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Issue 2 (29): 7 April, 2010

Dear EPF Members and Allies,

Welcome to the EPF Mailing. Over the last year, much attention has been focused on Obama's historic healthcare reforms in the United States that were finally adopted last month, amid continued political controversy. What do patients' organisations and health professional organisations in the US think? – Read an overview in section 33.

EPF President Anders Olauson was in Washington DC representing EPF at meetings on transatlantic cooperation on eHealth in late March – more on that in our next issue. EPF was also represented at eHealth week in Barcelona – read about our input there and plans on eHealth governance in section 11.

Since our last mailing significant developments have taken place in the European Parliament regarding information to patients, in section 2 read about the degree to which patients' views have been taken on board in the report drafted by Christofer Fjellner, rapporteur responsible for the dossier in the European Parliament Health and Environment Committee.

A small reminder that today is World Health Day. Many of you may be aware that the focus of this year's campaign is 'urban health' – and how to make our cities healthier (see section25).

Another important "day" is up and coming – "Patients Rights Day", please see section 24 for an overview of the events that Active Citizenship Network and patient organisations at national and regional level are planning. EPF will distribute a press release focused on Young Patients on 18 April to mark the Day, that will be taken forward in the framework of our forthcoming regional seminar in Budapest in October of this year.

The EU is turning its attention to global health, with the forthcoming Communication and conference on global health June 10 and 11, to which EPF has been invited. The background to the conference is increasing awareness of the need for the EU to act in a coordinated manner with the rest of the world in order to bring about greater coherence and impact of our efforts on a global scale in health. This recognises the need for a strategic course, policy coherence and common values in global health.

Another major conference will be taking place on 29 and 30 June – the Open Health Policy Forum that convenes over 500 health players from across the EU to discuss health policy developments and how they believe they should be shaped. EPF is involved in the steering group and is specifically responsible for a parallel session on the health dimension of the Structural Funds. Further information will be available in our next Mailing in May.

Invitations have been sent out to EPF members and patient group allies to participate in our Health Technology Seminar (HTA) and Annual General Meeting (AGM) on 18 and 19 May – please register by 13 April at the latest. Places to non-EPF member patient groups will be awarded on a first come, first serve basis. We look forward very much to welcoming you there!!

Warmest greetings,
Anders Olauson, President
Nicola Bedlington, Director

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Next issue of the EPF Mailing -deadline for articles 15 May 2010, distribution late May 2010.

Click here for previous issues of the mailing.

Recommended for our Readers:

2010 European Patients' Rights Day

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1. PATIENT SAFETY AND QUALITY OF CARE

Last month the Secretariat invited specific input from patients' organisations across the EU (EPF members and allies) to the draft Commission's reflection paper on Patient Safety and Quality of Care. EPF's Policy Advisory Group will also address this issue at their next meeting on 6 April alongside a discussion about the implementation of the recent Council Recommendation on Patient Safety in EU Member States. These contributions will be built into EPF's future input to the Commission's Patient Safety and Quality of Care Working Group (PSQCWG).

At the same time, the Commission sent invitations to the Permanent Representations of the Member States, with a request to nominate for every interested country a body that would participate in a possible future joint action[1] on patient safety and quality of healthcare. The Commission has recognised the added value of maintaining the patient safety momentum created by both the Council Recommendation on Patient Safety and the EUNetPaS project. In light of this, the 2011 early draft work plan of the Health Programme foresees the setting up of a joint action aiming at implementation and follow-up of the Council Recommendation on patient safety on one hand, and the development of activities relating to quality of healthcare on the other hand. EPF together with other health stakeholders, members of the PSQWG is exploring opportunities of getting involved in this joint action and will keep you informed.

For further information, please contact Roxana Radulescu.

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[1] A joint action is a financial mechanism of the Health Programme. It foresees a joint financing of actions between the Community and Member States or national competent authorities.

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2. PHARMACEUTICALS PACKAGE – WORK IN THE PARLIAMENT

March has seen much activity in the European Parliament on the three proposals making up the Pharmaceutical Package. Significant developments have taken place in particular regarding the Directive and Regulation on **information on prescription medicines**. Swedish MEP, Christofer Fjellner released his draft report on this legislative proposal at the beginning of March. The report was discussed in the Health and Environmental Committee (ENVI) meeting on 16 March and received strong support from the liberal (ALDE) and the right wing (EPP) parties, while the Greens and the Socialists expressed doubts about the social demand for changing the current situation, anticipating at the same time high costs for Member States to take up such a commitment.

The discussion looked at the possibility of postponing the examination of the proposal and to discontinue taking the report through the whole legislative procedure but rather to make an EP “own initiative“report. However, the Commission’s representative present at the meeting reiterated Commissioner Dalli’s firm intention to scrutinise the report agreed by the Parliament and take it forward with the Council.

Immediately after the meeting, the EPF Secretariat sent letters to health coordinators in all political groupings calling them to take into account the patient community views and give this proposal a real chance to be debated and improved in the European Parliament through the parliamentary legislative procedure.

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Regarding the report itself, EPF is pleased that much of its input - prepared on the basis of our position paper and in close cooperation with the European Patients' Cancer Coalition - was included in the amendments proposed by Mr Fjellner. The report shifts focus from the right of pharmaceutical industry to provide information, towards the right of all patients across the EU to have access to quality information about the medicines they take. The report puts emphasis on health professionals as the main sources of information, while the market authorisation holders are seen as a valuable complementary source of non promotional information, in the context of a "wider information to patients" strategy.

EPF will continue to approach several key MEPs in the coming months to urge them to work with Member States to take forward this proposal through the whole legislative procedure to consider the wider information needs patients have and the valuable contribution that patient organisations can make. The deadline to table amendments in the ENVI Committee is 13 April, while the vote in ENVI is planned for 22 June and the vote in EP plenary session for 6 September.

On the **anti-counterfeiting proposal**, the EPF Secretariat will continue to work with MEPs before they vote in the ENVI Committee on 27 April to ensure the patients' voice is heard and later in the plenary session on 18 May. The same work is planned for the **pharmacovigilance proposal,** where the vote in ENVI Committee is scheduled for 4 May. The intention is for the entire Parliament to vote on the proposal on 14 June. Finally, the Spanish presidency is very much in favour of closing both files during their presidency.

Please review specifics of the report here.

For further information, please contact Roxana Radulescu.

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3. PATIENTS' RIGHTS IN CROSSBORDER HEALTHCARE

Readers will remember that under the Swedish EU Presidency Member States failed to reach a political agreement on the proposed "Directive on the application of patients' rights in cross-border healthcare" at the Health Council in December from 1 December 2009.

