



## Special Issue: 2012 Annual Review & Season's Greetings

Welcome to EPF's Review of 2012 which describes some of the highlights of this exciting year. It is not an exhaustive document - more details will be available in our Annual Report 2012 – but we hope it will give you a real flavour of key developments in the last 12 months.

We would like to take this opportunity to thank wholeheartedly all our member organisations, both new and old, which have contributed so much to the achievements of 2012, both in person at our various events and workshops, and also through regular written communication and input in our policy and programme work. This collective investment by our members drives EPF to be a united and effective voice for patients. We are very much looking forward to working with you in 2013.

We would also like to thank our many allies and fellow stakeholders who work with us on a daily basis to help to advance patient centred, equitable health care in Europe. We live in very challenging times, and only by really working together will we be able to engineer the changes needed for empowerment, quality and sustainability.

Our warmest greetings for the festive season and for the New Year!




Anders Olason, EPF President, and Nicola Bedlington, EPF Executive Director, on behalf of the EPF board and EPF Secretariat Team

JANUARY	FEBRUARY	MARCH	APRIL
MAY	JUNE	JULY	AUGUST
SEPTEMBER	OCTOBER	NOVEMBER	DECEMBER



# JANUARY



## **SUSTAINS project shifts into high gear**

The [SUSTAINS project](#) officially started this year in January 2012. This three-year project's objective is to develop and deploy a basket of services in 11 European regions providing patients' access to Electronic Health Records (EHR).

The project partners met several times in 2012 to get an [update of the state of play](#) of SUSTAINS' services implementation in the 11 participating countries/regions. EPF has been coordinating the implementation of user requirement groups and outlined the [end users' views](#) on the envisaged services in order to ensure these are aligned to the needs and expectations of patients and meet the requirements of health professionals.

*"Involving patients and health professionals through user requirements focus groups proved to be a very useful exercise for us to understand how the planned services can be improved to better match users' needs and expectations",* said Josu Xabier Llano Hernaiz, from the Dirección General del Ente Público Osakidetza –Servicio vasco de salud.

Except in very limited cases, there was large agreement among patients and health professionals that patient-accessible EHR, if properly designed, can present a window of opportunity for improving the quality of healthcare services. It can ensure the continuity of care and more regular contacts between patients and healthcare professionals. Withholding access to EHR to patients is no longer an option. All the participants agreed that granting access to personal health records is even becoming a fundamental right of the patient and constitutes an important step forward in strengthening the role of the patient in the healthcare process.



# FEBRUARY

## European Patients Academy on Therapeutic Innovation: a start up at top speed!

The [European Patients' Academy on Therapeutic Innovation \(EUPATI\)](#) was launched in February 2012 and has made good progress. It is an IMI-funded consortium project, led by EPF, to educate patients and the lay public about how medicines R&D work. A consortium of 29 organizations is developing training courses, educational toolkits and a web-based library to provide objective and credible information about medicines R&D and how patients can get involved. EUPATI will cover seven languages in 12 countries.

In its call for **educational material on medicines R&D**, 306 resources, including handbooks, publications, course materials, presentations and guides, were submitted to European Patients' Academy. 230 resources were selected for the first review report, which has now been finalized. The report forms the basis for the development of EUPATI's educational content.

The **syllabus for the European Patients' Academy's training courses** has recently been agreed. The "table of contents" lists about 200 topics relevant to fully understand the end-to-end processes of medicines R&D. As a next step, learning outcomes and editorial processes are being defined. **Web-based learning** will constitute a major part of the expert-level training courses for patient advocates. A first draft technical specification is currently under review.

More than 400 individuals are now members of the European Patients' Academy Network. **Please become a member of the EUPATI Network** by registering on the [patientsacademy.eu](http://patientsacademy.eu) website. All members of the Network will be kept up to date on major progress and events of the project.

**The Academy's 2013 Conference** will be held on 19 April 2013 in Rome. Please save the date! It will address patient involvement in medicines R&D, on how to grow competences and skills in the area, and how to educate the lay public.

For more information, please visit the website [www.patientsacademy.eu](http://www.patientsacademy.eu) or contact [info@patientsacademy.eu](mailto:info@patientsacademy.eu)





## **RENEWING HeALTH explored the perspective of telemedicine end users**



The large-scale telemedicine pilot project [RENEWING HeALTH](#) entered its third year of implementation in 2012. The purpose of RENEWING HeALTH is to implement multi-site randomised controlled trials for evaluating telemedicine services for patients suffering from three of the most common chronic conditions: diabetes, cardiovascular diseases and Chronic Obstructive Pulmonary Disease (COPD). The ultimate goal is to gather evidence on the use of telemonitoring in real life settings. EPF participates as co-manager of the [User Advisory Board \(UAB\)](#).

An ad-hoc workshop was held in Treviso, Italy, in February 2012 in order to analyse data being collected in the various pilot sites. The meeting has proved to be very successful in enriching the user requirements framework through hands-on experience of end users involved in the local sites. Likewise, the meeting was reported by the local partner (Regione Veneto) as to have been very useful in helping them better understand what needs to be done in order to maximise end-users' acceptability, as one of the key pre-conditions for integrating the piloted telemedicine programmes into mainstream regional health services.

The User Advisory Board (UAB) has been busy finalising the [second version of the User Requirement document](#). This document, which is continuously reviewed and improved throughout the project lifecycle, provides for a reference framework for representing needs, constraints and expectations of end-users of telemedicine services. This second version complements the initial literature review carried out in 2010 with outcomes of two rounds of consultations. The third version will be released in 2013 and will include the outcomes of a series of local meetings with end users of the piloted telemedicine services.

