

EPF Mailing

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Dear EPF Members and Allies,



“Meaningful involvement of patients” has been EPF’s mantra since our establishment back in 2003. How does EPF as an organisation involve meaningfully the whole spectrum of patients affected by diseases and conditions in our governance and in our daily work? We had the opportunity at our Regional Advocacy Seminar in Budapest a few weeks ago to

address this in relation to the involvement of young patients within EPF. Half of the seminar participants were young patient leaders from different parts of Europe, and a dedicated workshop took place with them to explore the development of a youth strategy for EPF. This built on the work undertaken in Sweden two years ago, on behalf of EPF, by a group of young patients there that identified some of the key challenges ([Young Patients’ Perspective project](#)). Read about the outcomes of our event in Budapest and next steps in this issue’s [Special Feature](#).

Looking forward, in 2011 our conference under the patronage of the Polish Presidency will address the specific needs and rights of older patients, and how to include this perspective more explicitly in our work. An important backdrop to this is the recently launched EU Innovation Partnership on Healthy on Active and Healthy Ageing in which EPF will be involved (See [section 13](#)).

This autumn is a milestone for a number of health related legislative proposals. Go to [section 2](#) for an update on our dossiers on Information to Patients and Patients’ Rights in Cross Border healthcare. EPF’s own event under the patronage of the Belgian Presidency on 1st December will be a salient reminder to policymakers of the importance of the Directive on Cross Border Healthcare, and the deal breakers from our perspective.

This issue also reports on EPF’s work at the European Health Policy Forum Gastein, where we were involved in sessions on transparency, health literacy, personalised medicines and a football match! (Read more in [section 8](#)), and our presence at the Ministerial Conference on Chronic Diseases under the Belgian Presidency in October, and its follow up at Council level ([see section 11](#)).

Finally, it is our pleasure to share with you other on-going policy and project developments and representation work over the last few weeks. As ever, we thank you for your contributions, comments and input to all of our work. This is invaluable as we prepare our work plan for 2011 and beyond.

Warmest Greetings
EPF President Anders Oluson
EPF Director Nicola Bedlington

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1. EPF's Regional Advocacy Seminar for Patient Leaders



On October 25-27 EPF held a regional seminar for 50 patient leaders from Hungary, Slovakia, Czech Republic, Bulgaria, Slovenia, Romania, and Italy. The Seminar took place in Budapest and was co-hosted by the Hungarian Osteoporosis Patient Association (HOPA).

We were particularly pleased to welcome Hungarian Secretary of State for Health Dr. Miklós Szócska who gave an overview of the upcoming Hungarian EU Presidency said, "We wanted to propose a topic that would start with patients". This is a clear indication that patient-centred healthcare and patient involvement are at the core of Hungary's Presidency approach to health. (More details in the next issue of the Mailing). EPF will work closely in the coming months with the Hungarian Presidency to continue

integrating effectively the patients' voice in the Presidency's EU health priorities.

The full Seminar report will be available shortly, however we wanted to provide a few highlights of the main issues that were tackled and some key outcomes that took place during the seminar.

This year's seminar had the following objectives:

- Promoting stronger involvement of young patients within patient organisations in order for them to become effective advocates
- Strengthening capacity building for patient organisations' leaders on how to work and get involved in EU-level policy-making.
- Brainstorming on an EPF Youth Strategy with the youth representatives



Involving young patients

The first day of the Seminar was dedicated to addressing the first objective, by looking particularly at challenges and benefits of involving young patients in patient organisations. The discussion was enriched by concrete examples and experiences from different patient or youth-focused organisations which have been very successful in actively integrating young people in their activities as well as in their governance structures. The main issues emerged during the morning debate were then taken forward for further discussion within the small-group workshops held in the afternoon.

The key aspects which emerged in relation to this theme are briefly summarised below.

Empowerment of young patients: Both speakers and participants acknowledged that we need to invest in young patients' skills and competences if they are to become empowered partners in healthcare. In this respect, more work is needed to understand the capacity of a young person by looking beyond the age factor, and rather look at the individual, social and legal context of youth. In empowering young patients, parental involvement is key. The challenge is, however, to get the balance right between young patient's autonomy (autonomous decisions) and protection. Inter-generational interaction needs also to be further explored. The aim should be to move from determination by adults towards more self-determination by young people.

Learning how to listen to young patients: A major challenge for patient organisations is to learn how to listen to young patients but also to help young patients themselves better understand the perspective of experienced patient leaders. This is a key aspect in developing inter-generational partnership. Stigmatisation is a major barrier to young patient involvement in patient organisations. A major challenge not only for patient organisations but for societies as a whole is to find ways to help young patients to overcome this





barrier by motivating them and offering an environment where they can feel protected and feel they can realise their ambitions.

Youth-oriented health care: There are few youth-friendly health services. Also, there is often no appropriate health information available specific to young patients' concerns, nor about their rights. At a political level, there needs to be more investment in youth-friendly services and policies for young patients.

