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EPF Mailing

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Dear EPF Members and Allies,

Welcome to the EPF Mailing – a briefer issue that usual as we wanted to inform you of recent important developments before the Christmas break. The highlight of the last few weeks was EPF's High-Level Roundtable on "The Draft Directive on Patients' Rights in Cross-Border Healthcare: Moving Forward on Health Inequalities, Patients Rights, Quality, and Safety" 1st December 2010 . Read about this event in our special feature, and get an update on where the negotiations between the Commission, European Parliament and Council are right now. There has also been a significant development on information to patients, with the adoption of the Fjellner report in the European Parliament in November. (see section 3)

A. Olauson thanking T. Lönngren for his commitment to patient involvement in EMA

On the 15th December, we attended the EMA scientific conference that said good bye to executive director Thomas Lönngren.

The EPF board met in early December and approved a draft Work Plan for 2011 that has now gone to the EPF membership for final consultation. The board also approved a new Youth strategy to engage young patients in EPF's activities and this is reflected in our priorities for 2011.

Looking forward to 2011, EPF will launch its new project "Chain of Trust", funded under the European Public Health Programme in January and much planning is already underway. "Chain of Trust" will explore how to build confidence and trust in eHealth solutions among patients and health professionals. We are delighted to be working with fellow health stakeholders representing doctors, nurses, pharmacists, carers and health managers in this venture. More details under section 11.

The year 2011 will see EPF's participation to a new project, funded by FP7, as associate partner. The "International Research Project on Financing Quality in Healthcare" - InterQuality will explore health financing systems' effect on quality of healthcare by researchers from seven EU countries and US. The project is coordinated by the Medical University of Warsaw and EPF will lead the work package on dissemination. More details under section 12.

EPF will hold its Annual General Meeting and Value + Programme for EPF members on 12 and 13 April in Brussels. Please note the date and further information will be sent to you in the New Year.

We would like to take this opportunity to wish you, as EPF members and allies all the very best for the festive season and very best wishes for a happy and successful 2011. The EPF board and team have enjoyed enormously working with you in 2010 – it is has been a very rewarding year. We look forward to our strong collaboration in 2011 to continue to work towards our vision of patient centred, high quality, equitable healthcare for all patients across the European Union.

Warmest Greetings,
EPF President Anders Olauson
EPF Director Nicola Bedlington

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1. EPF High-level Roundtable: Stakeholders sent a strong message to policy-makers on the draft directive on cross-border healthcare

On 1 December 2010, EPF organised a High-Level Roundtable on the theme "The draft directive on patients' rights in cross-border healthcare: moving forward on health inequalities, patients' rights, quality and safety"

The event, held under the patronage of the Belgian EU Presidency at the Solvay Library in Brussels, brought together 51 policy-makers and stakeholders, including members of the European Parliament, representatives of the Commission, the Belgian Presidency, several Member States' representations, as well as leading health stakeholder organisations.

The message that emerged clearly from the speeches and discussions was that the recommendation of the European Parliament has the broad overall support of the health community. EPF has worked closely with the EP Rapporteurs and supported many of the provisions (see EPF's last position statement). We hope that those key aspects will be preserved in the current negotiations with the Council, which has so far taken a more reserved stance.

If adopted in the next few months, the draft Directive will be an important milestone for patients: for the first time, patients' right to seek healthcare in another Member State and to be reimbursed for it will be codified into European law. It will also serve as an important basis for future cooperation to improve the safety and quality of healthcare in all Member States.

While the Directive will not offer a perfect solution to all patients' needs, it is nevertheless an important step forward on patients' rights. **Mr John Dalli**, Commissioner for Health and Consumers, in his statement stressed the proposal's original aim to clarify the rights of patients to safe and good quality treatment across borders, and asking all parties to show flexibility to reach an agreement in the next months. Mr Dalli's speech can be viewed here in full. Mme Grossetête, Rapporteur for the dossier within the European Parliament described the position of the European Parliament.

Among the speakers were representatives of the Belgian National Institute of Health and Disability Insurance (NIHDI); the European Parliament, the European Commission, and high-level representatives of health professionals (nurses, doctors, medical specialists, and community pharmacists), managers (hospitals and health managers), patients, and the pharmaceutical and medical devices industry.

Immediately after the event, EPF distributed a summary statement with key messages to the press, MEPs, Member State representations, members and allies. The statement and a full report are available on EPF's website.

Next steps:

- Following the "trilogue" meeting (informal negotiation meeting between the Council, Commission and Parliament) that took place on the evening of 1 December, the directive was discussed in the Council on 6 December at the technical level, but not yet at the Health Ministers level, as several issues were still under debate.

2. Latest update from Council on cross border healthcare

Just before "going to press" we learned that on the "trilogue" meeting of 15 December, the Parliament and Council have reached an agreement on second reading concerning the legislative proposal on Cross-Border Healthcare. The Belgian Presidency has made a great effort to press the matter in order to reach an agreement; failure to do so would have resulted in the need to launch a conciliation procedure between the Institutions.

Although the details of the agreement are yet to be published, according to unofficial sources the key contentious issues have been agreed as follows:

- **Provisions for rare diseases**. The compromise solution does not make exception for any specific patient groups. The stated aim is to respect the provisions of Regulation 883/2004 on the coordination of social security systems, while strengthening cooperation, in particular through the use of the Orphanet database and European Reference Networks.
- **Upfront payment**. Provisions to be confirmed.
- **Prior authorisation and reimbursement**. Patients will be entitled to reimbursement of the same, or similar, treatment as would be provided under their own healthcare system. Member States will be able to set up prior authorisation systems, which will apply to hospital care, care involving specialist equipment or infrastructure, particular patient safety risk, and treatment that could raise serious concerns. Reasons for refusing prior authorisation were contentious; the outcome reflects a half-way house between the Council, who wanted broader definitions, and Parliament, who wanted a precise, defined list.
- **eHealth, Quality and safety standards**. The ambitions of the Commission and Parliament in these areas had to be downscaled. These questions will not now be addressed at EU level, but through cooperation between Member States.

