspective into this process, based on our previous input, which includes our response to the Commission's consultation in 2008, and our participation in the exploratory exercise organised in 2009 to map out challenges in the medical devices sector and possible actions at EU level, as well as feedback from the Policy Advisory Group.

Medical Devices will be one of the topics on the agenda for the Second MedTech Dialogue organised with Eucomed which will take place on 11 October. The dialogue between patient organisations and the medical device industry aims at learning about each other's priorities and needs objectives and thus enhancing our mutual understanding and exploring areas of shared interest. It creates further opportunities for patient organisations to educate industry on the needs and day-to-day challenges of their members.

Next Steps:

The Commission is expected to adopt a legislative proposal in the first quarter of 2012. Our membership will be consulted to form EPF position, once the substance of the Commission's proposal is known.

14. EPF Policy Advisory Group: new structure and role and a call for interest to participate

The EPF Policy Advisory Group met in Brussels on 8 September. The Group was set up in 2009 and has since had two meetings a year. It has started to play an increasingly important role in the policy consultation process, as the policy areas EPF engages in have increased. The workload on the members, who volunteer their time and effort, has also increased, with many of the topics being complex and demanding a lot of time and consideration.

For this reason the EPF Board in its meeting in July 2011 decided that the PAG's role within the EPF policy formulation process should be clarified, and the link with the general membership consultation strengthened. The responsibility areas of its members could also be made more specific. The Board stressed the value of the Policy Advisory Group and EPF's commitment to facilitating its effective functioning.

The renewed PAG will encompass a number of smaller task groups that will provide expertise in specific policy areas. The whole PAG group will still be involved in the process, but preparatory work and background information will be more focused on the task groups. Organisations who are already participating are asked to indicate their priority areas of interest/expertise, but also other member organisations are invited to join. The policy areas are identified based on EPF's strategic plan and annual work plan. Further information will be circulated to members in the coming weeks.

Other items on the PAG's agenda included: reviewing EPF's campaign work on the next EU programming period and the draft input to the Commission; reviewing EPF's contributions on the Professional Qualifications Directive and clinical trials; updates on the medical devices legislative review and the Innovation Partnership on Healthy and Active Ageing; and review of a draft guidance document prepared for members on the implementation of the cross-border healthcare legislation.

As usual, the discussion was lively and useful, and the Secretariat would like to acknowledge the contributions of all participants and thank them most warmly for taking the time to attend this meeting. The next PAG meeting will take place during the first half of 2012.

What is the Policy Advisory Group and what does it do?

The EPF Policy Advisory Group, or "PAG", was created by the Annual General Meeting of EPF in 2009 in response to the growing demand on EPF in recent years – both in terms of our growing membership and in terms of the increasing complexity of health policy at EU level. The purpose of this group is to support the policy work of the EPF Secretariat and Board of Directors. The PAG provides input from the perspective of our member organisations, and exchange of ideas around existing and emerging policy issues – both in terms of strategy and in terms of content, complementing the broader EPF membership consultation process.

Current members

At the moment the PAG includes 13 representatives of EPF's member organisations:

- Robert Johnstone – National Voices (UK)
- Hanna Milczarek – Federation of Polish Patients
- Avril Daly – Fighting Blindness/Retina Europe (Ireland)
- Maria Navarro – Spanish Patients' Forum
- Alastair Kent – European Genetic Alliances Network (UK) – alternate: Nick Mead
- Flaminia Macchia – Eurordis (Brussels)
- Sophie Peresson – International Diabetes Federation Europe (Brussels)
- Rod Mitchell – European Federation of Crohn's and Ulcerative Colitis Associations (UK)
- Gunta Anca – Latvian Umbrella Body For Disability Organization SUSTENTO (Latvia)
- Ian Banks – European Men's Health Forum (UK)
- Brigitte Pineau – European Federation of Associations of Patients with Haemochromatosis (France)
- Hildrun Sundseth – European Institute of Women's Health (Brussels)
- Anthia Zammit – Malta Health Network

15. Chain of Trust – Project status update and launch of the National Workshops

Started in January 2011, the Chain of TRUST aims to assess the perspective of the main end users of telehealth services across the EU to see whether and how views have evolved since the initial deployment of telehealth and what barriers there still are to building confidence in and acceptance of this innovative type of services. The findings and the recommendations of this project are expected to constitute a unique tool to inform policies and decision-making at various levels.

The project consortium is led by the European Patients' Forum. The full list of partners can be accessed here.