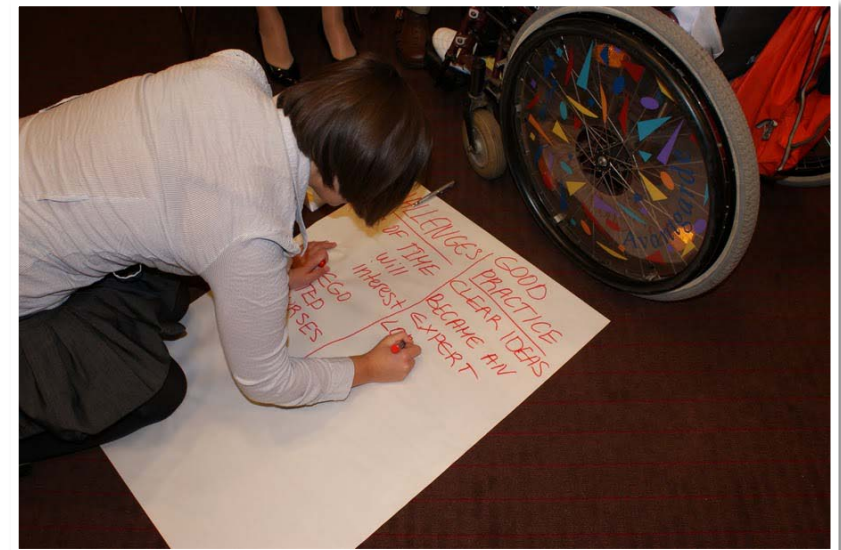
Strengthening capacity building

The second day looked specifically at capacity building for patient organisations' leaders. Particular emphasis was placed on understanding how the EU healthcare policy-making process works as well as on the strategic importance for patient organisations to join forces and work together in national coalitions.

For patient organisations, there are important benefits to working in a national coalition such as the increased ability to influence and participate in legislative matters affecting health and social welfare and the key opportunities to learn from each other and exchange good practices. Some participants highlighted that the overall conditions of chronic patients in their country improved significantly after the establishment of a national coalition because of the increased ability of patient groups to get involved in the decision-making at national level.

There are, however, some major challenges associated with establishing national platforms such as the need to identify common issues which are relevant for all patients and motivating patient organisations to work together.

The two speakers invited to present their experience of working in a national coalition highlighted how with good leadership and strong commitment these challenges can be overcome. This has been proven through the remarkable achievements of many national coalitions in various EU countries. The third day was dedicated to young



representatives only, who participated in an-hoc working session the main purpose of which was to lay the foundations for a youth strategy which EPF will draft in the near future.

As EPF Treasurer Mr. Timo Nerikko explained in his introductory key note speech, although it was the third time that EPF organised a regional advocacy seminar, this was the very first event bringing together young and more experienced patient leaders. This represents a new milestone in EPF's history. EPF now needs to build upon the outcomes of this seminar and take concrete action in order to better advocate for young patient needs.

The seminar's programme and all presentations are available [here](#).

For more information please contact [Liuska Sanna](#).

EU Policy Update

2. Pharmaceutical Package

Pharmacovigilance: draft Directive shortly to become law

As we reported in the last issue of this Mailing, the [draft Directive on Pharmacovigilance](#) was endorsed by the European Parliament on 22 September. It is expected to be formally adopted by the Council and published in the Official Journal of the European Union early in the new year, after which it must be implemented by all the Member States. The new legislative proposals (a Directive and corresponding Regulation) will amend the existing legal framework, namely [Directive 2001/83/EC](#) and [Regulation EC No. 726/2004](#).

EPF welcomed the new provisions, which largely reflected our input and will significantly strengthen the pharmacovigilance framework of the EU. We are particularly pleased that patients will be given several options for reporting of suspected adverse events, including directly to the national competent authorities.

On the eve of the Parliamentary vote, on 15 September, EPF jointly with PGEU (the Pharmaceutical Group of the EU, representing community pharmacists) organised [a joint event in the European Parliament](#) to present various stakeholders' views on the new pharmacovigilance rules, and focusing especially on the role of patients and pharmacists in the reporting of adverse events. A full report of the seminar is available on the [EPF website](#).

Eudravigilance Users' Group starts its work

[Eudravigilance](#) is the centralised European database of adverse reactions related to medicinal products authorised in the European Economic Area (EEA), and those subject to clinical trials. The Agency is now in the process of implementing an Access Policy, with the aim to increase transparency and make information about adverse drug reactions proactively available to healthcare professionals, research organisations, industry, as well as patients and general public ([see previous issue of this Mailing for a brief background](#)).

The objective of the Eudravigilance Users' Group is to prepare the practical implementation of the Access Policy. The Group will define, jointly with the Agency and the EudraVigilance Expert Working Group, the requirements on how to best implement the policy to meet the needs of the different target groups and make available as much information as possible while respecting the protection of personal data.

EPF is represented in this group together with other stakeholder organisations, who will work together to ensure that Eudravigilance will meet the real-life needs of patients and the public, to ensure the web interface is easy to use, and that appropriate guidance and instructions will be made available to enable users to interpret the information they extract from the database.

The Group held its first meeting on 28 October in London, where a first discussion took place and some first comments were made on the draft Access Policy. The next meeting will be held in December 2010 or January 2011 and look in more detail at the technical aspects of how the data will be presented.

The publicly available version of the Eudravigilance Access Policy is available [online through this link](#).

Information to Patients

(Proposal for a Directive on Information to the General Public on Medicinal Products Subject to Medical Prescription)

In previous issues of this Mailing we have reported extensively on EPF's work with the European Parliament, and the progress of this legislative proposal. On 28 September, the ENVI Committee adopted [the report](#) of Mr Fjellner MEP, with several amendments. EPF broadly welcomes the report. We have worked intensively with the Rapporteur on this dossier, and we are pleased to see the extent to which our arguments are reflected in the text.

