EPF Mailing

Issue 2 (36)

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Dear EPF Members and Allies,

Welcome to the EPF Mailing! With the EPF Annual General Meeting and Value + Seminar just around the corner (12 and 13 April), much of our work is focused on finalising preparations for this important milestone in the year where our entire membership together with our board and secretariat can take stock, share ideas and learning and plan for the future. There has been a great interest on the part of our members to participate, and in particular, send young patient delegates alongside experienced patient leaders to the event, as part of our new youth strategy – we look forward to welcoming you there - a detailed report will feature in the next EPF Mailing.

Just prior to our AGM, EPF and several members will participate in the European Patients Rights' Day on 11 and 12 April, organised by Active Citizenship Network (ACN). EPF has collaborated with ACN in this initiative as a jury member for awards on good practices across Europe on patient rights, and will also make a presentation at the event.

In this issue of the EPF Mailing, in addition to important policy and project updates you will find a report on the outcome of the first stage of our Health Technology Assessment Research, – please go to section 17 for more details and an overview of next steps.

Readers will be aware that EPF led a Consortium of patient groups and academics that submitted an Expression of Interest in the framework of the Third Call for Proposals within the Innovative Medicines Initiative (IMI). The topic focuses on fostering awareness among patients on Pharmaceutical Research. We are delighted to report that the Consortium has been invited to the next stage of the process and to develop a full proposal together with EFPIA partners. The deadline for this is 15 June and we report back on progress in the summer issue of the EPF Mailing.

EPF has also been invited to two high level Commission activities in the policy arena – the Steering Group on Active and Healthy Ageing that will meet for the first time on 2 May 2011, and a new High level task force on eHealth that will meet for the first time in Budapest during the eHealth week in May. Anders will be representing EPF at both events with support from the secretariat and members with a particular interest in these areas.

Planning is well underway for other EPF events this year. Our Conference on the Needs and Rights of Older Patients will take place on 12-13 July 2011, in close collaboration with our Polish Member organisation, the Federation of Polish Patients (FPP), under the auspices of the Polish EU Presidency. A "Save the Date" has been circulated and registration will start soon – look out for further information of the EPF website.

EPF has also visited our member organisation COPAC in Romania to start the planning of our Regional Advocacy Seminar there on 26-27 October 2011, this event will have a particular focus on the vital relationship between patients and medical professional organisations. More information will be available in the next issue of the EPF mailing and invitations sent shortly to patient group allies in the countries involved. This will be our first event in Romania and we look forward greatly to working closely with COPAC to ensure its success and resonance.

Wishing you all a joyful and productive spring-time.

Warmest Greetings,
EPF President Anders Olauson
EPF Director Nicola Bedlington

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Deadline for:	Date:
Commission Consultation on Clinical Trial Directive: - Member responses to 1st phase - Approval of EPF draft response by Members - Deadline to send response to the Commission	 15 April 11 May 13 May
Submission of proposals for projects, operating grants, conferences and Joint Actions under the Work Plan 2011 of the European Agency for Health and Consumers	27 May
Joint Action on Patient Safety and Quality of Care Submission of proposal	27 May
Innovative Medicines Initiative Project: Development of full proposal by the Consortium with EFPIA Partners	15 June

1. Pharmaceuticals Package

Anti-counterfeiting Directive – EPF's perspective on the adopted text

As announced in our last issue, the EU Directive on the "prevention of the entry into the legal supply chain of falsified medicinal products", amending Directive 2001/83/EC, was adopted by a strong majority (569 votes for, 12 against, 7 abstentions) in the European Parliament on 16 February 2011, following informal agreement reached by the EU Institutions at the end of December 2010. The provisional text is available here.

While the European Parliament had to compromise on some of the points that were raised in MEP Marisa Matias' report, overall EPF welcomes the final text as it provides a stronger European-wide framework to combat falsified medicines. In our we described the main elements of the final proposal. Here, we give a more in-depth analysis on the text as promised in our February issue.

Read more...

2. Platform on Access to Medicine in Europe

The Platform on Access to Medicines in Europe is a part of an Initiative on Corporate Responsibility in the Field of Pharmaceuticals, launched by DG Enterprise & Industry in September 2010.

EPF is participating in the Steering Group of the Platform as a stakeholder organisation representing the patients' view. The Steering Group includes representatives of the EU Member States and EFTA countries, as well as stakeholder organisations including patients, consumers, health professionals, health managers, social insurance, and industry.

The Platform aims to facilitate fair and timely access to medicines, following their market authorisation. It will not introduce any new regulation, since pharmaceutical pricing and reimbursement policies fall within the competence of Member States and each

government is responsible for the organisation of its healthcare system. Rather, it aims for enhanced collaboration between EU Member States and all stakeholders.

The Platform will do its work in practice through a number of projects on specific topics.
A patient representative was identified for each project through a call for interest among EPF's membership. For a description of the projects and their participants, see the previous issue of the EPF Mailing.

The Steering Group will undertake a broader reflection on how to identify areas with the highest medical needs, and how to define innovation. A first meeting will be held on 7 April 2011, and following this meeting we will extend an invitation to our members to give input from their specific disease-areas and national perspectives. Several of our members have already expressed an interest to participate in this work.

Link: DG ENTERPRISE website.

3. Cross-border healthcare adopted by Council

On 28 February, the Council formally adopted the Directive on the application of patients' rights in cross-border healthcare. We have presented the new Directive in detail in our previous issue's special feature.

