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LATEST NEWS

EPF President Anders Olauson was awarded with H.M. The King's Medal at the Royal Palace in Stockholm on 28 of January. This prestigious award was presented to Anders for his extensive commitment in the field of patients rights and his tremendous support for families with young patients in Sweden – please go to the EPF website for more details.

Dear EPF Members and Allies,

A warm welcome to the first EPF mailing of 2010 – we hope that the year has also started out well for you. 2010 promises to be another very active year for EPF and its members and allies and we look forward very much to working together with you to advance patient-centred EU healthcare policy and programmes.

In this issue you will find an overview of the latest policy developments. We share with you an impression of the Commissioners' Public Hearings in the European Parliament and an analysis of John Dalli's input as the new Commissioner for Health.

In the last few weeks important EPF responses were submitted to the Commission on the Clinical Trials Directive impact assessment (see section 4) and the Review of EU Financial Regulation (see section 10). We were also a part of the drafting group of the European Union Health Policy Forum's document on Barroso's 2020 Strategy (see section 12).

Go to section 2 for an overview of the European Parliament Reports on Pharmacovigilance and Anti- counterfeiting – EPF is very pleased that much of the content of our position papers on these issues have been included in the draft reports.

The European Commission's Exploratory Process on Medical Devices concluded with a final meeting on 21 and 22 January. EPF congratulates the Commission on this process, and the report which raises important public health issues and competitive questions which will require further debate in the follow up process. (see section 3)

We have started planning our seminar for patient group leaders on Health Technology Assessment that we will combine with our Annual General Meeting on 18 and 19 May – please save the date. More information on this will be sent to EPF members and patient group allies in the coming weeks.

We are also delighted to announce that EPF will launch a new, more accessible and vibrant website on 18 February to coincide with the EPF board meeting in Brussels. We look forward to your comments on the new website, and also members' contributions to the website!!

Warmest greetings,
Anders Olauson, President
Nicola Bedlington, Director

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Next issue of the EPF Mailing -deadline for articles 25th March 2010, distribution early April 2010.

Where are previous issues of the mailing? Click on the image!

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1. HEARING OF THE NEW HEALTH COMMISSIONER

On 14 January, the European Parliament's Committee on Environment, Public Health and Food Safety (ENVI), as well as delegations from the Internal Market and Consumer Protection Committee (IMCO) and Agriculture and Rural Development Committee (AGRI) held the hearing of Commissioner Designate John Dalli. Mr. Dalli, a Maltese national, made a strong performance with very promising changes and progress in healthcare initiatives.

Mr. Dalli promised to be the guardian of consumers' and patients' interests in the Commission and highlighted that the underlying theme of his work would be "Patients First, Consumers First". His vision is to see: "EU citizens live longer and healthier lives and informed consumers make informed decisions". Concerned by the question of sustainability of healthcare systems in Europe, Mr. Dalli pointed out the need to invest more in prevention and health promotion. Highlights in his opening address were: access of all our European citizens irrespective of nationality and socioeconomic status to good and timely treatment and to affordable medicines; close the gap in health inequalities; high food safety standards; move forward on the GMOs cultivation and protect consumers' interest, with scrutiny and independent review of any decisions.

On the role of patients' organisations, Mr. Dalli highlighted that there were key sources of information and feedback for decision-makers and that it was his duty and that of the MEPs to ensure that they were properly supported. Despite the small budget for public health, he committed to find other ideas and put something of his financial expertise to support these groups and ensure their independence.

Mr. Dalli tackled several specific policy issues during the hearing (see attached). With extensive ministerial experience, determined and committed to take the lead, Mr. Dalli came well prepared, showing extensive knowledge

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of the different dossiers. However, on certain dossiers he did not offer firm proposals about how to tackle certain challenges such as health inequalities.

We need indeed a strong Commissioner who can keep his promise of putting patients and consumers first and carry out these actions, making a case for health in all policies among his fellow colleagues in the European Commission. The problems facing health systems and the current economic situation requires strong, courageous political leadership from the Health, Finance and other Ministers across the EU Member States and from the respective European Commissioners to embrace solutions that put EU citizens first.

For further information on the hearing:
www.europarl.europa.eu/hearings/press_service/product.htm?language=EN&ref=20100113IPR67206&secondRef=0

2. PRIORITIES OF SPAIN AND BELGIUM EU PRESIDENCIES

The Trio Presidency of Spain, Belgium and Hungary, calls for solidarity and innovation in health. Its purpose is to promote health across the EU policies in line with principles shared by Member States and the EU health strategy adopted for 2008-2013. Special attention will be paid on the promotion of healthy lifestyles, including healthy nutritional habits.

The **Spanish presidency** of the European Union, which started in January 2010, will focus on three key elements with regard to health, namely health inequalities, human organs and chronic diseases.

Concerning the first priority, an expert conference will be held in April ahead of the informal Council of Ministers meeting from 22-23 April, to agree on "better indicators" and improved health information systems across the EU and make it easier to identify inequalities based on socio-economic criteria.

Furthermore, Spain will try to reach an agreement on the organs directive proposal at the Health Council on 8 June. An expert conference on this issue will be held on 23 March in Madrid.