A second local meeting with RENEWING HeALTH users took place in Luleå, Sweden, in June 2012. The event was attached to the 2012 [Arctic Light eHealth Conference \(ALEC\)](#) where EPF was represented by our President Anders Olauson and Senior Programme Office Walter Atzori. It helped to increase the understanding of how the telemedicine services piloted in Norrbotten are perceived by the different groups of end-users and to involve real users of the piloted telemedicine services in defining, through a bottom-up approach, the user requirement framework being developed by the User Advisory Board.





# MARCH



## **EPF on the move!**

EPF Secretariat moved in its new premises in March 2012. This was due to an enlargement of the EPF Secretariat Team to service the EPF membership and implement our work programme.

We also needed our own meeting room large enough for our on-going governance and project meetings and policy workshops. Ideally located in the EU quarter, the office is also fully accessible to patients with reduced mobility.

The EPF secretariat address is: **Rue du commerce 31 - 1000 Brussels, Belgium**

Do not hesitate to come and visit us!



## **Patient Representation at DIA EuroMeeting**

Several EPF members and representatives were present at the DIA Europe meeting in Copenhagen, as part of the DIA Fellowship Programme. It was an important opportunity to launch the EUPATI project, with a special session chaired by Anders Olauson.

The DIA EuroMeeting represents a great opportunity for patient advocates to increase their knowledge on latest drug development issues and regulatory affairs, as well as to network with high-level healthcare stakeholders from pharmaceutical industry, biotech, academia and representatives from the European Medicines Agency (EMA), the European Commission and national competent authorities.



# APRIL

## **EPF's Annual Meeting elects new board and plans a 2014-2020 strategy**

Following the European Patients' Forum's 2012 Annual General Meeting (AGM), five members of the Board were re-elected for a two year term. EPF members voted in Anders Olauson, nominated by the European organisation for Rare Diseases (EURORDIS), Susanna Palkonen nominated by the European Federation of Allergy and Airways Diseases Patients' Organisations (EFA), Tomasz Szelagowski nominated by the Federation of Polish Patients (FPP), Avril Daly nominated by Retina Europe and Philip Chircop nominated by Malta Health Network. They maintain their previous appointments as Board members of EPF and the board voted Anders Olauson as President, Susanna Palkonen as Vice-president and Tomasz Szelagowski as Treasurer. Current board members, Vida Augustiniene, Maria D. Navarro, Marco Greco and Robert Andrew Johnstone will continue their mandate for a further year.



The AGM approved several new membership requests. Europa Colon, European Network of Fibromyalgia Associations (ENFA) and World federation of Incontinent Patients (WFIP) became provisional members. EPF represents now 56 official members which are chronic disease specific patient organisations operating at EU level and national coalitions of patients organisations. The Bulgarian Association for Patients' Defence (BAPD) has been accepted as an associate member.

## **Strategic Planning Seminar**

EPF dedicated the second day of this meeting with members to a strategic planning seminar with various reflection workshops. During the course of this summer the secretariat team has been working on this material, to arrive at a draft framework document with proposals and open questions that will lead to the development of the Strategic Plan itself. It was also agreed at the seminar that EPF should set up a small working group made up of appropriate representatives of its members. They met in November to provide input and expertise to develop the draft Plan. This will then be circulated to the broader membership for wider consultation during the early part of 2013, and we will also discuss it with selected health stakeholders and allies.



## EPF's report on the rights and needs of older patients

EPF released a [report](#) in April on the outcomes of the conference on ageing organised by the EPF) and the Polish Patients' Forum (FPP) in Warsaw on 12-13 July 2011. Over 100 participants, including high-level policy makers, representatives of health professionals, patients' organisations, and older patients themselves, gathered to explore key challenges and opportunities around ageing and older patients.

Ageing is a theme of particular importance from EPF's perspective. Our activities on ageing started in 2010 when the EPF board decided to develop a strategy for the needs of older patients, with the aim of enhancing intergenerational solidarity in the patients' movement. EPF initiated work in this arena with a member consultation during December 2010 and January 2011, resulting in a strong [patients' contribution](#) to the Commission's consultation on the pilot European Innovation Partnership on Active and Healthy Ageing. The European Patients' Forum has been very closely involved in the Partnership: EPF President Anders Olauson was represented on the High-Level Steering Group, which during 2011 drafted the Strategic Implementation Plan for the partnership. The EPF Secretariat participated in "Sherpa" meetings and preparatory workshops, in which several members were also involved.



In this context, the aim of the EPF/FPP conference was to exchange experiences and insights with stakeholders at EU and national levels on how to ensure high-quality, patient-centred, equitable care for older patients, and how to face this challenge while addressing their needs, respecting and improving their rights, quality of life and dignity.

EPF is currently developing a position paper on the rights and needs of older patients, building on the outcome of this conference and our previous input into the innovation partnership and the reflection process on chronic diseases. The paper is scheduled to be published in early 2013.





# MAY

## Follow us and make **THE patients' voice loud!**

EPF launched into the social media sphere in May 2012! We wanted to make sure the patient community had the opportunity to connect with and contribute to our work, to understand the dynamics of our policy and project work on patient-centred healthcare and, most importantly, to promote unity across the EU patients' movement. The feedback we received has been very positive and we thank our followers for making these platforms alive and we hope to reach even more people in 2013.