Next steps:

- The Directive is now awaiting publication in the EU Official Journal and will come into force 20 days following its publication. After this, Member States will have 30 months to transpose it into their national legislations.

- The implication of the cross-border healthcare Directive for patient organisations at national level will be discussed during one of the parallel capacity-building sessions at the EPF AGM on 12-13 April. This discussion will feed into the development of a strategy to support EPF member organisations in the implementation of EU directives.

4. Health inequalities – European Parliament's Resolution adopted

EPF welcomes the adoption on the 8th of March in Plenary Session of the Resolution on reducing health inequalities in the EU, with 379 MEPs in favour, 228 against and 49 abstentions. In our previous issue, we highlighted that EPF had liaised with MEPs including Mrs Edite Estrela (S&D, Portugal) who drafted the report for the ENVI committee, to promote the patients perspective (see our position statement). While this Resolution is non-binding it has political weight. Its adoption highlights the commitment of the European Parliament to take action to tackle health inequalities.

EPF had called for the recognition of *patients with chronic diseases as a specific group whose needs should be addressed*, and MEPs took this point on board. The final text states that "patients living with chronic diseases or conditions form a specific group which suffers inequalities in access to diagnosis and care, social and other support services, and disadvantages including financial strain, poor access to employment, social discrimination and stigma", highlighting other vulnerabilities that are linked with chronic illnesses. The resolution recommends putting in place targeted programmes for vulnerable groups to improve access to prevention and primary and specialised healthcare services. EPF also advocated for *older patients* to be recognised as a subgroup. The European Parliament calls on Member states and the Commission to make equitable access for older patients a priority in 2012.

Access to high quality affordable healthcare for all patients is a core priority for EPF. There are presently huge disparities within the EU in many chronic diseases, both in terms of access to healthcare, and in the standards of care. Therefore we welcome the call on Member States to ensure that vulnerable groups have equitable access to healthcare. The European Parliament highlights that accessibility of healthcare system includes effective diagnosis and access to pharmaceutical treatments. It also asks Member States to develop methods to guarantee access to care for all patients, including the most disadvantaged. Moreover, the Member States and the Council are encouraged to evaluate and take measures to restructure healthcare systems to provide high-quality equitable access without discrimination throughout the EU.

However, the final text lacks specific provisions on *patient empowerment and health literacy*, which in EPF's view are fundamental aspects of tackling health inequalities among patients with chronic diseases and their families. But the resolution does stress the importance of ensuring access to information on health, healthy lifestyles, healthcare prevention opportunities, early diagnosis and suitable treatment, in an easy to understand form and language, including through the Internet. It stresses the importance of monitoring information that pharmaceutical firms provide to patients, and in the context of cross-border healthcare, notes there

is a need for increased transparency of information for patients on their rights, redress, and on healthcare professionals' regulations.

The European Parliament also supports *stakeholder involvement* as it asks the European Commission and Member States to step up dialogue with civil society, the social partners and NGOs regarding health and medical services. In EPF perspective, patients' organisations should be involved in all actions to tackle health inequalities when they relate to patients with chronic illnesses.

Finally the European Parliament also shows its support to the *health in all policies* approach. EPF strongly supports the call on the Commission to mainstream an "equity and health in all policies" approach in all EU internal and external policy; the calls on the Commission and Member States to recognise health as part of fighting exclusion and to include indicators for health inequalities in the Europe 2020 strategy; and the call to make better use of EU Cohesion Policy and Structural Funds to address health inequalities.

Next Steps:

- Member States are currently beginning a Joint Action on health inequalities, funded through the Health Programme. This action includes work on health inequality impact assessment, regional and scientific networks and stakeholder initiatives.
- EPF invites more feedback from our members on the issue of health inequalities, to feed into future work in this area; especially on the ongoing impact of the financial crisis. We encourage all member organisations to share their experiences and knowledge with us. Please contact Kaisa Immonen-Charalambous.

5. Anti-Discrimination Proposal

On 2 July 2008, the European Commission adopted a proposal for a new Directive to set a framework for the prohibition of discrimination on the grounds of religion of belief, disability, age or sexual orientation.

Discrimination in the field of employment is already covered under Directive 2000/78/EC.. The new proposal applies to areas outside the field of employment, for public and private bodies, in relation to social protection (including social security and healthcare), social advantages, education, access and supply of goods and other services available to the public, including (health) insurance.

The draft Directive was discussed during the March meeting of EPF's Policy Advisory Group, which gave a strong endorsement for EPF's involvement in this area. From EPF's perspective, anti-discrimination law is one important way to combat health inequalities, in particular regarding access to healthcare services. The anti-discrimination proposal contains some important elements from a patients' perspective:

- *Chronic diseases and disability.* The original proposal doesn't establish a common definition of disability, which is the main issue for EPF within this legislation. Different definitions of disability currently apply across Member States; and patients with chronic diseases are not always comprised in the definition, depending on their disease-area and the Member State they live in. From EPF's perspective, patients should be included the scope of the Directive as a group that may be subject to discrimination as a result of the chronic illness.

- *Prohibiting discrimination in access to healthcare.* Evidence shows that patients face discrimination in access to healthcare for example on the grounds mentioned in the draft Directive, and also as a result of their illness. Some patients with chronic diseases (e.g. from the mental health arena) are affected by stigmatisation by the healthcare staff, and face barriers in access to treatment and information, but they would only be protected under the legislation if recognised as "disabled".

