# EPF Mailing

#### STOP PRESS: EP approves new EU rules on counterfeiting

Issue 1 (35)
Peanpatients' forum On 16 February the European Parliament adopted a new Directive on counterfeit medicines, after political agreement with the Council was achieved in December. Read a summary of the main points of the new rules on page 8. EPF will distribute a detailed analysis and views on the Directive to its members very shortly.

#### Dear EPF Members and Allies,

Welcome to the first EPF Mailing of 2011. As we go to press, we are planning our board meeting in mid-February where our draft Annual Report and Accounts for 2010 will be discussed, in preparation for the Annual General Meeting on 12-13 April 2011. EPF members – please save the date – important EPF business will be agreed at this meeting and in-depth interactive Advocacy Sessions will take place on the policy and project themes you have indicated you would like us to engage in more actively.

In addition to our AGM and Advocacy Sessions in April we are starting to plan our EPF Conference under the EU Polish Presidency focussing on the needs and rights of older patients on 12-13 July in Warsaw. We will be using this opportunity to explore further the European Innovation Partnership on Active and Healthy Ageing, once the strategy has been published in late spring. Please see section for EPF and our members' response to the recent consultation on this issue. We hope very much that EPF members and allies representing all stakeholders will be able to join us at this timely and very relevant event.

Two important project launches have already taken place this year – our own project CHAIN OF TRUST, funded under the EU Public Health Programme, explores trust and confidence in eHealth solutions, with which we are proud to work with our health professional stakeholders and carer allies - see section 11. A very productive first meeting took place at the end of January.

www.eu-patient.eu

INTER-QUALITY, an FP 7 funded project had its kick-off meeting in mid-January. The project is exploring good practice across EU health systems in enhancing sustainability whilst enhancing quality of care. EPF is an associate partner – in addition to ensuring a patient's viewpoint in all aspects of the project, we will play a specific role regarding dissemination. See section 12 for more details.

One of the core aspects of our work plan for 2011 are preparations linked to a major campaign together with other health stakeholders to ensure that the next EU Programming period includes a very strong patient centred component in relevant funding programmes and initiatives, echoing the progress we have made in relation to the 7th Framework on Research and Development where patient involvement is a criterion for one of the Health Calls on Clinical Trials. We will keep you posted on our plans and hope very much we can count on your support in the coming months to really embed the patients' voice in future EU health programming.

Warmest Greetings, **EPF President Anders Olauson EPF Director Nicola Bedlington** 

# TABLE OF CONTENTS

SPECIAL FEATURE			
1. CROSS-BORDER HEALTHCARE: THE EUROPEAN PARLIAMENT ADOPTS THE DRAFT DIRECTIVE AT SECOND READING; EPF GIVES ITS VERDICT ON THE FINAL C	COMPROMISE 1		
EU POLICY UPDATE	7		
2. PATIENT SAFETY AND QUALITY OF CARE	7		
3. Pharmaceuticals Package	8		
4. RARE DISEASE DAY	13		
5. PLATFORM ON ACCESS TO MEDICINES IN EUROPE	13		
6. HEALTH INEQUALITIES: ESTRELA REPORT ADOPTED IN COMMITTEE			
7. EUROPEAN INNOVATION PARTNERSHIP ON ACTIVE AND HEALTHY AGEING	16		
8. Alzheimer Report adopted by Parliament	17		
9. Priorities of the Hungarian EU Presidency	19		
10. THE EUROPEAN COMMISSION LAUNCHES A CONSULTATION FOR THE REVISION OF THE PROFESSIONAL QUALIFICATION DIRECTIVE	20		
PROJECTS	22		
11. CHAIN OF TRUST — KICK OFF MEETING	22		
12. International Research Project on Financing Quality in Healthcare – InterQuality – Kick off meeting	23		
13. JOINT ACTION ON PATIENT SAFETY AND QUALITY OF CARE	24		
14. Renewing Health - 3rd Steering Committee Meeting			
15. EPF RESEARCH ON EU PATIENT INVOLVEMENT IN HEALTH TECHNOLOGY ASSESSMENT (HTA)			
OTHER INTIATIVES	28		
16. PatientPartner	28		
17. EUROPEAN PATIENTS' RIGHTS DAY	30		
CONFERENCES AND EVENTS	30		
18. STAKEHOLDERS CONFERENCE ON THE REVIEW OF THE TRANSPARENCY DIRECTIVE, BRUSSELS, 15 DECEMBER	30		
19. EMA Scientific Conference, 15 December 2010 London	32		
20. EGAN MEETING, 13, 14 JANUARY 2011, BASEL	33		
SECRETARIAT	33		
21. GOODBYE ASTRID	33		
22. WELCOME LAURÈNE	33		
23. DIARY	34		



# 1. Cross-Border Healthcare: the European Parliament adopts the draft directive at second reading; EPF gives its verdict on the final compromise

EPF welcomes the adoption by the European Parliament of the <u>draft Directive on Patients' Right in Cross Border Healthcare</u> in plenary sitting on 19 January.

As announced in our last issue, the "trilogues" held in December between the Council, Parliament and Commission resulted in an agreement on second reading. The compromise text was adopted by an overwhelming majority at the Parliament and is now awaiting the formal approval of the Council. This is expected at the beginning of March.

The Commissioner for Health and Consumers, Mr John Dalli, declared that the adoption of the Directive "marks an important step forward for all patients in Europe" while MEP Françoise Grossetête, rapporteur for this Directive, called it a "victory for patients' rights and for a Europe of Health".

EPF has had a long and intense involvement in the draft Directive, having worked closely with the Commission, the EU Presidencies, and MEPs throughout the first and the second readings to ensure that a patients' perspective was strongly reflected in the Parliament's position. In our view, the final compromise does fall short of our ambitious vision. The Parliament clearly had to compromise with the Council on contentious areas in order to reach agreement on the text on second reading, and avoid a conciliation procedure and possible failure of the Directive. Thus some aspects EPF considered crucial were not fully preserved in the final agreement.

Nevertheless, the draft Directive is still an important milestone for patients: It creates a legal framework for the patients' right to seek healthcare in another Member State than their Member State of affiliation, and to be reimbursed for it. It also provides a legal basis for enhanced European cooperation in key areas of healthcare and in border regions.



EPF believes many aspects of the Directive can be built on, particularly the provisions on Health Technology Assessment, quality and safety of healthcare, eHealth and rare diseases. We hope that Member States will be encouraged to uptake and make full use of the opportunities to improve cooperation in these areas.

#### EPF's perspective on key points in the Directive

Below we set out the key aspects of the Directive from the perspective of patients.