On our [Facebook page](#) and our [Twitter account](#), you can follow us on an almost daily basis. You will find quotes, information about our attendance to events, the latest news and even pictures and videos. Keep up to date on what's happening at EPF!

The [EPF blog](#) adds more depth and richness to the communication of our work by providing contextual information and new angles to a specific policy or project area. We will welcome our members as invited guests to link their own experience as a patient organisation to our work. If you wish to contribute to our blog as an author, please contact [cynthia.bonsignore@eu-patient.eu](mailto:cynthia.bonsignore@eu-patient.eu). You can read our blog [here](#) and do not hesitate to share your own experience!

And finally we are also present on [YouTube!](#) Watch the latest footage where our Board Members reveal their plans and hopes for EPF. Keep an eye on this channel because we plan to post a lot of videos in 2013!

By launching the debate on our blog posts, looking at our videos on YouTube, becoming a fan on Facebook or following our tweets on Twitter you can make sure that you hear the latest news first on the patients' perspective on EU healthcare policy developments. This blog is for YOU. And YOU are invited to use it, to make it, to transform it! We look forward to hearing from you!







## **InterQuality: smarter financing, improved quality for patients**

How to spend money efficiently in healthcare? The [InterQuality project](#) partners held a meeting on 24-25 May in Italy to pave the way of the answer. Launched in December 2010 and led by the Medical University of Warsaw, the project intends to develop scientifically validated tools to help decision-makers choose the right financing mechanisms in different areas of healthcare systems. The meeting was the occasion to evaluate the results until now and to focus on theoretical deliverables.

As one of the nine associate partners, EPF leads the dissemination of the project's progress and results in close cooperation with CPME – the Standing Committee Of European Doctors. At the meeting, EPF presented the last dissemination tools: [newsletters](#), a [leaflet](#), an updated [project website](#), first interviews for a project documentary to be presented at the final conference, collaborative work with partners.

The next steps for EPF are the development of communication strategy guidelines on the implementation of innovative healthcare financing models. The final role of EPF will be the organisation of the project's final conference in late 2013.

More information about the project and to subscribe to the newsletter: [www.interqualityproject.eu](http://www.interqualityproject.eu)





## EPF response to chronic diseases consultation stresses patients' central role



The spotlight is very much on chronic diseases, both at EU level and globally. Tackling chronic diseases is seen as a key requirement for the sustainability of European health systems. From EPF's perspective, this must involve not only greater attention to prevention and health promotion, but also fundamental changes to the way healthcare is delivered. Health systems must become more efficient and, importantly, genuinely patient-centred.

EPF responded in May 2012 to the European Commission's stakeholder consultation, having previously contributed to the [response of the EU Health Policy Forum](#) (EUHPF), of which EPF is a member. [EPF's paper](#) submitted in response to the stakeholder consultation focuses on the role of the healthcare system, equity of access, quality of care, patient involvement and patient empowerment. EPF believes that healthcare reforms need to focus on providing high quality care that meets patients' needs and results in concrete improvements in people's quality of life – not become a byword for cuts in healthcare budgets.

Chronic disease strategies and reflection on healthcare systems sustainability is a crucial area where patients can and must contribute: *"The patients' perspective on chronic disease is unique: patients live with their disease, learn to manage it, and to navigate the health system to get the right care. This is why we believe that patients play a key role in identifying unmet service needs, pointing out inefficiencies and waste in the system, and ensuring that strategies to address chronic disease are effective and sustainable"*, explained Kaisa Immonen-Charalambous, EPF Senior Policy Adviser.

Following a request by the Council in its Conclusions on "Innovative approaches for chronic diseases in public health and healthcare systems", adopted on 7 December 2010, the Commission launched a reflection process on chronic diseases in early November 2011. The reflection process aims to produce an EU strategy on chronic diseases, focusing on the sustainability of health systems. The process is likely to conclude during the first part of 2013.



## The European Union Network on Patient Safety and Quality of Care is up and running!



The “European Union Network on Patient Safety and Quality of Care” or “PaSQ” Joint Action (JA) officially started with a kick-off conference in Denmark on 24-25 May. This three-year Joint Action is led by the French Haute Autorité de Santé (HAS) and EPF as an Associate Partner is actively involved in several key work packages. The overall aims of

the project are to support the implementation of the [Council Recommendation on Patient Safety](#) (2009) and to create a permanent platform for future cooperation between Member States in the area of patient safety and quality of care.

EPF's role is particularly important as one of the specific objectives of the Joint Action is to promote patients' empowerment and patient involvement in patient safety and healthcare quality. Our tasks in the work packages of the JA include the identification of existing and proven good practices in patient safety and quality of care focusing on patient empowerment and involvement, and identification of strategies for improving quality of healthcare through patient empowerment and involvement. We are also involved in building network sustainability and effective dissemination.

Since the kick off, the partners have done a lot of work to develop the detailed work plans for each work package, as well as a literature review and a Glossary and Framework. For the latter, EPF has contributed a definition of patient empowerment and involvement. E-Questionnaires have been developed to gather information on good practices in patient safety at the clinical level (WP4), as well as good organisational practices relating to quality management systems (W6). The data collection task on these questionnaires, led by EPF, is taking place during late 2012 and early 2013, and preliminary results will be discussed at the third coordination meeting, which will take place in Berlin on 14-15 January 2013 and an.