Since then, the Spanish EU Presidency has not yet announced any meeting in the Council on this issue, despite the personal commitment of the Spanish Health Minister to find a political agreement on the text. It seems that the latest Swedish compromise text could be used as a working basis and that the work could concentrate on solving the few remaining issues (for example, the issue of private healthcare providers who do not have a contract with the healthcare in the host country). If an agreement is to be found under the Spanish EU Presidency, it must be achieved by the Health Council on 9 June.

There are no developments on this front in the European Parliament, since the first reading of the Council is not completed. The rapporteur for the second reading in Parliament, MEP Françoise GROSSETÊTE (FR, EPP) has however stated her strong commitment to work with her colleagues from other Member States to revive the proposal.

The EPF Secretariat has been doing some background work with the European Parliament and national governments to remind key players of patients' on-going views, at this juncture. The Secretariat will also meet with the Commission's representatives in April 2010 to discuss next steps on this topic. We will keep our membership and patient group allies informed.

For further information, please contact Roxana Radulescu.

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4. EMA LAUNCHES PUBLIC CONSULTATION ON ITS ROAD MAP TO 2015

In January 2010 the European Medicine Agency (EMA) disseminated the draft of its road map "The Agency's Contribution to Science, Medicines and Health" for a public consultation which will last until the 30th of April. The goal of the roadmap is to set out the Agency's long term strategy taking into consideration the main drivers for change and the future challenges.

There are three main strategic priority areas that are proposed: addressing public health needs, facilitating access to medicines, and optimising the safe use of medicines. It sets objectives for future action, notably taking into account patient experience to improve decision-making through and the safe use of medicines involving patient organisations. The EMA also intends to take into account the demands for more transparency through giving more information targeted for users such as patients. After the consultation the EMA will publish a new document "From vision to reality", taking into account responses.

To view the draft EMA road map, please go here:
http://www.ema.europa.eu/htms/general/direct/roadmap/roadmapintro.htm

To view the policy brief on the EMA road map from one of EPF members, EFA please click here.

A response is under preparation by EPF, and will be sent to EPF Members for consultation this week.

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5. EUROPE 2020 STRATEGY FOR SMART, SUSTAINABLE AND INCLUSIVE GROWTH

On 4 March the Commission adopted its proposal for the Europe 2020 Strategy which you can consult through the site http://ec.europa.eu/eu2020, as well as a document presenting a more detailed overview of the key ideas presented by the different groups of stakeholders in response to the consultation. All the contributions to the consultation will be accessible on this site soon.

EPF contributed via the EU Health Policy Forum.

Please go to a brief resume of the main elements of the Communication from the Commission:
Europe 2020 A strategy for smart, sustainable and inclusive growth
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6. REVIEWING CLINICAL TRIALS PRACTICE

The EU's Clinical Trials Directive (2001/20/EC) was implemented in 2004 with a view to improving research standards and protecting patients. However, in order to assess the functioning of the Directive across Member States, the European Commission has launched a public consultation which ended in January 2010. In this context a series of workshops have been organised, called Road Map Initiative for Clinical research in Europe, to bring together all of the relevant stakeholders, and to develop a body of recommendations for the European Commission.

On behalf of EPF, policy assistant Magdalena Machalska, attended the final Workshop to summarise main issues discussed during previous workshops. Each workshop focused on different themes, namely on the

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Single Clinical Trial Approval (CTA) Process, co-sponsorship and contractual issues, risk-based approach, ethics committees and Pharmacovigilance.

In this final Workshop the proposals made in the previous seminars were summarised and discussed by all stakeholders involved. The aim is to design a proposal to the Commission for an overall new regulatory environment for clinical trials in Europe that attracts and encourages clinical research in Europe which benefit patients.

David Haerry from European AIDS Treatment group (EATG) called for effective and safe clinical trial practices for all patients across Europe. He further expressed that a clear need for harmonised informed consent across Europe as well as for more transparency through the whole procedure. With regard to risk-based assessment, he explained that quality control measures should be adopted according to a risk-based approach and patients and patients´ organisations must be included in the assessment of risk. David Haerry further noted, “The next steps towards improving the clinical trial situation in Europe must be an intense exploration of the forces hindering a smooth clinical trial environment and the options for change”.

The effectiveness of clinical trials throughout the EU is of fundamental importance for EPF and its members. Therefore, EPF is working closely with the EU institutions and other relevant stakeholders to achieve patient-centred EU legislation on clinical trials and will continue to provide input on this issue to ensure that patients’ views are reflected in the forthcoming policy and legislative developments.

To view the Clinical Trials Directive, click here.
To view the consultation, click here
To view the roadmap click here
For more information on EPF’s response to the public consultation please visit our website:
www.eu-patient.eu/Initatives-Policy/Policy/Clinical-Trials or contact the EPF Secretariat.

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7. FOURTH CALLIOPE WORKSHOP

The fourth CALLIOPE Workshop was held in Brussels on 11-12 February as a joint epSOS– CALLIOPE (CALLepSOS) Workshop.

EPF attended the second day of the Workshop which was dedicated to two main topics: the operationalisation of the Recommendation on Cross-border Interoperability of Electronic Health Record Systems and the development of the Roadmap.

As agreed in the previous CALLIOPE meeting no additional work should be invested in any proposed amendment of the Recommendation. The main question for consideration during the first part of the Workshop was, therefore, to take a step forward in order to explore which role CALLOPE can play in fostering organisational interoperability. Four different approaches were presented and discussed: cookbook (i.e. set of guidelines on eHealth interoperability); bench-learning through small piloting exercises and 'concertation' meetings among service providers; good practice and its circulation/acceptance; and mutual trust enforcement of policy and strategies. CALLIOPE partners are currently considering advantages and drawbacks of these different approaches. A concrete strategy on how to operationalise the Recommendation will be discussed in the next Calliope Workshop.

In the afternoon session the participants discussed the structure of the Roadmap and the key issues to be included. It was agreed that the Roadmap document will start with a high-level vision and outline the contributions expected from eHealth. It will then proceed to an analysis of key interoperability challenges and from there on derive process recommendations towards interoperability.

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The Roadmap will address the four areas stipulated at eHealth Governance meetings held in late 2009 for joint efforts towards European eHealth interoperability, notably:

1. Legal & ethical (including regulatory and organisational issues)
2. Identification and authentication
3. Standardisation / technical issues
4. Semantics / terminology

Two break-out sessions with smaller interactive groups were organised to make it easier for the participants to focus more closely on these four cross-cutting interoperability issues. EPF participated in the first break-out session which tackled the first two topics, i.e. legal and ethical issues and identification and authentication.
The outline of the Roadmap was briefly presented during the eHealth week 2010 organised from 15 to 18 March by the Spanish Presidency in Barcelona to which EPF also attended.