The third priority of the Spanish authorities is to tackle the problem of chronic diseases. The Presidency is going to organise two expert conferences on this issue: one will focus on eHealth and the other on patient safety related to infectious, cardiovascular and chronic mental health diseases. To promote eHealth and new information technologies applied to medical care, a ministerial conference will be held in Barcelona between 15 and 18 March.

Moreover, the Spanish Presidency is going to work on **patient safety** and is planning to continue with the review of the legislation on medicines started by previous Presidencies, especially the directives and regulation on counterfeit medicines and pharmacovigillance. EPF representatives will be speaking at both these events.

However, little progress is expected on the cross-border healthcare directive, since Spain was opposed to the last compromise text from the Swedish EU Presidency. On Tuesday 26th January in the European Parliament, the Spanish Minister of Health, Ms. Trinidad Jimenez Garcia-Herrera, stressed that it is essential to request prior authorisation or to establish a system of control for public and private health centres across the EU.

Belgium is going to take over the EU Council Presidency from July 2010. This will be driven by the motto 'health safety'. A number of conferences will be held in Brussels to draw attention to disease prevention and special attention will be paid to promote the Belgian Cancer Plan. Together with the European Commission, Belgium is going to organise a conference on chronic diseases in October 2010 where patient organisations

will have the opportunity to be involved in these discussions. Ageing Europe will be another priority. Moreover, an informal meeting will be held this July regarding the European Commission's Green Paper on the EU Workforce for Health.

For more information, please consult:

- www.eu2010.es/en/documentosynoticias/noticias/trinibruselas.html
- www.europolitics.info/social/organs-health-inequalities-consumer-head-spanish-priorities-art258933-26.html
- www.standaard.be/artikel/detail.aspx?artikelid=B357126661001 26&word=EU

3. CONCLUSION OF THE MEDICAL DEVICES EXPLORATORY PROCESS

The EU **exploratory process on the future of the medical devices sector** began in October 2009 to map the existing public health and industrial challenges in the sector and investigate possible topics of reflection at the European level. This process was an opportunity for industry, users, and consumers of medical devices to share views, experiences and aspirations. Various members of EPF have been involved during the entire process.

The objective was to gather an **overview of existing public health and industrial challenges, to identify current dynamics of the industry and highlight key topics of interest at the European level** which should result in a set of **suggested themes of potential further reflection**.

The process was organised around two discussion sessions with representatives of the stakeholders organisations and experts in the field of medical devices involved. In addition to a plenary session, the participants explored more in depth challenges covered within three distinct work streams.

- Future challenges and opportunities for public health and medical technologies developments
- Balance between the patients' needs and financial sustainability
- Competitiveness and Innovation of the medical devices industry

The final meetings on the exploratory process on medical devices took place on 2 and 23 January 2010. For this last meeting, EPF in collaboration with BEUC (EU consumer organisation) presented a discussion paper on information to patients on medical devices, drawing on the Pharmaceutical Forum process and the quality principles agreed in this context.

Please go to http://ec.europa.eu/enterprise/sectors/medical-devices/competitiveness/exploratory-process for a copy of the final report that outlines the core themes for further reflection and details the discussions that took place in the three work streams outlined above. EPF was pleased with the process and the concrete outcome which gives a clear framework for future work and created greater awareness across different stakeholders on the range of concerns and opportunities in the medical devices field.

For more information please contact Nicola Bedlington.

4. COMMISSION'S CONSULTATION ON CLINICAL TRIAL DIRECTIVE

Readers will recall that EPF participated in a Commission meeting on the Clinical Trials Directive Impact Assessment back in November, alongside a number of other patient groups. On the basis of this meeting, EPF prepared a memorandum to its membership outlining the issues at stake and inviting comments and experiences to feed into the Commission's Consultation process on the Clinical Trials Directive.

The formal procedure closed on 8 January but EPF obtained an extension to 19 January in order to refine and finalise our contribution with our members and the Policy Advisory Group. We also drew on evidence from the Value+ project, the PatientPartner project which is coordinated by VSOP, the Dutch Genetic Alliance, in the Netherlands, the INVOLVE group in the UK, the RESPECT project on the meaningful involvement of young patients in clinical trials and the work we are undertaking with EMEA in relation to Third Country Clinical Trials and the Patients and Consumers Working Party.

Our response focused on the inclusion of key patient issues that were not featured in the consultation paper, namely:

- Ensuring that there is meaningful patient involvement across all aspects of clinical trials, so that they are centred on patients. We believe that this will enhance and improve the outcome of clinical trials. This may also increase patients' participation rates in clinical trials.

- Giving patients access to quality information regarding clinical trials.

- Transparency concerning the results of clinical trials (even if the clinical trials failed or did not achieve the expected results)

- Meaningful informed consent, especially regarding patients from the mental health arena

For a copy of the Commission's Consultation document, please go to:
http://ec.europa.eu/enterprise/sectors/pharmaceuticals/files/clinicaltrials/docs/2009_10_09_public-consultation-paper.pdf

For a copy of EPF's response to the Consultation, please click here.