Information to Patients: Member States will be required to establish National Contact Points to provide accessible, clear and reliable information to patients about cross-border healthcare. In particular, patients will be able to receive information related to reimbursement of costs, the safety and quality standards in place within the Member State that provides the treatment, including the provisions on supervision and assessment of healthcare providers and which healthcare providers are subject to these provisions. Information on the accessibility of hospitals for people with disabilities, and on the available mechanisms for complaints and redress in case of harm must also be provided. Information about cross-border healthcare must distinguish clearly between the rights patients have by virtue of the Directive and the rights arising from the existing EU regulations on the coordination of social security systems (mainly Regulation (EC) No 883/2004).

Healthcare providers will be required to provide information on treatment options and availability, the quality and safety of the healthcare they provide, their authorisation/registration status and legal liability provisions, as well as clear information on prices and invoices, in order to enable patients to make an informed choice.

EPF particularly welcomes that the National Contact Points will have to consult with patient organisations. This was one of our key demands as it is absolutely crucial to ensure that the information provided meets patients' real-life needs and is provided in patient-friendly formats.

**Member States' right to limit cross-border healthcare:** Member States may restrict the application of the rules on cross-border healthcare only based on the principle of "overriding reasons of general interest", due to planning requirements in order to ensure



sufficient and permanent access to a balanced range of high-quality treatment on national territory; the wish to control costs; or the wish to avoid waste of resources. Restrictions must be limited to what is necessary and proportionate, and may not constitute arbitrary discrimination. Based on this reasoning, Member States may limit overseas patients' access to cross-border healthcare, put in place a system of prior authorisation for their own citizens, and in certain cases refuse such prior authorisation or reimbursement.

*Prior authorisation*: Reimbursement of cross-border healthcare must *in principle* not be subject to prior authorisation; certain exceptions are provided in <u>Article 8</u> of the Directive. Prior authorisation is limited to only the following types of healthcare:

- Healthcare that is subject to the above planning requirements or costs/resources factors, and that either involves overnight hospital accommodation or the use of highly specialised medical infrastructure or equipment;
- Healthcare which presents a particular risk for the patient or the general population;
- Healthcare provided by a provider that could raise "serious and specific concerns relating to the quality or safety of the care". This is to be judged on a case-by-case basis.

Member States must make publicly available which types of healthcare are subject to prior authorisation.

Refusal of prior authorisation: In principle, prior authorisation cannot be refused if the patient is entitled to it, and if the healthcare cannot be provided in the home country within a medically justifiable time-limit (based on objective medical assessment). There are limited exceptions to the above, defined in <u>paragraph 6 of Article 8</u>:

- the patient is likely to be exposed to an unacceptable safety risk;
- the general public is likely to be exposed to a substantial safety hazard;
- the healthcare provider in question raises concerns regarding their respect of safety/quality standards.

*Reimbursement*: In principle, the costs of cross-border healthcare must be reimbursed if the person is entitled to it under the benefits of their national health insurance system. (Certain derogations are provided for referring to the EU regulations on coordination of social security systems, and relating to pensioners – some Member States grant more rights to pensioners residing



in another Member State.) Member States must have a transparent mechanism for calculating the costs that are reimbursed, based on objective, non-discriminatory criteria known in advance.

Exceptions to reimbursement of cross-border healthcare are provided in Article 7, paragraph 9 of the Directive, again under the principle of "overriding reasons of general interest". Member States must inform the Commission about any limitations of reimbursement of cross-border healthcare. When considering requests, Member States must take into account the patient's medical condition, the urgency of the case, and individual circumstances. "Reasonable" time limits must be set for dealing with the administrative procedures, and these must be made public. Decisions must be subject to review and capable to being challenged in court with provision for interim measures.

Although EPF was in favour of even more limited justifications for Member States to restrict the application of patients' right to cross-border healthcare, we are nevertheless pleased that there is a closed list defining the types of healthcare which Member States can make subject to prior authorisation, the justifications for refusal of prior authorisation, and that Member States are required to communicate any restrictions they put in place to the Commission. However, Member States will be the sole judges of what "necessary and proportionate" means. Furthermore, it is left up to national authorities to define what constitutes a "reasonable" time to take a decision on prior authorisation. We are concerned that leaving these definitions open may lead to inequalities between Member States, and we aim to monitor the situation closely.

Costs to patients: The Directive is based on the principle of non-discrimination: Member States of treatment must not charge higher fees for overseas patients than for national patients. Patients should be reimbursed by their national healthcare systems to the same amount that would have been given if the healthcare had been provided in the home country. EPF advocated strongly in favour of a flexible approach by Member States regarding the same or similar healthcare, and we are pleased that this is reflected in the text. Member States may also choose to reimburse the full cost of treatment to the patients as well as related costs such as travel, if they wish.

One of EPF's key demands was a system of direct cross-border payment, in order to ensure equitable access and avoid patients and their families having to bear the financial burden upfront. This was a point of contention in the Council. The Directive finally does include such an option, albeit on a voluntary basis, and encourages Member States to use the existing systems under the



coordination of social security systems. While the compromise is less than we asked for, this point did encounter a lot of resistance so its inclusion in the text is in itself an achievement. We will work with our member organisations during the implementation process to encourage Member States to provide options for direct payments.

Safety and quality in healthcare: The Directive states that cross-border healthcare has to be provided to patients in accordance with the safety and quality standards and guidelines in place in the Member State of treatment, and where applicable EU legislation on safety standards. Member States will be required to make their national standards and guidelines publicly available. The Directive also requires Member States to cooperate with each other on safety and quality standards and guidelines, and to ensure that information in their national/local registers on specific health professionals' right to practise is made available upon request to other Member States.

While EPF called for more EU-level coordination on safety and quality standards, we consider the provisions for mutual cooperation and the transparency requirements regarding national standards and guidelines as very important. They could pave the way towards better cooperation between EU Member States and better patient safety and quality of care across the Union.

Continuity of care and recognition of prescriptions: EPF welcomes that the Directive sets rules to ensure continuity of care, as it is important to ensure patient safety and quality of healthcare. Patients who have received treatment in another Member State are entitled to a record of the treatment, and if medical follow-up proves necessary, the home country must provide the same follow-up as for treatment received in its territory. Prescriptions issued abroad must as a rule be recognised, though whether the medication is reimbursed remains the prerogative of the Member States. The European Commission will prepare guidelines on interoperability of ePrescriptions and other measures to enable health professionals to verify the authenticity of prescriptions.

e-health and telemedicine services form an essential support to patient safety and continuity of care across borders. While we welcome the creation of a European eHealth Network to foster cooperation between Member States and to draw up guidelines on cross-border patient data, this cooperation is weakened by its being entirely voluntary, and with no stakeholder involvement. Furthermore, we regret that the Directive omits to apply the same safety and quality standards to eHealth as to non-electronic health services.