More information about the objectives of PaSQ, its work packages and a full list of partners is available on the new website: [www.pasq.eu](http://www.pasq.eu)





## A toolkit to understand the EU pharmacovigilance legislation

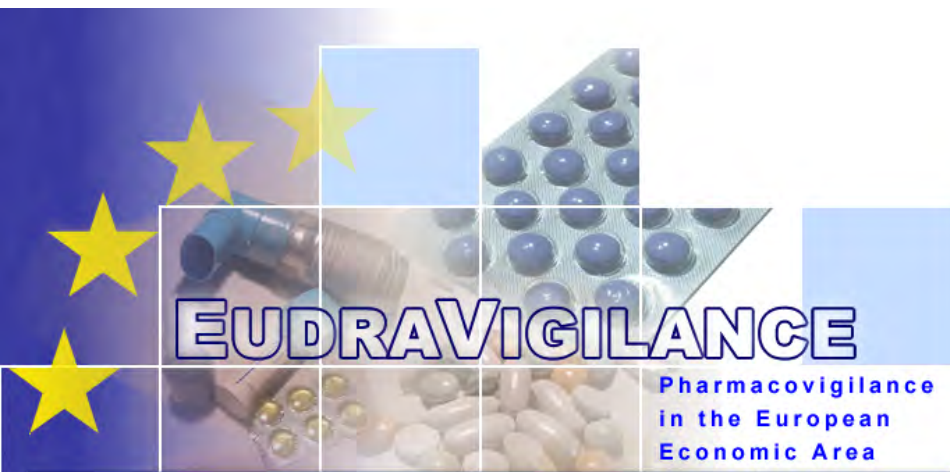
EPF has developed a “toolkit” on pharmacovigilance that includes a set of [recommendations](#) and [guidance](#) on the new EU legislative framework. Our guidance for patient organisations gives an overview of the different aspects of the new EU pharmacovigilance legislation that are important for patients. Our recommendations for a patient-centred implementation aim at encouraging the development of a strong, open and transparent pharmacovigilance system that ensures the confidence of patients, health professionals and regulators alike, throughout the EU. Through these resources, we hope to contribute to building a patient safety culture, where all actors including patients work together, and which encourages openness and transparency around adverse events to better prevent them.

Pharmacovigilance is a system designed to monitor the safety of medicines after they have been authorised to be marketed and used in parts or in the entire EU. It plays an important role in public health and protection of patients’ safety. One essential pillar of pharmacovigilance is the reporting of side effects of medicines (or adverse drug reactions) by patients to their healthcare professionals.

EPF was very active in providing a patients’ perspective to the European Commission’s legislative proposals on pharmacovigilance, which were published in 2008 and finally adopted at the end of 2010. We participated in many internal and external debates, and worked with key stakeholders and decision-makers to ensure the final legislation would improve patient safety and the quality of medicine, as well as being patient-centred. We were successful: the new pharmacovigilance

legislation puts the patient at the centre in many ways. In particular, it obliges all Member States to put in place a system for direct patient reporting of suspected adverse drug reactions to national authorities, and it gives the public access to more information on safety of authorised medicines through the creation of national medicines websites and public access to the [Eudravigilance database](#). The new legislation also offers opportunities for patient organisations to be involved at national and EU levels. The implementation by Member States of this legislation and, we believe, the way they will engage with patient organisations, is essential to deliver on its promise.

EPF continues to be active in the implementation of this legislation, for example through our involvement with the European Medicines Agency and participation in a number of stakeholder seminars and other events.





# JUNE

## EPF advocates a patient perspective on the “Health for Growth” proposal



In June, EPF liaised closely with MEPs on amendments to the [European Commission’s proposal](#) for a health programme 2014-2020, titled “Health for Growth”, published in November 2011. EPF has been vocal in giving input in the run-up to the publication of the proposal, both independently and jointly with the European Public Health Association (EPHA).

The main concern of the “Health for Growth” proposal is to support Member States in adopting innovative solutions in health and prevention that will contribute to the sustainability of health systems; and in implementing EU health legislations.

EPF proposed a number of amendments to the Commission’s proposal, focusing primarily on health inequalities, patient empowerment and health literacy. *“We believe a strong recognition of the fundamental European values of solidarity and equity is particularly important in the current financial climate. The concept of “European added value” should include the potential for achieving key social objectives, such as the reduction of health inequalities as well as patients’ and citizens’ empowerment”*, said Kaisa Immonen-Charalambous, EPF Senior Policy Adviser. Many of our amendments were taken on board by the ENVI Committee in its June vote.

Patients’ empowerment in particular is a crucial strategy for creating future health systems that are responsive to the needs of citizens and to deliver high-quality and equitable care in a sustainable way. Improved health literacy is a key empowerment tool and may have substantial impact on reducing healthcare costs. But empowerment also needs to be tackled from a systems perspective, through implementing principles of patient-centred healthcare and facilitating patients’ and their representative organisations to be involved at all levels of healthcare policy-making.

The future EU health programme will provide a framework for the annual work plans of the Commission and the actions prioritised in the field of health. It will therefore have a direct or indirect impact on patient communities across the EU.

For more information about the European Parliament draft report (April 2012), [click here](#) and about the Europe 2020 Strategy, [click here](#). To read the joint letter of EPF-EPHA, [click here](#).