EPF's role in the development of the Roadmap will continue in the coming months to ensure that this document will effectively contribute to improving the quality, safety and equity of eHealth services in Europe.
For more information on CALLIOPE contact Liuska Sanna, or visit the project's website www.calliope-network.eu

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8. STARTING A NEW FP7 PROJECT: INTERQUALITY

InterQuality is the acronym for International Research Project on Financing Quality in Healthcare, a new research project financed under the Seventh Framework Programme (FP7), in which EPF will participate as an associate partner. This project will run for 36 months until early 2013.

Why InterQuality Project?

InterQuality moves from the assumption that spending more on healthcare often doesn't result in improving quality, effectiveness and access to service. Evidence from existing research and data available from the various European countries shows that huge amount of resources is wasted because of either poor management, inefficient model of payment and care delivery, or a combination of the two.

So far, there is no European defined protocol for evaluating financing systems' effect on quality of healthcare. Scientifically validated tools to help decision-makers choosing the right financing mechanisms in the different areas of healthcare systems are, therefore, greatly needed.

Which is the Main Expected Outcome of the Project?

The knowledge gained from the research should provide support for project partners to choose the right financing mechanisms in the different areas of the healthcare system, according to their needs and possibilities, to not pay more, but to pay smarter.

Which Are the Countries Involved?

The research will be conducted in five European countries, notably Poland, Italy, Denmark, Germany, and the United Kingdom as well as the United States. As each of the chosen countries presents very different

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healthcare financing systems, the comparison of the results and outcomes, in particular between chosen EU countries and the US, is expected to advance the knowledge base on sustainability of the health systems.

What Is the Role of EPF in the Project?

EPF will lead work package 7 on Dissemination. While our main responsibility is to develop and implement a project dissemination strategy, we will also perform a wide range of activities throughout the project life-cycle ranging from raising awareness of the project progress and results amongst healthcare stakeholders at national and European level to developing a specific evaluation of the effects of patients' education programs on efficiency, quality and equity of care.

What will be the Added-Value of InterQuality Offer for European Patients?

The scope of InterQuality research will cover aspects which are strongly relevant to European patients, notably quality of care, including equity of access, patient satisfaction and safety of treatment. The research will take into account needs of four different patient groups (sectors), affected by hospital care, outpatient care, pharmaceutical care and integrated care.

The costs of resources allocated by each sector will be analysed in relation to their utilisation and efficiency as well as risk of overuse, underuse or misuse. In particular, the access to treatment will be measured using data on length of time on the waiting lists for medical procedures and access to innovative therapies.

Comparative analysis of patient satisfaction with quality of medical services will be performed. The research will also assess the cost, efficiency and benefits of different interventions as regards patient safety, including their implementation and their outcomes in terms of effectiveness, efficiency and equity (including disadvantaged groups). InterQuality will then identify more efficient ways to manage healthcare system ensuring the highest standards of patients' safety and make recommendations to European and national policy-makers.

For additional information on InterQuality, please contact Liuska Sanna

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9. RENEWING HEALTH KICK-OFF MEETING

In the February issue of our EPF Mailing we anticipated the launch of RENEWING HEALTH, a new project in which EPF is participating as an associated partner and member of the Users Advisory Board. The project, which is financed under the Competitiveness and Innovation Programme (CIP) - ICT Strand, will implement 20 large-scale real-life test beds in nine European regions for the validation and subsequent evaluation of innovative telemedicine services using a patient-centred approach and a common rigorous assessment methodology (MAST).

On 8-9 February RENEWING HEALTH's partners gathered in Venice (Italy) for the first project meeting (kick-off meeting) held at the picturesque Venetian-Gothic style Palazzo Franchetti. This event marked the official launch of this 14-million-Euro project which will be running for 32 months until late 2012.

RENEWING HEALTH's partners during the Kick-off Meeting at Palazzo Franchetti, Venice.

The first day was dedicated to presenting the final configuration of the project plan after negotiations with the European Commission as well as to clarify the role of both the coordinator and Work Package leaders. Pilots with similar features have been grouped in clusters according to pathology and type of service provided. The idea is to have each cluster of pilots operate as a multi-centre clinical trial governed by a specific scientific trial protocol.

The second day was devoted to clarifying the role of the various partners throughout the various phases of project implementation. Particular attention was placed on discussing the assessment methodology to be used to assess the effectiveness of the telemedicine services to be piloted.

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As member of the Advisory Board, EPF will monitor the implementation of the pilots making sure that the needs and demands of chronic patients are effectively met to the fullest extent possible and that all the activities of the project are centred around the interest of the patient. In order to achieve this goal EPF will establish continuous contacts with other Work Package leaders so as to ensure, that clinical trials protocols are developed to not only answer specific research questions but also to safeguard the health and rights of the participants. Moreover, EPF has already provided its first feed-back on the assessment methodology asking, among others, for a better clarification of patient-related indicators and the inclusion of criteria for effectively evaluating the contribution of these telemedicine services to the reduction of health inequalities.

In the months ahead EPF will be involved in the establishment of the Users' Advisory Group and the elaboration of the users' requirements. The partners will meet again in Berlin (Germany) for three days from 4 to 6 May. The first day will be dedicated to the meeting of the project's Steering Committee. During the second day the partners will attend a seminar on the use of the assessment methodology, and on the last day they will have the opportunity to participate in the meeting organised for the clinicians involved in the implementation of the pilots.

For further information about RENEWING HEALTH, please contact Liuska Sanna, or visit the project's website: www.renewinghealth.eu

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10. RESPECT-PATIENTPARTNER WORKSHOP ON PAEDIATRIC CLINICAL TRIALS

On 10 April, RESPECT and PatientPartner projects will organise a joint Workshop aimed at exploring how to improve outcomes of clinical trials research involving children.

Why a joint Workshop? RESPECT and PatientsPartner have been looking into paediatric clinical trials from different angles. While the key goal of RESPECT is to understand the needs and motivations of children and their families who have participated or might participate in clinical trials in Europe, PatientPartner's objective is to explore new ways to improve the role of patients' organisations in research. Hence, despite adopting different approaches, both have an important common feature: making sure that clinical research meets patients' needs.