**Health Technology Assessment:** EPF is pleased that the European HTA Network created by the Directive will be required to involve stakeholders in its functioning and is given clear objectives and principles of good governance. This was one of our key demands, in view of the growing contribution of HTA to the sustainability of health systems across the European Union, and the importance of knowledge sharing and transparency in this arena. Patients' involvement is essential to ensure that health services are genuinely patient-centred and address patients' needs effectively.

Rare diseases: The provisions on rare diseases were one of the most difficult areas in the negotiations. A compromise was finally reached whereby a new article was inserted that asks the Commission to support the Member States in cooperating with each other to develop capacity for diagnosis and treatment of rare diseases, particularly through the European Reference Networks, which are given a legal basis and specific focus on rare diseases. Moreover, the possibilities offered by Orphanet and the existing Social Security Regulation will be better exploited for the referral of patients abroad even for diagnosis and treatments which are not available in the home country. EPF considers that this compromise is broadly satisfactory; while more could have been done, it is nevertheless step in the right direction.

**Implementation and monitoring:** As many of the provisions of the Directive are optional or leave room for interpretation by Member States, much depends on the way the Directive is implemented. Its full impact on patients, and all the other involved parties, will only become clear in the course of the coming years.

The Commission will monitor and report on the effect of the definition of Member State of affiliation under Article 3(c)(1) and the provisions regarding prior authorisation, within two and a half years of entry into force. The first report concerning the overall operation of the Directive will be prepared within four and a half years after its entry into force, and will include information on patient flows, the financial dimensions of patient mobility, the restrictions put in place by Member States, and the functioning of the European Reference Networks and National Contact Points. Member States will be required provide all available information for this purpose.



Although the strong element of stakeholder involvement in the Parliament's position has been weakened in the final text, which does not contain explicit provisions for compulsory involvement of stakeholders in monitoring of the implementation of the Directive, EPF aims to engage actively with our members to ensure that the patients' views are heard in that process. Furthermore, we aim to monitor the situation in Member States and provide our feedback to the Commission regarding the implementation of the Directive.

#### **Next Steps**

The Council must adopt the text without further modification within a time limit of four months after its adoption by the Parliament. It is expected this will happen in the EPSCO Council meeting in March.

Once the Directive enters into force, Member States will have 30 months to transpose it within their national legislations.

EPF will prepare a guidance document to this legislation, including next steps and proposal for action in order to help our member organisations to fully participate in the implementation of the Directive at national level.

**EU Policy update** 

# 2. Patient Safety and Quality of Care

The Commission's Patient Safety and Quality of Care Working Group met on the 26<sup>th</sup> of January 2011. The Group discussed a questionnaire to Member States to gather information on the progress of the implementation of the <u>Council Recommendation on patient safety</u>. The Council Recommendation includes a number of specific recommendations concerning the empowerment and involvement of patients. EPF considers it is important to gather feedback also from the perspective of patient organisations as to what extent these provisions are being implemented in Member States, and we will be inviting our members' views on these shortly.



The second part of the meeting focused on several presentations on patient safety-related initiatives and projects, including the HANDOVER project, EPSO, the European Forum of Primary Care and the WHO initiative on patients' rights and patient safety, in which EPF is a participant.

The agenda and presentations from this meeting are available to the public on the Commission's website: <a href="http://ec.europa.eu/health/patient\_safety/events/ev\_20110126\_en.htm">http://ec.europa.eu/health/patient\_safety/events/ev\_20110126\_en.htm</a>

# 3. Pharmaceuticals Package

#### 3.1. Directive on Counterfeit Medicines adopted by EP

The EU legislation on the prevention of the entry into the legal supply chain of counterfeit medicinal products, amending Directive 2001/83, was adopted by the European Parliament on 16 February, following informal agreement reached by the EU Institutions at the end of December. The vote comes after months of delay due to several issues that needed to be ironed out in the negotiations. The Directive is now awaiting formal adoption by the Council.

EPF had worked closely with the rapporteur, MEP Marisa Matias, who in her report took on board many of the suggestions made by EPF and the European Coalition of Cancer Patients (ECPC). (see our <u>November 2010 Mailing</u> for background information on EPF's position). EPF's key principle was that all strategies developed to combat counterfeiting should be in line with the principles of patient-centred healthcare, considering the impact on the patient in terms of access to safe, quality and appropriate treatment and information. Only with the involvement of patients and patient organisations can such strategies be truly patient-centred.

The main elements of the new Directive are as follows:

• Stronger oversight of the distribution chain; all supply chain players including brokers will need to be authorised, and exports from the EU to third countries as well as imports will be more strictly regulated.



- A system of product recalls and rapid alerts. Member States must have in place systems to prevent dangerous medicinal products from reaching the patient; in cases where a serious risk to public health is suspected, Member States must notify all other Member States and all actors in the supply chain via a rapid alert system. If such products may have reached patients, urgent public announcements must be issued within 24 hours to recall them.
- Safety features will be mandatory for prescription-only medicines. National authorities must notify to the EC products that they consider not to be at risk of falsification, the product will then be assessed. The EC will prepare a list of such products. All other prescription-only medicines will be equipped with a unique identifier that will enable pharmacists to check each pack for authenticity before dispensing to the patient. This would protect against dispensation of counterfeit products, but also out-of-date and recalled products. When products are re-packaged for sale in another EU member state (parallel trade), repackagers must replace any safety feature they remove with a feature that is equally effective according to certain criteria.

Non-prescription medicines will not have mandatory safety features, except those that are deemed to be at risk following an assessment.

EPF had called for safety features to be mandatory on *all* medicines, including non-prescription medicines. All medicines if falsified can have dangerous consequences for patients. The restrictions on safety features, though no doubt based on practical considerations, thus fall short from a patient safety perspective.

• Provisions on Internet sales include mandatory registration of legitimate online pharmacies, which will need to display a common logo that will be developed by the Commission and must be displayed on the website. Member States must set up national websites with information about online sales and authorised Internet pharmacies, as well as the risks of buying medicines online. These will be linked to a website of the European Medicines Agency.

EPF had called for a strong, multi-faceted proposal from the Commission for tackling illegal Internet sales, something which was not part of the original Commission proposal. We are pleased that the MEPs and Council have included measures to tackle this, as it is a major route by which fake medicines enter the market.



• *Public awareness campaigns* will be organised to raise awareness of teh dangers of counterfeid medicines, including the risks of Internet sales, and the function of the common EU logo.

Regrettably the Directive does not clearly state that patient organisations must be involved in the information campaigns, even though it does require Member States to organise meetings involving patients' and consumers' organisations in order to communicate public information about actions undertaken to combat counterfeiting.