Key provisions

The Rapporteur recognises that patients and citizens have a right to access, in their own language, to high-quality, non-promotional information on medicines. While national competent authorities and health professionals should remain the main source of information, Member States and the Commission must make more efforts to facilitate access to high-quality information. Pharmaceutical companies ("marketing authorisation holders") may be an additional source of non-promotional information on their products, and the Directive seeks to define what information, under what conditions and through what channels, companies may make available.

The ban on advertising of prescription medicines to the public is maintained. Information must not be disseminated actively to the public by the company; it must, however, be made available to the public if they wish to proactively seek information. The types of medicinal products that fall under this legislation are all prescription-only compounds or therapies, including homeopathic or herbal medicinal products if they are prescription-only.

What information will companies be able to make available?

Companies will be obliged to provide the most recent version of the documents that have been approved by the competent authorities (national or EMA) in the course of marketing approval – i.e. the Package Leaflet (PL) and labelling, the Summary of Product Characteristics (SPC), and the public version of the assessment report.

Other information that may be made available by companies is limited to a specific list and must be pre-approved by the competent authority that granted the marketing authorisation. Such information can include prices, pack changes, adverse-

reaction warnings, environmental impact, and instructions for use. Companies will also be allowed to answer questions from members of the public regarding specific products.

No information may be provided by companies via television, radio, newspapers, magazines or similar publications. Companies would be able to make available the permitted types of information using three channels only:

- I. Dedicated Internet websites registered by the companies and monitored by the Member States where they are registered. These websites will include clear notices that they are developed by a company and are subject to monitoring.
- II. Answers to specific requests for information about a medicinal product by a member of the public
- III. Printed materials containing the information defined above

Patients as the consumers will have the option to notify authorities if they come across information they consider inappropriate or misleading.

[Read more...](#)

3. Patients' Rights in Cross-Border Healthcare

Background: EPF's work in the European Parliament

Cross-border healthcare has been among EPF's core policy dossiers since 2008. We were successful in incorporating a patients' perspective in the text adopted by the European Parliament in the first reading in April 2009. We continued this work with the new Rapporteur appointed for the second reading, Mrs Françoise Grossetête MEP, and we were pleased to see that her Draft Recommendation for the second reading reflected our key points to a great extent and was clearly based on the principles of universality, access to good quality care, equity and solidarity.

The Council's position

The Council reached a political agreement in June 2010, and adopted a [common position](#) in September 2010. This reflects Member States' various concerns, but is not very satisfactory from a patients' perspective as it ignored the Parliament's position on many

important issues. The Council is also still divided on the dossier, with Poland, Slovakia and Portugal voting against the proposal, and Romania abstaining. The Council is expected to consider the proposal again on 6 December.

Latest developments

On 27 October, the ENVI Committee adopted the [Draft Recommendation](#) of Mrs Grossetête almost unanimously (only two votes against and one abstention). There were 227 amendments tabled, and six consolidated amendments. EPF had sent its [position](#) to all ENVI members on 22 October.

While EPF has not yet published an official position regarding the outcome of the vote in the ENVI Committee, we are pleased Mrs Grossetête's recommendations have largely been taken on board. We are also pleased that our collaborative work with EURORDIS on behalf of patients with rare diseases, and our insistence on finding alternatives for upfront payment, are reflected in the result:

- The reasons for which Member States of affiliation can refuse prior authorisation are restricted to cases where the patient is not affiliated to the social security system or is exposed to a safety risk that cannot be considered acceptable. Once prior authorisation has been granted, a Member State may not refuse to reimburse the patient.
- MEPs encourage Member States to avoid upfront payment by patients, seeking alternative arrangements such as direct contact between the relevant authorities, or payment by the social security systems of the Member States (already in place regarding Regulation 883/2004/EC for the coordination of social security systems). If a patient would have to pay upfront, MEPs say they should be reimbursed in a reasonable time-frame.
- Another consolidated amendment resulted in a compromise on patients with rare diseases, who will be entitled to seek healthcare in another Member State and to be reimbursed, if the diagnosis or treatment in question is not possible in their own country. However, this will be subject to prior authorisation.

Next steps

EPF recognises the need to reach a compromise with the Council in order to take the draft Directive forward, but we are concerned that these key issues should be maintained and the focus of the Directive should remain on patients' needs. We will continue to advocate our [core issues](#) with the MEPs, who are due to vote on the dossier in the plenary session on 17 January 2011. We will also send a strong message through the [EPF High-Level Roundtable event](#) to be held in Brussels on 1 December, on the eve of the Council session.

The Council's common position is available online at:

www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/116482.pdf

The European Parliament dossier can be accessed online at: www.europarl.europa.eu/oeil/file.jsp?id=5661632

EPF's position of 22 October can be accessed through [this link](#).

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

4. Work with the European Medicines Agency - Clinical Trials in Third Countries

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

Earlier this year the EMA launched a public consultation on the [Reflection Paper](#) on the "Ethical and GCP Aspects of Clinical Trials Conducted in Third Countries for Evaluation in Marketing Authorisation Applications for Medicines for Human Use, Submitted to the EMA" prepared by the working group. EPF consulted its Policy Advisory Group and its membership before submitting its response to EMA on 30 September. We also worked closely with IAPO.

In summary, EPF welcomed EMA's efforts to develop practical guidance regarding the ethical standards of clinical trials outside the EU. There are still areas where further improvements are needed, particularly regarding patient involvement in all aspects of clinical trials; comprehensive and good quality information to patients and their families; how to make the process of informed consent really meaningful, with specific strategies regarding individuals or groups in vulnerable situations; and transparency of the process and outcomes. EPF's feedback is available to [read online](#).