During the first quarter of 2011 the Chain of Trust consortium conducted a **literature review** with the objective of understanding patients' and health professionals' views, needs and barriers regarding telehealth as expressed in the literature and gathering information as to communication approaches and tools used to raise awareness of telehealth and communicate it to the end users.

The literature review of the project was completed in late April and its results set the ground for the design and implementation of an online survey targeting the four user groups identified for this project (patients, doctors, nurses and pharmacists). The purpose of the **online survey** was to collect additional information on patients' and health professionals' perceptions and experience of telehealth in order to validate and complement the findings of the literature review. We received a total number of 6704 responses from across 30 European countries. The analysis of the responses is currently being finalised and the results will be merged with the findings of the literature review into an intermediate deliverable which will be made public in November 2011.

The consortium is now working towards the third core project activity, i.e. the **national workshops**. These national workshops will be carried out between October and mid-November 2011 in six European countries, namely Greece, Latvia, the Netherlands, Norway, Poland and Portugal. Their ultimate objective is to assess through a qualitative approach the views, needs, benefits and barriers related to telehealth from the perspective of the four telehealth user groups in six European countries in order to enable the Chain of Trust consortium to validate and further complement the findings of the literature review and the online survey. The

national workshops will be organised and delivered with the fundamental support of local members of the partners of the Chain of Trust consortium.

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

16. Renewing Health – Project status update and Mid-term workshop

RENEWING HeALTH,"**REgioNs of Europe WorkINg toGether for HEALTH"**, is a three-year project started in February 2010, aiming at implementing large-scale real-life test-beds for the validation and subsequent evaluation of innovative telemedicine services in nine European regions for patients suffering from chronic conditions, notably diabetes, cardiovascular diseases and Chronic Obstructive Pulmonary Disease (COPD).

The first 18 months of the project were dedicated to the preparation of the clinical protocols, the specification of the assessment methodology, i.e. definition of outcomes, and identification of key indicators and the various tools/methods to be used to measure progress against them, the procurement of necessary hardware and software and recruitment and training of patients. At the time of writing the intervention has started in almost all pilot sites.

The reader may recall that EPF is involved - together with EHTEL (European Health Telematics Association) - in the management of the User Advisory Board (UAB) whose primary mission, as defined in the UAB Terms of Reference, is to operate as a standing advisory committee to advise and provide on-going feed-back to the project team on the needs of users of the piloted telemedicine services.

The fourth meeting of the UAB took place in Brussels on August 30 to discuss the revision of the User Requirements Deliverable - a document designed to serve as a reference framework for the representation of user needs, requirements and expectations in relation to telemedicine - and define the workplan for 2012.

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

You can register to the RENEWING HeALTH Mid-term workshop here.
For further information please contact Walter Atzori or visit the project's website at: www.renewinghealth.eu

17. Steering Committee of the eHealth Governance Initiative

We have presented in previous issues the EU eHealth Governance (eHGI) initiated by the EU Member States and supported by the European Commission with the involvement of key stakeholders including EPF.

This political initiative was set up in 2009 and built on the political document "Council Conclusions on a Safe and efficient healthcare through eHealth", adopted by the EPSCO Council on 1 December 2009 and was formalised in 2011 with the support of two different EU financing instruments: a Joint Action through the Public Health Programme and a Thematic Network through the CIP-ICT programme.

The eHGI aims to establish an efficient, appropriately governed and sustainable platform to enable EU Member States and stakeholders to further develop cooperation on eHealth issues to help implement and deploy interoperable eHealth services across Europe. There are 40 beneficiaries including Member States, governmental agencies and eHealth user stakeholder groups, who joined the eHGI. The work packages address the issues of building trust and acceptability (EPF is co-leader of this work package), legal aspects, road-mapping and mainstreaming, standardisation and all the issues revolving around technical and semantic interoperability.

The eHGI will work very closely with the High-Level-eHealth-Governance-Group (State Secretaries and Director Generals) also called Network Art. 14 (of the Directive 2011/24/EU) to ensure effective links and synergies between the political decision making level and the results of more technically oriented work.

As such the eHGI will support the setup of a European eHealth environment for the benefit of European patients (e.g. support and guidance for implementation, deployment and use of eHealth services throughout national health care systems, increasing patient safety and quality, better use of health care resources). It is therefore of the utmost importance that EPF s fully involved in this process.

The eHGI held its first Steering Committee in Brussels on September 28 whose main objective was to define working priorities until spring 2012.