5. HEALTH TECHNOLOGY ASSESSMENT (HTA) STAKEHOLDER MEETING (EUNETHTA)

The report from the HTA Stakeholder meeting on 6 November is now available online
(see EPF report in the last EPF mailing)

www.eunethta.eu/Public/Home/Stakeholder-involvement-in-HTA-meeting-November-6-2009-Brussels-Belgium

During the first two months of the EUnetHTA Joint Action which started its activities in January 2010 , the EUnetHTA Secretariat is developing an application procedure to become a member of the EUnetHTA Stakeholder Forum. EPF has already expressed an interest to be part of this Forum.

The first EUnetHTA Stakeholder Forum meeting is scheduled for June 6, 2010 in Dublin (in connection to the HTAi Annual Conference, www.htai2010.org/site)

EPF is organising an HTA seminar on 18 and 19 May to which we have invited the coordinator of EUnetHTA among other prominent HTA experts. We are also exploring involvement in a new HTA project under the EU Public Health Programme as an associate partner.

For more information from the Secretariat please contact Nicola Bedlington.

6. PATIENT SAFETY AND QUALITY OF CARE WORKING GROUP

EPF is a member of the Patient Safety and Quality of Care Working Group. In preparation of a meeting held on 2 February in Brussels, the Commission put forward a "Reflection Paper on Quality of Healthcare: Policy Actions at EU Level". The paper outlines some specific objectives that could contribute to improving the quality of healthcare in the EU, such as to:

- Achieve a common understanding of quality in EU Member States
- Propose a collection of comparable data
- Promote continuous healthcare quality improvements in all Member States
- Establish a culture of mutual learning among Member States

EPF provided feedback to the Commission outlining the need for a patient-centred approach and for patients' meaningful involvement in policies on safety and quality and the importance of patients' health literacy. We are pleased that these aspects were well reflected in the paper.

The Commission also proposed the following policy options:

- **Option 1:** Further work utilising existing opportunities - continuing the current work under the existing programmes, mechanisms and structures and include quality: use the Research Framework Programme, Health Programme, Health Strategy, Open Method of Coordination on Social Protection and Social Inclusion or the Commission Patient Safety and Quality of Care Working Group

- **Option 2:** An enhanced collaboration mechanism between Member States and the EU - setting up at the EU level a mechanism (for example a network, platform or joint action) to complement the actions taken by the individual Member States

- **Option 3:** A Recommendation on healthcare quality - This frequently used option in the area of health at the EU level would take the form of a Council Recommendation and consist of proposals to Member States and to the European Commission, aiming to put in place effective quality improvement strategies in the EU

- **Option 4:** Common quality standards for EU Member States. This would cover: setting up common EU requirements for the quality of health services, proposing quality standards, and putting in place common quality assurance systems.

While a few Member States like UK, FR, DE have expressed resistance to EU action on quality, new Member States seem to be much more in favour of a European cooperation and have called for a non-binding instrument from the Commission to encourage further work on quality of care at national level. EPF will work with its members on this issue to advance our unique patients' perspective and move forward the EU agenda on quality of care.

The reflection paper would be submitted to a wider public consultation in summer 2010.
For further information, please contact Roxana Radulescu.

7. PHARMACEUTICALS PACKAGE – WORK WITH THE EUROPEAN PARLIAMENT

EPF is very pleased that much of the content of our position papers on the Pharmacovigilance and Anti-counterfeiting legislative proposals have been included in the draft reports. EPF has intensively worked with the MEPs and proposed a series of amendments:

On anti-counterfeiting, we focussed on involving patients and consumer organisations in initiatives to increase awareness among patients and the general public on the risk related to purchasing medicinal products on the Internet. EPF also pointed out that safety features should be mandatory for all medicines listed in a restricted list of medicinal products conceived and developed by the European Commission, Member States, in consultation with stakeholders, including patients´ organisations.

On pharmacovigilance, EPF advocated for patients' organisations to be involved in providing information and training to patients and in developing public information campaigns in cooperation with regulatory bodies. We particularly welcomed MEP McAvan's report which outlined the need for alternative reporting formats to facilitate direct patients' reporting of suspected adverse reactions, in addition to web-based formats. EPF considered important to specify these: email, telephone, fax and letter.

EPF is also pleased that at the public hearing, Commissioner Dalli planned to move fast on the two legislative proposals and to ensure the highest possible safety for patients. He specifically stated that action was needed to fight counterfeit medicines sold over the Internet and committed to work with his colleagues on these issues.
For further information, please go to: www.europarl.europa.eu/oeil/file.jsp?id=5729472

Please see attached counterfeiting and pharmacovigilance amendments.

8. PATIENTS' RIGHTS IN CROSS-BORDER HEALTHCARE - AN UPDATE

After failure to reach an agreement in the Council on the Directive on Patients' Rights in Cross-border Healthcare (December, 1 2009), there has been some recent encouraging developments. In the European Parliament, the appointed rapporteur for the second reading, Member of the European Parliament (MEP), Françoise Grossetête expressed publicly her commitment to put pressure on the Member States and the Spanish Ministry of Health in particular to revive the proposal. "It's a deception, but nothing is lost" she stated.
Moreover, during his public hearing in front of the European Parliament, Commissioner –designate John Dalli committed to work hard with the Spanish EU Presidency, the Council and Parliament to hammer out a solution for the Directive. Several MEPs raised their questions on the future of the directive to the Commissioner. In particular, Lithuanian MEP Radvilė Morkūnaitė, who specifically encouraged the Commissioner to be active on this dossier and seek a common position.