The working group gathered for a second meeting on 8 November to discuss the results of the public consultation. The outcomes of this meeting will be reported in the next issue of the Mailing.

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

Projects

5. RENEWING HEALTH 2nd Meeting of the User Advisory Board



Launched in February 2010, RENEWING HEALTH project aims to implement large-scale real-life test beds in nine European regions for the validation and subsequent evaluation of innovative telemedicine services for patients suffering from chronic conditions, notably diabetes, cardiovascular diseases and chronic lung problems. The project uses a patient-centred approach and a common assessment methodology (MAST).

As the reader may recall, EPF is involved together with EHTEL (European Health Telematics Association) in the management of the RENEWING HEALTH's User Advisory Board (UAB), the primary mission of which is to operate as a standing advisory committee to advise and provide on-going feed-back to the project team on the needs of users of the piloted telemedicine services. UAB membership includes representatives of the various groups, who are either direct - i.e. patients, informal carers and healthcare professionals - or indirect users of telemedicine services, i.e. insurers, healthcare authorities and regional authorities. All three disease areas covered by the project are well represented in the UAB.

The second meeting of the UAB was held in Brussels on November 2nd. The key feature of this meeting was the direct participation of representatives from three pilot sites located in Veneto (IT), Norrbotten (SE), and Southern Denmark. They all provided an overview of the status of the work in their respective pilot sites laying emphasis on use of MAST to evaluate user perspectives. UAB members had therefore the possibility to ask specific questions and give advice on how best to align pilot's implementation

and evaluation with the needs, requirements and constraints of the user groups they represent. Given the usefulness of this exercise the participation of representatives from the pilot sites will be strengthened in future UAB meetings.

The second part of the meeting was focused on the presentation of the approach used to develop the first deliverable of the UAB “User Requirements”. As mentioned in the previous Mailing issue, this document, which is currently being drafted, will provide a comprehensive analysis of needs, requirements and expectations of end-users of telemedicine services. Starting from collecting existing knowledge and evidence through a literature review, this document will be developed using an iterative approach whereby a first version, which will be issued in early 2011, will be continuously reviewed and improved throughout the project life-cycle on the basis of evidence gathered from the pilots and feedback provided by the members of the UAB.

The next meeting of the UAB is scheduled on February 17th in Brussels right after the third project steering committee meeting which will take place in Klagenfurt, Carinthia (AT) on 26-28 January 2011. Details on project’s future developments will be provided in the next Mailing issues.

For more information on Renewing Health please contact [Walter Atzori](#) or visit the project website at: www.renewinghealth.eu

6. CALLIOPE

On 16 November, CALLIOPE held its closing event at the European Parliament hosted by Milan Cabrnoch, MEP. CALLIOPE is the European platform for eHealth interoperability, jointly supported by more than 20 Health Authorities and 13 stakeholder organisations representing physicians, community pharmacists, patients, industry and health insurers.

The event reflected upon the lessons learned in CALLIOPE and their linkages to the Proposal for a Directive on Patient Rights in Cross-Border Healthcare and the European Commission strategy for eHealth. One of the key outcomes of CALLIOPE is the European eHealth Interoperability Roadmap which was inherited by the eHealth Governance Initiative. MEPs, European Commission representatives and health stakeholders will have the opportunity to discuss the conclusions of and the way forward proposed by CALLIOPE.

For more information please contact [Liuska Sanna](#).

7. Joint Action in Patient Safety and Quality of Healthcare

Patient safety is a policy area where coordinated action at EU level is deemed to bring added value for Member States. A policy framework already exists, in the form of the [Commission Communication](#) adopted in 2008 and the [Council Recommendation](#) on Patient Safety adopted in 2009, and numerous projects have been done in this area including recently the EUNETPAS project in which EPF was an associate partner.

The Commission recently put forward a draft reflection paper on the quality of healthcare, which is a much more controversial area due to the lack of a common understanding of quality and the diversity of EU Member States when it comes to definitions of the concept, standards, and quality assurance.

A Joint Action was recently endorsed by the Council as a policy instrument that should be used to implement the Council Recommendation on patient safety, and take the first steps towards Member State cooperation on quality of healthcare. A Joint Action is an EU funding instrument that involves cooperation between Member States and the Commission – and in this case also a number of stakeholders' organisations.

We are particularly pleased that the importance of patient engagement and empowerment has been recognised by the Council's Working Group in Public Health at Senior Level, which specifically called for more work to be done in this area.

EPF has been invited as a partner in the Joint Action. The experience of EUNetPaS demonstrated clearly the importance of involving patients in a meaningful way, and of including primary care in the consideration of safety and quality. Currently patient involvement varies enormously, while there are good examples in some Member States, in others there is no patient engagement at all. Safety initiatives are also still quite centred on the hospital, which while important is not the only safety-critical environment.

A first preparatory meeting took place on 8 July, and the next meeting will be held on 19 November. Negotiations are currently ongoing between the Commission, the Member State representatives and the stakeholders as regards the structure of the Joint Action, its specific activities, aims and expected outcomes.

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

8. European Health Forum Gastein



From 6 to 9 October 2010 the 13th European Health Forum Gastein (EHFG) took place in Bad Hofgastein. A total of 580 participants came from 58 countries and made the Congress once again a great success. In accordance with the theme “2010 Health in Europe - Ready for the Future?” future issues of the European health policy were discussed. Main topics included themes like healthy aging, global health issues and investment in our health workforce of tomorrow.