The first priority area of the eHGI is the electronic ID (eID). What the eHGI should deliver by spring 2012 is a proposal of recommendations for a common EU framework on eID Management that should make possible cross border eHealth services within the framework of the Directive 2011/24/EU. An exploratory seminar on this topic will be organised in Athens on 9 November 2011, in the context of a major event marking the launch of the epSOS project pilots.

For more information on the eHGI please contact Walter Atzori.

18. New project in 2012 - EPF will coordinate a major IMI project EUPATI

EPF is pleased to announce the imminent launch of a major patient-led project named EUPATI, “European Patients' Academy on Therapeutic Innovation” aimed at creating better education and information tools for patients on pharmaceutical research.

The Innovative Medicines Initiative (IMI) is a public private partnership between the European Commission and EFPIA, the umbrella organisation of pharmaceutical industry and associations operating in Europe.

From 2012, the EUPATI academy will educate patient representatives and the lay public on personalised and predictive medicine, design and conduct of clinical trials, drug safety and risk/benefit assessment, pharmaco-

economics as well as patient involvement in drug development. EUPATI will provide educational material in six European languages targeting eleven European countries.

The consortium, led by the European Patients' Forum, comprises of 26 leading pan-European patient organisations, academic and not-for-profit organisations as well as EFPIA member companies. It features excellence across disease areas in state-of-the art, high quality, objective education to patients about therapeutic innovation. It will foster collaboration between patient organisations, academic institutions, regulatory bodies, ethics committees and the industry.

To improve the availability of both patient-centric information as well as educated patient experts, EUPATI will develop scientifically reliable, objective, comprehensive information on therapeutic innovation by:

- establishing certificate training courses to create 'expert advocates' on therapeutic innovation,
- developing a "tool kit" of educational multi-media material to be re-used by patient organisations for educational purposes, and
- developing an Internet-based library of up-to-date, unbiased information on medicinal development for patients and the public.

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

For more information please visit the temporary web-page of EUPATI within the EPF website or contact Nicola Bedlington (Consortium Leader).

19. EPF Youth Group. First EPF Youth Meeting took place in Brussels in August!

In our previous mailings we announced the official launch of the EPF Youth Strategy and the organisation of the first official meeting of the EPF Youth Group scheduled for late summer.

The overall objective of this Youth Strategy is to enable EPF to recognise, understand, meet and effectively represent the needs and expectations of young patients through their meaningful involvement and empowerment. The EPF Youth Group is the main pillar of our Youth Strategy. This group was established in the first semester of 2011 and is currently made up of 12 young patient representatives nominated by EPF members.

Well-matched to our aspirations, the first meeting of the EPF Youth Group took place on 19-21 August in Brussels, as Marta Dimitrova, President of the EPF Youth Group, reports in her article below.

By Marta Dimitrova – President of the EPF Youth Group:

Between 19th and 21st August in Brussels, Belgium, the first official meeting of the Youth Group of the European Patients' Forum (EPF Youth Group) took place. Ten young representatives of patient organisations from seven European countries – Estonia, Poland, Bulgaria, Romania, Lithuania, Malta and the Netherlands – attended the meeting.

The meeting was organised by the representatives of EPF - Mr Walter Atzori and Miss Özgün Ünver. They met the youngsters in Brussels and led the planned activities during the three days of the meeting.

The main objective of the youth meeting was to acquaint the participants with the goals and activities of the European Patients' Forum, to discuss and articulate

the needs of the young patients in modern Europe, to plan future activities and last but not the least, to choose the managers of the EPF Youth group.

The program of the meeting was very dynamic, interesting and useful. Activities of the day of arrival were associated with creative workshops to "break the ice" and establish cohesion of the young people involved. The program of the first day was very intense and interesting. Different presentations were made related to the work of EPF, European institutions and patient organisations.

Mr Walter Atzori introduced these issues and the young people actively participated in discussions on them. Ms Kaisa Immonen-Charalambous briefed the participants about the activities of the European Commission and European Parliament and the place of EPF among those important institutions for European society. Mr. Marco Greco from the EPF Board and President of the European Federation of Crohn's & Ulcerative Colitis Associations (EFCCA) talked about options and ways to establish a youth organisation within the patient groups and his experience in EFCCA.

Different workshops and role games were conducted, whose goal was to operationalise the strategy of EPF Youth Group. Also the logo of EPF Youth group there was chosen. In the afternoon of the second day, through an anonymous voting among the young people, the youth board was elected: Marta Dimitrova (BG) - President, Alin Bujan (RO) - Vice President and Borislava Ananieva (BG) - Board member.In the evening, after the working day, the young people had the opportunity to walk around Brussels and sightsee.