Finally, on 26 January, the Spanish Minister of Health, Trinidad Jiménez Garcia-Herrero presented the Spanish EU Presidency's priorities for health and committed to drive forward the proposal and to achieve consensus among Member States. She explained that it was important to focus on quality so that the proposal "respects the basic principles of patient safety and quality''.

EPF will monitor the forthcoming developments on this issue and will continue to engage with the Spanish EU Presidency, the Commission and the Parliament and advocate for ALL patients' fundamental rights to quality healthcare, in their country and abroad.

For further information, please go to:
www.europarl.europa.eu/activities/committees/publicationsCom.do?language=EN&body=ENVI

9. eHEALTH

On 21 January, Roxanna Radulescu attended a meeting on the European eHealth Governence Initiative/Joint Action. This is an initiative that DG Sanco and Infso have been working on with the Member States and Spanish Presidencies.

The meeting presented findings of the initial preparations for the drafting of the proposals both for the Joint Action on eHealth and Thematic Network (TN). The main goal of the meeting was to plan the content and deliverables for the formation of a European eHealth Governance Initiative and plan for next steps in regards to available funding mechanisms and to also bring together Members States to participate voluntarily in the initiative and all relevant stakeholders. Keynote speakers included a welcome from the Spanish Presidency and the Swedish Ministry of Health.

For further information on the European eHealth Governance Initiative, please contact Artur Frutado (artur.furtado@ec.europa.eu) or Flora Giorgio (flora.giorgio@ec.europa.eu).

10. EC REVIEW OF THE FINANCIAL REGULATION - CONSULTATION

The European Commission launched a consultation late last year on a review of the financial regulation. The main objective of the review is to simplify the financial rules and procedures applicable to the EU Budget. EPF consulted its members and patient group allies concerning the consultation and submitted a response on 18 December.

EPF will continue to work vehemently with the European Commission to ensure core funding for patient groups to be able to play their role effectively, based on principles of transparency, independency and also diversity of funding sources.

For a copy of the public consultation, please go to:
http://ec.europa.eu/budget/consultations/FRconsult2009_en.htm

For a copy of EPF's response, please see attached.

For more information contact Nicola Bedlington.

11. EMA WORKING GROUP ON THIRD COUNTRY CLINICAL TRIALS

The European Medicine Agency (EMA) Working Group on Third Country Clinical Trials met on 26 January in London. Roxana Radulescu participated in the meeting on behalf of EPF. The International Alliance of Patients Organisations (IAOPO) was also invited to take part in the meeting.

Readers will recall that the aim of the Working Group is to develop practical proposals for guidance regarding ethical standards required for clinical trials conducted outside the EU. EPF contributed to the discussions and the drafting of the paper and highlighted the need for adequate and complete information to patients and their families participating in the clinical trials. EPF also recommended the introduction of a glossary to explain some of the technical terms used in the paper in order to facilitate public access to EMA's recommendations.

The draft consolidated document should be adopted and circulated for public consultation by the end of

March 2010. The consultation period should last about three months. Moreover, a workshop will be organised this September for interested parties, regulatory authorities and patients organisations from countries outside EU.

For further information, please contact Roxana Radulescu.

12. THE EUROPEAN UNION HEALTH POLICY FORUM'S (EUHPF) CONTRIBUTION TO THE COMMISSION'S CONSULTATION ON THE FUTURE "2020" STRATEGY

EPF was part of a drafting group set up by the EU Health Policy Forum to contribute, from a public health perspective to the Consultation launched by the European Commission on the future strategy for 2020. Please see http://ec.europa.eu/eu2020/pdf/eu2020_en.pdf.

Please see attached the final version together with a cover note to President Barroso, which integrates as far as possible the wide range of comments from members of the EU Health Policy Forum.

For more details please contact Nicola Bedlington.

13. ANIMAL DIRECTIVE REVIEW

In November 2009, EPF co-signed a letter with other patient groups led by EGAN addressed to the AGRI committee members in the European Parliament regarding the impact that the review of Directive 86/609/EEC on Animal Research will have on patient communities.

There is now a compromise text with which the Council of Member States, the Commission, and the ENVI committee rapporteur are happy with. It has reached a political compromise and therefore requests of various stakeholders has been delivered to some extent. The patient's requests for there to be no "hard" limit on the use of non-human primates (NHP), and for decisions on NHP use to be made by ethical review have not been implemented, but the defined areas in which use of animals is permitted are just about broad enough for EGAN's concerns to be relaxed.

These definitions are open to both interpretation, and to mistranslation. EGAN hopes assistance is given to Member States to ensure that these errors do not occur and this directive is implemented evenly across the EU by Member States.

A plenary vote on this directive, like a number of other directives, is stalled due to the ongoing changes to EU comitology procedure following the Lisbon Treaty.