The speakers of this year’s Forum included John Dalli, EU-Commissioner for Health and Consumer Policy, Paola Testori Coggi, Director General, DG SANCO, Alois Stöger, Federal Minister of Health, Austria and other key decision-makers from the fields of health policy, research, administration and management.

EPF President Anders Olauson, Nicola Bedlington and Kaisa Immonen participated actively throughout this year’s meeting. Anders was a speaker in a panel debate on Transparency, and was also a ‘player’ in the Gastein Football Match – from Health kick to goal. Kaisa represented EPF in the pre-conference workshop on chronic diseases and personalised medicine. Nicola presented EPF’s views on health literacy in a parallel session and was a jury member for the [Gastein Health Award](#).

For a full article, please [click here](#).

Full article includes: Lunch workshop “From health kick to goal”, Gender and health, The “missing link” between EU and Member States, We need a broader vision of health, Patient involvement, Workshop conclusions and recommendations, Pre-conference workshop on Chronic Diseases, Workshop on Transparency, Workshop on Personalised Medicine.

9. Eucomed MedTech Forum – Brussels, October 13



Nicola Bedlington represented EPF at the Eucomed Medtech Forum in a policy debate session entitled, *Safe, Smart and Sustainable: Are we Aiming at a Modern ‘patient centred’ Device Regulation that also Balances Health Budgets?*

Revision of the EU legal framework for medical devices was a key topic during this third annual MedTech Forum in Brussels. From a patient, European Commission, FDA and Member State perspective the policy debate focused on whether the new rules would put the EU ahead in both patient-centred thinking and smart use of tax payers’ money.

Jacqueline Minor, Director Consumer Affairs of DG SANCO, and responsible for the EU Medical Device regulatory framework, stated: *“Through the Recast we want to shape a robust framework that paves the way for a healthier future where responsible innovation can flourish and meet the needs and expectations of patients and consumers. Achieving our objectives of the highest level of health protection for all, while at the same time promoting the competitiveness and the innovation capacities of the medical device sector, calls for a continuous dialogue between us all – Patients, Consumers, Healthcare Professionals, Industry and Regulators”.*

European Commission proposals for the recast of the EU directives on medical devices, active implantable medical devices and *in vitro* diagnostics could be finalised by the beginning of 2012. EPF will be working closely with the European institutions in relation to the patient’s perspective on these developments.

For a copy of Nicola’s presentation made during the debate session, and more information about the event please go to www.eucomed.org/Home/portal/mtf2010_presentations/mtf_presentations.aspx.

10. eHealth Event in the European Parliament

Antonyia Paravanova, MEP hosted a multistakeholder workshop entitled "[Towards enhanced eHealth governance: What next for cross border healthcare and further deployment of sustainable ICT applied to health?](#)"

The workshop was an opportunity for speakers and participants to hear and exchange views on eHealth governance in Europe. There were also wide ranging discussions on the benefits of and the barriers to the use of ICT in health and the current policy landscape. Watch [podcasts](#) from some of the workshop's expert speakers.

The event began with a speech from Antonyia Parvanova MEP before moving onto a best practice session with a series of high profile speakers involved in the success application of ICT in healthcare around Europe. Nicola Bedlington presented to the audience EPF's initiatives to date on eHealth and some key messages on patient involvement. This was followed by a lively multistakeholder panel debate. During the discussion a consensus emerged on the huge potential that eHealth has to improve patient care and reduce the costs of healthcare across Europe. Especially against the background of an aging population, higher patient expectations and the rising cost of healthcare provision. Participants, however, were concerned that there still remains a large number of obstacles, including lack of interoperability and data protection issues, which are hindering the development of eHealth.

One of the highlights of the day was a key note speech from Commissioner John Dalli who joined participants for a session looking at the policy options for healthcare within the European Union. Commissioner Neelie Kroes contributed to the debate with a video message to attendees.

A range of other stakeholders present at the event also helped contribute to laying out the possible next steps required to improve the application of eHealth across Europe and helping to provide a useful foundation for further discussion and policy development on this matter.

For a full report of the meeting and presentations please go to <http://hanovercomms.eu/news-events/past-events/ehealth-governance-in-europe/default.aspx>.



11. Belgian Presidency Ministerial Conference on Innovative Approaches for Chronic Diseases in Public Health and Healthcare Systems

The EU Member States are increasingly facing common challenges with the growing burden of chronic diseases in the European Union. Chronic diseases represent 86% of mortality in the WHO European Region and have significant economic implications. Chronic diseases require “ongoing management over a period of years or decade and cover a wide range of health problems” (WHO, 2002).

Many of these diseases are preventable and are linked by common risk factors such as tobacco use, overweight and obesity, hypertension, alcohol abuse and sedentary lifestyle. They require coordinated care from a wide range of professionals within a system that promotes patient empowerment.

The Belgian Presidency of the European Union drew attention to this crucial issue by organising a Ministerial Conference on 20 October. Against a background of innovation and solidarity, this Ministerial Conference aimed at bringing the Member States, patients and other relevant stakeholders together to discuss and share experiences and best practices in the field of chronic diseases. The perception of people living with chronic conditions by the society and by patients themselves was a central theme of the conference.

On 19 October, two pre-events on musculoskeletal diseases and chronic respiratory diseases were organised in collaboration with the European League against Rheumatism – EULAR respectively the European Respiratory Society – ERS. At both the conference and the pre-events, innovative, patient-oriented and collaborative initiatives in the area of prevention and care were discussed.

