

EPF Mailing

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Dear EPF Members and Allies,

Welcome to the summer issue of the EPF Mailing. This issue focuses on our Conference on the Rights and Needs of Older Patients organised with the Polish Patients' Federation, which took place in Warsaw on 12-13 July. It also gives a brief overview of policy and project developments during the early summer.

We are delighted to report that the Conference was a success, thanks to the contribution of various stakeholders during the plenary session ([presentations are available on EPF Website](#)) and lively debates took place with participants during parallel sessions on five major themes. This conference is an important milestone for EPF, as recommendations from the workshops and conclusions will feed into our work in current debates on healthy ageing, demography, sustainability and chronic disease management. To read a more detailed account of the conference please see our special feature. A detailed report of the event will also follow in the early autumn, and we will work towards the adoption of an EPF position paper on the rights and needs of older patients with our membership.

Recommendations of the conference will particularly fit in with our active involvement in the European Innovation Partnership on Active and Healthy Ageing ([article 3](#)). EPF President Anders Olauson will attend the next meeting of the Steering Group on 16 September. EPF also gave input into other important ongoing policy dossiers (the clinical trials framework, the Transparency Directive, and the future of the Public Health Programme) as you can read in our [Policy Section](#).

Follow up work on the high-level task force of advisors on eHealth took place this month. EPF president Anders Olauson was involved in a preparatory meeting for the next expert meeting in Tallinn in mid-September. A detailed report will be included in the next issue of the EPF Mailing at the end of September.

In the project area, the online survey we launched last month to gather the view of patients and professionals on telehealth as part of Chain of Trust has had 5,000 replies. The deadline to participate in this survey, available in 11 languages at www.chainoftrust.eu, has been extended until 25 July.

Planning for the end of the summer and autumn 2011 is well underway, as you can see in our [Diary](#): In August, the EPF Youth Group will hold its kick-off meeting in Brussels, marking the beginning of the implementation of our Youth Strategy. In September, we will hold a lunch debate together with CPME, PGEU and EFPIA on the key theme of adherence to therapies. You will find more information on these and other key events coming ahead in the autumn (such as the European Health Forum Gastein and EPF's Regional Advocacy Seminar in Bucharest) in our next issue.

It is our pleasure to welcome warmly a new member of the Secretariat team: Gaya Ducceschi, who joined us on the 18 July as Programme Officer. We will introduce Gaya in more detail in our next issue.

The EPF Secretariat remains staffed during the summer, so please do not hesitate to contact us. Our warmest wishes to you all for a relaxing summer break and thank you, once again, for your on-going commitment to the work we do.

Warmest Greetings
EPF President Anders Olauson
EPF Director Nicola Bedlington

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1. EPF-FPP Conference under the Polish EU Presidency – The Rights and Needs of Older Patients, Warsaw, 12-13 July 2011

Report by Jenny Sims

Urgent action is needed at EU and national levels to tackle the health and social care needs of older people in Europe, the European Patients' Forum (EPF) and Polish Patients' Forum (FPP) conference in Warsaw on The Rights and Needs of Older Patients, agreed.

Speakers drew a graphic picture of many healthcare professionals not understanding older patients' needs, and of many older patients not knowing their rights to services and care. A key message was that innovative policies and practice were essential in dealing with the multiplicity of challenges posed by an ageing population, increase in chronic diseases, and shortage of healthcare professionals and financial resources.

Possible solutions included eHealth and personalised medicine. But greater partnerships between all stakeholders – including doctors, carers and older patients themselves – was called for as a cornerstone for change.

Speaking in the opening plenary, **Andrzej Witold Włodarczyk**, the Polish Undersecretary of state for health noted that “the topic of the conference fits within the Polish Presidency of the EU, as the ministry of health suggested older age problems as one of the leading subjects”. He presented actions to meet the challenge of the ageing population in Poland, including the creation of an Institute of Geriatrics to train specialists, promote a holistic approach to older patients, and develop solutions to be implemented in the Polish healthcare system.