For more details please contact Nick Meade nick@gig.org.uk

14. THE GOTHENBURG CONFERENCE MARKED THE SUCCESSFUL COMPLETION OF EPF-LED VALUE+ PROJECT

The flagship conference held on 9-10 December 2009 under the patronage of the Swedish EU Presidency marked the successful completion of the two-year Value+ project. Value+, which was launched in February 2008, represented the first effort ever made to achieve an overarching EU-wide overview and analysis of current practice and trends regarding patient involvement in EU projects and to raise awareness about the added-value of involving patient organisations in EU supported health projects. To this end, the project has strongly relied on effective exchange of information, experiences and good practices among key stakeholders in the healthcare sector.

The conference, during which emphasis was laid on tools and results of the project, was particularly important to giving more visibility and thus strengthening project's outcomes and represented a constructive platform for furthering political commitment to enhancing meaningful involvement of patients.. Hence, it can be argued that the Gothenburg conference represented in many ways also the beginning of new networks and partnerships through which to continue the exchange of information, thoughts and ideas on how to enhance meaningful patient involvement beyond the lifetime of the project.

The conference unveiled the project's three key deliverables, notably the Value+ Toolkit, Handbook and a set of Policy Recommendations.

The Toolkit was developed to support patient and patient organisations in participating in European health-related projects and policy. To this end, the Toolkit, through which the importance of good practices already identified is

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thoroughly stressed, developed a model for meaningful patient involvement and a way to assess the involvement against the model.

The Handbook is targeted to projects coordinators and leaders with the aim of helping them maximise the benefits of involving patients and patient organisations in European health-related projects. In addition to providing recommendations and examples, the Handbook suggests further information that were regarded as particularly useful to those involved in EU projects.

The Policy Recommendations were developed on the basis of the assessment of a number of important areas where improvement is needed to effectively achieve a meaningful involvement of patients and patient organisations. The Policy Recommendations were strongly endorsed by the conference participants who also put forward many ideas on how to successfully translate them into reality not only at European, but also and perhaps more importantly at national level.

Future steps

The Value+ team, following discussions of the Steering Group and suggestions provided at the Swedish conference has many ideas on post-project activities that could even lead to developing a new project. Some scenarios foresee the promotion of Value+ resources through workshops and awareness-raising campaigns; the creation of a centre of excellence on patient involvement; support to patient-led research; setting up a training programme for different stakeholders. This year EPF will focus on disseminating the project results and deliverables while at the same time reflecting on a strategy for a next phase.

You can access information and resources of Value+ at www.eu-patient.eu/Initatives-Policy/Projects/ValuePlus/ or contact Liuska Sanna.

15. SECOND JOINT CALLIOPE-EPSOS WORKSHOP

Following the successful outcomes of the first CALLepSO workshop held on September 2 2009, CALLIOPE's and epSOS' partners gathered together in Brussels in mid-November 2009 for a second joint workshop in order to take further steps towards the elaboration of a common EU eHealth Interoperability Roadmap.

The workshop was organised around three main thematic and interlinked sessions:

The **first session** revolved around three topics: electronic Identity (eID) Management, the epSOS approach to patient consent, and the pilot delivery of services. The cluster on eID Management focused its attention on the key issues concerning heterogeneity of models across European countries (i.e., using cards vs using national ID portals), whether an EU action is needed, and the need for an EU-level common understanding of key concepts. Participants have strongly advocated the need for improved standardisation of common terms and more harmonization at European level. It was recognized, however, that the latter will be difficult to achieve. Thus, for the time being, rather than urge Member States to adopt one unique ID it has been decided that emphasis should be placed on soliciting the introduction of one unique ID mechanism.

The cluster on patient consent focused on how to establish the basis for epSOS consent in particular when the need to transfer patient summary data abroad is at stake. While acceptability and trust in the large-scale pilots and balancing legal with organisational requirements have been singled out as critical issues, the participants stressed that the real challenges are to assure an appropriate level of security and to re-assure patients that all the measures needed have been taken.

Identifying priorities and the structure of the Roadmap was the aim of the second session. On that occasion it was particularly stressed that the Roadmap should address not only national and regional authorities but also

and perhaps more importantly all organisations that have a mandate for the planning and deployment of eHealth as well as the European Commission services. A possible content and structure of the Roadmap has been then proposed and discussed. The idea is to conceive it as a set of stepping-stones which are directed towards a vision of an eventual integrated healthcare information system. It was also pointed out that a shared vision of the Roadmap, its process of development as well as an initial proposal that would support strategic and policy decisions at the European eHealth high-level group is to be defined and validated well in advance of the high-level conference to be held in Barcelona in March 2010.

The **last session** explored the responses of Member States to the Commission Recommendation on cross-border interoperability of electronic health record systems. During the discussion three main points where particularly stressed. First, Member States have different needs, diverse challenges, and are at different status of implementation with regard to eHealth interoperability. Second, the size of the country matters when it comes to making concrete decisions concerning needs and actions to be implemented. Hence, whereas bigger countries seems to be well capable of and prone to taking full responsibility for taking action, smaller countries tends to prefer to first learn much more about the process. Third, it is important to take into consideration which tasks should be dealt with and performed at a European level, and what should be left instead in the hands of Member States. The participants agreed on the fact that no additional work should be invested in any proposed amendment of the Recommendation.

With regard to CALLIOPE's future steps two major headings have been singled out: a) continue to develop and detail an EU Interoperability Roadmap of activities to be carried out at EU level, with clear added value for Member States; b) launch practical activities that would provide support to the Member States in the implementation of this Roadmap. Although these activities still need to defined, they were seen as being oriented towards site visits, peer reviews, and support from experts. In all cases, they are to be provided on a voluntary, "take it or leave it" basis.