From the position of EPF, considering our constructive efforts with the Parliament throughout the process, this outcome if confirmed appears somewhat disappointing. Clearly, Member States have chosen to take a more cautious approach than the

Parliament, and patient groups, would have wished. However, EPF will analyse the agreed provisions in depth as soon as possible and inform our members accordingly. As participants widely agreed at the EPF High-Level Roundtable held on 1 December 2010, the mere fact that a legal framework for cross-border healthcare is being set up for the first time, is in itself a milestone in EU health policy. We hope to find provisions in the finally adopted text that can serve as starting points for building greater European cooperation in future.

Next steps: The Council is due to formally adopt a common position on 21 December. According to the EP Rules of Procedure, if the EP does not adopt amendments to, or a motion to reject, the common position, within a certain time, then the act will be deemed to be adopted.

3. Information to patients

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

On 24 November 2010, the European Parliament adopted at first reading the two legislative reports on information to patients with a sizeable majority: the Directive by 558 votes in favour, 42 against and 53 abstentions, and the Regulation by 564 votes in favour, 41 against and 45 abstentions.

Having worked intensively with the rapporteur, Mr Fjellner MEP, EPF broadly welcomed his report, which formed the basis of the first reading position. His major achievement was to shift the focus of this dossier on to the right of patients to access quality information, from the rather narrow proposal originally put forward by the Commission that focused on the right of industry to provide information.

Key to reaching a compromise in the Parliament is a differentiation between "push" and "pull" information: "pull" meaning information actively sought by patients, and "push" meaning unwanted information or disguised advertising. The former should be easily accessible while the latter should not be allowed.

EPF put out a statement following the vote in the Parliament, which can be read online at www.eu-patient.eu, summarising the key points of the EP position on the draft Directive and the Parliament vote.

Some remaining concerns from the patients' perspective

EPF has been very supportive of the work of Mr Fjellner, and we believe that the EP vote presents a significant step forward on patient information. The establishment of national information portals, particularly, will contribute towards more equitable access to key information across the EU. Nevertheless, certain issues should be addressed.

- *Quality criteria*. EPF believes strongly that the quality criteria should apply to all information to patients, whatever its source, to ensure that the information is patient-centred. There is no logical reason to exclude Member State provided information from the scope of the quality criteria. We recommend that the Core Quality Principles developed by the Pharmaceutical Forum should be adopted as the basis of the quality criteria.
- *Clinical trials*. While it is welcome that companies may provide information on trials, we regret that the draft Directive does not take a bolder approach for more transparency. From the patients' perspective there is a great need for more transparent information on clinical trials, including the outcomes of 'failed' trials, which are a very valuable source of information to patients.
- *Patient organisations' participation*. EPF is concerned that certain parts of the proposal as amended appear to qualify the involvement of patients by referring to "independent" patient organisations, without defining how this independence would be assessed, or by whom. Collective qualification like this is problematic and, if defined too narrowly, could have the unintended consequence of excluding groups of stakeholders from having a voice in the democratic process. EPF recommends, as a model of good practice, the criteria used by the European Medicines Agency in its work with patients' and consumers' organisations, which are, in fact based on EPF's own criteria.

A step forward in the wider process

EPF has called consistently for an EU-wide "information to patients and health literacy" strategy and argued that this legislative proposal should be seen as only one component in the wider policy context. We warmly welcome and support the explanatory statement, of Mr Fjellner where he states that "everyone interested should be able to find accurate and unbiased information on healthy lifestyle, the prevention of illness and specific diseases, and various treatment options … The Rapporteur … expects the Commission to present a new proposal in a near future as a part of such wider 'information to patients strategy'".

Next steps

During the Council meetings on 6-7 December, Commissioner John Dalli confirmed the Commission will now present a modified proposal in order to take into account the concerns of the Member States and Parliament.

The Hungarian Presidency, which will start its work in January 2011, also announced its willingness to address this file with priority as soon as the modified proposal has been presented.

EPF will continue working with the EU Institutions during the next stage in the process, to ensure that the current political momentum on patient information is used to drive progress in this area that is of such importance for all patients.

4. Pharmacovigilance dossier adopted by Council

On 29 November the Council adopted the new legislation on pharmacovigilance as "A" point (to be adopted without debate), having reached agreement with the European Parliament on first reading. The legislative texts (Directive 2001/83/EC and Regulation 726/2004), incorporating the new rules, will be published in the EU Official Journal soon, and will enter into force 20 days later. Member States will have 18 months to transpose the rules into their national legislations (mid-2012).

In previous issues we reported on the EPF's position on this issue, and the joint event organised in September 2010 with PGEU to highlight the new rules and how stakeholders, particularly patients and community pharmacists, can cooperate for more effective reporting of adverse drug reactions.

Key provisions under the new rules:

- EU Member States must ensure they have in place a *pharmacovigilance system* with the necessary expertise. They must collect reports of suspected adverse drug reactions even in cases where the drug is not used within the terms of its marketing authorisation – i.e., also for cases of overdose, misuse, abuse and medication errors.