Anders Olauson, President of the EPF, said a key aim of the conference was to enable patients' organisations to contribute meaningfully to EU policies on healthy and active ageing, and to the pilot European Innovation Partnership's goal to achieve two extra healthy life years for European citizens by 2020. The recommendations will also be fed into the Polish Presidency of the EU which will be producing a report before the end of the year.

Tomasz Szlagowski, Director of the Polish Patients' Forum, drawing an analogy with rebuilding a great capital city, said the aim was to eventually build great healthcare systems.

Top EU policy-makers, healthcare specialists and patients' leaders laid bare problems for older persons – ranging from poverty, ageism and inequity of access to health services, to inappropriate prescribing of medicines. And following in-depth workshop discussions, delegates drew up a range of recommendations for action. (See boxes 1–5).

Martin Seychell, Deputy Director-General of DG SANCO, warned that many older people were increasingly spending their last years in poor health and social isolation. He claimed the Innovation Partnership plan, which it is hoped will be adopted in November, could trigger “a paradigm shift” in better care and quality of life, partly through the introduction of innovative products, devices and services. Its three main work areas were focusing on early diagnosis and screening, care and cure, and independent living. Achieving its goals was critical, and work needed to start early, but it was only the start of what needed to be done, said Mr Seychell.

Commenting that professional “silos” were a barrier to innovation and needed to be broken down, he called on delegates to be “actively engaged in partnerships” to implement innovative policies and practice and bring about social inclusion.

“Ageing Europe needs informed patients,” he added, and patients' organisations have a major role to play in this area.

Marie-Claire Pickaert, from the European Federation of Pharmaceutical Industry Associations (EFPIA), which is supporting the Innovation Plan, said its vision of making two extra healthy life-years a reality by 2020 would produce a triple win: healthy elderly, healthy public finances and healthy business. But she warned: “Learning how to introduce innovation in healthcare systems is another key challenge.” An integrated approach was needed to prevention, early diagnosis, care and cure, to improve standards and adherence and better use of resources.

Prof Boleslaw Samolinski, Chairman of Subcommittee of Ministry of Health for Priorities of Polish Presidency at the Medical University of Warsaw, said public health priorities were “to close the gap in the health status of the EU’s member states”. Concerted action was needed for decreasing premature mortality through public health measures aimed at reducing harm caused by smoking, hazardous alcohol drinking, inappropriate diet and lack of physical activity. He announced a ministerial conference would be held on 7-8 November 2011 in Poznań. In addition, an expert conference on Ageing, Stroke and Alzheimer’s Disease: Finding Innovative Solutions, will be held on 18 November in Warsaw.



A second public health priority of the Polish Presidency was the prevention and control of respiratory diseases in children, focusing on the prevention and control of asthma and allergies. An expert conference is to be held on 21-22 September in Warsaw. And a third priority was the prevention and treatment of communication disorders in children, including the use of eHealth and innovative solutions.

Ms Christine Rolland, Vice-President, European Federation of Allergy and Airways Diseases Patients’ Associations (EFA) said new thinking was needed in finding solutions for the millions of patients with COPD, allergy and asthma. Describing the scale of the problem, she said currently in Europe, 4 to 10 per cent of adults have COPD (or 44 million), costing €102 billion and increasing; 21 per cent of COPD patients are severely disabled; and “COPD is predicted to be the third leading cause of death in 2030” according to WHO.

In addition, 80 million people have allergy, and one person every hour dies from severe asthma in the Western world. She said that older people, including those with chronic disease, should be seen as a resource – not a burden. The focus should be on what could be done – not what could not; and that greater use should be made of the “army of volunteers”. Solutions should include greater home care support and use of eHealth, more patient-centred care and personalised medicine, greater integration of health and social care, better service infrastructure to support mobility and activity, more focus on prevention, and the development of “care ambassadors”.