- *Effective access for disabled people.* The draft Directive states that this would have to be provided "by anticipation", meaning it shouldn't be necessary for people with a disability to have to ask for measures to be taken. The need for adjustment/modification should be anticipated, and reasonable access for persons with disabilities should be provided when necessary if it is not a disproportionate burden to do so. (The draft Directive gives criteria to assess this.)

- *Obligations for Member States.* The draft Directive would oblige Member States to ensure that judicial and/or administrative procedures for the enforcement of the provisions of the Directive are available to people who consider they have been victim of discrimination. Member States should also inform the public of their rights and set up National Equality Bodies. The role of these bodies would be to promote equal treatment, provide independent help to victims of discrimination, conduct independent surveys, and draft recommendations.

This proposal is discussed through the consent procedure, meaning that the Council must act unanimously to adopt a draft of the legislation. Parliament's consent (approval) must be sought for the draft text, but Parliament cannot ask for amendments to the text.

The Council has been discussing several contentious aspects within this Directive. Some Member States have general reservations on the proposal as a whole, because they feel there is a problem of distinction between *access* to fields such as education, healthcare and social protection, and the *organisation* of these fields – which is a national competence.

The European Parliament made a recommendation in a consultation report by MEP Kathalijne Buitenweg, which highlights some areas where the proposal could be improved. A key element in the report is a suggestion to adopt the definition for disability used in the UN Convention on the Rights of People with Disabilities. The current rapporteur is now MEP Raul Romeva i Rueda (Greens/EFA, Spain).

Next Steps:

- The Council will discuss the proposal in June 2011 and issue a progress report on the discussion.
- EPF will prepare a member consultation to collect patients' evidence and case stories about discrimination encountered by patients with chronic diseases, as well as invite views on the other areas of this Directive, to define an official position. Meanwhile, we encourage member organisations to share their experiences and knowledge with us. Please contact Laurène Souchet.

6. European Innovation Partnership on Active and Health Ageing

In our last issue we presented the European Innovation Partnership on Active and Healthy Ageing, a novel concept of the Commission to address societal challenges through linking research and innovation and turn them into concrete actions. The Partnership will provide stakeholders with a forum to identify barriers to innovation and to discuss solutions to overcome these barriers.

The Partnership revolves around three main goals:

- Enabling EU citizens to lead healthy, active and independent lives while ageing;
- Improving the sustainability and efficiency of social and health care systems;
- Boosting and improving the competitiveness of the markets for innovative products and services.

The overall objective of the Innovation Partnership is to increase healthy lifespan in the EU by two years by 2020.

EPF gathered input from our members for our contribution to the Commission's public consultation (see EPF's response). Our contribution highlighted our commitment to playing an active and constructive role in the three work packages of the Innovation Partnership, to ensure that it results in concrete actions that have benefit for older patients. Older patients with chronic diseases have specific needs that need to be considered in addition to older people in general. Furthermore, patients with chronic diseases are growing older thanks to better therapies.

Next Steps:

- The Commission will shortly announce the Steering Group for the PartnershipThe group will then map the specific objectives and draft a strategic implementation plan. EPF will be represented in the Steering Group, and we will seek the active input of all our members who are interested in contributing to work on Healthy and Active Ageing and the perspective of older patients.

- The Commission will publish an analysis of all the contributions to the public consultation.The Commission received more than 500 contributions, a level equivalent to that of EU 2020 strategy.

- EPF is organising, in close collaboration with the Federation of the Polish Patients**,** a conference on the "Rights and Needs of Older Patients", which will take place in Warsaw on 12-13 July 2011. The conference will be under the official patronage of the Polish Presidency of the EU. Exchange of information and discussions which will take place during this event will be one important way for EPF and our member organisations to contribute to the current debates on healthy ageing and demographic changes.

Link: The European Commission Active and Healthy ageing webpage.

7. Professional Qualifications Directive

Following a consultation of our members, EPF has sent a contribution to the European Commission's public consultation on the evaluation of the Professional Qualifications Directive (2005/36/EC). In our previous issue, we had described the main areas of concern for patients within this Directive.

On 15 March 2011, EPF and the European Public Health Alliance (EPHA) issued a Joint Statement to affirm that quality and safety must remain high on the EU political agenda. They call on the European Commission and Member States to ensure that minimum training conditions to allow healthcare professionals to benefit from automatic conditions are not downgraded, and that other requirements are maintained.

These points were also highlighted in EPF's response to the Consultation. Further to this, we stressed some other elements in our response:

- The Commission proposes that training requirements could be updated. From a patients' perspective, EPF considers that at least the following competences should be included in health professionals' training: communication with patients; skills related to ICT and eHealth; and a gender perspective. EPF also highlighted the importance of training specialist nurses.
- EPF would welcome a proactive alert mechanism between competent authorities in case of malpractice by a healthcare professional. Increased transparency on the fitness to practice of healthcare professionals is clearly an important objective from a patient perspective. Options to achieve it should be explored with other stakeholders.
- As for language skills of healthcare professionals, in particular these which are in direct contact with the patients, EPF insisted that it should be made clear that a high level of proficiency is required.

EPF was also invited to participate in an expert roundtable on the review of the Directive organised by the European Healthcare Management Association (EHMA) on 10th March 2011. Participants included health managers and professionals, representatives from DG Internal Market of the Commission, educators, regulators and competent authorities.

Various options were explored by the participants for training, including minimum requirements, Continuing Professional Development (CPD), the pros and cons of a European Professional Card, and testing of language, in light of their experience with the current rules set by the Directive. Patient safety was raised as a concern by some participants when discussing certain aspects

of the Directive, notably for language and the currency of training. A report will be published by the EHMA website on this discussion.