EPF believes that the involvement of patient organisations is key for successful and effective public information campaigns, particularly to ensure that patients do not stop taking their medicines unnecessarily. Patient organisations should be used to communicate messages to the patient communities that they know well; and, in collaboration with health professionals, patient organisations should be used to empower patients to know their medicines, to assess their quality and provenance, and to be vigilant for signs of counterfeiting.

#### **Next steps**

- When formally adopted and published in the EU Official Journal, Member States have two years to transpose the text of the Directive into their national legislations. However, the practical implementation of some of the measures, such as the technical specifications regarding safety features, will take significantly longer.
- EPF will prepare a detailed analysis of the Directive, which will be shared with our members shortly.

#### 3.2. New EU Pharmacovigilance legislation to be transposed by Member States

On 29 November 2010 the Council adopted the new legislation on pharmacovigilance amending the EU legislative framework (Directive 2001/83/EC and Regulation 726/2004). The amending acts were published in the EU Official Journal on 31 December 2010. Member States will now have until July 2012 to transpose the rules into their national legislations.



In the <u>previous issue of this Mailing</u> we reported on the key provisions under the new rules.

The spirit of patient involvement is embedded in the legislation, which provides opportunities for patient organisations to engage in the pharmacovigilance process at national level. EPF is preparing guidance documents for our members in the next months; we encourage member organisations to communicate with their national health ministries, letting them know they are aware of the new rules and requesting to be involved in their implementation. EPF will also be working with the European Medicines Agency (EMA) regarding the new provisions for direct patient reporting of adverse reactions, and how that might work in practice.

At European level there will be several opportunities for EPF and our members to get involved:

- The Commission will be required to consult patients organisations on the readability and value to the public of the package inserts in medicine packages in order to make proposals for their improvement.
- The Commission will put out a public call for interest in order to appoint a patient representative member for the new Pharmacovigilance Risk Assessment Committee within the European Medicines Agency. (For more information on the role of this committee see our <u>previous issue</u>).
- The EMA will consult patients organisations on the future European Medicines web portal, for the dissemination of information on medicinal products authorised in the Union.

At national level, Member States may involve, on a voluntary basis, patient organisations in order to encourage patient reporting of adverse reactions. Patients organisations could for example suggest different means of reporting adverse reactions, or propose to establish guidance documents for patients wishing to report an adverse event.

In addition, we have identified several other areas where patients' organisations could give spontaneously a valuable input to their Member States in the future. EPF will provide more information on this through specific guidance documents to support our member organisations in their national advocacy work.



#### **Next steps**

- The rules within the Regulation will apply from 2 July 2012, and the provisions of the Directive will apply from 12 July 2012.
- The Commission must report to the Parliament and Council on the shortcomings of package leaflet and summary of products by January 2013.
- The Member States have to do an audit of their pharmacovigilance system and provide a report to the Commission by September 2013 at the latest.

#### Links

- The legislative documents published in the EU Official Journal: <u>link to the Regulation</u> and <u>link to the Directive</u>
- Report of EPF-PGEU joint event held on 15 September 2010 on the new Pharmacovigilance legislation

#### 3.3. Information to Patients

As announced in our <u>previous issue</u> following the adoption of the first reading position of the European Parliament, the European Commission is now required to submit a modified proposal in order to take into account of the concerns expressed by the Member States and the Parliament.

The original proposal by the Commission in 2008 was rather narrow from the patients' perspective, focusing on the right of industry to provide information. EPF worked intensely with the EP rapporteur, MEP Christofer Fjellner, whose <u>report</u> put the focus squarely on the right of patients to access quality information.

EPF was broadly satisfied with the Parliament's position, though it could be made to work better for patients in some respects (see <u>our verdict on the EP vote</u>). We have, nevertheless, emphasised that the current legislative proposal should be seen as only one



step in a wider EU strategy on information to patients, encompassing health literacy. Mr Fjellner has supported this approach in his explanatory statement.

#### **Next steps**

EPF will continue to work with the EU Institutions in the next months, in particular with the Commission and Parliament, to help formulate a proposal built upon a more ambitious and patient-centred vision in order to uphold patients' right to clear, accurate, unbiased and accessible information.

# 4. Rare Disease Day

February the 28th is Rare Disease Day, an annual event coordinated by EPF Member <u>EURORDIS</u> at international level, and by national coalitions of patients' organisations at national level. Patients' groups will organise various activities and events to raise awareness on rare diseases and challenges encountered by patients. This year's Rare Disease Day will focus on health inequalities, and will draw attention to unequal treatment of patients with rare diseases in healthcare, employment, education and various other aspects of everyday life. The aim is to advocate for equal access to care and social rights for rare disease patients, wherever they live, as currently there are differences between and within countries in Europe. Patients with rare diseases are encouraged to share their stories about unjust situations they have encountered on the <u>rare disease day website</u>.

# 5. Platform on Access to Medicines in Europe

The second meeting of the steering group of the Platform on Access to Medicines in Europe was held in Bruges on 17 December 2010. EPF is participating as a stakeholder organisation in this initiative, launched by DG Enterprise & Industry in September 2010 as part of its Initiative on Corporate Responsibility in the Field of Pharmaceuticals.



The steering group includes representatives of the EU Member States and EFTA countries, as well as stakeholder organisations of patients, consumers, health professionals, health managers, social insurance, and industry.

The Platform will work 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 work on a number of specific projects, each led by one Member State. The projects will focus on the following topics:

- 1. Mechanism of coordinated access to orphan medicinal products led by Belgium, with EPF patient representative Yann Le Cam (EURORDIS)
- 2. Capacity building on managed entry agreements for innovative medicines led by Italy with EPF patient representative Albert Jovell (Spanish Patients' Forum)
- 3. Facilitating the supply in small markets led by Slovenia with EPF patient representative Soteris Yangou (Pan-Cyprian Federation of Patients' Associations & Friends)
- 4. Promoting a good governance for non-prescription drugs led by UK with EPF patient representative Ian Banks (European Men's Health Forum)
- 5. Market access for biosimilars led by Denmark with EPF patient representative Darryl Gibbings-Isaac (National Voices)

A patient representative was identified for each project through a call for interest among EPF's membership. The steering group will undertake a broader reflection on how to identify areas with the highest medical needs, based on work done by the WHO and



European Medicines Agency. This is an area of crucial importance to all patients, and we will extend an invitation to all our members to identify priorities and needs from a perspective of patients in different countries and disease areas.

#### **Next steps**

- The projects will prepare their work plans during the first quarter of 2011.
- EPF will prepare a consultation of its membership on the steering group-level task on unmet medical needs, with the aim of providing input into the next meeting of the steering group which will be held in Budapest in May 2011.