By targeting representatives of patients' organisations and associations and parents with knowledge of paediatric clinical trials, the joint workshop will try to gather information on the following issues:

- Needs of children and their families participating in clinical trials
- Methods, approaches and good practices for increasing children's' participations and empowering them
- Patients' organisations' current involvement in paediatric clinical trials and the role they could/should have in the future

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In order to collect background information on these topics RESPECT has carried out a number of on-line surveys targeting both patients' organisations and families. The key finding of these surveys will be presented during the first session of the Workshop.

Through an exchange of ideas and experience between participants, the Workshop will strive to contribute to developing a model of empowerment based on Value+ Model of Patient Involvement.

For more information on this event and on RESPECT project, please contact Liuska Sanna, or go to www.patientneeds.eu

Events and Conferences

11. HIGH LEVEL EHEALTH CONFERENCE, BARCELONA, SPAIN, 15-18 MARCH

The Health Ministry of Spain, the country holding the presidency of the Council in the first semester of 2010, hosted the 2010 European eHealth conference jointly organised with the European Commission, in cooperation with the government of Catalonia and the TicSalut Foundation.

During the four-day conference, politicians, health administrators, researchers and suppliers, along with health professionals and patients' representatives from five continents met to share their experiences and to discover what is new in the fast-evolving area of eHealth. The goal of this unique setup was to encourage the development of online health services in Europe, and present the latest technologies in online health, tools, applications and the best practices.

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With the theme: "eHealth for sustainable healthcare: global changes through local actions", this eighth edition of the ehealth ministerial conference acknowledged the urgency to take note of a rapidly ageing European society, the prevalence of chronic illnesses, the lack of prevention and prediction of illnesses, the growing demand for quality attention, the lack of electronic health and the interoperability of these systems (nationally and internationally).

Prior to the conference opening, the meeting of European Ministers marked an important milestone in the eHealth sector by agreeing on a digital agenda for Europe. This agenda sets the priorities and the objectives for the years to come. This important outcome is linked to the European eHealth governance recently established that is moving forward through the joining of Members States in a Joint Action (JA) to be financed by the EC Public Health Programme. The purpose of this Joint Action is to formulate strategic and political actions that can support the deployment of eHealth in Europe.

The conference was very rich in terms of content and topics addressed from an eHealth perspective, which included some of the following topics: business models, Telemedicine, IT solutions to support quality of care, interoperability, e-prescribing, electronic health records, procuring, market, clinical research, and more.

The conference offered interesting and relevant information to the patient community. Presentations were given on patient safety, continuity of care for chronic diseases, patient empowerment, information to patients, patient-oriented eHealth products and services, and use of patient data. A strong patient perspective was presented by EPF Director Nicola Bedlington, who received very positive feedback on her core message – meaningful involvement of stakeholders in e-health governance is the right way to go.

EPF believes that the conference's outcomes in terms of e-governance and research perspectives were very positive. We will be involved in the Joint Action that will be launched this year and we will be monitoring how the new digital agenda will shape the work of the Commission. We will follow closely the plans of DG INFSO

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and DG Research and strengthen our pre-existing cooperation with theses DGs to ensure that the Framework Programme 8 and other eHealth initiatives take on board patients' concerns around access, health equality, ethics, safety, privacy and data protection.

All presentations are available here www.ehealthweek2010.org/slideshows?set_language=en

The programme, photos and further information can be found at www.ehealthweek2010.org/ehealth-ministerial-conference-1

For further information on the conference please contact Liuska Sanna, EPF Programme Officer.

12. EPF ATTENDS DRUG INFORMATION MEETING FOR THE FIRST TIME

EPF President Anders Olauson and Director Nicola Bedlington participated in sessions on information to patients at the Drug Information Association (DIA) meeting in Monaco during early March. Anders chaired a session looking at patients' use of currently available information. In particular, looking at how patients use information that they get from healthcare professionals, fellow patients, providers of the treatment and other sources. This session focused on diseases that affect the wider society (e.g. oncology, stroke, diabetes etc). Tomasz Szelągowski, Director of the Polish Patients Forum outlined some of the key barriers and opportunities for patients in Poland, and Joana Gabriele, Director of the Patients' University in Spain described the evolution of the Patients' University and health literacy strategies in Spain.

In a session, chaired by Paul Woods from the European Federation of Pharmaceutical Industries and Associations (EFPIA), Nicola Bedlington presented EPF's views on the legislative proposal on information to

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the General Public on prescription only medicines. Martin Terberger from the European Commission also presented the latest thinking within the Commission with regard to the proposal. It was a really valuable opportunity to meet several patient group representatives at DIA and EPF will work closely with DIA and other patient group leaders to ensure that the event continues to be as patient focussed as possible.

For more information please go:
www.diahome.org/DIAHome/FlagshipMeetings/Home.aspx?meetingid=20292

13. WORKSHOP ON LEGAL ASPECTS OF TELEMEDICINE

On 2 March EPF participated in the Workshop organised by the DG INFSO of the European Commission whose purpose was to encourage the sharing of good practice in the area of eHealth and address the legal and logistics dimensions in telemedicine practice.

The Workshop was part of a broader initiative of the European Commission aimed at providing more clarity on existing EU legislation regarding telemedicine services launched with its 2008 Communication "Telemedicine for the benefit of patients, healthcare systems and society".

For the EU law, telemedicine is both a health service and an information society service and as such it falls under Art. 56 of the Lisbon Treaty and existing EU secondary legislation, in particular Directive 2000/31/EC (the so-called e-Commerce Directive), which defines rules for the provisions of Information Society Services both within and between Member States. The Directive provides for an important exemption from the so-called "country of origin principle" which applies to business-to-consumer situations (which is relevant to telemedicine services) in which the service must comply with rules of the recipient's country.

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In line with the principle of subsidiarity, while the definition of medical acts is a matter for the Member States, national legislation should respect the fundamental principle whereby telemedicine services shall meet the same level of requirements as non-telemedicine services. Providers of telemedicine services have to comply with Directive 95/46/EC on the processing of personal data as well as with Directive 2002/58/EC which deals with the protection of privacy in electronic communications.

Under the existing framework, however, there are a number of key issues requiring further legal clarification, in particular with regard to licensing, accreditation and registration of healthcare professionals providing telemedicine services, reimbursement of costs for telemedicine services, liability, personal data protection, patient consent and conflict of jurisdictions.

EPF is concerned that the lack of legal clarity in telemedicine, particularly when it comes to cross-border healthcare, can affect negatively patient care and put patient's privacy and safety at risk. Awareness about which rules and norms currently apply to telemedicine is a primary prerequisite for ensuring that the patient who consciously accepts remote treatment understands clearly not only his rights but also the responsibilities therein involved.