## Health and the life continuum from a gender perspective

EPF was proud to partner with the [European Men's Health Forum \(EMHF\)](#), the [European Cancer Patient Coalition \(ECPC\)](#), and the Danish Men's Health Society (MHS), to organise a landmark conference on Gender and Health Through Life on 14-15 June in Copenhagen, Denmark. The conference was supported by the Danish Ministry of Gender Equality and was attended by over 270 participants from over 30 countries.

EPF Vice President Susanna Palkonen gave a presentation that focused on the gender dimension of patient-centred chronic disease management. She made reference to the [EPF Value+ Handbook](#) which aims at facilitating patients' involvement in European projects: *"Gender should definitively be considered in relation to health. Women and men should be treated equally wherever they have common needs. At the same time, their differences should be addressed in an equitable manner."*

Nicola Bedlington, EPF Director chaired a number of sessions and also participated in a special 'mock trial' on ageing that stressed the importance of valuing older people, regardless of their health status, and their contribution to society.

The conference closed with a resume of the recommendations collected during the two day session from Dr Ian Banks, President of the European Men's Health Forum and member of the EPF Policy Advisory Group. He concluded: *"If we ever needed confirmation that women's and men's health organisations need to work more closely together for the benefit of both sexes then this conference supplied the evidence by the bucketful."*

EPF will continue to engage with EMHF and the European Institute for Women's Health to support gendered health policies, from our perspective representing patients already diagnosed with a chronic disease and the gender specific research, information, treatment and support that this implies.

For more information – please contact [Ian Banks](#) at [ian.banks@emhf.org](mailto:ian.banks@emhf.org).







## **Three reports to shape patient involvement in HTA**

Health Technology Assessment (HTA) is a multidisciplinary tool that ideally should involve patients' perspectives; however, in reality there is still a long way to go in achieving meaningful patient involvement in HTA. EPF has released three consecutive reports to help patients gaining a foothold in the HTA process.

Three reports, three different stakeholder groups: HTA agencies (first stage), HTA appraisal committees/policy makers (second stage) and patient organisations (third stage). Through surveys and discussions, EPF collected the views, needs, ideas and expectations of these stakeholders in order to shape the role and scope of patient involvement in HTA processes.

All the reports and more information are available [here](#).

The final step will be a comprehensive report that will integrate the results of all phases and therefore a complete overview of the three stakeholder groups. The aim is to provide an as accurate as possible state of the art picture of patient involvement in HTA in Europe.

For more information, please contact [Liuska Sanna](#), EPF programme manager.



## EPF takes a stand on the Professional Qualifications Directive



Health professionals' skills have a direct impact on patient safety and are of great concern for the patient community. Ensuring that healthcare professionals have the right training, and are fit to practice when they move from one EU Member State to another is of crucial importance for safety and quality of care. This is the reason why EPF released in June its [position statement](#) on the European Commission's proposal to review the [Directive 2005/36/EC](#) governing the recognition of professional qualifications.

Healthcare professionals are the most mobile category among the regulated professions in the EU and their mobility is likely to increase in future. Mobility of the health workforce can help balance workforce shortages and surpluses, and lead to exchange of good practices across Europe. But there is also a potential risk to patient safety and of increased health inequalities, if quality standards for healthcare are not assured. EPF called for several changes to the proposal, to make patient safety a priority over internal market considerations. This includes clearer provisions on the checking of the language competences, the verification by authorities of healthcare professionals' fitness to practice, the alert mechanism between competent authorities to extend to fraudulent diplomas, and the inclusion of patient involvement in identifying healthcare service needs.

EPF has welcomed the opinion adopted by the Environment and Public health committee (ENVI) of the European Parliament on 8 November 2012. It takes on board many provisions we had advocated for in our [position statement](#) and our letter to MEPs in ENVI. EPF will strongly support the amendments proposed by the ENVI opinion in the plenary vote on the review of the Professional Qualifications Directive in 2013. The ENVI opinion is accessible [here](#).

In January 2013, the Internal Market and Consumer Protection (IMCO) Committee will vote on the draft report of MEP Bernadette Vergnaud (S&D, France) and the 700 amendments tabled by MEPs in October (accessible [here](#)). EPF sent a letter to members of the IMCO committee to support amendments and compromise that reflect our position and seek to promote higher standards of safety and quality of care in the European Union.



# JULY

## EPF to empower its members' capacity and advocacy skills

We launched our Capacity Building Programme (2012-2014) for patient organisations in July. The objective is to strengthen the organisational and advocacy capacity of both Member State and European level Patients' Organisations. The idea is to enable them to be more effective in achieving their objectives and aspirations, also in feeding their experiences and expertise into the work of EPF and utilising the outcomes of this collective work in a national, and/ or disease specific context.

EPF is leading the Capacity Building programme with the support of its national members in the various countries participating in the programme. *"The Capacity Building Programme responds to needs and concerns which have been identified by EPF membership during previous activities. With this programme we aim at strengthening the impact of work undertaken by our members and their members, which should ultimately contribute to stronger more effective patient organisations at both national and European level"*, said Liuska Sanna, EPF Programme Manager responsible for the EPF Capacity Building Programme.

30 patient organisations from Bulgaria, Hungary, and Romania and eight pan-European disease-specific patient organisations will take part in the programme in 2012. This year EPF has been working with Hungary and Romania, where 10 organisations were selected per country in collaboration with national patient coalitions, to identify their capacity needs. Based on this information, a strategic planning and risk assessment exercise will be organised at the start of 2013 and we will tailor make a programme providing training on communication, fundraising, governance, project writing and much more.