For more information on CALLIOPE please contact Liuska Sanna or go to www.calliope-network.eu

16. STARTING A NEW EC CO-FUNDED PROJECT: RENEWING HEALTH

The kick-off meeting of the project RENEWING HEALTH took place on 8-9 February; EPF attended in quality of associated partner and member of the Users Advisory Board.

RENEWING HEALTH is the acronym for **REgioNs of Europe WorkINg toGether for HEALTH**, a project focusing on Telemedicine financed under the Competitiveness and Innovation Program - ICT Policy Support Programme (CIP-ICT PSP) – Pilot A actions.

The premise of RENEWING HEALTH is that innovative ICT-based services represent a new way of delivering healthcare to patients suffering from chronic conditions because they rely upon a new paradigm where the specifications of the services are derived from the needs and the demands of the patient.

Innovative services for the telemonitoring and the treatment of chronic patients are already operational at local level in nine of the most advanced regions belonging to nine Member States (Veneto IT, Southern Denmark DK, Country of Norrbotten SE, Region Northern Norway NO, Catalonia ES, South Karelia FI, Central Greece EL, Carinthia AT, Berlin DE). In order to help ensure the EU-wide interoperability of this ICT healthcare solutions, RENEWING HEALTH will implement in each of the participating region a large-scale real-life patient-centered pilot with a view to validating and evaluating existing innovative telemedicine services covering the main chronic pathologies affecting the European population i.e. cardiovascular, diabetes and COPD.

The project will yield many long term as well as short term benefits which can be categorised as clinical outcomes, patient/user, economic and organisational objectives:

- **Clinical objectives**: improve the quality of life of chronic patients

- **Patient/user perspective objectives**: provide clinical services through ICT that take into proper consideration patients' and professional users' needs, capabilities, risks and benefits
- **Economic objectives**: reducing the cost of chronic patients care to the society by promoting de-hospitalisation and more affordable homecare
- **Organizational objectives**: promotion of a new organisational model for telemedicine services

To achieve its goals, a total duration of 32 months has been envisaged for the project, out of which 18 will be devoted to the actual trials of the services in real-life conditions.

Consortium

The consortium is composed of 21 members comprising different types of players, i.e. regional health authorities, regional healthcare providers, competence centres in telemedicine, patients' and health professionals' groups, and industry. This variety of players will ensure the coverage of the entire value chain underpinning the RENEWING HEALTH business model.

The Role of EPF

Relying on its long-lasting engagement in the area of acceptance of telemedicine by patients and healthcare professionals, EPF will play a key role within the consortium by ensuring that these two crucial eHealth stakeholders fully understand the advantages of innovative telemedicine systems and services and are, therefore, willing to accept them.

Moreover, EPF will play an advisory and monitoring role in the project to voice the needs of chronic patients making sure that their demands are effectively met to the fullest extent possible and that all the activities of the project are centered around the interest of the patient.

Outcomes of the kick-off meeting

The kick-off meeting was held in Venice on 8-9 February 2010. On that occasion the partners discussed the various activities to be undertaken as part of each of the 19 WPs and the critical aspects relating to the implementation and coordination of the 21 pilot projects in the nine participating regions. During the meeting the role of the two Advisory Boards (users and industrial) and their relation with the other WPs was clarified, the cluster leaders were appointed and the MUST assessment methodology was presented and discussed. Partners will meet again in Berlin in May 2010 for a training workshop on the MUST assessment methodology while the second project meeting will be held in Thessaly, Greece in mid-September just before the start of the clinical trials in the participating regions.

For further information, please contact Liuska Sanna.

17. PUBLIC HEALTH PROGRAMME 2008 – 2010 – CALL FOR PROPOSALS 2010

The Call 2010 marks some changes in the approach taken by the European Agency for Health and Consumers (EAHC).

First of all the timeframe - the call was launched in December 2009 with deadlines for application in March 2010 whereas previous Calls took place in the period March-May. Second, the funding has been reduced, therefore the selection will be stricter and competition higher.

The Agency emphasises that only proposals with excellent award criteria will have a chance to receive funds. The funding forecast is described in the table below*:

Instrument	Projects	Joint actions	Operating grants	Conferences	General PH conferences
Indicative average size of the Commission contribution in Euros	1.000.000	1.000.000	400.000	80.000	200.000
Indicative number of funded proposals	13	10	5	5	1
Indicative number of proposals on the reserve list	5	Depending on availability of funding	2	2	0

**Table taken from EAHC website*

Evaluation teams will particularly welcome proposals having:

- Balanced participation
- A more comprehensive and long-term approach creating synergy with past and current efforts funded under EU and national programmes
- Including a full, independent evaluation
- A professional and effective dissemination of results to relevant target groups
- Arrangements facilitating an effective uptake of new public health approaches by relevant decision makers

If you are interested in becoming involved in the evaluation teams you can express your interest at: http://ec.europa.eu/eahc/phea_ami/

The deadline for submission of proposals is the 19 of March 2010. The specific Calls and related documents can be found at http://ec.europa.eu/eahc/.