EPF President Anders Olauson made a presentation at this event and chaired a session.

Draft Council Conclusions on Chronic Diseases published

On 29 October the draft Council Conclusions on “Innovative approaches for chronic diseases in public health and healthcare systems” were published. The [draft Conclusions](#) invite member states to further develop patient-centred policies for promotion, prevention and care of chronic diseases, and identify and exchange good practices. Moreover, the Conclusions invite member states and the Commission to initiate a reflection process on the challenges of chronic diseases together with relevant stakeholders including patients, professionals, healthcare payers and providers, and summarise the outcomes in a reflection paper by 2012. EPF will be following up on this initiative very closely.

The Commission is also invited to integrate, where possible, chronic illnesses as a priority in current and future European research and action programmes.

For a copy of the programme and conclusions please go to <http://www.health.belgium.be/eportal/Aboutus/eutrio/19064868>. The conclusions on chronic diseases will be presented to the EPSCO Council in December 2010.

For a copy of Anders’ presentation please contact the [EPF Secretariat](#).

12. European Journalist Workshop

The Fondation Mérieux organised an important workshop on 18-19 October exploring facts, perceptions and myths about vaccines and vaccinations and how to report on health topics, building on the lessons learnt from the H1N1 Pandemic.

Nicola Bedlington attended the Workshop and was involved in a panel discussion on the role and responsibilities of different stakeholders.

For a copy of Nicola’s intervention please contact the [EPF Secretariat](#).

For more details on the event and the Merieux Foundation please go to www.fondation-merieux.org

13. EU Health Policy Forum

Nicola Bedlington represented EPF at the EU Health Policy Forum on 21 October. During the Forum, a number of crucial themes were addressed including the future of the EU Public Health Programme, the work of the European Centre for Disease Prevention and Control, the future framework programme of research and development (FP 8) and opportunities for input. An agreement was reached on the 2011 work plan for the EUHPF and significant information was shared regarding the Belgian Presidency advances on health, and plans for the Hungarian Presidency.

EPF circulated a report on the parallel session it coordinated during the Open Health Forum in June of this year on putting health at the centre of future structural funds/cohesion policy and stressed the importance of collective campaign work in this area.

One issue that is particularly imminent is the new European Innovation Partnership on Active and Healthy Aging (AHAIP).

Ms Maria Iglesia Gomez, Head of unit in DG SANCO/02 Strategy and Analysis gave a [presentation](#) on the European Innovation Partnership on Active and Healthy Aging (AHAIP), including the reasons for launching the EIP on Active and Healthy Ageing which was selected as a pilot project to be launched by January 2011, how to set it up and its objectives. She presented the work areas (packages) that will allow the development of the work:

- Work area 1 – individuals as patients and consumers
- Work area 2 – social and health care systems
- Work area 3 – developing EU and global markets

Ms. Gomez highlighted the fact that the timetable for this project was tight and that the aim was to adopt a multi-annual strategic work programme early summer 2011 in view of presenting some outcomes of the project by the end of 2011.

DG SANCO will soon launch an online consultation and will hold a stakeholder consultation meeting on 26 November 2010. At present, the Commission is discussing with Member States and the European Parliament, stakeholder organisations and industry representatives, then it will go to the head of states with whom it will discuss fast tracking, and bottlenecks at the policy level. If they give the Commission their green light the official launch will be in January 2011. At the end of 2011, the European Commission and the Member States will assess if the model concluded with deliverables and if so, the model will be adopted for

other initiatives. DG SANCO is working together with other Directorates General, such as IFMSO and RTD, and with the cabinets. The head of the project is Commissioner Ms. Geoghegan-Quinn.

EPF will be responding to the consultation via the European Union Health Policy Forum and a draft response has been sent to our Policy Advisory Group for comments. We will also be represented at the consultation meeting on 26 November.

EPF will follow up on all of these issues specifically with our membership and readers. For those who would like further information on any of the topics, you are invited to contact the EUHPF Secretariat at euhealthforum@epha.org.

14. GSMA Europe – The Power of Embedded Mobile Solutions

On 6 October EPF was invited, together with representatives from the EU institutions, the ICT sector and industry, including healthcare industry to attend the fourth event of the GSMA Europe Mobile Breakfast Meetings Series – the European interest group of wireless operators - to discuss opportunities and challenges of the mobile market. Walter Aztori attended on behalf of EPF.

Participation in this event was part of EPF’s increasing commitment to putting patient’s perspective at the heart of current and future developments in the eHealth arena, including its mobile segment.

Embedded mobile solutions are applications based on a computer system designed to perform one or a few dedicated functions. Concrete applications in the health sector can be as diverse as patients’ being able to do self health checks, doctors’ remotely monitoring vital parameters of patients with chronic conditions, diagnosing conditions and providing direct support and advise the patient on medications and changes in nutritional regimes. These applications present a number of opportunities for the patients such as better access and continuity of care, more independent living conditions and active involvement in the management of the disease.

Speaking at the event, industry representatives highlighted that despite evident benefits to society, the market for embedded mobile has not yet reached its full potential, especially in the healthcare sector. While the technology already exists and the infrastructure is in place, large scale rollout of mobile applications is not happening. Market and legal fragmentation, privacy and confidentiality concerns as well as public sector's resistance to change have been identified as major barriers hampering embedded mobile development, not only in the healthcare sector but more generally in the wider market.