Dr Antonia Parvanova, MEP (ALDE, Bulgaria) said health had to be included in any examination of the rights and needs of older people, but EU Member States were reluctant to co-operate on health policy. She said: “The question of subsidiarity has been an excuse for member states to do what they want.” Pointing out huge differences in morbidity rates for tuberculosis and cancer between countries, she said: “We have to challenge this subsidiarity issue at EU level.” She also stressed that by 2020 there would be a shortage in Europe of one million healthcare professionals: doctors, nurses and other professionals. New ways had to be found of attracting young people into caring for older people, including better training and pensions.

Ms Halina Potocka, Vice President, AGE Platform Europe, said there should be greater focus on elderly people being a resource, “not a burden”. AGE manages six expert groups in 27 different countries, tackling issues from discrimination to pensions and health, aiming to voice and defend the interests of older people. 2012 is the European Year for Active Ageing and Solidarity between generations, and Ms Potocka emphasised this as opportunity to promote positive images of older people.

Dr Piotr Bledowski, a gerontologist representing Eurocarers, pointed out the increasing 80-plus cohort, the low birth rates, and the rise of single households of people aged over 65; thought should be given to “who will take care of the silent army of informal carers?” Profound changes to social services were needed to help families and individuals, and it was of the utmost importance that public administration gave support to informal carers, he said.

Opportunities for patient involvement

Research on ageing is a relatively young field, said Ms Beatrice Lucaroni, Project Officer at the European Commission’s Directorate General for Research and Innovation, who gave an overview of new opportunities within the EU Framework Programme 7, which has received 6.1bn Euros for collaborative research.



Patient involvement is an evaluation criterion in some calls, and projects like Value+ and PatientPartner are used as a reference for good practice. For more information on Value+ (overview and analysis of current practice and trends on patient involvement in EU health supported projects, practical support tools) visit <http://www.eu-patient.eu/projects/valueplus>. For more information on Patient-Partner (patient involvement in clinical trials) visit www.patientpartner-europe.eu

Ms Avril Daly, Chief Executive of Retina International, a charity which has successfully funded research in Ireland, gave the patients' perspective and put the economic argument for investment into research into prevention and cure, versus decades of costly treatments.

Dr Michal Kazmierski, of the High Level Working Group for Innovation in Healthcare at the Medical University, Warsaw, drew attention to the fact that most clinical trials excluded people aged over 65, so little was known about how innovative treatments work in older patients. He called for change to include older patients in research to ensure the benefits and side effects of treatments are known.

The High Level Group's main goal is to increase access to modern treatments and technologies through proposing systemic solutions supporting healthcare reforms. "Now is the time for action. It will be harder if we don't act", he said.

Dr Eva Nilsson-Bagenholm, the newly appointed National Coordinator for Elderly Care at the Swedish Ministry of Health and Social Affairs, reported that Sweden was beginning to introduce a "payment by results" system to improve health and social services for elderly patients. Currently patients can choose the hospital they want, but the government wants to extend that choice to social care, too. It has allocated 3.75 billion SEK for a three-year programme because widespread system reform is needed. It is a huge task, and they are developing quality indicators, making a start with the treatment and care of the most vulnerable group, the frail elderly. Polypharmacy is a major challenge because different laws govern health and social care, but Dr Nilsson-Bagenholm said that in her opinion, by 2014, Sweden would have taken quite a few steps towards coordinating health and social care throughout the country.

Prof. Antonio Cherubini, representing the European Union Geriatric Medicine Society (EUGMS), talked of the unmet needs of geriatric patients: evidence-based treatments, geriatric education and training of health care professionals, and integrated long-term care systems with appropriate services and methodology.

Summing up from the patients' perspective, **Philip Chircop**, EFP Board member from Malta, said: "There is clearly a growing need for a comprehensive approach to chronic diseases, both at EU and national levels – and specifically for the needs of older patients." Speakers had paid particular attention to inequalities in health and how innovation could be harnessed to alleviate them. "Member organisations in the EPF have a wealth of experience and expertise in this, and we are more than happy to share them", he said.