Only a few Member States have a clear legal framework in place enabling telemedicine. In some Member States for a medical act to be recognised as such, the law requires the physical presence of the healthcare professional and the patient in the same place. This constitutes a major hindrance to the deployment of telemedicine, not to mention the lack of clarity as to how to preserve the fundamental rights of the patient.
In order to address these issues, the Commission will publish a Staff Working Paper (SWP) on Community legal framework applicable to telemedicine in spring 2010. Through our participation in this Workshop EPF wanted to ensure that such document takes into account the interests of European patients and promotes the highest standards of patient safety.

For more information, please contact Walter Atzori.

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14. YOUTH HEALTH INITIATIVE

As a part of its idea to empower young people to become active partners in improving their health, the European Commission launched a new Youth Health Initiative. The purpose is to gather all youth-related initiatives in health and related policy areas across the Commission under one banner.

In this context, the youngest colleague at the EPF Secretariat, Magdalena Machalska, represented EPF at a meeting which took place on 11 February in Brussels with youth organisations, national youth councils and other stakeholders to exchange views on how to communicate health to young people. The meeting was convened by DG SANCO to illustrate the main aims of the Youth Health Initiative and its state of play, as well as to exchange views on the Youth Health roadmap.

On this occasion EPF expressed its concerns about young chronic patients and highlighted the need to empower them through training to help them shape policies that affect their every-day life.

The forthcoming European Patients´ Rights day on 18 April will be an opportunity for EPF to promote young patients across Europe. On this occasion, EPF will publish a press release on the Youth Health Initiative website to inform young citizens of the forthcoming Autumn Advocacy Seminar. The main purpose of the seminar will be to build capacity for patients' organisations' young representatives, from Central and South-Eastern European countries. In particular, the seminar will focus on developing participants' communication and advocacy skills to influence policies that affect their lives and ultimately to engage in shaping the future of healthcare and ultimately their society.

For further information on the Youth Health Initiative please visit http://ec.europa.eu/health-eu/youth/index_en.htm or contact Magdalena Machalska.

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15. EUROPEAN PARLIAMENT INTEREST GROUP ON CARERS

On February 23, the first Carers Interest group meeting took place at the European Parliament. In attendance were Members of the European Parliament (MEPs), European Commission representatives, council members and civil society organisations among others. This group started in 2007 and re-launched after the 2009 elections to raise awareness of and ensure EU level attention to carers and their issues. Frank Goodwin from Eurocarers discussed the importance of carers that are often described as the invisible workers. In Ireland, 3.5 million hours of unpaid care is provided by approximately 160,000 carers each week. Representative from the EC provided an overview of current and future Commission/Council initiatives. Overall, there was general disappointment of the lack of reference to carers in the EU2020 consultation. The interest group will meet between four to six times a year and will continue to work with its members and external stakeholders to ensure an active policy development role.

For further information on the meeting please click here to read the report.

16. EUROPEAN VOICE HEALTH CHECK DEBATE

EPF was present at the debate hosted by the representation of the Stockholm region in Brussels on 24 February and brought together numerous representatives of industry, Member States, EU institutions, NGOs, and health professional organisations. It offered a timely opportunity to discuss the political barriers around the current Commission's proposal on Information on Prescription Medicines and on concrete examples of how to provide patients with quality and accurate information on diseases and available treatments, in the age of the Internet.

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Representing the patients' voice, Jan Geissler, director of the European Cancer Patient Coalition (ECPC) highlighted a prevalent need across the EU for quality information, in the country's own language. He explained the necessity of patients' organisations to monitor and assess the information that is made available to patients and "translate" this in a patient-friendly language. Regarding the Commission's proposal he called for a speedy agreement to reduce patients' inequalities in accessing information about medicines and treatments across the EU.

For further information, please see the Debate report.

17. ENVI COMMITTEE WORKSHOP ON INFORMATION TO PATIENTS

Roxana Radulescu represented EPF at a workshop on "Information to patients on prescription medicines" organised by the Committee on Environment, Public Health and Food Safety (ENVI) in cooperation with the committee on internal market and consumer protection (IMCO).

The aim of the workshop was to provide Members of the European Parliament (MEPs) with a comprehensive and balanced overview on the issues and interests at stake. The workshop looked at the views of independent experts from universities around Europe and the views of key relevant stakeholders. MEP Christofer Fjellner hosted the workshop.

The event provided EPF the opportunity to voice the patients' perspective when it comes to the information provided on prescription only medicines. In our view the current legislative proposal has a narrow scope and requires a public health perspective which should be looked at in the context of a wider information to patients strategy. This means a commitment to health literacy – education for patients to better understand and use the information and training of health professionals to better communicate to patients. It is also vital

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that patient organisations should have an important contribution in the process of developing the information, validating it and making it available to patients.

For further information and a copy of the presentations, please contact Roxana Radulescu.

18. EUROPEAN PATIENTS' FORUM IS INTRODUCED TO THE EUROPEAN SOCIAL INSURANCE PLATFORM (ESIP) COMMITTEE ON HEALTHCARE

In February, EPF was invited to address the ESIP committee on healthcare at their quarterly meeting. The purpose of this meeting was to look at how to enhance understanding and cooperation between EPF and ESIP on EU policy dossiers and to explore specific funding collaboration, in line with EPF's principles on transparency and independence.

EPF is looking forward to more communication with ESIP as one of the key health stakeholders at EU level, representing the insurance sector alongside AIM (Association Internationale des Mutualités).

For more information or a copy of the presentation please contact Nicola Bedlington.

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19. 2ND PAN-EUROPEAN CONFERENCE ON HAEMOGLOBINOPATHIES, BERLIN

Nicola Bedlington attended, on behalf of EPF, the 2nd Pan-European Conference on Haemoglobinopathies, in Berlin on 13 and 14 March 2010. Panos Englezos, President of the Thalasaemia International Federation (TIF) and member of the EPF board, welcomed participants highlighting the added value of such a largescale educational event. This was an important opportunity to meet several hundred patients and allies from TIF, and other related organisations and to learn more about their views on the latest scientific and policy developments in this area. A particularly strong intervention was made by patient advocate Chris Sotirelis on Adherence to therapies – a patient's perspective. Chris outlined for the audiences the philosophical and social differences between compliance, adherence and concordance – calling on more emphasis on the latter in the spirit of 'let's face (this condition) together'. To read more on the conference from the organiser, Thalassaemia International Federation please go the members section.