The second day of the meeting began with a presentation of good practices from completed projects and activities for young patients and disadvantaged young people from different organisations in Bulgaria which are members of National Patient Organization in Bulgaria. The aim of the activities that day was to initiate ideas for future projects involving EPF Youth group. For this purpose various role games and workshops were led.

In conclusion, these three days were very useful and inspiring for the young participants. Everybody had the opportunity to fully communicate, to learn a lot from

the presentations of experts, to discuss, share experiences and practices that can create new ideas.

The end was filled with enthusiasm to fulfil everything planned, with a desire to multiply knowledge and of course, anticipation of the next meeting.

Below you will find the experiences of two more members of the Youth Group, Andrew and Marlou.

Andrew Zammit McKeon – Member of the EPF Youth Group:

Hi, my name is Andrew Zammit McKeon and I am a 21 year old student studying Mechanical Engineering. I have a chronic condition - diabetes to be specific, and I am a member of the Maltese Diabetes Association. My objective in the association is to help other youths like me learn more about their condition and learn how to accept their new way of life. This year I helped in the Annual Diabetes Summer Camp for Children with Diabetes. I represent the International Diabetes Federation – Europe (IDF-Europe) in the new EPF Youth Group. My participation at the First Youth Meeting as a Youth Member of EPF is a great opportunity for me to meet other people from different nations who also have a medical condition. It is also a great opportunity to contribute to my own organization and to help other youth patients in any way I can. The experience gained is invaluable and broadens my perspective in life. I look forward to our next meeting.

***Marlou Schenk – Member of the EPF Youth Group**:*

"As the representative of the Fabry Support & Information Group Netherlands, I attended the first real Youth Group Meeting from the European Patients' Forum in Brussels. My name is Marlou Schenk, I am 20 years old and I live in the Netherlands. The Youth Group of EPF was brought to my attention by a woman from Poland, who had met someone from our patient organization and told that the group was looking for expansion. I am member of the Dutch Patient Organization because I am Fabry affected, a lysosomal storage disorder, that can affect heart, kidneys and the brain.

Of course I didn't know what to expect, because my nomination was completed and approved just a week before the meeting was scheduled. In Brussels I met a group of young people with all kind of disorders and from different places in Europe. Unfortunately almost everybody already knew each other, but pretty soon I was included in the group. A lot of information was shared during this

week-end, but the presentation of a member of the board of EPF, Marco Greco was the most impressive for me who talked about how he started a youth group.

I know I have to learn a lot before I can fully understand all what was said, also because English is not my mother tongue, just like the most, who however speak fluently.

For further inquiries on the EPF Youth Strategy and the Youth Group please contact Walter Atzori.

Other Initiatives

20. Third stage of the EPF HTA Research Initiative launched!

In the previous issues of the Mailing we informed our readers that EPF was conducting a series of surveys 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 the EU Member States. Consequently, the HTA research was broken down into three stages: The first stage was a survey conducted with 40 HTA agencies and/or national bodies responsible for HTA from 22 European countries and was completed in February 2011. The second stage of the HTA research was completed in the summer of 2011, which was a survey for healthcare decision-makers who use evidence from HTA reports with the aim 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 first and second stages of the research have been successfully completed and the online questionnaire for the third phase of the HTA research was launched on 19th September. **This survey** consults with **patient organisations** that give patient perspectives/evidence to HTA with the objective of **getting the perspective of both patients' organisations that have been involved in HTA and those that have tried to contribute to HTA processes but for whatever reason were not successful. The questionnaire will be accessible until 10th October** and EPF will particularly value the support of its members and broader readership to disseminate this online questionnaire across patient organisations. You can find the questionnaire in the following link: www.surveymonkey.com/s/FZSLWNZ

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

Conferences and events

21. 19th International Health Promoting Hospitals & Health Services (HPH) Conference

EPF Vice- President Susanna Palkonen attended the conference "Improving health gain orientation in all services: Better cooperation for continuity in care", held on June 1-3, 2011 in Turku (Finland). The Conference was organised by Health Promoting Hospitals & Health Services (HPH), a network which aims at improving the somato-psycho-social health gain for patients, staff and community members, and to contribute to protecting the environment. She brought the patient's perspective in a panel discussion on the role of health systems and service in promoting equitable population health gain, which also comprised the perspective of healthcare managers, doctors and nurses. She highlighted that patients can face obstacles relating to the organisation and delivery of health care. She also stressed that patients need adequate support from the healthcare team and healthcare services, through improved coordination and continuity of care.