- *Patients will be able to report adverse reactions directly* to the national competent authorities if they wish, rather than only through a health professional. Member States must facilitate patient reporting and provide alternative options in addition to an electronic method.
- The *packaging of all medicinal products* will include a standardised text asking patients to communicate any suspected adverse reaction to their doctor, pharmacist, healthcare professional, or directly to the national spontaneous reporting system, and explaining what options are available for reporting.
- The existing EU pharmacovigilance database, *the Eudravigilance database, will become the single point of receipt* of pharmacovigilance information for human use medicines authorised in the EU. The capacity of the database will be built gradually. Companies and Member States will report reactions directly to the Eudravigilance database, which will immediately notify all Member States electronically. Reports of serious suspected adverse reactions must be sent to Eudravigilance within 15 days, and reports of non-serious ones within 90 days.
- Patients, healthcare professionals, research organisations and *the general public will get appropriate access to Eudravigilance*. The EMA recently published a draft Access Policy and created a working group of stakeholders to work out the practical application of the Access Policy while guaranteeing personal data protection, and to prepare guidance on how to interpret the data.
- Member States must set up *national medicines web portals* to inform the public, which will be linked to the EU web portal. The information on the national portals will include the summary public assessment report, summary of product characteristics and patient information leaflets; summary of the risk management plan, and information on the different ways to report suspected adverse reactions.
- Two years after the publication of the Directive, the Commission must present a *review on the shortcomings of the Patient Information Leaflet (PIL) and SCP*, which are widely considered not to be user-friendly. The commission must consult stakeholders and present proposals on how these documents could be improved in order to better meet the needs of patients and health professionals.
- A new *Pharmacovigilance Risk Assessment committee* will be created at EMA to advise the CHMP on the risk-benefit assessment of centrally authorised products, and to advise the EMA's coordination group on questions related to the pharmacovigilance of all EU-authorised medicines and any variations to the terms of their marketing authorisations.
- The *requirements for marketing authorisation* will continue to require companies to set up a pharmacovigilance system for monitoring and supervision of their authorised products, but only the key elements must be submitted for assessment in

order to get marketing authorisation. Companies must, however, maintain a detailed file available for possible inspections by competent authorities.

- Companies may not refuse reports of suspected adverse reactions provided in an appropriate format by health professionals or patients.
- The Commission will be empowered to require companies to conduct *post-authorisation safety and efficacy studies*, as part of the marketing authorisation. The EMA may require a company to operate a risk-management system if there are concerns about the risk-benefit balance of an authorised product. To ensure that non-interventional post-authorisation safety studies (i.e. safety studies of authorised products that are not clinical trials) requested by competent authorities are non-promotional, there will be stronger harmonised guiding principles and regulatory supervision. Currently, companies must submit to EMA periodic safety update reports. In future, these reports will constitute a scientific evaluation of the risk-benefit balance of the product, since individual case reports will already be submitted to Eudravigilance.
- *Products under additional monitoring* (e.g. products with new active substances, biologicals and other products if required under the terms of marketing authorisation) will be identified by a black symbol and an explanatory sentence on the packaging, that encourages patients to report any adverse reactions and gives instructions on how this can be done.
- Member states are asked to consider measures to monitor and evaluate the *environmental effects of medicines*. The Commission will produce a report on scope of the problem, and assess if the relevant EU legislation should be amended.
- Member States are encouraged to *involve health professionals and patients* in the follow-up of reports to ensure good quality data, and to involve patients' organisations in the development of national measures to promote adverse reactions reporting.

Adoption of the Pharmacovigilance Directive and Regulation: what will happen now?

The legislative texts (Directive 2001/83/EC and Regulation 726/2004), incorporating the new rules, will be published in the EU Official Journal in the near future. They will enter into force 20 days after their publication in the OJ. Member States will then have 18 months to transpose the rules into their national legislation. EPF will be working with its members to encourage this process at national level, reflecting the spirit of patient involvement embedded in the legislation.

Links:

- Council press release including links to the legislative documents

- Report of EPF-PGEU joint event held on 15 September 2010 on the new Pharmacovigilance legislation.

5. Access to medicines

Commission Initiative on Corporate Responsibility in the Field of Pharmaceuticals

Launched officially in September 2010, the Corporate Responsibility initiative is led by DG ENTERPRISE as a follow-up activity to the Pharmaceutical Forum (2005-2008). The process will focus on access to medicines after the granting of marketing authorisation, and on corporate social responsibility in the field of pharmaceuticals.

Three platforms of discussions are to be set up under the Initiative: (1) Ethics and transparency; (2) Access to medicines in the least developed countries focusing on Africa; and (3) Access to medicines in Europe.

Platform on Access to Medicines in Europe

The Platform on Access to Medicines in Europe was the first to be launched, with a first meeting of the Steering Group taking place in Brussels on 24 September 2010. EPF was invited as a stakeholder organisation to participate in the Steering Group, which includes representatives of the EU Member States and EFTA countries, and also other stakeholder organisations such as health professionals, health managers, social insurance, consumers and the industry.

The Platform on Access to Medicines in Europe will aim to reinforce the collaboration between the Member States and stakeholders in order to ensuring fair and timely access to medicines following their market authorisation. Framed in the existing legislative and regulatory context, it will bring together certain specific and innovative initiatives and projects.

Since pharmaceutical pricing and reimbursement policies fall within the competence of Member States, each government is responsible for the organisation of its healthcare system and is free to take measures to ensure the financial stability of its health insurance scheme. Based on the outcomes of the Pharmaceutical Forum, the Platform on Access to Medicines in Europe will be dedicated to enhancing collaboration among Member States and relevant stakeholders in order to find common (non-regulatory) approaches to ensure timely and equitable access to medicines.

In practice, the Platform will work on a number of specific projects, for which expressions of interest were invited among EPF's membership. EPF through its Secretariat will be represented in the Steering Group, which has an overall coordinating role on the work of the Platform. The Platform overall is chaired by DG ENTERPRISE. The next meeting of the Steering Group will take place on 17 December in Bruges.

Link to the website of DG ENTERPRISE:
http://ec.europa.eu/enterprise/sectors/healthcare/process_on_corporate_responsibility/index_en.htm

6. Health Inequalities

EPF comments on the European Parliament draft report. In 2009 the European Commission launched a public consultation on tackling health inequalities as part of the EU Health Strategy "Together for Health". EPF consulted its membership and developed a response, framed around our vision of high quality, patient-centred, equitable healthcare across the European Union, and our strategic goals on equity, empowerment and inclusion.

Based on this consultation, the Commission published a Communication titled "Solidarity in health: reducing health inequalities in the EU". From the patients' perspective, the Communication was less than satisfactory, with no reference to the particular needs of patients or the importance of health literacy.