Llink: DG ENTERPRISE website.

## 6. Health Inequalities: Estrela report adopted in Committee

The <u>report</u> prepared by Portuguese MEP Edite Estrela on health inequalities was adopted in the ENVI (Environment and public health) Committee of the European Parliament on 25 January 2011. Some 200 amendments were tabled on the report. This is not a legislative report, however it does carry a certain amount of political weight, and is an important message from the Parliament that it is concerned about health inequalities.

EPF submitted a <u>position statement</u> and proposed amendments, to reflect the concerns raised in our <u>previous feedback</u> to the Commission's public consultation in 2009. Currently the political debate on health inequalities focuses strongly on prevention and health promotion, while EPF believes that prevention and health promotion, and patient-centred chronic disease management are complementary and must be addressed in parallel.

Our input stressed that the needs and perspective of patients should not be neglected, and that 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. It also reflected our belief that patient empowerment 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.

#### **Next steps**

- The Estrela report is set to be voted in plenary session on 7 March 2011 (indicative date)
- EPF will undertake a further consultation of its members in the course of 2011 to gather more feedback 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.

#### Links

- EPF's response to the Commission's public consultation (2009)
- Commission Communication "Solidarity in health: reducing health inequalities in Europe" (2009)
- EPF's input to the Estrela report

# 7. European Innovation Partnership on Active and Healthy Ageing

The "Innovation Union" is one of the flagship initiatives designated under the <u>Europe 2020 Strategy</u> that aims to contribute to smart, sustainable and inclusive 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. The innovation partnership seeks 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.

Based on a consultation of our membership, we provided input into the European Commission's public consultation, which closed on 28 January 2011. We responded to an online questionnaire and submitted a complementary document addressing some important issues not included by the questionnaire. EPF's contribution can be read <a href="here">here</a>.

EPF is committed to playing an active and constructive role in the Innovation Partnership to ensure that it results in concrete actions that have benefit for older patients. We will seek the views of our members as the Innovation Partnership progresses and its objectives are further defined. Our <u>flagship conference under the Polish EU Presidency</u> will contribute to this work by focusing specifically on the needs of older patients and inter-generational solidarity.

External link: EU Innovation Partnership for Healthy and Active Ageing

## 8. Alzheimer Report adopted by Parliament

The European Parliament adopts a Resolution on Alzheimer's disease and other dementias.

On 19 January the European Parliament adopted a non-legislative resolution on a <u>European Initiative on Alzheimer's disease</u> and other dementias, with 646 votes in favour, 6 against and 6 abstentions. It calls on the Council to declare Alzheimer's disease and other dementias an EU health priority.

In our previous issue we presented the main topics dealt with in the report drafted by Portuguese MEP Marisa Matias, as well as the action of the European Commission in this field. In July 2009, the Commission adopted a <u>Communication</u> on a European Initiative on Alzheimer's disease and other dementias. The Communication lists 4 areas on which the Member States should take action: public health, research, exchange of best practice in the social and care field, legal and ethical priorities. At the same time, the Commission presented a <u>Proposal for a Council Recommendation</u> on a pilot joint programming initiative to combat neurodegenerative diseases, in particular Alzheimer's.



In its Resolution, the European Parliament asks the Commission and the Member States to raise public awareness on Alzheimer' disease and dementias in Europe, in particular to facilitate recognition of early symptoms and access to early diagnosis and treatment, which are key to put in place adequate support for the people with the disease and their carers. The resolution recommends further cooperation between Member States on research, prevention and care.

EPF particularly welcomes the call on Member States to recognise the role of Alzheimer organisations as prime partners, and to involve patients' organisations in information and prevention campaigns, in research programmes, and in sharing best practice on supporting measures for patients.

EPF welcomes this resolution and congratulates our member organisation <u>Alzheimer Europe</u>, the Rapporteur and Shadow Rapporteurs for their work. EPF now looks forward to seeing these recommendations turned into concrete actions in the Member States.

#### **Next Steps**

The actions proposed by the Commission Communication and the European Parliament Resolution will serve as a basis to the Joint Action between the European Commission and the Member States. A report on the implementation of the recommendations in the Communication is expected in 2013.

#### Links

Alzheimer Europe's press release

Summary of the EP resolution

Commission Communication



# 9. Priorities of the Hungarian EU Presidency

On 1 January 2011, Hungary takes over the rotating Presidency of the European Union from Belgium. The Hungarian Presidency has as its overall theme "the human factor, as the basis for intelligent, sustainable and inclusive growth" and will build its political agenda around four main topics:

- 1. Growth and employment for preserving the European social model;
- 2. Stronger Europe;
- 3. Citizen friendly Union;
- 4. Enlargement and neighbourhood policy.

In the area of health, the priority areas of the Hungarian Presidency include:

- Patient and professional cross-border mobility, with a conference on "Patient and professional pathways in Europe" on 4-5 April;
- *Prevention*, with a major expert-level conference on 30-31 May that will provide a forum for exchange of views on best practices, concrete actions, awareness-raising initiatives in Member States for promoting healthier lifestyles;
- Another area focuses on *healthcare workers*, under the theme of 'Investing in the healthcare of the future and human resources for health" and exploring how Member State governments can be supported in their efforts to modernise their healthcare systems;
- eHealth where a ministerial level conference will be organised in Budapest on 10-12 May;
- The Presidency will also focus on mental health, injury prevention, anti-microbial resistance, and health security (emphasis on childhood immunization).



The full programme of the Hungarian EU Presidency can be read <u>here</u>.

Visit the website of the Hungarian Presidency: <a href="https://www.eu2011.hu">www.eu2011.hu</a>.

EPF will report on events where EPF or our members have attended, in future issues of the EPF Mailing.

# 10. The European Commission launches a consultation for the revision of the Professional Qualification Directive

EPF would like to inform its members that the Commission's Directorate General for Internal Market and Services has launched a public consultation on the Professional Qualification Directive (<u>Directive 2005/36</u>) to prepare the upcoming revision of this text in 2012.

This Directive establishes the rules for mutual recognition of qualifications when professionals (including from the health sector) want to provide their services or establish themselves in another Member State. It also sets minimum training requirements for general care nurses, doctors, midwives dentists and pharmacists in order to allow them to benefit from automatic recognition of their qualifications.

Ensuring that healthcare professionals have the right training and are fit to practice when they move from one Member State to another is important for patient safety and quality of care. Some issues within this consultation could be of interest for patient organisations:

• A Proactive alert system for health professionals: The Commission consults on the possibility to develop a proactive alert system between competent authorities for recognition of qualification in case of malpractice by an healthcare professional, and on defining when it should be used.