For more information on this conference, please read the HPH newsletter.

22. World demographic and ageing conference- St Gallen, 28-30 August

As a member of the Philips Think Tank on Ageing Well, Nicola Bedlington participated in the World Demographic and Ageing Conference in St Gallen Switzerland in late August. The Think Tank met on 29th August and led a WDA panel discussion on their reflections on 30 August. For more information on the work of the Think Tank please contact Nicola Bedlington. Nicola's main contribution relates to EPF's work on the rights and needs of older patients, and the outcomes of our recent conference, and our contribution to the European Innovation Partnership on Active and Healthy Ageing.

For more information on the event and a copy of the presentations please go to www.wdaforum.org

23. EU Commission meeting on Transparency, 1 September

As part of the so-called "Tajani" Initiative of Access to Medicines (see section of EU Policy Update) and its pillar on transparency and ethics, a meeting was hosted by DG Enterprise on 1st September to explore next steps in the development of a EU Transparency Charter. The meeting convened high level representatives from the spectrum of the Pharmaceutical Industry, as well as key stakeholders including consumers (BEUC), doctors (CPME), Pharmacists (PGEU), Hospitals (HOPE) and patients (EPF). There was a strong agreement on the added value of such a comprehensive Transparency Charter that would look at industry's relationship with health professionals, public authorities and the patient community, but emphasis was placed on the importance of an inclusive approach, involving all relevant institutional and stakeholder players. A series of workshops will take place over the next few months to develop the Charter, the first one focusing on patient/ industry relations, to be co-chaired by the European Commission and EPF. This will draw on existing Codes of Ethics, and Codes of Practice and examine opportunities to move forward. EPF will be consulting our membership in advance of this meeting to gather their views and experiences in this area.

For more information on the EU Transparency Charter, please contact Chloe.SPATHARI@ec.europa.eu who is the Commission official responsible or Nicola Bedlington, who is leading this work for EPF.

24. Europabio patients' advisory board – 13 September

EPF's Senior Policy Adviser, Kaisa Immonen-Charalambous attended a meeting of the EuropaBio Patient Advisory Group on 13 September in Brussels. Europabio is the European association of biotechnology industries.

The patient advisory group was originally launched in 2008 and comprises representatives from a number of patient organisations and Europabio member companies. Following a survey in 2010 on interest among patient organisations, EuropaBio proposed to relaunch the group. The meeting on 13 September focused on discussions on the objectives and terms of reference of the group, including a change of name and issues around membership and governance. The group will aim to become a platform for exchange of views and constructive dialogue between industry and patient organisations on topical issues involving biotechnology.

The second half of the meeting focused on personalised medicine and included presentations from the European Commission DG Research on the Commission's actions in the area, and from the industry. A discussion followed. One issue that emerged in the discussion from the patients' perspective was the terminology used, the concept of personalised/stratified medicine, and how to communicate complex scientific information in a language that is understandable to lay persons.

See also: Projects – EUPATI.

25. Task Force of high level advisors on eHealth- Tallin, 15 September

Ander Olauson represents EPF is in this Task Force that met for the second time in Tallin on 15th September. His specific role is to examine how to bring eHealth Innovation closer to patients. In his intervention, he stressed the following key points

- There is no doubt that users' acceptance of eHealth innovations has to be acknowledged as a top priority for these to be embedded in health systems and infrastructure.
- In order to achieve patient empowerment we need to build necessary skills and knowledge to enable patients to use innovative eHealth solutions with confidence by investing in health literacy.
- Innovation should be need- and demand-driven instead of technology.
- Patients should be involved in both eHealth policy-making and service design from the very beginning since they are the ones who will benefit the most from eHealth innovation.
- A patient-centred holistic approach should be adopted in healthcare innovation through the use of ICT.
- We need to capitalise on existing good practices and apply these in wider contexts. Patients' organisations can play a facilitating role in this respect.

26. European Innovation Partnership on Active & Healthy Ageing - Steering Group – Brussels, 16 September

Nicola Bedlington replaced Anders Olauson in this meeting where further steps were discussed regarding the development of the Strategic Implementation Plan for the Partnership

See http://ec.europa.eu/health/ageing/innovation/index_en.htm for more background.