With European Organisations, EPF is running until March 2013 needs' assessment sessions with each organisation, with the objective of identifying relevant training modules including, if needed, strategic planning skills and competences.

In 2014, we will be implementing further training modules and planning future relevant activities and 'mainstreaming' the capacity building programme in other countries.







## **EPF welcomes the proposal for a new EU framework on Clinical Trials**

**EPF has welcomed the proposal for a new Regulation on Clinical Trials on medicinal products for human use adopted in July by the European Commission. The proposed Regulation will replace the controversial EU Clinical Trials [Directive 2001/20/EC](#), which, although it introduced important provisions to protect patients participating in clinical trials, has been widely perceived as having had an overall detrimental effect on the conduct of clinical trials in Europe.**

The draft Regulation proposed by the Commission is an important step in the direction of a much needed simplification and standardisation of clinical trials administrative processes. Indeed the legal form of a Regulation provides an important harmonising effect as it will eliminate the need for transposition into national laws and will enable the planning and conduct of clinical trials, including multi-national ones, on the basis of one common regulatory framework, rather than on the basis of a “patchwork” of 27 national frameworks.

In addition the Commission proposes a more risk-adjusted approach that, while continuing to uphold patient safety, aims to tailor regulatory requirements more accurately to the actual risks of a trial (e.g. depending on whether a trial is to test a completely new medicine or one that has already been approved ). Patient safety is paramount to EPF; similarly, the effectiveness of the clinical trials framework throughout the EU is of fundamental importance, as ultimately it impacts on the development of new and improved treatments responding to unmet medical needs. A good regulatory framework therefore incorporates and balances all relevant stakeholder inputs and expectations, holding these in a creative tension, not an overly rigid, stifling framework.

EPF has been consulting its membership on the proposal during the second semester of 2012. We also organised an internal workshop on 13 December 2012 to enable our members to exchange views on the draft regulation and to address specific questions raised by this proposal to representatives of the European Commission that were attending the discussion. Following this consultation, we will finalise a formal position statement. EPF has also worked closely with key MEPs in the responsible Committees, attending several meetings and workshops, and proposing amendments to the Commission’s proposal in line with our priorities.

Previous EPF position statements and consultation responses are available [here](#).





## A toolkit to understand the Cross-Border Healthcare Directive

EPF sees in the Cross-border Healthcare Directive the potential to reduce health inequalities for patients in access to healthcare. In July 2012, we developed the EPF “toolkit”, including a [set of recommendations](#) and [guidance](#) on the Directive to help you make your way through it.

The purpose of the [guidance](#) is to provide basic information about the Directive’s content, and the rights it provides to patients. It also aims at highlighting areas where patient organisations can contribute to the implementation of the Directive at national level. This guidance document will be regularly updated as new information on the implementation of the rules becomes available.

The [set of recommendations](#) aims to provide the authorities and bodies in EU Member States tasked with the transposition and implementation of [Directive 2011/24/EU](#) with advice to ensure that this Directive, as intended, brings tangible benefits for patients and represents a step forward for high-quality, safe, equitable, patient-centred healthcare throughout the Union.

At EPF, we believe that many aspects of the Directive can be built upon to achieve better quality care for all patients – such as stronger European cooperation in the crucial areas of quality and safety, HTA, eHealth and rare diseases. We will monitor closely the implementation of the Directive, including raising awareness in the patient communities across the EU on the new legislation and supporting patient organisations’ involvement at national level.

Click [here](#) to know more about our work in the area of Cross-Border Healthcare.





# AUGUST

## **EPF Youth Group to shape the EMPATHY project**

The [EPF Youth Group](#) laid the foundations of its work for the next months during its second Annual Youth Meeting in August. This year's meeting served as the springboard of the annual meeting of the Youth Group and as the kick-off meeting of the first youth project "[EMPATHY](#): Europe Meets Young Patients" where they will hold responsibilities.

The EMPATHY project will organise a four-day seminar in mid-2013 in Brussels for young patients, European policy-makers, and stakeholder actors in the fields of health, education, social and youth policy. The purpose is to promote a more holistic approach to addressing young patients' needs in EU-level decision-making processes. Thanks to this meeting, the young people acquired a better understanding of the project's objectives and their role within this youth project. They have worked at raising awareness about the project until the end of the year. In 2013, a logo will be created and an info sheet will be distributed in order to disseminate the project information locally. The Youth Group will also fix a date for the EMPATHY Seminar and identify and recruiting participants.





# SEPTEMBER

## First conference on health inequalities in the new EU Member States

For the first time a conference has addressed the challenge of health inequalities in the Southeastern region from the specific perspective of patients with chronic diseases. The event took place on 20-21 September 2012 in Sofia, Bulgaria and was initiated and organised by the Bulgarian National Patients' Organization (NPO) with EPF collaboration and under the patronage of Mrs. Desislava Atanasova, Minister of Health of Bulgaria and Mr. Andrey Kovatchev, MEP. The Croatian Deputy Minister of Health, Dr. Marijan Cesarik and Mrs. Antoniya Parvanova, MEP and officials from the Bulgarian Health Institutions were also present. Participants included European and national policy makers as well as patient leaders from the 12 new EU Member States, alongside candidate and accession countries.