For more information on the conference and a copy of the presentations please go to www.thalassaemia.org.cy

20. EU HEALTH PORTAL MEETING

EPF Director Nicola Bedlington represented EPF at the EU Health Portal editorial meeting on 16 March in Barcelona. The meeting was an opportunity to review and make suggestions regarding the Health Portal developments, and also examine the new DG SANCO website. Nicola Bedlington called for more systematic references to Health Stakeholders' work in the EU Health Portal, and specific links via the European Union Health Policy Forum membership list. In the context of the revamping of the EPF website, EPF is exploring how to work best with the EU Health Portal.

For more information please contact Nicola Bedlington or Kia Megas.

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21. SANCO WORKSHOP ON DATA PARTNERSHIP

The Directorate General for Health and Consumers (DG SANCO) of the European Commission organised a Workshop on Data Partnership on 17 March in Brussels. Roxana Radulescu represented EPF at this meeting. The workshop was organised as a follow-up of an internal reflection process DG SANCO initiated during the course of 2009 - known as the Data Strategy project - and following the Future Challenges exercise and the conclusions of the related conference on Delivering for Tomorrow's European Consumer (29-30 October 2009).

The objective of this Data Strategy is to ensure that SANCO uses the most efficient processes and the best possible quality of evidence throughout the policy-making and for its impact assessments. While SANCO is as a big data generator (statistical data, information about policies' implementation, qualitative knowledge, etc) stakeholders are also important providers of health related-data and therefore there is a need to decide together common principles of transparency and quality.

Stakeholders invited at the meeting (industry representatives, NGOs) exchanged views on data-relating challenging such as: asymmetries in capacities to produce, collect and access data between different stakeholders, the need to respect existing rules on confidentiality, the need for clear quality indicators on how the data was assessed and how it will be used, transparency principles, and other views. SANCO will use this input to draft a consultation document by 15 April which will be open for comments thereafter for four weeks.

EPF contributed in the past to the Future Challenges process and participated in the related conference on Delivering for European Consumers. The Secretariat will follow this process and will prepare a response in consultation with our members reflecting on best options, from a patient organisation perspective, to access more easily data and use it for analyses and future initiatives.

For further information, please contact Roxana Radulescu.

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22. PROMOTION AND PROTECTION OF PATIENTS' RIGHTS AND ACCESS TO HEALTHCARE AT THE EUROPEAN COMMISSION

Kia Megas attended "Promotion and Protection of Patients' Rights and access to healthcare" at the European Commission on March 25 where she presented EPF and the Value+ project "Patient Involvement in EU Health-related Projects".

The event was organised in co-operation with the Veneto Region Brussels Office and included approximately 30 participants from civil society organisations in the Western Balkans and Turkey. The aim of the event was to provide civil society organisations from beneficiaries to familiarise themselves with EU structures, policy making process and programmes related to community-based services relating to promotion and protection of patients' rights and to access to healthcare.

The "study tour" gave participants the opportunity to learn and discuss how to improve access to healthcare, especially among those socially excluded through promoting equity and advocating for patient rights at all stages of their lives.

23. IAPO 4TH GLOBAL PATIENT CONGRESS

On February 23 – 25, Kia Megas represented EPF at the International Alliance of Patients' Organization's (IAPO) 4th Global Congress that took place in Istanbul, Turkey. The event brought together patient representatives from around the world. The event "Strengthening Healthcare Systems Globally: The Value of

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Patient Engagement", explored and discussed meaningful engagement in healthcare design and delivery. Guest speakers included representatives from the World Health Organization and the Council of Europe.

Kia Megas and Elizabeth Winder from EPF moderated and presented a workshop at the congress. The workshop on improving patient involvement in the European Union and was framed around the Value+ model and definition of meaningful patient involvement. This session provided participants with an overview of patient involvement within the European Union (EU) through the findings of the Value+ project and highlighted examples of successful and unsuccessful involvement and then later examined how involvement in that context can be improved.

For outcomes, photos and presentations of the conference please go to:
www.patientsorganizations.org/congress

24. EUROPEAN PATIENTS' RIGHT DAY

Join Active Citizenship network and other patient organisations around Europe to celebrate and promote the 4th European Patients' Rights Day which will be held this year on April 18. In modern healthcare, where moving towards a more 'expert' or 'informed' patient approach, for example, to chronic disease management, is becoming the norm, there is an increasing need to view the patient as an active citizen who participates in their treatment. And therefore putting patients at the centre of EU policy making is essential. This can only be effective with the cooperation and commitment of all health stakeholders in every EU country. Active Citizen Network believes that celebrating European Patients' Right Day can increase awareness regarding the importance of patients' rights and everyone's responsibility in guaranteeing their respect.

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EPF will be participating by writing a press release reiterating our commitment to young patients and their importance to be at the centre of health policy. We encourage you to join in on the celebration and get involved in the 4th European Patients' Rights Day. For more information on how you can participate or become involved, please click on the call for participation. Please click here for the report.

25. WORLD HEALTH DAY

On April 7, the world will be celebrating World Health Day 2010. Every year, this momentous day focuses on different health issues that face our world today. This year, the focus is on urbanisation and health. The campaign "1000 cities – 1000 lives" organises events around the world calling upon cities to open up their streets to health activities. For more information on World Health Day, go to the World Health Organization's website at www.who.int/world-health-day/2010/en

26. EPHA ROUNDTABLE ON THE ENGAGEMENT OF POLISH HEALTH STAKEHOLDERS IN EU-LEVEL ADVOCACY

On 23 February, Roxana Radulescu and Magdalena Machalska represented EPF at a meeting organised by the European Public Health Alliance in the frame of a 2-day workshop on the engagement of Polish health stakeholders in the EU-level advocacy.

The purpose of the meeting was to identify a current model of civil society in Poland and to discuss how to foster its greater participation in public health policy-making process.

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During the round table discussion where several Polish associations as well as European representative organisations participated, it was discussed how to ensure further developments of Polish civil society in the public health environment. Although the Polish civil society has been built in a specific historical and political context, a clear need for support from European partners was identified during this meeting.

For more information, please visit www.epha.org/a/3839

Member News

27. COLLABORATION BETWEEN ALL STAKEHOLDERS IS ESSENTIAL TO IMPROVE SERVICES FOR PEOPLE LIVING WITH THALASSAEMIA AND SICKLE CELL DISEASE IN EUROPE

The conclusion of the 2nd Pan-European Conference on Haemoglobinopathies, held on 13–14 March 2010 in Berlin, was that closer collaboration between medical and patient communities, as well as national and EU-level decision-makers, is needed to improve the quality of life of patients with haemoglobin disorders across Europe.