Box 1. Shared decision-making and empowerment for older patients

Moderator: Prof. Dieter Lüttje. Rapporteur: Gareth Davies

- Single person should have the coordinating role in managing overall care.
- Existing good practice models from national level should be collected, evaluated and learned from.
- EPF should take on a campaigning role on health literacy.
- Specific education on the needs of the elderly for carers, care givers and older people is needed. Good strategies always include prevention.
- NGOs should promote the changing of public perceptions: an old person is a person, with rights.

Box 2. Linking health and social care in self- management

Moderator: Ian Banks. Rapporteur: Hanna Milczarek

- Key needs of older patients were identified as (1) keeping their autonomy; and (2) to be listened to by the stakeholders.
- NGOs should be a premier source of collective information on needs of older patients. NGO representatives should be present in decision-making.
- National plans should be established for dealing with the problems of older patients. Patients should have individual choice of social carer.
- NGOs's expertise and examples of good practice should be used in bringing this topic from the local to the national patient groups, and European Innovation Partnership should be used as the platform for exchanging experiences and discussion.

Box 3. Cultural and psychological aspects of ageing with chronic diseases

Moderator: Maria Navarro. Rapporteur: Heather Clarke

- The rights of older people should be taken into account, including those of informal carers. This needs political acknowledgement and support, as well as resources. The employment rights and conditions of both groups need to be considered, as well as the rights of those who have lost independence and need protection.
- There is a need to invest in prevention – prevent what is preventable, and start with children. Children can educate their parents for healthier life styles.
- European standards should be created for holistic, integrated care of chronic conditions, with the involvement of patients' organisations.

Box 4. Low-tech and high-tech innovation for older patients

Moderator: Dr Konstanti Radziwill (CPME)

Rapporteur: Jacqueline Bowman-Busato (Epposi)

- the definition of "high-tech" and "low-tech" innovation should be further addressed.
- Cross-stakeholder attitudinal change is necessary. A partnership approach is key.
- Financial investment in the outcomes is needed to ensure long-term benefits.

Box 5 (e-) Health literacy and information for older patients

Moderator: Paul de Raeye.

Rapporteur: Peggy Maguire

- *The EPF definition and recommendations on health literacy (2008) are still valid, but should be reviewed in light of older patients' needs.*
- *Health literacy needs a life-span and cross-sectoral approach. It should be a priority in the Innovation Partnership, with links to other initiatives such as the EU Health Literacy Survey.*
- *Health literacy should be seen as an overarching term comprising several distinct areas – e.g. health information and awareness, patients' empowerment...*
- *Older patients and persons are not a homogenous group: familiarity with and competence in eHealth varies considerably, information for older people needs to be presented in a variety of formats and languages.*
- *Awareness and capacity-building is needed not only for patients but for politicians – EU and national level – on the importance of information and health literacy.*
- *Many good practice models exist that can be used & adapted to suit local contexts – but we need to know what they are (“the evidence barrier”).*

POLICY

2. Pharmaceutical Package – Falsified medicines

On 1 July 2011, the [new EU legislation on falsified medicines](#) (Directive 2011/62/EU) was published in the [EU Official Journal](#), having been formally adopted on 27 May without a debate at a session of the Transport, Telecommunications and Energy Council. The new legislation will be applicable from 2 January 2013.

The term “falsified” medicines is used by the EU to distinguish the issue from intellectual property (IP) violations, which are termed “counterfeit”. Falsified medicines are fake medicines that pass themselves off as real, authorised medicines. They can

contain ingredients of bad quality, in the wrong dose, or no active ingredients at all. We have outlined the main elements of the new EU rules [in a previous issue of this mailing](#).

Next steps:

- The EPF Secretariat will monitor the implementation of this Directive, including through the Medicines Agency where appropriate, and will update the membership on relevant developments in the next issue of this mailing.