The European Parliament has recently prepared a draft report on health inequalities, led by Portuguese MEP Edite Estrela, which is scheduled for vote in the ENVI Committee in January 2011. EPF has submitted a position statement and proposed some amendments, to reflect the concerns that were first raised in our member consultation and discussion in the PAG. It appears that the political debate on health inequalities centres very heavily on prevention and health promotion, threatening to eclipse the importance of chronic disease management and patients' needs.

Our position statement sent to the members of the Parliament's ENVI Committee stresses the following key points:

- *Ongoing research is important, but action is a priority.* In our view, there is already a very good body of research on health inequalities across the EU. Whilst we agree that ongoing research is still important, to explore in depth specific aspects of health inequalities, this should not stand in the way of action now. EPF believes there is now an urgent need to translate the existing evidence base into coherent policies, both at EU and MS level.
- *The needs and perspective of patients must not be neglected*. The political agenda on health inequalities – whether at EU or Member State level – must not be seen as exclusively focused on prevention and health promotion, vital as those are. Patients with chronic illness constitute a distinct "constituency" that is subject to specific vulnerabilities, and their needs must be considered within any action on health inequalities.
- *Patient empowerment, patient-centeredness, and health literacy* are vital concepts that should be embedded in all EU actions tackling health inequalities, insofar as they relate to the needs of patients with chronic conditions.

EPF plans to undertake a further member consultation in early 2011, to gather more data and update the situation at national level, as well as in specific disease-areas, in view of the ongoing impact of the financial crisis which continues to be felt by chronically ill patients across Europe. In the meantime, we warmly encourage member organisations to share their evidence and perspectives relating to health inequalities. Please contact Kaisa Immonen-Charalambous.

7. European Innovation Partnership on Active and Healthy Ageing (AHAIP)

The "Innovation Union" is one of the flagship initiatives designated under the Europe 2020 Strategy that aims to contribute to smart growth. The European Innovation Partnership is a novel concept of the Commission to address societal challenges through linking research and innovation and turn them into concrete actions.

Active and healthy ageing was formally adopted as the second "innovation partnership" by the EU Member States on 6 December. EPF, through its representation in the EU Health Policy Forum, has already given its preliminary input, in consultation with the Policy Advisory Group. In addition, Nicola Bedlington, EPF Director, participated as a speaker in the Stakeholder Conference of the Commission, held on 26 November in Brussels.

Europe's ageing population is one of its most pressing societal challenges, with the number of people over 65 expected to rise from 81 million (2008) to 151 million in 2060, while during the same period the ration of people of working age to people over 65 is expected to decrease from 4:1 to 2:1. This demographic change has far-reaching implications for the budgets and sustainability of the health and social systems, including healthcare, pensions and long-term care. It is compounded by a dwindling health and care sector workforce.

The innovation partnership will seek to realise the potential and promise of the health sector, looking at it not only in terms of expenditures but also in terms of growth and adaptation to such challenges. The partnership will address bottlenecks and weaknesses in the way of innovation, including barriers related to people's ability to use innovations, public procurement, regulatory frameworks, and incentives and models for integrated care.

Its triple target is to enable EU citizens to lead healthy, active and independent lives until old age; improve the sustainability and efficiency of social and health systems; and develop EU and global markets for innovative products and services, thus creating new opportunities for European businesses. The overarching goal is, by 2020, to increase the average healthy life years (HLY) in the European Union by two years.

Three areas of work or "work packages" have been proposed by the Commission:

Work package 1

This will target individual patients and consumers and focus on developing innovative solutions, clinical tests, medicines and treatments to combat and address major chronic and rare diseases. Projects may include developing cost-effective preventive and treatment strategies for major disease-areas affecting older patients; developing personalised medicine and care applications specific to older people; or work around older people's self-management and adherence to therapies.

Work package 2

This will address social and health at systems level, by developing innovative policies and business models for more integrated care, including home-based and self-care, and EU wide cooperation on HTA. Projects may focus at integrated care systems encompassing all the various dimensions, addressing the health workforce shortage, aiming for more evidence-based choices on new interventions and products for older people, information sharing at EU level.

Work package 3

The third area will address EU-related markets, and enabling older people to lead independent and active lives, and may focus on promoting the development and deployment of innovative products, devices and services, including ICT-based,

specifically suitable for older people; for example addressing the barriers to the uptake of innovative solutions and their practical use by older people, interoperability through EU or global standards, public procurement barriers, exchange of good practices and cooperation, and evidence-based guidance.

Next steps:

- The Commission's online public consultation is open until 28 January 2010. EPF has sent out a short consultation questionnaire. Interested members are encouraged to respond and also to contribute directly to the Commission if they wish.
- A multi-annual strategic work programme is to be adopted in early spring 2011.

Link to the EU Innovation Partnership for Healthy and Active Ageing.
For more information and details of the launch event 2011. For a copy of Nicola's intervention, please contact the EPF secretariat.

8. ENVI committee adopts a draft report on Alzheimer's disease

On 30 November the Environment, Public Health and Food Safety (ENVI) Committee of the European Parliament adopted an own-initiative report "A European initiative on Alzheimer's disease and other dementias", drafted by Portuguese MEP Marisa Matias (GUE/NGL) with 48 votes in favour, none against and 1 abstention. Prior to the vote, Ms Matias stated that she encouraged member states to increase their cooperation and pool their efforts in the field of research. She welcomed the scientific breakthroughs made recently, but emphasised that she would like to see an involvement further than pharmacological research. She also welcomed the amendments focusing on the dignity of the patients and the care devoted to the family members.

In July 2009, the European Commission published a Communication on an European initiative on Alzheimer's disease and other dementias, which focused on four dimensions:

(i) public health and the prevention of dementias;
(ii) the coordination of research in order to improve the understanding of dementia conditions;
(iii) sharing best practices related to treatment and care; and
(iv) respect for the rights and autonomy of people with dementias.

Furthermore in July 2009, the European Commission also adopted a Proposal for a Council Recommendation to combat neurodegenerative diseases, in particular Alzheimer's, through joint programming of research activities.