Next Steps:

- The Commission will issue an Evaluation Report and a Green Paper in autumn 2011, with the view to issue a legislative proposal on the **modernisation of the Directive in 2012**.
- The consultation on the Green Paper will be a renewed opportunity for EPF and our member organisations to ensure that the patients' voice is heard in this debate, and that a patients' perspective is well reflected in the legislative proposal.

Useful link: Directive 2005/36/EC: A user's guide.

8. European Medicines Agency

The Human Scientific Committee's Working Party with Patients' and Consumers' Organisations (PCWP) met on 22-23 February 2011 at the European Medicines Agency in London.

Day 1 – brainstorming on training and information needs

The first day was spent in an informal brainstorming session to improve the EMA training strategy and develop an information pack for patients. The group discussed training materials for the EMA website, how to improve the in-house training events, and how to increase the visibility of patient involvement in EMA and disseminate information.

One of the issues that emerged in the discussions was that there is a need for basic information about what EMA is and what it does/does not do. The legal framework and the regulatory process should be explained in a lay-friendly language and format, including visually. This will help all patient groups who seek information about EMA, and it will support the organisations that are already involved to disseminate information more effectively to their members and increase awareness of the role that patient organisations play within EMA.

Another issue that emerged was the gap between patient organisations' participation at EMA, and their participation in the regulatory and government bodies at national level. There are major differences across the EU, and barriers including administrative and attitudinal ones, to overcome.

At the moment, there is a training day once a year for patient representatives. The group suggested that this could be increased, with one training for basic things including the regulatory process, and another training day for specific topics that could be identified by patient groups themselves. The Agency will consider whether this could be done.

Day 2 – Working Party meeting

The official Working Party meeting took place on the second day. Key topics included the following:

The new Pharmacovigilance legislation

A brief update was given; the new legislation will have an impact on several areas of the work of the Agency, and patient organisations will be invited to contribute. Among other things there will be a public consultation of stakeholders on this topic.

Update on the revision of the EMA template for the package leaflet

The Agency has recently worked on a new template for the information to be included on package leaflets, to improve its user-friendliness. The actual order in which the information is presented is governed by legislation, so cannot be changed, but more patient-friendly information will be included and specific improvements will be made to some sections. This is still a work in progress, since the provisions of the Pharmacovigilance legislation will also need to be incorporated. However, it is encouraging to see that many issues raised by patients and consumers have been taken on board. At this point the EU consumers' organisation presented a survey done in Portugal on consumers' preferences regarding package leaflets. This survey, although not representative of patients with chronic conditions, seemed to reinforce what is already known: that readers dislike small print and want the information to be in a clear and logical order. Short leaflets and visually easy-to read design were also preferred.

The EMA eligibility criteria

The eligibility criteria of EMA are in the process of being revised to make them clearer and more appropriate. The revised criteria may be finalised this year. Patients' and consumers' organisations who fulfil these criteria are considered eligible to become involved in EMA activities in general; it does not automatically mean that the organisation will be member of a committee or

working party. The criteria are available here, and a list of organisations that fulfil the criteria is available here. For more information on how patient organisations can be involved in EMA activities, see here.

Patients involvement in EMA activities

An evaluation by EMA showed overall that the experience of patients' participation in the Agency's activities has been positive. Patients feel that their views are taken into account, and that the practical arrangements and support provided by EMA are good. Better differentiation could be made between the "newcomers" and "old hands" to extract more detailed responses.

Medicines under additional monitoring

The group discussed a draft document and commented that the reasons for additional monitoring should be explained more clearly, as otherwise the patients may become unduly worried. It should also be clarified what additional monitoring actually means. EMA clarified that 'additional monitoring' actually means that reports of suspected adverse reactions are monitored more frequently than other drugs, not in a different way. The aim of additional monitoring is to detect any signals more quickly. All drugs are monitored regularly, and any drug could be at one time subject to additional monitoring for various reasons. It does not mean that the drug is unsafe to use.

The new Pharmacovigilance Directive includes specific provisions for medicines under additional monitoring, which will need to be taken into account when developing the document further.

Useful links:

- European Medicines Agency
- EMA information for patients and carers
- Information on the Patients' and Consumers' Working Party
- Eligibility criteria for patient organisations for involvement in EMA activities

9. Clinical Trials – review of the EU Clinical Trials Directive

In October 2009, the European Commission issued a public consultation on the assessment of the functioning of the 'Clinical Trials Directive' (Directive 2001/20/EC), to which EPF provided input based on a consultation of our membership.

The Commission has now published a concept paper, in which it gives its preliminary appraisal of which options it considers most appropriate for revising the Clinical Trials Directive. The public consultation on this concept paper is open until 13 May 2011.

It is a matter of concern for EPF that the Commission's concept paper does not address the key issues for patients that were raised by EPF and our membership in our response to the previous public consultation. We have prepared a second consultation which was sent out to members on 22 March. We would invite all our members to give input to this response as far as you can in order to make our response as strong and robust as possible. If you are a unable to provide specific input, please indicate whether you support EPF's position.

The deadline for responses to the first phase is **15 April 2011**. After this EPF will send out a final draft of our response for approval by our members. The deadline for submission of final comments and approval will be 11 May 2011. EPF will then submit its response to the Commission.

For further information please contact Kaisa Immonen-Charalambous.