Links:

- [Commission Q&A on falsified medicines](#)

3. European Innovation Partnership 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 this EIP has proceeded at a remarkable speed: a number of preparatory workshops were organised by the Commission in Brussels in June, around three broad work areas: “Prevention/early diagnosis”, “Care/cure”, and “Independent living”. The EPF Secretariat worked hard to ensure that key EPF member organisations focused on older patients were invited to the workshops: for practical reasons, the Brussels-based member organisations focusing on older patients – IDF Europe, Alzheimer Europe and EPDA (European Parkinson’s Disease Association) – were selected to attend the preliminary meetings, while the Secretariat retains an overview and overall involvement. We will involve the wider membership in the next phases once the work of the EIP is launched in concrete terms.

A number of topics have been proposed to be put forward to the Steering Committee, which will ultimately decide in September what will be included in the Strategic Implementation Plan (SIP) of the Partnership. EPF has put forward a proposal concerning

health literacy, as this has been recognised by all stakeholders as being a key cross-cutting element in prevention as well as care, but was not sufficiently addressed in other proposals.

Next steps:

- The Steering Group will meet on 16 September and will select those priority areas for action it wishes to take forward.
- EPF will update the membership accordingly and invite your interest to participate.

4. Clinical trials – review of the EU Clinical Trials Directive

The Commission having completed its second public consultation on the review of this Directive on 13 May 2011, are in the process of preparing a legislative proposal that is scheduled for publication during the second quarter of 2012 (i.e. by June 2012).

As explained in the previous issues of this Mailing, EPF has followed the public consultation process closely and submitted responses and in addition a [formal Statement](#), reiterating our key principles centred around patients' involvement, information and access to treatment.

In view of the importance of this topic, EPF took the initiative to organise a meeting with Commission representatives to discuss further the issues outlined in our statement. This meeting took place on 7 July and was very constructive. Information gained will help us to formulate a strong position on clinical trials, focusing on what is feasible and realistic. The Secretariat will brief all members comprehensively after the summer break.

EPF was also invited to speak at several public events in the last months around the review of the Directive, including two lunch debates in the European Parliament, on 22 March and 22 June, hosted by Philippe Juvin MEP (EPP, France) and a one-day workshop organised by the European Forum for Good Clinical Practice (EFGCP) on 4 July.

Next steps:

- EPF will provide a detailed briefing to members on the current position and possible ways forward towards a more patient-centred EU regulatory framework on clinical trials.

5. Review of the EU Transparency Directive

As we explained in the last issue of this mailing, the Commission's timetable for the public consultation on the possible review of the so-called [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) was unfeasible for submitting a full membership input, and the format of the Commission's questionnaire was inadequate to reflect the concerns of stakeholders such as patient organisations. Nevertheless it was important to provide initial input, as the revision of the Directive can have a significant impact on patients' access to medicines and public availability of information.

For this reason EPF submitted an informal input approved by the Board – highlighting a number of key concerns and messages based on existing EPF positions - and in addition requested a meeting with the Commission to discuss this topic.

The meeting was very useful and constructive, and the information gained will assist us in formulating a draft position for member consultation, as and when the Transparency Directive is “reopened” and the Commission presents a legislative proposal. This is expected to happen in December 2011. EPF will seek our members' views to formulate an official position on the proposal.

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

6. Consultation on the Commission Green Paper on the Professional Qualifications Directive

Following a public consultation earlier this year, the Commission on 22 June published the [Green Paper “Modernising the professional qualifications Directive \(2005/36/EC\)”](#). The Deadline for response to the Commission is 20 September 2011.

Ensuring that healthcare professionals have the right training, and are fit to practice when they move from one Member State to another is important for patient safety and quality of care across Europe. During the public consultation, EPF issued a Joint Statement with EPHA to affirm that quality and safety must remain highest priorities that must not be degraded. We also submitted a response, highlighting the importance of training requirements especially on communication with patients and skills related to ICT and eHealth, and increased transparency on fitness to practice of health professionals.