In her draft report, responding to the Commission Communication, MEP Matias stresses the fact that dementia will be one of the main challenges for healthcare systems in the coming decades. In the context of an ageing and retiring population, Member States should increase cooperation and coordination of research efforts in order to share knowledge and practices, and increase financial investment in the area of neurodegenerative diseases.

A common research agenda establishing medium- to long-term needs and objectives would serve to reduce the existing inequalities in diagnosis and treatment between and within Member States. Research programmes should place the patient's choice and perspective in the centre and emphasise research on the link between dementia and the ageing process on the one hand, and the connection between dementia and depression on the other hand.

The report also encourages Member States to emphasise the psychological support for patients and their families, as well as to develop services which ensure equity of access to care and maximum possible coverage. Indeed, reducing existing inequalities and enhancing the rights and dignity of people with dementia must be priority objectives.

To this end, Member States should develop information campaigns for the general public with the involvement of many stakeholders, from medical organisations to patients' associations. The actions proposed by the Commission will be implemented by means of a Joint Action. The implementation report is expected by 2013.

Next steps: The Matias report is scheduled for vote in plenary on 17 January 2011. Draft report online.

Alzheimer Europe - EPF member driving this agenda for patients with Alzheimer's disease and other dementias.

9. The Commission's Work Programme for 2011

The Commission as published its annual Work Programme for 2011. The Work Programme translates the President's political guidelines into action and is updated each year with new strategic initiatives. The overarching objectives for the 2011 Work Programme are:

- exiting the economic crisis and creating sustainable growth and jobs (Europe 2020 Strategy)
- enhancing the rights and security of European citizens
- strengthening Europe's role in the world.

The specific priorities for EU calls for proposals for the various funding programmes are based on the priorities of the Commission's annual Work Programme. Regarding the Health programme, the Executive Agency for Health and Consumers (EAHC) is expected to publish the 2011 calls for proposals before the end of the year 2010.

Links:

- Commission's Work Programme 2011 and its annexes in 22 EU languages.
- The EAHC homepage.

PROJECTS

10. CALLIOPE THEMATIC NETWORK – Closing event

The closing event of CALLIOPE, a European platform for eHealth interoperability, took place at the European Parliament on the 16th of November and was hosted by Mr. Milan Cabrnoch, MEP. EPF participated to the stakeholders' panel.

The purpose of the event was to share the main outcomes of the project, in particular the proposal for a European eHealth Interoperability Roadmap towards Sustainable Health. The aim of the roadmap is to accelerate the deployment of eHealth services and to identify common ways to reach interoperable solutions. The final version will be launched in December 2010.

The results of CALLIOPE will feed some of the work of the forthcoming Member State driven Initiative on eHealth Governance the objectives of which were also presented. This initiative wants to achieve a consolidated approach and a strong political commitment to eHealth governance at policy, strategy and operational levels. EPF is involved as a stakeholder in the Initiative alongside other health stakeholder allies through the eHealth User Group.

For more information please go to www.calliope-network.eu

11. CHAIN of TRUST project: Kick-off meeting

EPF is pleased to announce that the EPF-led project on telehealth Chain of Trust will start officially in January 2011. The partners – CPME, EFN, NST, PGEU, SUSTENTO, TIF – will meet in Brussels on the 31st of January and 1st of February. The project is financed by the EC Public Health programme and will last for two years.

The paramount objective of the project is to advance the empowerment of patients, health professionals and national health authorities across the EU in their understanding and effective use of telehealth services in an effort to actively contribute to the vision of high quality, patient-centred, equitable healthcare for all EU patients. Through a series of focused and well defined actions the project will strengthen significantly the levels of awareness and trust for all key stakeholders.

To this end the project will improve available knowledge of the specific views among patients and health professionals with regard to telehealth services and will increase awareness and understanding of users' perspective on telehealth amongst patients' and health professionals' organisations and health authorities at European and Member State level.

If you would like more information you should contact Liuska Sanna.

12. InterQuality: Kick-off meeting

The year 2011 will see EPF's participation to a new project as associated partner. The 'International Research Project on Financing Quality in Healthcare' - InterQuality gathers the interest for financing systems' effect on quality of healthcare of researchers from seven EU countries and US. The project is led by the Medical University of Warsaw and EPF will lead the work package on dissemination.

The study, based on administrative and survey data, is designed for 36 months. It will take into account needs of four different patient groups affected by: hospital, outpatient, pharmaceutical and integrated care. The scope of research will cover: utilization of resources and efficiency, quality of care, including: equity of access, patient satisfaction and safety of treatment. Resources allocated by each sector will be analyzed in relation to risk of their overuse, underuse or misuse.

Critical appraisal of individual contracts will be based on the New Institutional Economics theory. Principal-Agent framework, the new standard approach to modeling relationships between payers and providers in healthcare, will be applied to the analysis of reimbursement schemes.

The research will be conducted in Poland, Italy, Denmark, Germany, United Kingdom and United States. Each of the chosen countries has different health care financing system therefore the comparison of the results and outcomes, addressing different aspects of financial incentives' effect on quality of care, will advance the knowledge base on sustainability of the health systems. Further knowledge gained from the project will provide support for Member States to choose the right financing mechanisms in the different areas of the health care system, according to their needs, in order to achieve better health with available resources.

If you would like more information you should contact Liuska Sanna.

13. Joint Action in Patient Safety and Quality of Healthcare

In the previous issue of this mailing, we covered the new Joint Action that is being prepared on patient safety and quality of care.

A Joint Action is an EU funding instrument that involves cooperation between Member States and the Commission – and in this case also a number of stakeholders' organisations. EPF was invited as a stakeholder partner in the Joint Action. The Joint Action was chosen by the Council as the most appropriate policy instrument to implement the Council Recommendation on patient safety, and take the first steps towards Member State cooperation on quality. Furthermore, the Council Working Party on Public Health at Senior Level in May 2010 called on the commission to facilitate the exchange of good practices in patient involvement and empowerment.