Useful links:

- European Commission – clinical trials
- Responses to the Commission's 2009-2010 consultation
- EU Clinical Trials Register

10. EU online Register of Clinical Trials launched

Since 22 March 2011, EU citizens have access to online information on the authorised pharmaceutical clinical trials that are taking place in the EU, through a new Register of Clinical Trials. According to the European Commission, there are approximately 10,000 ongoing clinical trials. The main objective of the new Register is to increase transparency and avoid duplication of trials. It includes clinical trials conducted by research institutions, but also by the industry, in one or more EU Member States. Clinical trials on authorisation of medicines for children are published even if they take place in third countries.

EPF has long called for greater transparency around clinical research, including information about clinical trials taking place across the EU, and more transparency regarding the clinical trials process. This new Register at EU level is very welcome and much needed.

In order to be a useful resource for patients, the information should be easily understandable and in a user-friendly format; we will continue to support the European Medicines Agency through the Patients' and Consumers' Working Party, to ensure that the Register is developed further to meet the practical needs of patients.

Furthermore, it is crucial that the upgrade of the Register, including information on the results of clinical trials, is implemented as soon as possible. Results of all clinical trials – including trials which 'failed' or did not produce the expected results – are a valuable source of knowledge, particularly in some disease-areas such as rare diseases, and individual patients and patient organisations are usually not able to access this information.

Useful link: The EU Clinical Trial Register: https://www.clinicaltrialsregister.eu

11. Publication of the European Agency for Health and Consumers (EAHC) work plan 2011 – priorities

The European Agency for Health and Consumers (EAHC) has published the 2011 Work Plan setting out details of the financing mechanisms and priority areas for action in implementing the Public Health Programme. The Work Plan includes the full list of

calls for proposals for projects, operating grants, conferences and Joint Actions, as well as the full list of the call for tenders to be published in the coming months.

The 2011 Work Plan can be accessed here: http://ec.europa.eu/eahc/documents/health/calls/2011/WP2011_en.pdf

The Work Plan is linked with two goals of the EU2020 strategy: Inclusive growth, as it finances measures to tackle health inequalities; and Smart Growth, as it focuses on preventing and addressing diseases which affect older people, with a particular focus on chronic and rare diseases. It also supports the Digital Agenda for Europe through financing measures to apply ICTs in Health.

The five priority areas for 2011 are:

1. *Health information and advice*. The work plan supports generating the data and scientific opinions that individuals, stakeholders and policy-makers need to be able to make informed decisions. It also finances the setting up of user-friendly dissemination channels to allow this information to reach its targeted audience.
2. *Disease-areas*. Work on disease areas focuses on *cancer*, to support activities to reach the goal set by the Commission's Communication Action Against Cancer to reduce cancer incidence by 15 percent by 2020. It also focuses on *rare diseases*, to improve diagnosis and treatment through pooling resources across Member States. The Council Recommendation on action in the field of rare diseases sets the framework for activities in this area. This work plan also finances work on prevention strategies for *HIV and co-infections*, and in the area of *pandemic preparedness*.
3. *Health determinants*. This work plan supports activities on key social determinants of health and health inequalities: nutrition and physical activity, alcohol and tobacco.
4. *Health systems*. This area prioritises the safety and quality of cross-border healthcare and includes work on patient safety, health technologies and HTA, as well as on the health work force.
5. *Legislation on products and substances.* The work plan supports the implementation of the Action Plan on Organ Donation and Transplantation, and work related to legislation on human blood and blood components. It also finances work related to EU legislation on tobacco and medicinal products.

In addition to this, it also finances horizontal measures which support the implementation of the EU Health Programme.

Projects

The 2011 Work Plan includes seven calls for proposals for projects. The full list of calls for projects is available through the following link: http://ec.europa.eu/eahc/health/projects.html

For each one the application form is downloadable on the website. The total indicative amount for project grants is estimated at EUR 4,650,000, with a maximum rate for EU co-financing of 60 per cent. However, this may go up to 80 per cent if a proposal meets the criteria for exceptional utility.

Operating grants

The purpose of an operating grant is to provide financial support towards the functioning of an organisation in its core activities over one year. The activities of the organisation must correspond to the priorities of the Health Programme and to the priorities of the 2011 Work Plan. The total indicative amount for operating grants is estimated at EUR 4,000,000 with a maximum rate for EU co-financing of 60 per cent, or 80 per cent in cases of exceptional utility.

For more information on operating grants see: http://ec.europa.eu/eahc/health/grants.html

Conferences

Financial contributions may be awarded for the organisation of conferences which have as their primary goal one or more priorities of the annual work plan; have an EU-wide dimension; and are organised by a public or non-profit body established in a country participating in the EU Public Health Programme. For more information on conference funding see: http://ec.europa.eu/eahc/health/conferences.html

Joint Actions

Joint actions are activities carried out by the EU and one or more Member States. With the exception of stakeholder organisations operating at EU level, only organisations established at national level and have been nominated by their national government can participate in joint actions. The 2011 call includes five Joint Actions: rare diseases; cross-border; eHealth; Health Technology

Assessment; patient safety and quality of healthcare; and organ donation. More information on Joint Actions as well as a list of which countries plan to participate in which Joitn Action, is available at: http://ec.europa.eu/eahc/health/actions.html.

Public Procurement: Call for Tenders

The Work Plan for 2011 foresees a **significant number of calls for tenders for the provision of services**, in particular preparation of studies, surveys and analyses concerning various areas of public health. The total indicative amount for procurement is estimated at EUR 17.753.028.

Calls for tenders are envisaged to be published in the first semester of 2011 in the Official Journal. You can monitor upcoming call for tenders through the following link:

http://ec.europa.eu/eahc/health/tenders.html

The deadline for submitting applications is 27 May 2011.