We will continue to consult our membership to provide a strong input to the Commission on the Commission's Green Paper.

Next steps:

- Members will receive a draft response developed on the basis of previous consultations at the end of July 2011.
- Feedback and comments will be incorporated and circulated again at the end of August for to allow time for final comments and approval before 16 September.

Links:

- [EPF's response to the previous consultation on the Professional Qualifications Directive](#)
- [EPHA/EPF common statement on the review of the Professional Qualifications Directive](#)
- [EPF's response to the Commission Green Paper on the European Health Workforce.](#)

For more information or comments, please contact [Laurene Souchet](#).

7. Alliance for MRI - European Commission published EMF proposal & Alliance Annual Meeting

The European Commission has adopted a proposal for revising [Directive 2004/40/EC](#) on electromagnetic fields (EMF) and introduced an exemption for Magnetic Resonance Imaging (MRI) from the binding exposure limits proposed in the new directive.

After adoption of Directive 2004/40/EC the alliance for MRI, a coalition of MEPs, patient groups, leading European scientists and the medical community, informed the Commission that the limits in the directive would be an obstacle to the use and development of MRI.

Through the new EMF proposal, the European Commission has endorsed the position of the Alliance for MRI and has sought to ensure that the future of clinical and research use of MRI is not curtailed so that patients across Europe can benefit from this technology. The safety of MRI is established through an international safety standard (IEC/EN 60601-2-33), which ensures that there are no negative effects on workers from electromagnetic. Deadline for transposition of this Directive had then been postponed to 2012.

In addition, The safety standards for MRI will be supported by guidelines to ensure that worker safety can be adapted in line with technological developments.

Next Steps:

- The Commission's proposal will now be scrutinized by the European Parliament and the Council (under the ordinary legislative procedure). If there is agreement on the text, the revised proposal could be adopted swiftly into EU law - however there is a risk that other lobbies will be engaged in seeking to change the text to exclude other industrial workers which could slow down this process.
- The 4th Annual Meeting of the Alliance for MRI will be held on 8th November (tbc) in the European Parliament and will be hosted by Elisabeth Morin MEP.

Links:

- [European Commission's Proposal for a Directive on the minimum health and safety requirements regarding exposure of workers to the risk arising from electromagnetic fields \(EMF\).](#)
- [Alliance for MRI](#)

8. EU budget: Future of the EU Health Programme

EPF has been active within the context of the EUHPF ([European Health Policy Forum](#)) in preparing input for the Commission regarding the future of the Public Health Programme post-2013. The [response prepared by EUHPF](#) was submitted to the Commission ahead of the launch of the Commission's multi-annual financial framework which was published on 29 June.

Key elements stressed in the input included "health in all policies"; participation of public health stakeholders; need for adequate resourcing of health/public health actions; the importance of health as a cross-cutting value in all EU actions, contributor to economic growth and sustainability as well as a value in its own right; fighting inequalities; patient-centeredness and quality of life.

Already prior to the EUHPF input, EPF had prepared a joint letter with EPHA, sent to President Barroso and other key Commission officials, which strongly highlighted the achievements of the PHP and its key role in achieving the goals of EU 2020 as well as tackling the social challenges facing the Union.

Links:

- [Commission staff working paper, “A Budget for Europe 2020: the current system of funding, the challenges ahead, the results of stakeholders consultation and different options on the main horizontal and sectoral issues.”](#) (accompanying the Communication “A budget for Europe 2020”)
- [European Commission’s budget proposal](#)
- [EUHPF input on the Public Health Programme post-2013](#)

9. European Medicines Agency

9.1 Patients’ and Consumers’ Working Party

On 16 June 2011 EPF attended the annual joint meeting of the PCWP with the Health Professionals’ Working Group. Items on the agenda included updates on the ENCePP project; issues related to clinical trials (e.g. third country clinical trials, and the new EU clinical trials register); the new EMA strategy on geriatric medicines; and the new pharmacovigilance rules. The agenda of the meeting is available [here](#).