- Language skills: Communication between patients and healthcare professional is key to health literacy and quality of care. The Directive sets language requirements for professionals moving abroad but it forbids systematic testing of language. The Commission asks about eventual problems encountered under these rules.
- Training requirements for health professionals: The Commission is consulting on the need to update these requirements, on competences that would need to be added, and on acknowledging continuing professional development at European level.
- **Temporary mobility**: When healthcare professionals want to provide services temporarily in another Member State they have to do a prior declaration and can be subject to a prior check by the host Member State, the Consultation Paper asks whether temporary mobility should be facilitated.
- A European Professional Card: There is a proposal for a European Card which could be given to Professionals who ask for it, in order to help them to prove their qualification when they move to another Member State or come back. One of the proposed aims is to increase transparency towards the client (or patients in the case of healthcare professionals.)

The deadline for responses to the Commission is **15 March 2011**. EPF is preparing a draft response to the consultation, which we will circulate among our members shortly. In the meantime if your organisation can provide input or concrete examples from your own experience relating to the above points, or on any other aspects that you consider important to patients, we would encourage you to send your comments to the Secretariat as soon as possible but at the latest **by 13 March**. Your input is very much appreciated.

Please see the **Commission's consultation paper** for further information.



# 11. Chain of Trust - Kick off meeting

In the previous Mailing Issue we were particularly pleased to announce the start of a second EPF-led EU project called the "Chain of Trust", which is financed by the Public Health Programme and will last for two years. The consortium – EPF, CPME, EFN, NST, PGEU, SUSTENTO and TIF – met in Brussels on January 31<sup>st</sup> and February 1<sup>st</sup> for the kick-off meeting.

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. Ultimately the project will aim at strengthening significantly the levels of awareness and trust for all key stakeholders.

The innovative aspect of the Chain of Trust project is that it represents the first attempt ever made to bring together the key leading pan-European organisations representing direct telehealth users, namely patients, doctors, nurses and pharmacists in order to explore and assess users' view of and attitudes towards telehealth at both European and national level. The participation of pan-European organisations representing informal carers, health managers, insurers, as well industry players in the project's adhoc Advisory Board will ensure that the perspective of other key telehealth stakeholders is thoroughly integrated throughout the project life-cycle.

The project will start out carrying out a literature review aimed at assessing the state of the art in understanding users' perspectives in telehealth and gather information as to the communication approaches and tools used to raise awareness of telehealth.

The results of the literature review will set the ground for the implementation of the core activities which have been envisaged for this project, notably an online survey targeting the four user groups, six national workshops and four European focus groups.



The survey will be launched in the second quarter of 2011, while the second part of the year will see the implementation of the national workshops in different European countries. The European focus groups, whose objective will be to validate and refine the knowledge and information collected through the online survey and national workshops, will be taking place towards the end on 2011 and beginning of 2012.

EPF is currently working on the project website which is expected to be launched in early March.

If you would like more information on the Chain of Trust project you should contact <u>Liuska Sanna</u>.

# 12. International Research Project on Financing Quality in Healthcare – InterQuality – Kick off meeting

The project InterQuality, offically started in December 2010 held its kick off meeting in Warsaw on 18-19 January 2011. The project is funded by the 7th European Union Framework Programme (FP7) and is led by the Medical University of Warsaw and implemented by a consortium of eight partners in addition to the coordinator. EPF is involved as an associate partner and will lead the work related to dissemination of project progress and results.

The rational behind InterQuality is the acknowledgement that increasing health care spending often does not improve quality., efficiency or availability of medical services. The existing health financing reforms undertaken in Europe have encountered serious technical and polictical difficulties. It is therefore very much needed today to develop scientifically proven tools to help make decisions regarding the selection of appropriate financing mechanisms in different areas of the health care system. InterQuality has therefore the following objectives:

- 1. Invistigate ways of funding and incentive systems affecting the quality, effictiveness and equity of access to health care in four areas:
  - Pharmaceutical Care



- Hospital care
- Ambulatory care
- Intergrated health care
- 2. Develop practical integrated models of health care financing
- 3. Determining the feasibility and effectiveness of the developed models for the determinants of the health systems in the countries of the project partners.

The areas of research will be:

- Incentive Measures
- Clinical aspects: quality, clinical efficacy, and safety
- Economics: cost control, cost effictiveness, resource utilization
- Equality of access.

For more information please contact Liuska Sanna or visit the project website at <a href="http://interqualityproject.eu/">http://interqualityproject.eu/</a>

### 13. Joint Action on Patient Safety and Quality of Care

The third preparatory meeting for this Joint Action took place on 19-20 January in Luxembourg.

The Joint Action is structured like an EU co-funded project, except that it is led jointly by the EU Member States and the Commission and unlike a project, its aim is to create a permanent platform for future cooperation between Member States. The Joint Action will be led by the French health authority, the Haute Autorité de Santé (HAS). EPF has been invited to participate in



the Joint Action as a stakeholder organisation together with and organisations representing doctors, nurses and hospital managers.

The triple objective of the Joint Action is to support the implementation of the Council Recommendation on patient safety; to initiate Member State cooperation on quality of healthcare; and to facilitate the sharing of good practices in patient involvement and empowerment.

EPF is particularly pleased that the Member States and Commission have recognised the importance of patient empowerment and involvement, and this has been adopted as a cross-cutting theme for all work packages. According to preliminary agreement, the four "core" operational work packages will centre on:

- Patient safety good practices analysis of good practices in place in Member States, identification of good practices for sharing, sharing solutions for patient involvement;
- Patient safety initiatives implementation implementation of selected good practices in Member States, including good practices addressing patient involvement;
- Patient safety and quality network setting up an exchange mechanism on patient safety and quality improvement systems
  in place in the Member States;
- Network sustainability proposals to fulfil Member States' and stakeholders' needs in the field of patient safety and quality of care.

While the discussions are still ongoing and we cannot at this time give detailed information, EPF will take an active role in all the core operational work packages and will possibly co-lead one of them. We are also committed to contributing to the dissemination work package, and foresee a role in the governance of the Joint Action.

#### **Next steps**



- The publication of the work programme in public health and the call for proposals 2011 is expected at the end of February
- The content of the proposal will be developed between the partners. The deadline for submission of the application is 29 April 2011. Decisions are expected in the autumn of 2011
- If successful, the Joint Action will start work at the end of 2011 or in early 2012.

#### Links

- <u>Commission Communication</u> on patient safety
- <u>Council Recommendation</u> on patient safety and healthcare associated infections
- EUNetPas (European network on patient safety) project website

# 14. Renewing Health - 3rd Steering Committee Meeting



The third meeting of the RENEWING HEALTH project Steering Committee (SC) took place on January 27-28, in Bad Kleinkirchheim (Carinthia, Austria).