If you are preparing an application and have questions about these calls see the FAQ on the EAHC website: http://ec.europa.eu/eahc/health/faq.html

For information not available on the website you can contact the EAHC Helpdesk at EAHC-PHP-CALLS@ec.europa.eu

You may also want to contact Liuska Sanna or Walter Atzori.

12. Policy Advisory Group Meeting

The EPF Policy Advisory Group held its first meeting of the year on 17 March 2011 at EPF's offices in Brussels.

During this meeting, the group exchanged views and gave very valuable feedback to the EPF Secretariat on topics including the following: the review of the Clinical Trials Directive; active and healthy ageing, including the preparation of EPF's conference under

the Polish Presidency in July 2011; EPF work on anti-discrimination; and the development of EPF's strategy to support member organisations in the implementation of EU Directives at national level.

The group also discussed the latest key developments at EU level, other upcoming activities of EPF in 2011 and beyond, and revised its Terms of Reference to take account of the participants' experiences so far.

The Policy Advisory Group was set up in 2009 to advise the EPF Board and Secretariat on policy topics prioritised by EPF's annual general meeting and issues which, because of their complex, controversial and/or highly political nature, require detailed and in-depth discussion. The group is composed of representatives designated by member organisations, and its deliberations as a complement and support to EPF's broader member consultation process. The Group meets twice a year in Brussels.

Membership of the Policy Advisory Group remains open to all interested EPF member organisations. If you are interested in nominating a member to participate in the group, please contact Kaisa Immonen-Charalambous.

13. Rare Disease Day 2011

As announced in our previous issue, 28 February 2011 was Rare Disease Day. On this occasion, EPF Member organisation EURORDIS in partnership with the European Commission, organised a European Symposium around this year's theme: "Rare but Equal – Addressing Health Inequalities for Rare Disease Patients in Europe". The event, which highlighted the rising health inequalities for rare disease patients and led to discussions on how these inequalities could be tackled, attracted over 80 participants to the International Press Centre in Brussels.

The event was also an occasion to publish the key findings of the Eurobarometer Survey on awareness of Rare Diseases, published on the same day by the European Commission.

For more information about the European Symposium, including presentations by the speakers, please see EURORDIS article: "Rare Diseases Day a resounding success"

Useful link: Rare Disease Day Website.

14. Joint Action on Patient Safety and Quality and Safety of Care

In previous issues of this Mailing we have described in detail the new proposed Joint Action on Patient Safety and Quality of Care, which is currently in the preparation phase.

The overall aim of the Joint Action is to create a permanent platform for future cooperation between Member States in the area of patient safety and quality of care. Three specific objectives are to:

- Support the implementation of the Council Recommendation on patient safety;
- Initiate Member State cooperation on quality of healthcare;
- Facilitate the sharing of good practices in patient involvement and empowerment.

The Joint Action is led by the French health authority, the Haute Autorité de Santé (HAS). EPF has been designated as EU-level stakeholder organisation to participate in the Joint Action as Associated Partner. Other stakeholder partners include organisations representing doctors, nurses, dentists, health and hospital managers. The work packages are led by Member States.

Preparatory meetings have taken place during late 2010 and early 2011, and the details of the work packages and the detailed budget are now in the negotiation phase. The deadline for submission of the project is 27 May 2011. If successful, the Joint Action will start work at the end of 2011 or in early 2012.

Useful links:

- Commission Communication on patient safety
- Council Recommendation on patient safety and healthcare associated infections
- EUNetPas (European network on patient safety) project website
- Executive Agency for Health and Consumers – Joint Actions

15. eHealth Governance Initiative – Kick off meeting Project Steering Committee

We have presented in previous issues the EU eHealth Governance (eHG) initiated by the EU Member States and supported by the European Commission with the involvement of key stakeholders including EPF.

This political initiative was set up in 2009 and will be supported by two different EU financing instruments: a Joint Action through the Public Health Programme and a Thematic Network through the CIP-ICT programme.

The initiative has now officially been launched through its first Project Steering Committee meeting that took place in Brussels on the 24th of February. As any project kick off meeting the purpose was to discuss the project content; the working arrangements and the administrative procedures.

The eHGI aims to establish an efficient, appropriately governed and sustainable platform to enable all stakeholders to work in this political initiative. It will provide to the Member States, the European Commission, health authorities, competence centres, user groups, industry and other relevant stakeholders a European interoperability framework to facilitate involvement and usage of the work in the defined policy areas.

It supports the setup of a European environment for the benefit of European patients (e.g. support and guidance for implementation, deployment and use of eHealth services throughout national health care systems, increasing patient safety and quality, better use of health care resources). It is therefore of the utmost importance that EPF s fully involved in this process.

The defined areas of work of the eHealth Governance Initiative are legal issues, roadmapping and mainstreaming; semantics and terminology, identification and authentication; standardisation. Specific work packages have been set up for these areas of work and the activity plans are currently being finalised.

For more information please contact Liuska Sanna.

16. Renewing Health 3rd Meeting of the User Advisory Board

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

As the reader may recall, EPF is involved together with EHTEL (European Health Telematics Association) in the management of the project's User Advisory Board (UAB) - including representatives of the various groups, who are either direct or indirect users of telemedicine services - the primary mission of which is to operate as a standing advisory committee to advise and provide on-going feed-back to the consortium on the needs of users of the piloted telemedicine services.