The adoption of a [Resolution](#) by the participants concluded this meeting. The document recalls the importance of health inequalities as a main political priority: "The reduction of health inequalities forms a major pillar of the EU Health Strategy, 'Together for Health' and a major element in achieving the goal of 'inclusive growth' of the Europe 2020 Strategy". The Resolution reflects also the will to look at the discrepancies among the EU Member States with regard to access to healthcare and the quality of care, calling for recognition of "cultural differences in different regions of Europe and its impact on health inequalities". In their call for action, the participants urge the EU Member States, in collaboration with the EU Institutions and health stakeholders, to "recognise the alleviation of health inequalities in the New Member States and candidate countries as a political priority at European, national, regional and local levels." Finally, the Resolution paves the way for a wider debate with regard to better access to treatment and encourages interaction and collaboration among all stakeholders.



It was decided to organise a meeting in a near future on health inequalities that will convene the Ministers of Health from the new Member States and accession countries. This will be the occasion to identify and address main challenges such as immigration of highly skilled professionals and utilisation of financial resources. "The common problems of these countries imply common actions, and this meeting will provide a unique forum for the ministries of health from the region to outline these common actions for overcoming health inequalities", pointed out Minister Atanasova.



## Report “Redesigning health in Europe for 2020”

As member of the EU Task Force of high level advisors on e-Health, our President Anders Olauson [has presented the Task Force’s report “Redesigning health in Europe for 2020”](#) at the Danish eHealth Observatory's Annual Meeting on 9 September. In this report the task force has identified five levers that could create the momentum for a fundamental re-organisation of healthcare to make use of already existing information technologies:

- **“My data, my decisions”**: patients are the owners and controllers of their own health data, with the right to make decisions over access to the data and to be informed about how it will be used.
- **“Liberate the data”**: governments should ensure that health data is accurate, reliable, and up-to-date; that it is gathered in a standard way, and anonymised before it is made available to anyone that can add value to it in the best interest of the patient.
- **“Connect up everything”**: the digital environment is evolving rapidly with an increasing trend of interaction and sharing. Healthcare needs therefore to reap the benefits of the digital age in order to provide more integrated and personalised care to patients rather than “only” interventions.
- **“Revolutionise health”**: By that we mean creating the necessary conditions for patients to be able to make more informed choices about where and how we want to be treated. This will have real impact on resource allocation in health, as funding follows the patients and not the other way round.
- **“Include everyone”**: the needs of the vulnerable communities that are outside the reach of eHealth tools need to be accommodated otherwise chances are that eHealth could ultimately exacerbate existing inequalities rather than reducing them.

On the basis of these five levers the Task Force has formulated **five recommendations for action** to support their vision of health in 2020. These are addressed to policymakers at the European and national levels.

Anders Olauson concluded his presentation in calling the audience’s attention to the importance of focusing on patient acceptance in eHealth. “Although key to fostering eHealth uptake user acceptance is too often disregarded in discussions around eHealth strategies and policies. EPF is firmly convinced that the only way for eHealth solutions to work effectively is ensuring acceptance by the people who will eventually use them.”





# OCTOBER

## **EPF takes a stand on the EU Transparency Directive**

National measures on pricing and reimbursement of medicines have a direct impact on patients' access to therapies. This is why on 1 October we released our [position statement](#) on the so-called Transparency Directive ([Council Directive 89/105/EEC](#)). Overall, EPF welcomes the Commission's proposal as it marks a step forward for more transparent and effective processes. However, further steps are needed to strengthen good governance and improve patients' access to therapies.

The Transparency Directive sets rules for the administrative procedures relating to pricing and reimbursement decisions at national level. While Member States remain responsible for setting national pricing policies and conditions for reimbursement, the Directive provides a harmonised framework to ensure a timely and transparent decision-making process.

Delays in access to medicines, and therefore in treatment, have a long-term economic cost to society and lead to deterioration of health and reduced life expectancy for the patient. The wide divergence in affordability and accessibility of medicines across the EU is a main factor behind health inequalities. In this context, EPF welcomes measures for shorter time limits to take decisions, and the inclusion of all necessary steps in the time limits in which decisions should be made, including conduct of Health Technology Assessment. We also welcome the provisions that aim at bringing clarity to the assessment process.

However EPF considers that key elements are missing from the Commission's proposal, namely stakeholder involvement and real transparency: the concept of "transparency" is now understood to apply much more widely than at the time the Directive was adopted. Citizens have a right to know what decisions are taken, by whom and with what criteria.

The proposal has been voted in Committee in November 2012 and is scheduled to be voted in plenary in January 2013. The deliberations are expected to continue into the Irish presidency in 2013.



## How can we resource patient organisations in times of austerity?



The [Fifth EPF Regional Advocacy Seminar](#) took place in Lisbon, Portugal on 25-26 October 2012. The theme of this year's seminar was "Fundraising: Resourcing Patient Organisations for a strong Patient Movement". It has been a good opportunity for patients' organisations to learn how to diversify their funding in order to maintain their capacity and effectiveness to advocate for patient' rights.

In this climate of crisis and austerity it is of utmost importance that Patients' Organisations achieve financial sustainability. The overriding question of the EPF seminar organised in collaboration with Associação Protectora dos Diabéticos de Portugal (Diabetes Association of Portugal) was: "where to find the resources?"

The panellists emphasised the need to **diversify their sources of funding** in order to achieve financial sustainability. They felt it is also very important for patient organisations to invest in individual donor programmes and have inspirational and innovative ideas for fundraising. Finally, they pointed out to the need for ongoing evaluation in order to measure the efficiency of the fundraising activities carried out.

The report of the seminar will be published as toolkit in 2013. It will provide a detailed overview of the key discussions and outcomes as well as some tips and suggestions for patient organisations that want to increase their fundraising capacity.