If you are searching for project partners go to http://ec.europa.eu/eahc/management/finding.html.
For further information and support you can also contact Liuska Sanna.

Events and Conferences

18. HEALTH EXPERTS WARN EU POLICY MAKERS ABOUT A STROKE CRISIS AT A EUROPEAN PARLIAMENT BRIEFING IN BRUSSELS ON 9 DECEMBER 2009

Stroke affects some six million people in Europe and is one of the major cardiovascular diseases, second only to heart attacks. Atrial fibrillation (AF), the most common sustained abnormal heart rhythm, is a major risk factor for stroke. Importantly, AF-related strokes are more severe, cause greater disability and have worse outcomes than strokes in patients without AF.

However, 65% of these strokes are preventable with appropriate treatment, as was explained by prominent European health experts in the report How Can We Avoid a Stroke Crisis? The report was launched on 9 December in Brussels at the inaugural meeting of the MEP Heart Group, a cross-party group bringing together Members of the European Parliament (MEPs) who share an interest in cardiovascular diseases, and their management.

Advocating the prevention of avoidable strokes related to this abnormal heart condition is the ultimate goal of Action for Stroke Prevention (ASP), a coalition of prominent scientists and patient leaders who wrote the report which was endorsed by 17 European medical and patient organisations. Speaking at the event, Professor John Camm, Professor of Clinical Cardiology at St. George's University in London, called on EU decision makers to drive policy initiatives to improve early detection and management of AF. More equal and adequate administration of therapy is also needed to reduce the heavy toll paid to stroke by EU citizens.

Eve Knight, a member of ASP and Chief Executive of AntiCoagulation Europe, outlined the patients' perspective and described the human consequences of this disease. She highlighted the urgent need to better inform the general public and to promote patient education, a key step towards ensuring better adherence to treatment.
For more information about the report, please send an e-mail to secretariat@actionforstrokeprevention.org

19. HEALTH TECHNOLOGY ASSESSMENT SUMMER SCHOOL HELD AT THE LONDON SCHOOL OF ECONOMICS, 7 – 9 SEPTEMBER 2009

Article by Jean Mossman and Mary Baker.

Health Technology Assessment (HTA) is increasingly being used to support healthcare decisions about whether, and to which patients, treatments should be made available. It is, therefore, important that the perspective of patients and carers is incorporated in the decision making. However, many patient groups don't understand how HTA works, nor do they understand the health economics and other methodologies which underpin much of HTA.

The European Federation of Neurological Associations together with the London School of Economics ran a Summer School on HTA for patient groups in neurology and oncology. Participants from 11 countries

learnt in the three day course about the role of pricing and reimbursement; how HTA is used across Europe and how the European Commission is involved in a European network of HTA agencies; efficiency in healthcare and measuring health related quality of life. One of the talks by a patient group representative, Albert Jovell (Spain) described the gap between how HTA operates and how patients think.

Participants worked through a practical exercise, constructing a decision tree on the question 'Is coronary angiography necessary before aortic valve replacement?' Two of the participants, Christina Bergdahl (Sweden) and Jan Geissler (Germany), took part in a mock HTA appraisal committee meeting on a drug used in myeloma. To support the training, participants were given copies of a toolkit and a glossary both designed for patient group use (available at www.htai.org/index.php?id=85).

The course was evaluated extremely well and is scheduled to run again in 2010.

20. OPEN MEETING, EUCOMED

On January 21, Kia Megas from EPF gave a presentation at the "Open Meeting" of Eucomeds CRM Telemonitoring group on eHealth. She also shared with the audience EPF's activities and views on eHealth based on patients' experiences. On its second year, the "Open Meeting" aims to exchange information on recent industry activities at national and European level in support of reimbursement of remote CRM technology. The meeting's agenda included Eucomed CRM TM group's outcomes of its latest activities conducted at the European level and included representatives from a number of partner organisations that shared their views and activities around eHealth.

21. HEALTH FOR ALL, CARE FOR YOU; THE PROMISE OF PERSONALISED HEALTHCARE IN EUROPE ROUNDTABLE

Magdalena Machalska represented European Patients´ Forum at a roundtable debate on personalised healthcare organised together by Karolinska Institutet and Science|Business held in Brussels on 4 February.

The purpose of the meeting was to discuss with different stakeholders on possible barriers to application of the new IC technologies to medical care (personalised care), and to find possible solutions to these issues.

On this occasion, Karolinska Instituet and Science|Business presented the results of their opinion survey on personalised healthcare. The survey questions focused on broad areas namely familiarity of personalised healthcare and its development and impact on different stakeholders, benefits and barriers to personalised healthcare, health economics aspects and future implications of personalised healthcare. The final report will be presented during the conference, which will be held in London on April 2010.

22. ENUSP NEWSLETTER

EPF member, the European Network of (ex) users and survivors of psychiatry (ENUSP), is re-launching their newsletter after a prolonged break. Advocacy Update, a quarterly newsletter provides information and knowledge to their members and allies worldwide about ENUSP's movement. The newsletter contains community news, latest developments and campaign successes, and updates its members on upcoming events, offers interviews, art and book reviews.

ENUSP is an international NGO which provides representation and influences decisions that directly affect mental health service users and survivors across Europe.