This meeting marked the completion of the first year of this project, which, as the reader might recall, was launched with the overall objective of validating and subsequently evaluating innovative telemedicine services through large-scale real-life test beds in nine European regions for the remote management and monitoring of chronic patients with diabetes, COPD and CVD, using a patient-centred approach and a common assessment methodology (MAST).

This meeting was extremely important as it took place right before the project's entering its crucial phase with the start of pilots' roll-out process. While the recruitment of patients is ongoing in all participating regions, all pilot sites are busy working towards the finalisation of the methodology and quality standards of the trials and also the application of evaluation methods. EPF is actively contributing to this process by providing recommendations for refining the questionnaires to be used to assess users'



perspective, specifically the patient acceptability questionnaire. The latter is a very important element of the evaluation process as it should eventually provide useful information as regards patients' overall satisfaction with the piloted telemedicine services. The analysis of user acceptability questionnaires should ultimately enable the consortium to draw conclusions as to patients' willingness to continue to use these services beyond the pilot stage.

The meeting was also an opportunity to clarify the role of the User Advisory Board (UAB), the project's ad-hoc advisory body comanaged by EHTEL and EPF and set up to ensure that the needs of the users of the piloted telemedicine services are properly taken care of throughout project implementation. More specifically, the steering committee agreed on some general principles for enabling the UAB to provide its feed-back on documents and activities which have direct implications for the constituencies represented in the UAB, as well as on some proposals advanced by the UAB on how to enhance the cooperation between the UAB and the pilot sites.

During the meeting two important documents were also presented: a) the first version of the "User Requirements", a document produced by EPF and EHTEL on behalf of the UAB providing for a collection of needs and requirements of users of telemedicine services as identified in the literature; b) a "Report on security and privacy issues" at regional, national and European level which EPF has contributed to over the last few months. A set of recommendations to address privacy and security issues identified in this document is currently being developed.

The next SC meeting will take place in Tromsø, Norway in mid June, while the UAB will hold its 3<sup>rd</sup> meeting in Brussels on February 17<sup>th</sup>.

Key issues to be discussed at the UAB meeting are: the involvement of the UAB membership in the development of the second version of the "User Requirements", the improvement of user acceptability questionnaires, the possibility of meeting local telemedicine users involved in the pilots and holding some UAB meetings in loco.

Should you need further information on this project you should contact <u>Walter Atzori</u> or visit the project website: <u>www.renewinghealth.eu</u>.



# 15. EPF Research on EU Patient Involvement in Health Technology Assessment (HTA)

The EPF Seminar on HTA held in May 2010 concluded that patient organisations clearly need support to be meaningfully involved in HTA processes. As a follow up of the event recommendations, EPF started conducting primary research on patient involvement in HTA since November 2010. The aim of EPF's research is to understand the involvement of lay patients, informal carers and patient organisations in all the EU member states and to contribute this knowledge to inform HTA – research, policy, and practice. The outcome of this research work will be a good practice toolkit to be shared with HTA agencies, patient organisations and decision making bodies in the EU.

The research involves consultation with three main stakeholders - HTA agencies (1<sup>st</sup> phase), patient organisations (2<sup>nd</sup> phase) and HTA appraisal committees and decision makers (3<sup>rd</sup> phase) through surveys and discussions to get their views, needs, ideas and expectations in shaping the role and scope of patient involvement in HTA processes. The 1<sup>st</sup> phase with HTA agencies has already been completed with a good response rate and the research has been acknowledged by EUnetHTA, the European Joint Action on HTA. An interim report consisting of key findings and recommendations will be available by March. The 2<sup>nd</sup> phase with patient organisations will be launched soon and the 3<sup>rd</sup> phase with HTA appraisal committees and decision makers is expected to be launched in April.

In this regard, patient organisations that are already contributing to HTA or that have been trying to get involved can contact us.

OTHER INTIATIVES

#### 16. PatientPartner

PatientPartner was an FP7 funded project led by the Dutch Genetic Alliance (VSOP) in partnership with the European Forum for Good Clinical Practice (EFGCP), the European Genetic Alliances' Network (EGAN) and the Genetic Alliance UK. The three-year project began in May 2008. It aims to identify patient needs for partnership in the clinical trial context, develop dialogue with other stakeholders on those needs and identify regional differences, and come up with strategies and possibly binding



recommendations on how to work with patient organisations in clinical research. The project started off by conducting an inventory of best practices and needs of active involvement of patient organisations and their representatives in clinical trials and research. (<a href="http://www.patientpartner-europe.eu/en/inventory">http://www.patientpartner-europe.eu/en/inventory</a>). This was followed by a start up workshop in Brussels in June 2009 where over 100 stakeholders discussed the agenda for the subsequent Regional European workshops that were held in 2009-2010.

Throughout the regions the workshops showed that patient organisations wanted to be involved in all stages of the clinical trial development process to ensure the patient perspective was incorporated into the resulting trials. Furthermore important roles were seen for patient organisations in providing information on where to find and how to take part in clinical trials to their members as well as having a say in the agenda setting and ethical review of clinical trials. For academia and the pharmaceutical industry patient organisations were found to have an important role in making protocols more patient-oriented and patient information and informed consent documents more understandable. Furthermore these two stakeholder groups foresaw a role for patient organisations in facilitating patient recruitment as well as raising awareness on the availability and opportunity to take part in clinical trials in Europe. To fulfil their "new" role as a partner in clinical trials a certain level of training on the clinical trials development process needed to be provided. Finally, the conjoined stakeholders identified that both patient organisations and Academia and pharmaceutical industry struggle in the identification of the "right" partner to work with on a certain clinical trial as well as lack the knowledge of each other's competencies and drivers to do so. With these questions answered the final workshop held in December 2010 in Brussels focused on how to make the partnership between patient organisations and other stakeholders in clinical trial development work in practice.

#### Some of the key messages of the final workshop:

- Patient partnership should be present in all clinical research and in every single clinical trial, and from the earliest possible moment. Some countries are further along this road than others, and the sharing of best practice can help to encourage others.
- The draft ethical principles for the partnership between patient organisations and other stakeholders in clinical research (still under review) have a great deal of support. It needs to be rapidly revised, sent out to stakeholders for consultation and then used in practice.



• In the current situation partnership agreements and memoranda of understanding are preferred to attempts to create legal frameworks enforcing patient involvement.

The PatientPartner guide on partnership between patient organisations and other stakeholders in clinical research (including the above mentioned documents) as well as recommendations for policy makers how to facilitate this new partnership model will be made available via <a href="www.patientpartner-europe.eu">www.patientpartner-europe.eu</a> in the spring of 2011. For more information on the project please contact Ms. Kim Wever at k.wever@vsop.nl.