The presentations of the seminar are [available here](#).



## The European Health Policy Forum Gastein

The 15th edition of the European Health Policy Forum Gastein has closed its doors at the start of October 2012. The focus was on “Crisis and Opportunity – Health in a time of Austerity”. This topic is crucial for EPF as the economic crisis and austerity measure are affecting patients and their rights negatively.

Our President, Anders Olauson, took part in a plenary session entitled “What will European society look like in 2050” and, at the conclusion of the event, he outlined five key avenues of an effective empowerment strategy in order to face the health challenges of 2050. He framed these around the kind of society we want, the values we wish to uphold.

1. Promoting **health literacy** is a key strategy to equip patients with the knowledge and skills needed to take an active role in managing their health and healthcare.
2. There is a need for an overarching strategy at EU level on **information to patients**.
3. Patients must be involved in the **innovation process**, whether for low tech and high tech solutions, to ensure we invest our resources where there is added value and for innovations that take up with the end users.
4. An integrated, **holistic approach** is needed to address multi-morbidity throughout the “patient journey”, involving all the different services and care providers.
5. The last element is an **enabling healthcare environment**, whereby the principles of patient-centred healthcare are consistently embedded and applied.



In the EPF vision for the the future of healthcare, health care delivery systems, health care professionals and other relevant stakeholders shift dramatically their perspective and no longer consider the patient as being the problem, but consider the patient as a crucial part of the solution.

EPF also held our own event, sponsored by SANOFI, ‘Investing in Health, Creating Equity and Wealth’.

The details of the meeting are compiled in a [report](#) called “Investing in Health, Increasing Equity and Wealth”. For more information about the event, please go on the website: [www.ehfg.org](http://www.ehfg.org)





# NOVEMBER

## 4<sup>th</sup> Patients-Med Tech Dialogue Meeting 21 November

EPF attended the fourth, already well-established, get-together of representatives of patients' associations and the [MedTech](#) industry on 21 November 2012. Several EPF member organisations as well as [EUCOMED](#) and some of their member companies attended the meeting.

This event provides a constructive platform of exchange between patients' organisations and the MedTech industry. It was extremely productive, exploring specific actions to encourage a more patient centred approach in the industry, in the light of EUCOMED's new strategy. It was also the occasion to explore the need for instruments of conduct between patient groups and the medical devices industry. Such instrument could take a number of forms i.e. Guiding Principles, Code of Conduct, Code of Ethics, Code of Good Practice, Collaboration Model, etc.

"Transparency and independence are a prerequisite for effective cooperation between patients groups and industry. This is not only because of rightful strong public scrutiny but because this is the right thing to do and the most effective way to work" said Nicola Bedlington.

A steering group has been set up to take these issues forward in between the twice yearly Dialogue meetings.





# DECEMBER

## Chain Of Trust: the end of the telehealth project



**2012 ends with the closing of the ambitious EPF-led project Chain Of Trust started in January 2011. A [final conference on 24 January 2013](#) will share the main project findings and recommendations with the wide range of stakeholders as well as future strategies to take these forward. This will also be the occasion to increase awareness in telehealth services and the user perspective.**

The Chain Of Trust Project looked at assessing the perspective of the main end users of telehealth services across the EU to see whether and how views have evolved since the initial deployment of telehealth and what barriers there still are to building confidence in and acceptance of this innovative type of services. The paramount objective was to advance the empowerment of patients and health professionals in their understanding and effective use of telehealth services.

“After almost two years of intense work we are extremely satisfied and proud of the wealth of knowledge on user perspective we have managed to put together through this project. We hope this knowledge will make an important contribution towards more user-centred telehealth policies and services”, concludes Liuska Sanna, manager of the project.

You can already read the preliminary outcomes of the project [online](#).

## **EPF publishes its position on Data Protection**

**Patients' fundamental right to protection of their personal data is an important issue in many different contexts. EPF released on 10 December its [position statement](#) on the European Commission's proposal for a Regulation on personal data protection. This will ensure the patient's voice is heard in debates on the use of patients' health and genetic data in healthcare and research.**

Patients' health and genetic data are sensitive information, which requires a high level of protection to ensure they are not unnecessarily disclosed. At the same time, the smooth sharing of these data is absolutely crucial for the good functioning of healthcare services, patient safety, and for advancing research.

EPF welcomes in principle a stronger and more coherent framework for the protection of personal data. Our key concern is that the right balance needs to be reached between ensuring confidentiality of data on the one hand, and allowing their availability and sharing for public health, healthcare and research purposes on the other hand.

We strongly recommend that the EU institutions ensure those individual rights which apply to patients – the right to access one's personal data, to transparent information about processing, and the right to object or to erase data – are effectively implemented, with patient-friendly information and transparent processes.

EPF also calls for more cooperation between Member States on minimum security requirements to ensure an equivalent level of protection of personal data shared by patients across the European Union, and to facilitate cross-border healthcare and research.

MEP Jan Phillip Albrecht (EFA/Green, Germany) is expected to release his draft report in January. It is then forecasted that the Civil Liberties, Justice and Home Affairs (LIBE committee) will vote on the report in March or April (provisional information).



# **Season's Greetings**

**The EPF Board and Secretariat wish you all the very best for the Festive Season.**

**We hope you have a restful and happy break with family and friends, and we look forward to working together with you again in 2013.**

**The EPF Secretariat & EPF Board**