On February 17th the UAB held its third in Brussels. Cross-cutting focus of this meeting was telemedicine services for diabetes patients. In line with the modus operandi agreed for the UAB meetings a number of representatives from different pilot sites were invited to the meeting, precisely from Catalonia (ES), South Denmark, Veneto (IT) and Norway. The key focus of the meeting was the feed-back of the UAB on methods and tools used for the evaluation of users' service acceptability and patients' quality of life.

The second part of the meeting was focused on the presentation of the final results of the first version of the "User Requirements" deliverable. As mentioned in the previous Mailing issue, this document is meant to provide a comprehensive analysis of needs, requirements and expectations of end-users of telemedicine services.

The User Requirements deliverable was published on the Renewing Health website and can be accessed here.

Based on an initial literature review aimed at collecting the state-of-the-art knowledge on user requirements in telemedicine, this document will be further developed using an iterative approach whereby the recently issued first version, will be continuously reviewed and improved throughout the project lifecycle on the basis of evidence gathered from the pilots and feedback provided by the members of the UAB.

As part of this iterative approach a consultation with the UAB members will be launched soon with a view to validating the findings of the literature review, identifying gaps and suggesting additional user requirements. The feedback of the UAB will inform the drafting of the second version of the "User Requirements" which will be published later this year.

The fourth meeting of the UAB is scheduled on June 29th in Brussels right after the fourth project steering committee meeting which will take place in Tromsø, Norway on June 16-17, 2011. Details on project's future developments will be provided in the next Mailing issues.

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

17. HTA Survey – Report

For full HTA Report please visit the following link the EPF Website: www.eu-patient.eu/Documents/Initiatives

18. Towards EPF Youth Strategy

In order to better align our work with the needs and expectations of the young patient community, we dedicated our third Regional Advocacy Seminar, held in October 2010 in Budapest, to strengthening young patients' representativeness within patient organisations.

More information on the outcomes of the 2010 Advocacy Seminar can be found here.

This event was the very first opportunity for EPF to bring young and more experienced patient advocates from different EU countries together to discuss how to promote the meaningful involvement of young patients within patient organisations as well as to inform the development of an EPF Youth Strategy.

The EPF Youth Strategy is currently being developed in order to enable EPF to recognise, understand, meet and effectively represent the needs and expectations of young patients through their meaningful involvement and empowerment.

In order to be able to achieve this objective EPF is working towards establishing a "Youth Group". This group will be made up of 10-15 young patients who are being nominated by those EPF members interested in having a youth representative involved in this group.

The establishment of the EPF Youth Group is being done alongside the registration process for the 2011 EPF Annual General Meeting through soliciting our members to register a young patient as a second delegate. The kick-off meeting of the EPF Youth Group is scheduled to be held during the AGM.

We will report on the outcomes of this meeting in the next Mailing Issue.

For more information on the EPF Youth Strategy you should contact Walter Atzori.

19. OTHER INITIATIVES - Council of Europe Committee of Experts on Child Friendly Healthcare

EPF was invited to participate as an observer to the third meeting of the Council of Europe (CoE) Committee of Experts on Child Friendly Healthcare which took place on February 24 and 25 in Strasbourg, France.

This Committee of Experts was set up in early 2010 to support the CoE Directory General for Health in drafting a Recommendation for the 47 Member States of the CoE on child-friendly healthcare systems.

The Committee of Experts, supported by external observers representing stakeholder groups, has been tasked to:

- identify children's specific needs in order to promote their well-being in the health care setting, with special emphasis on their rights to child-responsive and child-friendly health care, whilst taking into account the social and family environment
- find ways to promote children's participation in decision-making in their own health care and in broader children's' health care
- examine approaches to increase the coping potential of children, their families and carers, including the importance of bringing parents into the arena
- make proposals to governments of Member States, defining possible strategies aimed at facilitating the exercise of children's' individual rights and mainstreaming them in health policy

The purpose of the third meeting of the Committee of Experts was to get a consensus around the messages and the content of the draft Recommendation on child friendly health-care.

The Child friendly healthcare model developed in the draft Recommendations comprises three pillars:

- **Participation** of children and their parents, families, care takers in the health care process, individual decision-making, health service planning and health policy level
- **Prevention** of health problems through the promotion and protection of children's' health, addressing the socio-economic and cultural determinants of children's health
- **Improving the provision of high-quality services** for both acute and chronic conditions to ensure that all the parts are in place and working well together to guarantee both safety and good outcomes.

The CoE Secretariat will soon launch a written consultation with all stakeholders in which EPF is planning to engage in close consultation with its members.

The last meeting of the Committee of Experts on Child Friendly Healthcare is scheduled to take place in Strasbourg from 5 to 6 May 2011.

For more information please contact Walter Atzori or visit the Council of Europe DG Health website.

CONFERENCES AND EVENTS

20. EFPIA Patients Think Tank – Nicola Bedlington (10 February, Brussels)

Nicola Bedlington attended the EFPIA Patients Think Tank on behalf of EPF, in addition to the usual policy updates also reported elsewhere in this Mailing, a specific session took place on the activities of various members of the Think Tank in relation to Health Technology Assessment, and also an intervention from the Commission on the European Innovation Partnership on Active and Healthy Ageing.

For further information on the meeting or a copy of presentations, please go to the EPF secretariat.

21. OECD – NATIONAL SCIENCE FOUNDATION WORKSHOP Building a smarter health and wellness future (17-18 February, Washington)

Anders Olauson participated in this meeting on behalf of EPF in a Round Table debate looking at End - to end solutions for patients. The debate addressed how to prevent siloed approaches and increase the value that patients/consumers derive from the new technical and socio-technical developments.