During the Steering Committee a number of action areas and specific projects within those areas were presented, according to the **following selection criteria**:

I. Certainty of delivery
II. Focus on the most mature, feasible and innovative actions that are supported from commitments of all relevant partners and hence ready for immediate implementation within the next two years;
III. Focus on action that can provide a framework to develop further proposals and ideas.

The projects described are:

1. "Prescription adherence action at regional level" –within the "Health literacy, patient empowerment, ethics and adherence" action. This action has received a strong backing from a wide range of stakeholders and demonstrated an important innovation component through the use of IT technology and personal medical assistance.
2. "Early diagnosis and intervention action on frailty and malnutrition to prevent functional decline among older people" – within the "Disease prevention, early diagnosis of functional decline". This action has been considered mature for innovative public health interventions, such as advanced screening.
3. "Program for falls prevention and early diagnosis". –within the "Innovation-enabled personal guidance systems". Following the meeting, this action will be reformulated, but essentially will continue to address the potentiality of combining innovative tools with new organizational and business models;

4. "Replicating and tutoring integrated care for chronic diseases, including remote monitoring in at least 50 regions and available to at least 1 million patients"–within the "Capacity building for successful integrated care systems". This action builds on successful collaborative examples that can easily be replicated in Europe;
5. "Global standards development, guidelines for business models and financing for independent living" –within the "Flexible and interoperable ICT solutions for active and independent living". This action aims to pool commitment of key-players (especially end-users) and help to address at least one of the main barriers to further implementation of ICT solutions in the health area

Two other topics are also being considered: "Vaccination for elderly people" and "Age friendly cities".

A key point that EPF and other steering group members made during the meeting is that health literacy and empowerment is a cross cutting theme of relevance to all actions, and should not only be seen in the context of adherence , as important and critical as this area of work is.

The Strategic Implementation Plan is currently under development by a drafters group and EPF will have the opportunity to review this twice. We will be involving directly EPF members that have been especially active in the EIP-AHA to date, namely Alzheimers' Europe, European Parkinsons' Disease Association and International Diabetes Federation –Europe, in this process. We will also send out a penultimate version to our wider membership, with a very short timeframe for comment.

A final draft will be sent to the Steering Group on 7th November for their approval.

See also update EU policy section.

27. EFAPH Lunch Seminar at the European Parliament, 20 September

EPF Policy Officer Laurène Souchet attended the Lunch Seminar organised on 20 September at the European Parliament by our member the European Federation of Associations of patients with Haemochromatosis EFAPH. The conference "*A European Public Health Challenge?* Genetic Iron Overload (Hereditary Haemochromatosis): Why act now for the prevention of this disease? How

do we fill the information gap in Europe?" aimed at raising awareness among EU decision makers, and healthcare professionals on Haemochromatosis, a disease which, if diagnosed early through a blood test, can be easily treated.

The speakers included MEPs Jo Leinen (S&D, Germany) and Antonyia Parvanova (ALDE, Bulgaria) and Corinne Lepage (ALDE, France) who highlighted that in Europe around 2 million people are affected by the disease, and that many lives could be saved with early diagnosis. Dr Brissot explained the functioning of this disease, its diagnosis and treatment, and the damage it causes in non-diagnosed patients. Mrs Margaret Mullett, President of the Irish Haemochromatosis Association spoke of the experience of her husband who was misdiagnosed several times- a common problem for this disease as non-specific symptoms are misinterpreted- and died as a result of severe damage to organs that were caused by the disease which was eventually diagnosed but too late. She highlighted difficulties to obtain treatment in some parts of the country.

Participants then discussed options for future actions, such as an awareness campaign involving doctors, guidelines for healthcare professionals for the diagnosis of rare diseases and the possibility for a written question in the European Parliament. MEP Antonyia Parvanova also stressed that a strong campaign for the maintaining of funding opportunities through the EU public health programme is also key to enable stakeholders to put in place projects and actions.

For more information, please consult the EFAPH website.

28. Polish Presidency conference on prevention and control of childhood asthma and allergy – EPF Vice-President says "Patient empowerment and involvement must be implemented across the EU", 21-22 September

EPF Vice-President, Susanna Palkonen, who is the Executive Officer of the European Federation of Allergy and Airways Diseases Patients' Associations (EFA), gave a presentation on patient involvement at an experts conference held in Warsaw on 21-22 September, under the Polish Presidency of the EU. The leading health priority for the Polish Presidency is the reduction of health inequalities and within this framework, the prevention and control of respiratory diseases in children.