The overall aims of the Joint Action are to support the implementation of the Council Recommendation by Member States through collaboration between Member States and stakeholders; and to strengthen Member State cooperation on issues related to quality of care and patient involvement. It aims to create a sustainable platform for cooperation in patient safety and quality that will continue working even after the Joint Action finishes.

Preparatory meetings on the Joint Action took place on 8 July and 19 November, with a view towards submitting the proposal under the 2011 call. If successful, work will start at the end of 2011 or early 2012. At the meeting on 19 November, the French health authority, Haute Autorité de Santé (HAS) was selected unanimously as the leader of the Joint Action.

In the discussions, EPF has stressed the importance of meaningful patient involvement and identifying good practices from Member States on patient involvement. EPF has also argued that patient safety actions should encompass primary care as well as the hospital environment, and called for inclusion of patient-centred criteria for assessing quality of care. At the current stage of discussions, the Joint Action now includes three work packages, two of which will focus on patient safety, but including wider quality-related topics of appropriate, and one which will concentrate specifically on quality. Patient involvement was recognised by partners as a cross-cutting theme that should be integrated in all work packages. To ensure this is taken forward on a concrete level, specific outcomes and indicators will be developed.

The next meeting, incorporating a training workshop for the participants, will be held on 18-19 January.

Links:

- Commission Communication on patient safety.
- Council Recommendation on patient safety and healthcare associated infections.
- EUNetPas (European network on patient safety) project website.

CONFERENCES AND EVENTS

14. Patient Link Workshop – Brussels, 11-12 November

In November EPF attended the annual Patient Link Workshop, supported by the Medtronic Foundation, at the Hotel Sofitel Europe in Brussels. The workshop is part of the Foundation's Patient Link programme which seeks to address the needs of people with chronic diseases and conditions.

The theme of this year's workshop was "The Turning Point – How Patient Groups Evolve and Grow". The two-day event started with a morning educational session on health technology assessment (HTA), including presentations on health economics, patient groups' role in HTA, and the EU-level cooperation, with presentations from EFNA, the London School of Economics, the European Commission and the French Diabetes Association.

Case studies around the theme of an organisational "turning point" took the spotlight in the afternoon, with descriptions by three patient groups – the Dutch Parkinson Association, the French Essential Tremor Association, and the German MS Association AMSEL – of a strategic initiative they undertook, planned and implemented, that led to "a great leap forward" in terms of the achievements of their organisation and long term benefits for the capacity and impact of the organisation.

The rest of the programme focused on aspects of organisational development and governance, with discussion about strategic planning, leadership, outreach to wider membership and society, advocacy at different levels, and resources. Examples on

engaging the board in the context of a "turning point" were presented by EMSP and EURORDIS. A lively discussion then concentrated on the role and composition of governing boards, and how a board can become more effective in leading the organisation.

15. EPPOSI Workshop "Patients' Engagement in HTA" – Brussels, 17 November

Patients must become full partners in HTA

Health technology assessment (HTA) agencies should support patients to become full partners in HTA policy and processes if their unique contribution is to be fully utilised to the socio-economic benefit of all in society. This was one of the main recommendations of a workshop on Patient Engagement in HTA, organised by EPPOSI (European Platform for Patients' Organisations, Science and Industry) on 17 November 2010 in Brussels, at which EPF participated.

The event, which brought together experts from patients' associations, national and regional HTA agencies, EUnetHTA, national health systems, public health and social science academics, clinicians and healthcare practitioners, and the pharmaceutical and biopharma industry, set out to identify the barriers to greater patient engagement in HTA and come up with concrete recommendations to address four key issues:

- When and how should we engage patients in the HTA process?
- What questions can patients ask of the "hard" evidence to be sure that they reflect patients' concerns?
- How can patient organisations collect evidence that will be useful for HTAs?
- What can HTA Agencies do to improve engagement with patients?

Liuska Sanna, EPF's Programme Manager, co-chaired the third breakout session on "how can patient organisations collect evidence that will be useful for HTAs?" and six main challenges emerged:

- patients' difficulties in gathering the evidence
- finding an acceptable format in which to submit the evidence to agencies
- the issue of independence of evidence (if only industry-funded)
- knowing which methodologies to use
- taking patients' informed preferences into account about how they take medicines or choose treatment options which are based on quality of life issues – for example, where a patient might choose to take a drug orally rather than intravenously even if they know it might not be as effective but where this is balanced by less stress and less disruption to the patient's daily life
- getting agencies to accept and use non-clinical data as part of the HTA process (eg quality of life assessments by patients) – what are the optimal ways for patient organisations to foster that?

Having identified the challenges, the follow-up sessions looked at what concrete recommendations could be drawn up to address these issues.

Summary of key recommendations

1 **HTA agency policy for patient engagement**: take examples of best practice internationally (eg including Canada and Australia) as well as from within Europe to generate minimum standards for involvement that can be adapted and replicated nationally and locally. Take examples from the European regulatory processes where patients and patients organisations are fully involved in the risk/benefit assessment and actively participate in the definition of what constitutes value in diseases management.

2 **Education:** patients must be educated to better understand the concepts underpinning HTA so they understand how to contribute evidence that provides added value to the process. Similarly, HTA decision-makers and clinicians need to be

better educated about patients' real-life experiences in order to move beyond clinical and cost-effectiveness issues when making decisions to take into account the full range of psychosocial aspects affecting patients' treatment and care: family and carer support, quality of life and wellbeing, employment etc.

3 **Resources:** increasing patient engagement will take manpower and resources and should be transparent (educational and financial support to patients' groups in order for them to participate, extra manpower at HTA agencies to help patients participate).

4 **Collaboration:** the only way to achieve real patient engagement in HTA is through greater collaboration between patients, HTA agencies, clinicians, academia and industry and to be clear about where and how collaboration can take place.