For further information please contact [Kaisa Immonen-Charalambous](#).

9.2 public information on side effects of medicines

On 8 July 2011, the European Medicines Agency published its plans for granting public access to the information held in its databases of the potential side effects of medicines.

The EudraVigilance database is the central repository for reports of suspected adverse reactions related to medicines authorised in the European Economic Area, as well as medicines being studied in clinical trials. The Agency prepared the policies with input from stakeholders, including patient groups; EPF was an active participant in meetings of the working group on EudraVigilance.

Further information is available here:

- [EudraVigilance access policy on medicines for human use](#)
- [Explanatory note](#)

9.3 EPF participates in second EMA forum on Pharmacovigilance

The second seminar on the implementation of the new EU pharmacovigilance legislation, held on 17 April 2011, gave an update on the progress of the implementation and focused on certain topics of particular relevance to patients and healthcare professionals, for which specific feedback was sought: public hearings, direct patient reporting and the EudraVigilance database.

EPF contributed actively to this meeting, including through an intervention delivered in the panel session on “direct patient reporting”. Our key points were:

- Effective implementation that fully benefits from the added value of patient reporting will depend upon effective dissemination of information to patient communities about: what pharmacovigilance is; how the new Directive will help improve medicines safety; and why it is important that patients report suspected adverse reactions, and what avenues are available to do it.
- EPF called for information and awareness campaigns by national authorities and the Commission/Agency. Since it is shown that public information campaigns often do not have a long-lasting effect, we stressed the key role patient groups can play in supporting awareness in the longer term, as they are in regular and close contact with grass-roots patient communities.
- EPF also called for specific training programmes on pharmacovigilance for patient groups to equip them to contribute into the implementation and work in partnership with national authorities. EMA could support by for example organising a capacity-building workshop for patient groups from national level together with MS representatives.

- The added value of patient reporting is already recognised. We called for a reporting systems that preserves the special richness of patient reports in the capture and analysis process. To increase motivation of patients, there should be some kind of feedback/follow-up about how the information will be used, and about the benefits of the report.
- The importance of trust in the patient-health professional relationship emerged as a strong concern in the discussions: one of the reasons why patients prefer to report directly is a lack of interest or engagement by the doctor. EPF stressed that direct patient reporting is not seen as a replacement of health professional reporting, but rather a complement.
- There is a clear need for training/education for health professionals in how to communicate and involve the patient in a concordance relationship. Building patients' health literacy is key – but the necessary counterpart to the “informed/empowered patient” is the health professional who welcomes this, and creates an “enabling environment” for a dialogue and partnership approach.
- We concluded that the new legislation represents a great opportunity for patient and health professionals' organisations to work together to promote best practices in shared decision-making and patient empowerment.

Documents and presentations from this workshop are [available here](#). Videos from the [first stakeholder forum](#) have now been uploaded onto the EMA website, [here](#). The video recordings from the second forum will be uploaded in due course.

For more information please contact [Kaisa Immonen-Charalambous](#).

9.4 EMA public consultation on a draft guideline on paediatric medicines

The European Medicines Agency has recently published a draft guideline on pharmaceutical development of medicines for paediatric use. The purpose of the guideline is to support the implementation of Regulation EC No. 1901/2006 (the "Paediatric Regulation")

The document is available for consultation [here](#). Comments should be provided using [the template provided by EMA](#). All interested parties are welcome to submit comments. The completed comments forms should be sent to EMA using the email address gwp@ema.europa.eu.

The deadline for comments for this draft guideline is 31 December 2011.

10. Respect Project Dissemination meeting

The RESPECT project which aims to empower children participating in clinical trials and their families is close to an end. The final dissemination meeting was held on the 25th of May at the University Foundation Club, in Brussels, and was successfully attended by fifty people.