# 17. European Patients' Rights Day

The 5<sup>th</sup> European Patients' Rights Day will be celebrated this year on 11 and 12 April in Brussels with a European Conference focusing on best practices in civic participation in the field of health, and cross-border healthcare. EPF will be represented in the Conference. Please visit <a href="www.activecitizenship.net/content/blogcategory/72/179/">www.activecitizenship.net/content/blogcategory/72/179/</a> for more information on the Patients' Rights Day, how to get involved, and how to submit best practices and link in with national patients' rights events.

**CONFERENCES AND EVENTS** 

# 18. Stakeholders Conference on the review of the Transparency Directive, Brussels, 15 December

EPF was invited to participate in a Stakeholders Conference held in Brussels on 15 December 2010 to consider possible ways to update the so-called Transparency Directive (Directive 89/105/EEC) on "Transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems".

#### **Background**



EU legislation provides a harmonised framework for the authorisation of medicinal products. This regulatory framework has contributed to the development of a single European market for medicines, but Member States are responsible for setting national pricing policies and conditions for reimbursement, in the context of national health insurance systems.

Since the Directive was adopted in 1989, many changes have taken place — in the pharmaceutical market, in scientific developments, and in national policies to control public expenditure on medicines. Pricing and reimbursement rules are more varied and complex today, requiring extensive interpretation of the Directive text. Many new forms of price control and reimbursement have been developed which are not encompassed by the Directive. Furthermore, the Directive does not cover medical devices, which are also subject to pricing regulation and reimbursement decisions in Member States.

The variety of pricing and reimbursement procedures results in great disparities between Member States in the availability and affordability of medicines. One of the main impacts of pricing and reimbursement regulations is the delayed entry of medicines on the market in individual MS.

#### The review process

The process is led by DG Enterprise. Participants at the December meeting included representatives of EU Member States, different Commission Directorates-General, and a number of stakeholder organisations representing patients, consumers, health professionals, and social insurance platforms.

The main issues to be examined were defined:

- Follow-up to the Pharmaceutical Sector Inquiry how to improve timing for pricing and reimbursement and access to medicines, both originators and generics;
- Adaptation to market evolution how to address contractual agreements, hospital medicines, tendering, and personalised medicines;
- Legal clarity how to ensure consistency with ECJ case law and clarify the scope of transparency obligations to facilitate implementation;



Medical devices – examine the relevance of the Directive to medical devices, should it encompass devices, and if yes which
ones.

The review will be based on the allocation of powers under the Treaty, i.e. respecting the principle of subsidiarity. The focus will be on procedural aspects of pricing and reimbursement, not the substance of the decisions. The Directive governs relations between the Member States' pricing and reimbursement authorities on the one hand, and the applicants (pharmaceutical companies) on the other. However, EPF will have the opportunity to give feedback and to respond to an upcoming Commission's consultation.

#### **Next steps:**

- An intermediate report will be prepared in January and a final report by February/March 2011.
- A Commission public consultation will be launched in early March 2011 at the latest.
- The Commission's initiative or regulatory proposal is foreseen for December 2011.

### 19. EMA Scientific Conference, 15 December 2010 London

Anders Olauson and Nicola Bedlington attended the EMA Scientific Conference, "Are Regulators leaders or followers?", on 15 December 2010. This event was also an opportunity to say good bye to EMA Director Thomas Lönngren, who retired from this post. Anders presented Thomas with a gift from EPF, thanking him for his personal commitment to patient involvement in EMA, and stressing the importance of this continuing following his mandate.

For more information on the event please go to

www.ema.europa.eu/docs/en GB/document library/Agenda/2011/01/WC500100967.pdf



# 20. EGAN meeting, 13, 14 January 2011, Basel

Nicola Bedlington attended the EGAN / Roche Annual Meeting that explored the theme "From Market Authorisation to Patient Access". Nicola gave a presentation on relevant EU policy developments. For more details about the meeting, please go to www.egan.eu

For a copy of Nicola's presentation please contact the **EPF Secretariat**.

SECRETARIAT

## 21. Goodbye Astrid

EPF said goodbye to their Policy assistant intern Astrid Smis, who left EPF end of December to begin her new job in the Belgian government. We wish her the best of luck in her new career endeavour and many thanks for her contribution to EPF during her short time with us.

#### 22. Welcome Laurène

Laurène Souchet started her internship with EPF at the beginning of this year. She holds a Master's Degree in European Affairs from the Institute of Political Studies of Lille (France). She also studied Politics and International Relations at the University of Kent, Canterbury (UK) as part of a one-year Erasmus exchange. She has previously done an internship at the European Federation of Allergy and Airways Diseases Patients' Association (EFA).

She will be working closely with Kaisa Immonen-Charalambous, EPF's policy officer in monitoring developments of EU health policies. Her responsibilities also include carrying out research and drafting documents in health-related areas.



# 23. Diary

Date	Details
10 February	Brussels
	EFPIA Patients Think Tank
	Attendance: Nicola Bedlington
11 February	Brussels
	Medical Devices Preparatory Meeting
	Attendance: Nicola Bedlington
17 February	Brussels
	Renewing Health project – User Advisory Board
	Attendance: Liuska Sanna and Walter Atzori
17-18 February	London
	4th European Forum of Healthcare Deciders, LSE
	Attendance: Nicola Bedlington
21- 22 February	Brussels
	EPF board meeting
24 February	Brussels
	eHealth Governance Initiative – Kick off meeting Project Steering Committee
	Attendance: Liuska Sanna
28 February	Brussels
	Rare Disease Day 2011 European Symposium
	Attendance: Kaisa Immonen-Charalambous
8 March	Brussels
	FP7 National Contact Points Networking meeting
	Attendace: Liuska Sanna
10 March	Health Professionals' Qualifications Directive meeting European Health Managers Association
	Attendance: Nicola Bedlington (speaker)



17 March	Geneva
	Economist Conference – European Healthcare
	Attendance: Nicola Bedlington
22-23 March	Brussels
	Medical Devices Congress
	Attendance: Nicola Bedlington (speaker)
24 March	Brussels
	PRISMA Symposium 2011 on end-of-life cancer care
	Attendance: Kaisa Immonen-Charalambous
28-29 March	Geneva
	DIA Meeting
	Attendance: Nicola Bedlington
27-29 March	Lyon
	BioVision, the World Life Sciences Forum
	Attendace: Anders Olauson (speaker)
30-31 March	Brussels
	Innovation in Healthcare
	Attendance: Anders Olauson (speaker)