Speaking during the concluding panel debate, Finn Børlum Kristensen, Chairman of the Executive Committee of the EUnetHTA Joint Action of Member States, commented that, "It's my view that all agencies should have policies for patient involvement. There is a clear need for more transparency on the work of agencies and clear indications on where patient engagement should take place."

The full recommendations will be published in early 2011 and will form the basis of a new thematic programme to be launched by EPPOSI to help facilitate better HTA processes by all partners.

For further information, please contact Jacqueline Bowman, Executive Director, EPPOSI, on tel: +32 (0)2 274 1750 or email: jacqueline.bowman@epposi.org or visit the website: www.epposi.org.

16. EHTEL – AER –EUREGHA Joint Symposium eHealth in European Regions, 22-23 November

On November 22-23, EPF was invited to speak at the Symposium "eHealth in Europe's Regions" which was jointly organised by the European Health Telematics Association (EHTEL), the Assembly of European Regions (AER) and the European Regional and Local Health Authorities (EUREGHA) and hosted by the Committee of Regions (CoR).

This event took place during the consultation phase on the EU's "Active and Healthy Ageing Innovation Partnership", a new initiative that will be launched in early 2011 (http://ec.europa.eu/research/innovation-union/index_en.cfm). For more information on this initiative please have a look at the article we wrote on this topic within this Mailing Issue by clicking here.

This Symposium showcased how regions can play a pivotal role in fostering innovation in healthcare using eHealth and telehealth services with the aim of delivering quality, efficient and secure health and social services. The Symposium was also an opportunity to understand the role of the regions in eHealth and to identify how, by working together in partnership with all healthcare stakeholders we can further deploy eHealth in Europe for the benefit of all citizens and patients.

Walter Atzori, who spoke at the Symposium on behalf of EPF, focused his presentation on the involvement of stakeholders in the RENEWING HeALTH User Advisory Board (www.renewinghealth.eu/). As the reader may recall from previous Mailing Issues, the User Advisory Board was set up to operate as a standing advisory committee within the RENEWING HeALTH project to advise and provide on-going feed-back on the needs of users of the piloted telehealth services with a view to improving the fit between these services and requirements, expectations and constraints of the various end user groups.

Walter's presentation can be accessed here.

EPF participation in this event was part of our commitment to continuous discussions and cooperation with European regional and local authorities. Being closer to the citizens sub-national authorities are in a better position to recognise and fulfil the needs and expectations of the patients. Working in partnership with regional and local authorities and their pan-European organisations is, therefore, key in advancing patient-centred healthcare services throughout Europe.

All presentations given at the Symposium can be downloaded here.

17. WHO initiative on Patient Safety and Patients' Rights, 29 November

A first coordination of a WHO (Europe) initiative on patient safety and patients' rights was held in Copenhagen on 29 November 2010. EPF was invited to participate in the meeting as the EU-level patients' representative organisation; other participants included representatives of academic institutions from several countries, and the European Commission.

The aim of this first meeting was to explore possible WHO-coordinated projects linking patient safety and patients' rights, both of which are high on the health agendas of countries in the European region. *The WHO European Region comprises 53 countries.*

While patients' rights are usually addressed via legislation and policy approaches, safety activities focus on projects and improvement actions related to concrete safety risks. WHO aims to explore the linkages between the two areas, and particularly the possibilities to improve patient safety by enhancing patient empowerment and health literacy.

Three areas were initially presented as foci for the planed work: blood transfusion, hospital infections, and patient handovers between different levels of care. A conceptual model was presented as a basis for the projects, in which the patient is presented as having an active role in risk management and safety control. (Longtin et al, Mayo Clin Proc'10, available online free of charge at www.mayoclinicproceedings.com/content/85/1/53.full)

The next step will be the preparation of a policy brief, including analysis of the links between patients' rights and patient safety, the legal aspects, and how the conceptual model can be applied to the three above-mentioned areas. The WHO's aim is to provide evidence-based policy guidance for application in patient safety and rights. The group will meet again in February 2011.

18. Rheumatic and Musculoskeletal Diseases Intergroup meeting, 30 November

EPF participated on the fourth meeting of the European Parliament's Interest Group on rheumatic and musculoskeletal diseases. The meeting, held on 30 November 2010, focused on health inequalities and was presided over by Mrs Edite Estrela, MEP from Portugal and the Chair of the Interest Group, who has also recently drafted a European Parliament report on health inequalities.

The first speaker was Mrs Paula Duarte-Gaspar, from the cabinet of Commissioner John Dalli, who presented the European Commission's initiatives in health inequalities. She was followed by Professor Ingemar Petersson, who gave evidence from the disparities between European countries in access to care, presenting data collected by the MORSE research centre. Kaisa Immonen-Charalambous, EPF Policy officer, presented the patients' perspective on health inequalities. The discussion that followed was led by Mr Jim Higgins, MEP from Ireland and Vice-Chair of the Interest Group.

Further information: see EPF's position on health inequalities

19. Conference: "21st Century Healthcare for Europe", Brussels, 3 December

Anders Olauson, EPF President represented EPF at the Conference 21st Century Healthcare for Europe, organised under the auspices of the Belgian Presidency and taking place in Senate. For a copy of Anders' intervention please contact EPF secretariat.

His key message – focussing on health inequalities was: Patients diagnosed with chronic conditions – which are often very serious and sometimes disabling – and their families – are by default in a vulnerable situation: due to the illness itself, due to their need for timely access to healthcare and other related support services; but also due to other vulnerabilities that are linked to chronic illness, such as inability to work and the resulting financial difficulties, or discrimination on the part of society.

Within the spectrum of "health equity" of citizens, patients therefore form a clear and distinct "constituency". Their needs must be explicitly included in any action taken on health inequalities. "Health equity" in our terms can be equated with *patient-centeredness of healthcare,* and *equity of access* to *high quality care.*

20. Employment, Social Policy, Health and Consumer Affairs Council meeting, 6-7 December

The Employment, Social Policy, Health and Consumer Affairs (EPSCO) Council met on 6-7 December 2010 in Brussels. At this second and last formal meeting under the Belgian EU Presidency, the Council adopted several sets of Conclusions, many of them flowing from the outcomes of conferences held under the Belgian Presidency, including:

- Innovative approaches for chronic diseases
- The European health workforce
- Innovation and solidarity in pharmaceuticals

The Council also adopted a general approach on a draft decision designating 2012 as the European Year of Active Ageing, pending the adoption of the European Parliament's opinion at first reading.