Five hundred patients, parents, doctors and other stakeholders from 34 countries, including 19 EU Member States, gathered in Berlin on 13–14 March 2010 for the conference, held under the theme “Patients and health professionals together for optimal care”. The conference was organised by the Thalassaemia International Federation in partnership with Charité-Universitätsmedizin Berlin, and supported by the European Commission in the framework of its Health Programme.

Thalassaemia and sickle cell disease are chronic conditions that require life-long care by a multi-disciplinary team. Patients also need support with psycho-social aspects, such as self-image, fear and insecurity about the future; education and employment issues; and help in navigating the complexities of the healthcare and social welfare systems. Haemoglobin disorders are still little known, both among medical staff and by service providers, and

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patients’ access to appropriate quality treatment varies across Europe. The situation is complicated by the fact that most patients belong to ethnic minority communities and are dispersed thinly across and within countries.
The focus of the 2nd Pan-European Conference on Haemoglobinopathies was on educating both doctors and patients on the latest medical advances, but also on empowering patients living with haemoglobin disorders to take an active part and get involved in the shaping of health services. A comprehensive conference report will soon be available on TIF’s website, www.thalassaemia.org.cy

EPF and Secretariat

28. OUTCOME OF EPF BOARD MEETING

The EPF board met for its quarterly meeting on 18 February to review our achievements in 2009 in accordance with performance indicators outlined in our 2009 work plan, and to agree on the EPF annual report 2009 to be presented at the Annual General Meeting in May for approval. It was also an opportunity to look at interim final accounts for 2009 and the financial position for EPF in 2010. Important discussions and decisions took place on developments linked to eHealth, research, and social media and our relationship with the new Commission and the Presidency Trio. New membership applications were assessed and a debate on strengthening the EPF statutes to ensure clarity regarding criteria for full membership from national platforms also were discussed. Draft amendments to the current Constitution will be discussed at the next board meeting on 31 March, that will further shape the Annual General Meeting.

For more information, please contact Nicola Bedlington.

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29. EPF MEMBERSHIP GUIDE

Earlier this year EPF launched a new publication. The Membership Guide was developed with two goals in mind. The first being to help our members maximise the benefit of their membership with EPF and the second being to inform potential new members about EPF. The guide provides useful information on topics such as the added value of joining EPF and what EPF as an organisation needs from its members to foster collaborative relationships to achieve common goals. We encourage you to browse through the Membership Guide and discover information that can help build the strong cooperation between EPF and its members. The guide is currently available online at EPF's website: www.eu-patient.eu/. We would also appreciate feedback from members on the Membership Guide and where we could improve.

30. EU STRUCTURAL FUNDS: WHICH ROLE FOR PATIENTS' ORGANISATIONS?

Originally conceived as mere redistribution mechanisms, the Structural and Cohesion Funds have become the main financial instruments to support growth and jobs across all EU Member States and regions. By addressing the major determinants of Health, Structural Funds can play a pivotal role in reducing health inequalities and ensuring more effective provision of healthcare services throughout the EU.

A first overview of Structural Funds programmes and projects has been undertaken as part of the EPF-led Value+ project with a view to understanding to what extent are patients' organisations being involved in Structural Funds-supported operations, particularly in connection with health-related initiatives. The analysis has revealed that patients' organisations involvement has so far been very limited in terms of both access to

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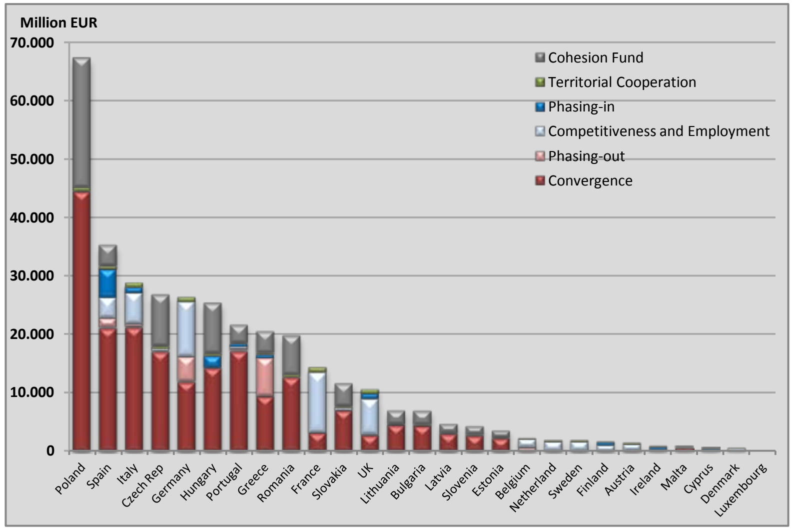

Structural Funds allocations across EU Member States in 2007-2013 (in Million EUR, current prices).

Source: Own elaboration based on DG Regio data

funding streams and participation in the preparation, implementation and monitoring of health relevant programmes. This is due to many factors: a) the types of eligible actions under both the European Regional Development Fund (ERDF) and European Social Fund (ESF). For instance, a clear link with the labour market is often a fundamental requirement for determining the scope of ESF-supported intervention in the area of Health; b) the type of projects supported which tends to target single beneficiaries rather than a large consortia in which patients' organisations can participate as associated partners (even though projects implemented by partnerships are not rare particularly under the ESF); c) too complex administrative requirements *vis-à-vis* patients' organisations limited internal resources; d) lack of knowledge and awareness of the opportunities presented by the Structural Funds; e) no-possibility to benefit from capacity building operations through Technical Assistance (TA) programmes, as in the large majority of cases TA is considered to be earmarked for the use mostly of the Managing Authority or other public bodies.

In the post-2013 programming period it will be important to ensure that patients' organisations will:

- Be regarded as potential beneficiaries of Structural Funds operations
- Have a say in the preparation of the strategic documents
- Be properly involved in setting objectives and priorities in the preparation of the operational programmes which include health-related measures and are included in their implementation and monitoring

In this context EPF commitment will be manifold.

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First, we will continue to disseminate our Model of Meaningful Patient Involvement developed as part of the Value+ project with a view to applying it to projects other than those receiving direct funding from the European Commission.

Second, we will develop an ad-hoc guide to assist patients' organisations in playing a more active role in Structural Funds delivery. This guide will not simply be a "how-to-guide" on how to obtain support from the Structural Funds, nor will it be a policy document providing for recommendation on how the Funds should be shaped to meet future healthcare challenges. Instead, by looking at the way in which the Structural Funds programming documents are designed, implemented, monitored and evaluated it will provide useful information and recommendations on how patients' organisations can play a pro-active role in that process.