Notwithstanding this, GSMA expects that 60% of the mobile market in Europe by 2030 will be driven by health-related technology. Given the ethical issues involved in using mobile technology for delivering healthcare to the patients, EPF is particularly concerned by the unclear legal nature of eHealth services in most EU countries, specifically in terms of protecting sensitive health data, preserving patient's privacy, ensuring the reimbursement for telehealth services, especially in cross-border situations. We hope that upcoming initiatives in the field of telemedicine and data protection, such as Commission's Staff Working Paper on Legal Aspects of Telemedicine due in early 2011, will help overcome some of the existing challenges in this area.

For EPF it is also extremely important to ensure that patients are recognised as equal partners in mobile health development, through better cooperation between industry, healthcare providers and patients and the involvement of the latter in the design, development and deployment of new applications.

EPF will continue to explore challenges and opportunities of mobile eHealth particularly through continuous and constructive dialogue with wireless operators. The next GSMA Europe Mobile meeting is scheduled on 1 December 2010 and will address data protection and privacy issues.

For more information on this topic please contact [Walter Atzori](#).

15. ENRICH Conference

On 21 October, Kaisa Immonen-Charalambous represented EPF at a conference on "Health network in Europe: the ENRICH experience". The event was hosted by the Committee of the Regions, Brussels.

[ENRICH](#) is a network of regions and local authorities working together to improve health and healthcare through an active cooperation with each other. Its aim is to involve different stakeholders within the sphere of public health to find new ways for the implementation of European policies to develop programmes for mutual assistance, information, sharing of best practices, research support and innovation.

The conference addressed three topical themes with a session dedicated to each: healthy weight, patient safety, and health inequalities. Speakers gave examples of successful ongoing projects and initiatives to tackle these challenges in different European regions, such as Algarve in Portugal, Andalucia in Spain, and Aquitaine in France.

In the patient safety session of the conference, Kaisa presented EPF's key activities and achievements in patient safety at EU level, including our work in the Commission's Patient Safety and Quality Working Group, the contribution to the Commission Communication and Council Recommendation on Patient Safety, and our work in the EUNETPAS and VALUE+ projects. She also gave examples of how EPF's member and allied organisations at national or regional level have been active in developing patient education and safety campaigns.

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

16. EDMA IVD Public Health Conference “Management of Chronic Diseases: A Major EU Challenge”

On 27 October, EPF was invited to participate in the IVD Public Health Conference on “Management of chronic disease: a major EU challenge”. The event was held in Brussels as part of the Annual General Meeting of EDMA, the European Diagnostics Manufacturers' Association. Kaisa Immonen-Charalambous represented EPF on this occasion.

Dr Jürgen Schulze started the conference by welcoming the audience and participants and outlined many of the issues around chronic care. The first part of the conference focused on the EU strategy on chronic disease, with an introduction by Andrzej Rys of the European Commission. Second, Joao Manuel Valente Nabais of the International Diabetes Federation (IDF) Europe presented the case of diabetes care and patients' information and involvement.

The second part of the conference was entitled “The social dimension of chronic conditions: what is available/missing and how can innovation help?” Kaisa opened the session with a talk about the patients' perspective: the importance of a holistic approach to chronic disease care and the integration of the different dimensions of care including medical and social. She also presented some of the key patients' expectations and concerns about innovation and new technologies, identifying quality information,

empowerment through health literacy, and patients' meaningful participation as the key factors to ensure that innovation is driven by patients' needs and technologies are developed in a patient-centred way.

Other speakers in this session were Dr Damien Gruson of the International Federation of Clinical Chemistry (IFCC), who gave an overview of diagnostic laboratory work and its challenges, and Jacqueline Bowman of the European Platform for Patients' Organisations, Science and Industry (EPPOSI) who outlined the new strategic plan of the organisation. An interactive panel discussion then took place with a lot of questions and comments from the audience.

The programme and presentations can be viewed online at www.edma-ivd.be/index.php?id=980

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

17. Anders Olauson represents EPF at Microsoft Government Leaders' Forum

At the Government Leaders Forum Europe in London on 4 November, there was a call for a new level of collaboration across industry and with government to advance progress on critical economic and social challenges in Europe.

The discussions at the Forum focused on five themes, all tied to EU2020 Agenda which include: competition, focusing on European competitiveness and the evolving role of jobs, skills and education; economics, exploring impact of technology and R&D on economic, social and environmental landscapes; health and welfare, which examine opportunities for new models in eHealth; Digital Single Market, discussing needed reforms and regulations; and eGovernment, exploring data governance and the evolution of digital citizen services.

The session EPF President Anders Olauson was involved in was entitled "Smart & Sustainable Healthcare – the role of eHealth", and fellow panellists included Mr. John Dalli, European Commissioner for Health and Consumer Policy.

Anders Olauson highlighted the importance of "connectivity". Connectivity between different sectors of industry: pharmaceuticals, medical devices, IT ; "connectivity" between healthcare systems and social care systems, which for too long have ran on separate tracks, rather than providing a patient-centred care model that will support the individual throughout the life continuum and in

particular older age; and ‘connectivity’ between the different stakeholders, patients, health professionals, insurers, industry and the policy-makers to enable data to flow more freely, more effectively and more safely. If this connectivity can be achieved then eHealth and smart technology in health can, indeed, enhance quality and access, whilst reducing costs, he said.

Technologies should develop from needs - not the other way round. EPF feels it is critical to ensure a user-centred approach in eHealth and telehealth design and implementation. Evidence has demonstrated that telehealth development which is driven exclusively by technological imperatives with little or no regard to the needs of the end-users and the organisational and clinical constraints, is likely to fail. Quality of Life Indicators should be used for developing, implementing and evaluating technologies, recognising that patients are NOT a homogenous group – our needs and preferences are different and will change with time and the experience of the disease.