Ministers exchanged views on the follow up of the lessons learnt from the pandemic A/H1N1, and a number of other issues, including the social dimension in the national reform programmes in the context of the Europe 2020 strategy, and adopted conclusions regarding the Joint Report from the Economic Policy Committee (EPC) and the Commission on Health Systems in the EU. They also debated the future of pensions systems and adopted Conclusions on adequate and sustainable pensions, a declaration on the fight against poverty and social exclusion, and Conclusions on social services of general interest.

The Council press release includes information on all the topics discussed and links to the documents adopted at the EPSCO Council on 6-7 December 2010.

21. EPPOSI Seminar: a European Strategy for Chronic Conditions, 9 December

EPF participated at the Second EPPOSI Seminar a “European Strategy for Chronic Condition” which was held in Brussels on December 9, 2010.

EPPOSI is a multi-stakeholder think tank bringing together patients' organisations, science and industry players.

This event was the follow-up on the EPPOSI's 2008 workshop on chronic conditions which identified the clear need for a Europe-wide strategy to ensure open, equal access to patient-centred care and treatment for all patients with chronic conditions.

The aim of this workshop, which was supported by the Belgian EU Presidency, was to turn this strategy into practice by helping formulate the principal elements of a holistic new model which can actively reduce the debilitating personal and economic burden of chronic conditions.

The seminar called for innovative approaches to chronic condition management and was closely linked to the EU 2020 Strategy – Innovation Union strategy for smart, sustainable and inclusive growth. In the health sphere, this includes innovations not only in products and treatment, electronic health records and IT services, but also in processes, funding and care management.

A Task Force in charge of developing a model for chronic disease management will be set up after the workshop based on its outcomes.

For more information contact Nicola Bedlington.

22. Winners of the EU Health Prize for Journalists 2010

On 30 November, Paola Testori Coggi, Director-General for Health and Consumers, announced the winners of the EU Health Prize for Journalists 2010, from among 750 articles submitted by journalists from all 27 Member States.

The EU Health Prize for Journalists, launched in 2009, rewards high quality journalism on health issues and especially on topics related to the Europe for Patients campaign. National juries select the finalists, and an EU jury choses the overall winner and the two runners-up.

The first prize this year went to Italian journalists Gianluca Ferraris and Ilaria Molinari for their article "Stealing hope", on obscure "healing clinics" that promise unproven therapies for many diseases. The second prize went to Lucie Hášová Truhelková from the Czech Republic for her article on organ donation and transplantation, "Love dwells in the kidney"; and the third place to Danish

team of journalists Kasper Krogh, Morten Crone, Line Holm Nielsen and Jesper Woldenhof, for an article dealing with patient safety, “The great failure”.

Link to the winning articles and other submitted entries:

http://ec.europa.eu/health-eu/journalist_prize/2010/winners/index_en.htm

23. EPF Board Meeting Outcomes

The EPF board meeting met on 2 December to discuss and agree our work plan and budget for 2011; to review accounts and financial position towards the end of 2010; comment on various project initiatives linked to the Seventh Framework Programme on Research & Development and the Innovative Medicines Initiative; and review and approve the EPF Youth strategy. Specific planning took place in relation to the EU Polish Presidency where board member Tomasz Szelagowski is playing a key role, particularly regarding the planning of our Conference under the auspices of the Presidency on the needs and rights of older patients.

For more information please contact Nicola Bedlington.

24. Welcome Astrid

Astrid Smis began her internship with EPF mid-November. She holds a Master in European Studies from the Free University of Brussels. Before starting her studies on European politics, she did an Erasmus Programme at the Sorbonne in Paris and in 2008, she graduated with Masters in History at the University of Ghent. She will be closely working with **Kaisa Immonen-Charalambous**, EPF’s policy officer, supporting her work in the area of public health policy from a patient’s perspective.

25. Goodbye Kia

EPF said goodbye to their communication officer, Efstathia Megas, better known as Kia. She left EPF mid-November to begin her new job in a consulting firm.

We wish her the best of luck in her new career endeavour and many thanks for her contribution to EPF over the last year.

26. Diary

14 December	Meeting on medication adherence with DG SANCO, EFPIA and PGEU, Brussels Attendance: Kaisa Immonen-Charalambous
15 December	Stakeholders Conference on the review of the Transparency Directive , Brussels Attendance: Kaisa Immonen-Charalambous
15-16 December	EMA Scientific Conference Attendance: Anders Olauson and Nicola Bedlington
17 December	Enterprise Steering Group, 2nd Meeting, Brugges Attendance: Kaisa Immonen-Charalambous
11 January	eHealth Joint Action EXCO meeting Attendance: Liuska Sanna
13-14 January	EGAN meeting, Basel Attendance: Nicola Bedlington

17-18 January	CONTINUA meeting Attendance: Nicola Bedlington
18-19 January	InterQuality project kick-off meeting, Warsaw Attendance: Liuska Sanna
26-29 January	RENEWING HeALTH 3 Meeting of the Project Steering Committee, Klagenfurt, Austria Attendance: Walter Atzori
28 January	Philips Health and Wellness Think Tank, Boston Attendance: Nicola Bedlington
31 January – 1 February	The Chain of Trust Kick off Meeting, Brussels Attendance: Walter Atzori and Liuska Sanna
10 February	EFPIA Patients Think Tank Attendance: Nicola Bedlington
15-16 February	OECD meeting on Health and Wellness, Washington Attendance: Anders Olauson
17 February	RENEWING HeALTH 3 Meeting of the User Advisory Board Attendance: Walter Atzori
21-22 February	EPF Board Meeting