Ms Palkonen explained to the audience that the goal and rationale of patient involvement in medical decisions is patient empowerment. She said: "Empowered patients know their disease, have the necessary skills and motivation to take good care in their everyday life, adjust treatment and be prepared in new or potentially exacerbating situations, detect side-effects, take contact with healthcare professionals when needed, and adhere to the treatment regime. Empowered patients will actively communicate with their treating healthcare professionals given the opportunity."

Children are a very specific group, but empowering and involving them is possible with right knowledge and tools. Many tools have been created to support empowerment: shared decision-making models, self-management templates, materials to help prepare for consultations, and patient education and information tools. However, a comprehensive approach to empowerment is lacking. Empowerment is a process that either starts or ends at the consultation. Ms Palkonen stressed that patient empowerment should become a key part of the health care professionals' professional training curriculum.

International guidelines in allergy and asthma recognise the need for patient involvement and empowerment, but there is a need to look at the way this is – or is not – implemented across the EU, both at individual and policy level. Tools and best practices should be shared to support empowerment and define the roles of different stakeholders. Ms Palkonen referred to a number of tools developed by EFA and EPF to support involvement in medical decisions at individual level and patient organisation involvement at policy level.

The programme of this conference is available online at http://presidency.wum.edu.pl/programme-draft For more information please contact the EPF Secretariat.

29. EFPIA Patient Think-Tank, 22 September

Anders Olauson and Nicola Bedlington participated in the EFPIA Patient Think Tank. Following a welcome and presentation by Richard Bergstrom, new Director General on his vision for the Think Tank, Anders outlined why the Think Tank continues to be an important platform for debate and exchange of views for patients. Key topics addressed in this meeting included Health Technology Assessment, with a presentation from EPF on our survey work with HTA agencies, decision-makers and patient

organisations, and a policy overview, a presentation from Lise Murphy, co-chair of the European Medicines Agency's Patients' and Consumers' Working Party (PCWP), followed by a presentation from Christoph Thalheim on the added value of patient involvement in EMA. A detailed discussion also took place on the current state of play regarding the European Innovation Partnership on Active and Health Ageing.

For a copy of all presentations, please contact Erica Poot. For more information on the discussions, please contact Nicola Bedlington or Secretariat of the Think Tank.

30. CEDAG Fundamental Rights and Citizenship Roundtable, 23 September

Laurène Souchet represented EPF at a Roundtable organised by the European Council of Association of General Interest (CEDAG). The aim of the event was to explore how non-governmental organisations use the Charter of Fundamental rights, and how to concretise these rights for European citizens. Representatives from various NGOs exchanged their experience on using concretely the Charter in their work and contributing to its implementation: While some organisations use it as a tool to promote rights at local level or in policy advocacy, other use it as a legal tool before courts of justice. Participating into research projects of the EU Fundamental Right Agency is another way to work towards implementing the charter. This discussion is also of high relevance for EPF as the charter guarantees everyone's right to access preventive healthcare and medical treatment. Participating NGOs also debated on a proposal for a European theme year that would focus on citizenship in 2013.

31. Welcome Gaya

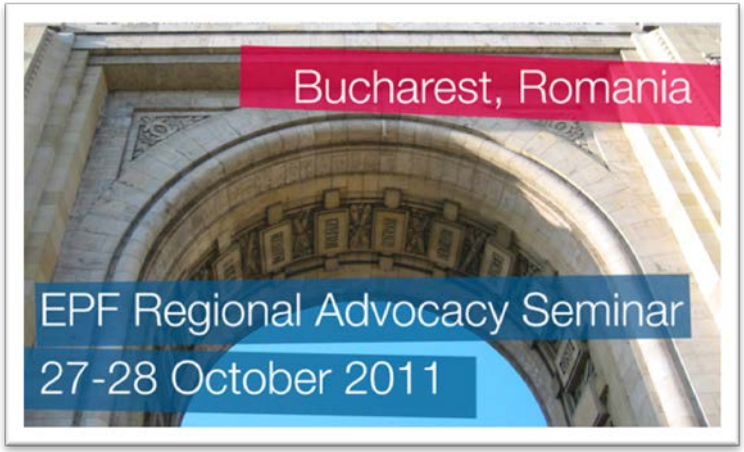
Gaya Ducceschi is responsible for managing EU projects and EU programmes. She joined the Secretariat in July 2011. Gaya holds a BA in Political Sciences and an MScEcon in International Politics. Before joining EPF, she worked for two years in the NGO sector in Brussels and she has overseas experience in the health sector.