For more details on the workshop and its outcomes please go to

www.oecd.org/document/55/0,3746,en_2649_33703_46913079_1_1_1_1,00.html

For a copy of Anders' presentation, please contact the EPF secretariat.

22. London - 4th European Forum of Healthcare Deciders, LSE – Nicola Bedlington (speaker) (17-18 February)

Nicola Bedlington represented EPF at the 4th European Forum of Healthcare Deciders, London School of Economics and Political Science. She made a presentation of the effectiveness of medicines policies from the patients' perspective. For more details about the event and a copy of the presentations please go to:

www2.lse.ac.uk/businessAndConsultancy/LSEConsulting/conferences/Health2011.aspx

23. High level conference on medical devices (22 March)

Nicola Bedlington represented EPF at this Conference and its preparatory meeting in February.

We were pleased with the overall Conclusions which reflects a strong patients' perspective http://ec.europa.eu/consumers/sectors/medical-devices/files/exploratory_process/hlc_en.pdf

Nicola also made a presentation in relation patients' safety and medical technology – please contact the EPF secretariat for a copy.

For more details regarding the event, please go to: http://europa.eu/rapid/pressReleasesAction.do?reference=IP/11/331&format=HTML&aged=0&language=EN&guiLanguage=en

EPF will be engaging in the Commission's consultation process on the Recast of the Medical Devices Directive and members will be contacted on this issue in due course.

EPF will also be working closely with EUCOMED, the European organisation representing the medical devices industry to set up a regular dialogue meeting between industry and patient group representatives. The first meeting will take place on 26 May 2011. EPF Members will receive more information on this in the next few days.

24. National Forum of Romanian Patient Organisations and EPF 2011 Regional Advocacy Seminar (11-12 March, Bucharest)

Walter Atzori was invited to speak at the second National Forum of Patient Associations of Romania held in Bucharest on March 11-13.

The meeting, hosted by the Coalition of Romanian Chronic Patient Organisations (COPAC), which is member of EPF, was attended by some 200 Romanian patient leaders, representatives of health professionals and government officials.

In his welcome speech Walter stressed the importance EPF attaches to establishing and empowering national coalitions of patient organisations throughout the EU as a means for making the patient voice not only heard but also, and more importantly, listened to in an attempt to promote the recognition of patients as equal partners in national healthcare.

On the second day he gave a presentation on the funding opportunities for Romanian patient organisations under the various EU funding programmes and the European Social Fund envelope for Romania.

The participation of EPF to this important event was also an opportunity to meet national patient leaders with a view to involving them in shaping the content of the next EPF Regional Advocacy Seminar, taking place in late October in Bucharest and involving patient leaders from Romania, and three other countries which are currently being identified.

Preliminary consultations with local patient leaders should ensure that the objectives of the Seminar are shared with the people who will ultimately benefit from participating and that both the programme and content meet to the largest extent possible the needs of local patient organisations. A consultation with patient representatives of the other eligible countries will be also carried out.

It is anticipated that the focus of the fourth Regional Advocacy Seminar, which will be co-hosted by COPAC, will be on strengthening the cooperation between patient organisations and health professionals' organisations.

Further information on the fourth EPF Regional Advocacy Seminar will be provided in the next Mailing Issues.

For more information please contact Liuska Sanna or Walter Atzori.

25. Economist Conference – European Healthcare (17 March, Geneva)

Nicola Bedlington represented EPF at a recent conference organised by the Economist in Geneva

Almost 200 senior healthcare stakeholders from 26 European countries gathered together in Geneva on March 17th to debate the future of healthcare reform in Europe.

Please go to the following link and a copy of the presentations and main conclusions.

http://eu.economistconferences.com/event/european-healthcare-summit

26. Goodbye Abi

EPF EPF said goodbye to their trainee, Abinaya Rajan. Abi left EPF beginning of March. Abi is a PhD researcher at the Netherlands Cancer Institute - Antoni van Leeuwenhoek Hospital (NKI-AVL) located in Amsterdam. She will continue her work on HTA survey from Amsterdam. We wish her the best of luck in her new challenge and many thanks for her contribution to EPF.

27. Diary

Date	Event	Attendance
27-29 March	BioVision, the World Life Sciences Forum, Lyon	Anders Olauson (Speaker)
30-31 March	Innovation in Healthcare, Brussels	Anders Olauson (Speaker)
5-8 April	International Forum on Quality and Safety in Healthcare, Amsterdam	Nicola Bedlington (Speaker)
06-08 April	Med-e-Tel Annual Conference, Luxembourg	Walter Atzori
07 April	EFPIA Think Tank, Brussels	Nicola Bedlington
06-08 April	Med-e-Tel Annual Conference, Luxembourg	Walter Atzori
11-12 April	European Patients' Rights Day, Brussels	Nicola Bedlington (Speaker)
12-13 April	EPF Annual General Meeting and Value+ Capacity Building spring seminar	
15 April	Meeting on the implementation of the Pharmacovigilance legislation – European Medicines Agency, London	Kaisa Immonen-Charalambous (Speaker)
4 May	Anti- Counterfeiting Conference, London	Nicola Bedlington (Speaker)
9-13 May 2011	eHealth week	Anders Olauson, Nicola Bedlington, Walter Atzori
12-13 May	European Perspectives on Personalised Medicine, Brussels	Anders Olauson (Speaker)
25-28 May	EULAR/PARE Conference 2011, London	Kaisa Immonen-Charalambous (Speaker)