To view the first issue of Advocacy Update, click here.

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23. MEETING WITH NATIONAL VOICES

On 23 January, Nicola Bedlington met Jeremy Taylor, the new CEO of our member organisation in the UK, National Voices. Formed in 2008, National Voices is a coalition of more than 200 national health and social care organisations, coming together to ensure a stronger voice for all those who come into contact with the NHS and care services, and the voluntary organisations that help them. Its independence of government, and wide representation, rooted in service user experiences, gives National Voices the authority it needs to influence decision makers.

"We believe in people shaping health and social care services. We work to ensure that patients' and carers' voices are heard and that they influence decision makers in England. We strive for a world in which people are partners in their care: with more choice, control and autonomy in the way they receive services. This results in better quality care, higher satisfaction with services and better value for money".

Mike O'Donovan, EPF Treasurer, is former co-chair and trustee of National Voices and Mark Platt, Director of Policy at National Voices is a member of the EPF Policy Advisory Group.

For more information on National Voices, please go to www.nationalvoices.org.uk.

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24. AGM AND HEALTH TECHNOLOGY ASSESSMENT SEMINAR – SAVE THE DATE

EPF is pleased to announce that the date has been set and the location has been finalised for their 2010 Annual General Meeting.

EPF's AGM will take place in Brussels on May 19 in conjunction with the EPF Health Technology Assessment Seminar on May 18. EPF members and patient group leaders will receive more information in the coming weeks.

25. LAUNCH OF EPF NEW WEBSITE

New Year, New Look. EPF is pleased to announce that we will be launching our new website on February 18. The EPF website continues to be a vital communication tool to our members. And for this reason, EPF has decided to improve the new website to include features such as upgraded accessibility, a new search engine which allows easier archiving of articles and documents, upgraded website structure both technically and visually, improved navigation and an upgraded Content Management System (CMS) which allows for faster uploads of content. This will ensure that our members and readers will receive the latest information on our website.

Visit our website at: www.eu-patient.eu.

26. WELCOME TO EPF'S NEW INTERNS

Magdalena Machalska, a Polish native is the new assistant policy officer who started her internship with EPF at the beginning of this year. She holds a masters degree from Free University of Brussels and the College of Europe. Her studies focused on European Public Affairs from a social and healthcare perspective. Magdalena is particularly interested in the process of Europeanization of Member State's welfare systems, especially its impact on patients' rights. Magdalena's previous internships focused on environmental health and healthcare within the Member States of the European Union. At EPF, Magdalena's responsibilities will focus on EU health policies such as eHealth, Pharmaceutical Package and Cross-Border Patient Mobility and will include monitoring of health policy developments and research in areas of interest of EPF, as well as preparing draft policy documents requested.

EPF's new assistant programme officer **Walter Atzori** joined the Secretariat 27 of January. Walter, a native Italian holds an undergraduate degree in Political Science from the University of Sassari, and a masters degree in European Studies. While completing his internship at EPF, Walter is pursuing his second masters from Vrije University in management. Before joining EPF, Walter briefly worked at a consultancy firm, a major regional organisation (CPMR), and was trainee at Cedefop. His expertise focuses on EU funding in various EU policy areas, including healthcare. Walter's academic and professional experience also focused on territorial issues and the impact of EU policies on spatial development dynamics. He is particularly knowledgeable on issues such as bridging health inequalities and improving access to quality care across Europe. At EPF, Walter will be working on the RENEWING HEALTH as well as assisting with the Value+ dissemination and being involved in fundraising and diversification of funding sources.

27. DIARY

Mon, Feb 8 -- Tue, Feb 9	RENEWING HEALTH Project Kick off meeting Attendance: Walter Atzori Place: Venice, Italy
Thu, Feb 11 -- Fri, Feb 12	epSOS Workshop and CALLIOPE Meeting Attendance: Liuska Sanna Place: Brussels, Belgium
Wed, Feb 17 -- Thu, Feb 18	EPF Board Meeting Place: Brussels, Belgium
Tue, Feb 23 -- Thu, Feb 25	IAPO Congress Place: Istanbul, Turkey Attendance: Kia Megas
Wed, Feb 24	The European Voice Helth Check debate "The right to know? Should information to patients be restricted?" Attendance: Roxana Radulescu Place: Brussels
Wed, Mar 3 -- Sat, Mar 6	DIA Meeting Place: Monaco Attendance: Nicola Bedlington, Ander Olauson

Sat, Mar 13 -- Sun, Mar 14	International Thalassaemia Federation Congress Place: Berlin Attendance: Nicola Bedlington
Mon, Mar 15 -- Thu, Mar 18	World of IT, eHealth Conference Barcelona, Spain Attendance: Nicola Bedlington, Liuska Sanna
Tue, Mar 16	EU Health Portal Barcelona, Spain Attendance: Nicola Bedlington
Wed, Mar 17	DG SANCO Workshop for Data Partnership "The right to know? Should information to patients be restricted?" Attendance: Roxana Radulescu Place: Brussels
Tue, Mar 23	EMA Working Group on Clinical Trials Place: London Attendance: Roxana Radulescu
Thu, Mar 25	European Generics Association Place: Brussels Attendance: Nicola Bedlington (Panel)