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

18. Reducing Health Inequalities from a Regional Perspective: What Works and What Does Not



Genk's old mine site reconverted into a modern conference and exhibition centre was chosen as the venue of the Conference.

The Flemish Agency for Care and Health organised under the framework of the Belgian Presidency a Conference that was held in Ghent (Belgium) 8-9 November 2010 at the city's former mine site recently renamed C-Mine.

The purpose of this event was to examine how regional policy can efficiently eliminate disparities in health by addressing the social determinants of health. Central to this are the following questions: Which measures work? Which initiatives do not produce any results (and why)? And finally, how can research outcomes be translated into policy and practice?

Health inequalities are commonly understood as differences in the presence of disease, health outcomes, quality of health care and access to health care services. There is high evidence of large health disparities not just across EU countries, but also among

regions of the same country as well as across socio-economic strata. One of the key messages of the Ghent conference was that the EU, Member States, regional and local authorities acting in partnership with the civil society need to find new more effective ways to address the whole spectrum of social determinants which are thought to cause health disparities. The participants have called therefore for a more holistic approach to health inequalities, one which addresses the structural causes of such inequalities by looking at how different policy interventions in the health area and beyond impact on health.

We need however to recognise that there are a number of challenges in any attempt to apply a holistic approach to tackling health inequalities. While there is large evidence of large-scale health inequalities across the EU a lack of proper indicators to measure existing disparities is present. Without appropriate indicators it is not possible, for instance, to track and measure the impact of policies on health inequalities, nor can we undertake any sort of Health Impact Assessment before launching new policies or interventions.

On the other hand, experience suggests that integrating health into socio-economic development policies is very difficult to realise in practice. It was suggested that regional and local authorities should do more in this respect, as these are the territorial levels which are closer to the citizens and this proximity should make it easier for decision-makers to make more strategic decisions aimed at better harmonising health policies with other policies which have an impact on citizens' health. The problem here seems to be one of competence and resources. Oftentimes regions do not have full control over channels and lack financial resources needed to bring about changes that may have a positive impact on health determinants.

Committed to patient-centred equitable healthcare throughout the EU, EPF is particularly concerned by the existing differences across the EU in terms of access to quality care for patients. EPF strongly endorses the need to foster a more holistic approach to health inequalities which enables health gains to be generated from all policies and not just from deliberate national/regional strategies that have the explicit aim of improving citizens' and patients' health.

For more information on this topic please contact [Walter Atzori](#).

19. Welcome Abi

Abinaya Rajan began her internship with EPF at the beginning of November. She was awarded an international grant by the European Commission for her academic excellence and holds a joint Erasmus Mundus European Master's degree in Sustainable Regional Health Systems from the University of Deusto (Spain), Corvinus University (Hungary), Vilnius University (Lithuania) and University of Verona (Italy). She has done several EU internships that mainly include - Health Technology Assessment, Health Systems Research and Foreign Languages. Abinaya will be working closely with Liuska Sanna, EPF's programme manager supporting her work in the area of research, specifically on Health Technology Assessment.

20. Goodbye Magdalena

EPF said goodbye to their policy intern, Magdalena Machalska. She left EPF at the end of October to begin her new job as Junior Project Manager at AIM (Association Internationale de la Mutualite) where she will work on EU social and health policies as well as other current dossiers on the EU health Agenda. While at EPF, Magdalena worked on EU health policy dossiers such as eHealth, the Pharmaceutical Package and Patients' Rights in Cross-Border Healthcare. She monitored new developments in these areas as well as prepared draft policy documents. We wish her the best of luck in her new career endeavour.

21. Diary

November 11-12	Careum Congress Zurich Speaker: Nicola Bedlington
November 11-12	Patient Link Workshop Brussels Attendance: Kaisa Immonen
November 16	Friends of Europe 2010 European Policy Summit on Healthcare Brussels Speaker : Anders Olauson
November 17	EPPOSI Workshop "Patients' Engagement in HTA" Brussels Attendance: Liuska Sanna
November 18	EFPIA Patient Think Tank Brussels Attendance: Nicola Bedlington
November 19	Joint Action on Quality of Care and Patient Safety Second Meeting Brussels Attendance: Kaisa Immonen
November 29	WHO Europe Meeting on Patient Rights and Patient Safety Copenhagen Attendance: Kaisa Immonen
November 30	Advisory Board Microsoft Brussels Attendance: Nicola Bedlington
December 1	EPF High Level Roundtable on the Draft Directive on Cross Border Healthcare Brussels Attendance: Anders Olauson, Nicola Bedlington, Kaisa Immonen

December 2	EPF Board Meeting Brussels
December 3	21st Century Healthcare for Europe Conference Brussels Attendance: Anders Olauson
December 7	TOPRA EMA Conference London Speaker: Nicola Bedlington
December 8	AMCHAM Healthcare Meeting Brussels Speaker: Nicola Bedlington
December 7-8	InterQuality Project Kick-off Meeting Warsaw Attendance: Liuska Sanna
December 15	Review of Transparency Stakeholder Meeting Brussels Attendance: Kaisa Immonen
December 15-16	EMA Scientific Conference London Attendance: Anders Olauson, Nicola Bedlington
December 17	Enterprise Steering Group 2 nd Meeting Brugges Attendance: Kaisa Immonen