Among key stakeholders there were valuable contributions from representatives of patient organisations, clinical research practitioners, academics, regulators and the pharmaceutical industry.

The project Consortium presented the results of the project and the recommendations per thematic areas and from the perspective of different stakeholder groups like children, parents, patient organizations, clinicians, ethic committees. EPF presented the perspective of patient organizations in terms of the role they could play in supporting and empowering the role of actual and potential participants to paediatric clinical trials. EPF called for more transparent and accurate information provided to participants, better sharing of key findings and especially for a stronger position for patient organisations as intermediate.

All presentations are available on the website www.patientneeds.eu

The project Consortium is currently preparing a final project report that will include recommendations on how to improve the participation and quality of paediatric clinical trials.

For further information please contact [Ms Gaya Ducceschi](#), EPF Programme Officer.

11. Chain of Trust



telehealth and what barriers there still are to building confidence in and acceptance of this innovative type of services.

The "Chain of Trust" project, led by EPF, started off in January 2011 with the overall objective of assessing the perspective of the main end users of telehealth services across the EU to see whether and how views have evolved since the initial deployment of

As the reader may recall from the previous Mailing issues the consortium has completed a literature review on patients' and health professionals' perspective of telehealth during the first quarter of 2011. With a view to validating the findings of the literature review we launched an online survey in 13 languages for patients and health professionals in early June. The survey has attracted a lot of interests from all across the EU with some 5000 replies having been received already at the time of writing.

The deadline for participating in this survey has been extended until **July 25th**. You can take part in the survey following the link: www.chainoftrust.eu.

More details on project's latest developments will be provided in the September Mailing.

Please contact [Walter Atzori](#) for more information on this project.

12. First EPF Youth Group Meeting to take place in August!

As anticipated in the previous Mailing issues, the members of the EPF Youth Group will meet for the first time in Brussels on August 19-21. The objectives of this meeting are to discuss how to move forward with the implementation of the EPF Youth Strategy, identify the policy areas the Youth Group is interested in becoming involved in and agree on the governance rules and procedures for this group, which will include the election of a youth board and distribution of responsibilities among members. The logo and motto of the Youth Group will also be adopted at this meeting. We will report on the outcomes of this meeting in the next Mailing.

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

13. EPF Diary

Date	Event	Attendance
July 21/22	Respect meeting- Gothenburg	Gaya Ducceschi
August 21-22	1 st Meeting of the EPF Youth Group	Walter Atzori Özgün Ünver
August 29,30	World demographic and ageing conference- St Gallen	Nicola Bedlington (Speaker)
August 30	Renewing Health User Advisory Board meeting	Walter Atzori
September (date tbc)	EUPATI preparatory meeting	Nicola Bedlington
September 1	EU meeting on Transparency	Nicola Bedlington (co-chair)
September 8	AGM - European federation of associations of patients with haemochromatosis – Brussels	Walter Atzori (speaker)
September 8	EPF Policy Advisory Group meeting – Brussels	
September 13-14	EPF Board Meeting – Brussels	
September 13	EUROPA BIO patients' advisory board – Brussels	Nicola Bedlington

September 14-15	Chain of Trust project 2 nd Steering Committee Meeting – Riga	Walter Atzori Gaya Ducceschi
September 15	Task Force of high level advisors on eHealth- Tallinn	Anders Olauson, Member and Speaker
September 16	European Innovation Partnership on Active & Healthy Ageing - Steering Group – Brussels	Anders Olauson
September 21	Lunch debate on Adherence to Therapies – organised jointly by EPF, PGEU, CPME and EFPIA – Brussels	Tbc
September 22	EFPIA Think Tank	Nicola Bedlington
September 27-28	RENEWING HEALTH Steering Committee Meeting – Barcelona	Walter Atzori
September 28	eHGI PSC Meeting – Brussels	Walter Atzori
October 27-28	EPF Regional Advocacy Seminar- Bucharest	Walter Atzori, Nicola Bedlington, Kaisa Immonen-Charalambous