Last but not least, EPF will play an active role in the upcoming policy debate over the post-2013 Cohesion Policy to advocate in favour of a stronger recognition of patients' organisations in the context of the EU structural spending.

For more information, please contact Walter Atzori.

31. EPF AGM AND HTA SEMINAR

EPF's Spring Seminar on Health Technology Assessment (HTA) and the EPF Annual General Meeting (AGM) will take place on 18-19 May. This closed event for EPF members and patient groups leaders will be held at the Crowne Plaza Europa Hotel in Brussels. EPF is delighted to announce that our honorary guest speaker at the AGM will be new Health Commissioner John Dalli. The meeting will be an exciting blend of business, vision, policy reflection and dialogue with our new Commissioner for Health. Also on the agenda are board elections. The current two year term for some members will come to an end and elections for the new board

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will be taking place. The HTA seminar, undertaken in conjunction with the AGM will gather approximately 70-80 patient leaders across Europe to learn more about the science, methodologies, processes and policies behind HTA and how they can become involved in a meaningful way as patient representatives.

For more information, please visit our website www.eu-patient.eu/Initatives-Policy/Events/Annual-General-Meeting-2010/

32. STAFF NEWS

In March of this year, EPF said goodbye to Valentina Strammiello, EPF's office manager who began with us in October of 2008. To replace Valentina EPF recruited a new office manager and we welcomed in March this year Veronique Tarasovici to the EPF team. Veronique, is a native Belgian with more than 10 years of working in an administrative support role for both NGOs and companies. Veronique has a degree in Social and Fiscal Administration. In her last job, as office manager she was responsible for the overall set up of the Secretariat office. We wish Valentina all the best in her new endeavours and give a warm welcome to Veronique.

33. US HEALTHCARE REFORM BILL – WHAT DO PATIENT ORGANISATIONS REALLY THINK

The historic healthcare reform bill that recently passed on March 21 and signed by President Obama on March 23 after a very controversial debate was received by many US citizens with mixed feelings. However, patient organisations and health professionals in the U.S. have unanimously welcomed the bill with a positive outlook for healthcare in the United States for patients.

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The American Cancer Society believes that the new healthcare reform bill (which proposes significant investment in cancer prevention through screening programs) will avoid up to 60 percent of cancer deaths. They believe that the current system is too costly for cancer patients who often have to fight not only for their lives but for the life savings.

The American Diabetes Association and Mental Health America who also strongly support the bill believe that the new healthcare system will help provide better access for those patients with specific conditions. It will further help patients with an already pre-existing condition receive treatment or access to healthcare that was previously deemed impossible.

The CEO of the American Heart Association said the following“: *We are very pleased that the Affordable Health Care for America Act makes health care more accessible and affordable for millions of Americans by enhancing coverage, promoting preventive care and improving delivery of care. But this milestone also serves as a sober reminder of the tremendous amount of work we still have before us if we are to ensure that the legislation that ultimately emerges from Congress and is sent to the President retains the patient protections and provisions that are in line with the association’s tenets of healthcare reform and are so important to individuals struggling with heart disease and stroke and their families”.*

On the other hand, the National Nurses United believes that the healthcare bill gives away too much to insurance companies and “fails to meet the test of a true healthcare reform” guaranteeing high quality, cost effective care for American citizens. Little is done to control the prices which will force Americans to have to buy insurance. While the American Medical Association (an American-based association that help doctors help patients to work on the most important public health issues) while recognising the imperfections of the reform bill, they firmly support it noting that the bill is a step forward in providing coverage to all Americans and improving the nation’s overall healthcare system.

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34. DIARY

April 6	EPF Policy Advisory Meeting Attendance: Nicola Bedlington and Roxanna Radulescu
April 10	Joint Workshop RESPECT and PatientPartner projects Location: Brussels Attendance: Walter Atzori and Liuska Sanna
April 14	Meeting with the Cabinet of the Commissioner for Enterprise Location: Brussels Attendance: Anders Olauson, Nicola Bedlington
April 14	Impact of Internet Pharmacy Services and Medicine Services on Patient Healthcare and Safety, European Parliament Location: Brussels Speaker: Nicola Bedlington
April 15	Meeting with PGEU Representatives Location: Brussels Attendance: Nicola Bedlington, Roxanna Radulescu, Liuska Sanna
April 22	Media Workshop on Health Location: Annecy, France Speaker: Nicola Bedlington
April 22	Health for All Care for You – The Challenges of Personalised Medicine Location: London Attendance: Mike O'Donovan
April 27	EPFIA Think Tank Location: Brussels Attendance: Nicola Bedlington

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April 27 – 29	Vitalis Conference Location: Gothenburg, Sweden Speaker: Anders Olauson on eHealth
April 21-23	Autumn Seminar planning meeting Location: Budapest, Hungary Attendance: Liuska Sanna
April 23	eHealth Users Stakeholder Group Meeting Location: Brussels Attendance: Liuska Sanna
April 30	European Society for Quality in Healthcare Location: Istanbul, Turkey Attendance: Magdalena Machalska
May 4-6	RENEWING HEALTH project meeting Location: Berlin Attendance: Liuska Sanna
May 4	National Pharmacist meeting and Portuguese Patient Group meeting Location: Lisbon, Portugal Attendance: Nicola Bedlington
May 18	EPF HTA Seminar Location: Brussels
May 19	EPF Annual General Meeting Location: Brussels
May 20	High Level Commission Inter-DG Conference Clinical Trials Location: Brussels Speaker: Anders Olauson
May 20	EU Health Policy Forum Location: Brussels Attendance: Nicola Bedlington

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May 20	Health Executive Summit Location: Paris Attendance: Anders Olauson
June 4	Patient Safety Meeting Location: Madrid Speaker: Nicola Bedlington
June 6	EUNETHTA Stakeholders meeting Location: Dublin Attendance: Nicola Bedlington
June 6	National FP7 Coordinators meeting Speaker: Susan Palkonen
June 8	Open Information Day Health Calls FP7 Speaker: Nicola Bedlington
June 10 and 11	Global Health Conference Location: Brussels Attendance: Anders Olauson and Nicola Bedlington
June 14-17	RESPECT meeting Location: Brussels Attendance: Liuska Sanna
June 24	FP7 Advisory Council Location: Brussels Attendance: Anders Olauson
June 28-29	Open Health Forum Location: Brussels Attendance: Nicola Bedlington and Anders Olauson

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