A warm welcome to Gaya.

32. Fourth EPF Autumn Regional Advocacy Seminar

We have the pleasure to announce that the Fourth European Patients' Forum (EPF) Autumn Regional Advocacy Seminar will take place in Bucharest, Romania on 27-28 October 2011. The seminar is organised in cooperation with the Coalition of Patients' Organisations with Chronic Diseases in Romania (COPAC), member of EPF.

The seminar has a two-fold purpose: capacity building for patient organisations' leaders in order for them to become more empowered actors in national and European health policy arena, and strengthening the cooperation between patients' and health professionals' organisations in national health-related policy-making. Approximately 60 representatives of patients' and health professionals' organisations (i.e. general practitioners, specialist doctors, nurses, and pharmacists) from Bulgaria, Romania, Estonia and Hungary will attend this event.



This seminar will be an opportunity for the participants and their organisations to establish dialogues and build up partnerships with EPF and other patient and professional organisations to learn and share experiences about the implications of some key EU policy initiatives for patients and national healthcare as a whole.

The Seminar will also make a strong contribution towards enhancing the cooperation between patient and professional organisations in order to foster better health policy and health outcomes at national level.

We kindly acknowledge the support of the Medtronic Foundation and Sanofi in the form of unrestricted grants for the organisation of this event.

For more information on the seminar please consult the webpage of the event or contact Walter Atzori or Véronique Tarasovici.

33. EPF Diary

Date	Event	Attendance
To be confirmed	Transparency Charter	Nicola Bedlington
October 05-08	European Health Forum Gastein, Bad Hofgastein	Tomasz Szelągowski (speaker) Nicola Bedlington (speaker) Kaisa Immonen-Charalambous (speaker)
October 04-05	National conference on Quality Registers, Stockholm	Anders Olauson
October 11	EPF EUCOMED Dialogue, Brussels	Nicola Bedlington (co-chair) Gaya Ducceschi Laurène Souchet
October 12	European Health Policy Forum, Brussels	Nicola Bedlington
October 13	MEDTECH Forum 13 October Brussels NB speaker	Nicola Bedlington (speaker)
October 12	eHealth 2020 – What Synergies for Europe, European Parliament	Susanna Palkonnen
October 18-19	EDMA 2011 Annual European IVD Forum: Excellence in Diagnostics for a Healthier Europe, Brussels	Tbc
October 19	Third Annual Fit for Work Europe Conference, Brussels	Tbc

October 19	EUPATI Consortium Meeting, Brussels	Anders Olauson Nicola Bedlington
October 20	Conference on "Clarity and Quality: Bringing Cross-Border Healthcare in Europe Closer to Reality", Brussels	Nicola Bedlington
October 20	Third Pharmacovigilance Stakeholder forum, European Medicines Agency, London	Kaisa Immonen-Charalambous
October 27-28	EPF Regional Advocacy Seminar, Bucharest	Walter Atzori Nicola Bedlington Kaisa Immonen-Charalambous Özgün Ünver Véronique Tarasovici
November 07	Meeting of the Steering Group of the European Innovation Partnership on Healthy & Active Ageing, Brussels	Anders Olauson
November 09	- European Commission Research Advisory Board,	Anders Olauson (speaker).
November 07-11	Joint epSOS - eHealth Governance Initiative event, Athens	Watler Atzori
November 10-11	Ministry of Health in Slovenia conference "Excellence in Healthcare: Comparability of Quality, Patient Safety, Competences and International Accreditation", Ljubljana	Tbc
November 28	EPF Board meeting	Board members
November 29	Microsoft Health User Group	Board members
November 29	HTA Conference, London	Nicola Bedlington
November 30	RENEWING HEALTH Mid-Term Workshop, Brussels	Walter Atzori
December 01	EHTEL Symposium "Seamless Integration for Personal Health Services – Evidence and Sustainability", EESC, Brussels	Walter Atzori
December 07	5th Meeting of the RENEWING HEALTH User Advisory Board	Walter Atzori
December 08	ABC Project European Forum on Patient Adherence to Medication, Brussels	Kaisa Immonen-Charalambous
December 10	Chain of Trust European-level patient focus group on telehealth	Walter Atzori

December 13	Meeting of the Steering Group on Access to Medicines in Europe, Warsaw (tbc)	Nicola Bedlington Kaisa Immonen-Charalambous
December 15	Meeting on "eHealth and Equity in the Global Health Communities", Brussels	Kaisa Immonen-Charalambous