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Issue 5 (25): 29 September, 2009

MEMORIAM

We have some very sad news to share with readers. Rudi Hocks, who coordinated EPF's work with Lupus Europe, one of EPF's newest members, passed away in early September. Rudi was a tireless campaigner for Lupus patients, and made a real impact in the time he worked with EPF, through both his warmth and his vision. Rudi's memoriam from Lupus Europe pays homage to this. Our sincere condolences go to his family and friends.

Dear EPF Members and Allies,

Welcome to the first autumn issue of the EPF Mailing. Much has happened since the summer break. Last week, we held our Regional Advocacy Seminar in Sofia, Bulgaria bringing together 50 patient leaders from 6 different countries in the region to look at how best to work with EPF to really make a difference – Read about this land-mark meeting in our special feature.

The seminar was a great opportunity to test out some of the tools developed in the framework of our EU funded Value + project on involvement of patients, that will be presented in Gothenburg at the EPF Conference in December, under the patronage of the Swedish Presidency. Preparations are well underway to ensure that this conference helps to advance meaningful involvement of patients on the EU agenda, creating new momentum in a new political environment.

With the new European Parliament now in place, unfinished business from the last term will be a major priority for EPF – namely the proposal on a Directive on Cross Border Healthcare, together with the Pharmaceutical Package of proposals on Information to Patients, Pharmacovigilance, and Counterfeiting. Get an update of our work with both the European Parliament and the Council in these areas under section 4. We will be counting on the support of the 100 MEPs from across the Groupings who have expressed an active commitment to EPF's work to influence their colleagues.

The Manifesto Campaign continues in the member states – read about its impact in Poland under section 18.

EPF is also embarking on a number of new policy areas, echoing the Commission's own work priorities – Find out more about developments on the scoping exercise on medical devices in section 7. Other new areas include our involvement in Health Technology Assessment and a Review of the Clinical Trials Directive. EPF will attend Commission meetings in these areas in the next few weeks and will report on next steps in the next issue of the Mailing.

Following an equal opportunities recruitment procedure, EPF will welcome a new senior staff member to the Secretariat from October. Efstathia Efstathia Megas who will lead on communications, is from Greece and has a strong public health, patients' rights and communications profile. Read more about Kia under item 23.

We hope this latest EPF mailing helps to update you on EU health developments from a patients' perspective – and we look forward to seeing many of you at the European Health Forum Gastein in the next few days. For those not attending, a report on this meeting will feature in the next issue of the Mailing.

Warmest greetings,
Anders Olauson, President
Nicola Bedlington, Director

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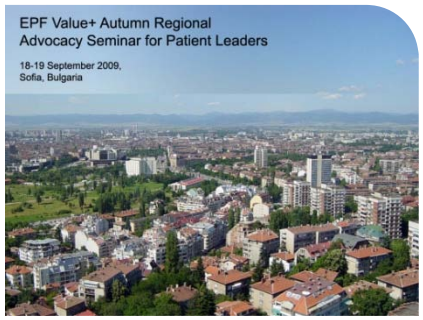
The next issue of the EPF Mailing will be distributed 18 November 2009. The deadline for submission is 10 November 2009.

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

Recommended for our Readers:

The Pharmaceutical Forum

1. VALUE+ EPF AUTUMN REGIONAL ADVOCACY SEMINAR FOR PATIENT LEADERS



On 18-19 September 2009, EPF and the VALUE+ Consortium held a seminar for 50 patient leaders of patients' organisations from Bulgaria, Romania, Hungary, Slovenia, Greece and Cyprus. The seminar took place in Sofia, Bulgaria, and was co -hosted by the Bulgarian Confederation "Health Protection" (KZZ), one of the members of the Value+ Consortium.

The purpose of the seminar was to:

- Build knowledge and know-how on working at EU level through and with EPF and influencing effectively the EU health policy debate through initiatives at national and regional level;
- Explore findings from the VALUE+ project and glean feedback from grassroots organisations as well as discuss some of the VALUE+ deliverables.

The first part was dedicated to an introduction to EU policy-making and decision-making processes with contributions from representatives of the European Parliament, the European Commission and patient leaders. The other main focus was Value+, which was introduced to the delegates. Value+ has carried out an assessment of patient involvement in health-related projects supported by the EC and the findings of that assessment were shared. Moreover, participants were very interested in the deliverables the project will produce: in particular a Toolkit for patients' organisations; a Handbook for project coordinators and promoters from other types of organisations and finally policy recommendations that EPF will make to EU Institutions.

Click here to read full article.

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2. THE EU SPANISH PRESIDENCY

The health priorities of the Spanish Presidency have not yet been published, however there is likely to be significant emphasis on Influenza H1N1, ageing and e-health. EPF has been working very closely with its member in Spain, the Spanish Patients' Forum. A joint article for publication in health reviews and the Health Ministry's own health journal has been drafted by the Spanish Patients' Forum and EPF, outlining the direction we would like to see the Presidency take. Key issues included:

- Promotion of concrete actions on **Health Literacy**
- Brokering the adoption of the **Directive on Cross-border Healthcare and the Pharmaceutical Package** that puts patients at the centre
- Support for a legislative instrument on the institutionalisation of **patients' involvement** in policy and programmes
- Monitor **Health Technology Assessment** initiatives at EU level, to ensure patients' involvement
- Encourage the practical implementation of the Council Recommendation on **Patient Safety**
- Take forward the actions outlined in the Commission's Communication on **Telemedicine**.

For a full copy of the article, please contact Maria Navarro.

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3. THE PHARMACEUTICAL PACKCAGE

As reported in previous issues the legislative package includes a proposal on information on prescription-only medicines, a proposal on counterfeiting and illegal distribution of medicines, and a proposal on strengthening the EU system for the safety monitoring (pharmacovigilance) of medicines.

The three legislative proposals will be discussed in the coming months in the European Parliament committees. In the European Parliament, the key rapporteurs from the Committee on Environment, Public Health and Food Safety (ENVI) are:

- Swedish MEP Christoph FJELLNER (EPP) on Information on prescription medicines, with Gilles PARGNAUX (FR, S&D), Carl SCHLYTER (SE, GREENS), Jiří MAŠTÁLKA (CZ, GUE), Anna ROSBACH (DK, EFD), Marina YANNAKOUDAKIS (UK, ECR) as shadow rapporteurs.
- British MEP Linda MACAVAN (S&D) on Pharmacovigilance with Antonyia PARVANOVA (BG, ALDE), Michail TREMOPOULOS (GR, GREENS), Marina YANNAKOUDAKIS (UK, ECR), Jiří MAŠTÁLKA (CZ, GUE) and Pilar AYUSO (SP, EPP) as shadow rapporteurs.
- Portuguese MEP Marisa Matias (GUE) on Counterfeiting, with Françoise GROSSETÊTE (FR, EPP) , Holger KRAHMER, (GE, ALDE), Dagmar ROTH-BEHRENDT (GE, S&D), Antonya PARVANOVA (BG, ALDE) as shadow rapporteurs.

As regards the Council work, the proposals are under examination in the Council working groups and a Health Council meeting with this topic on the agenda planned for 30 November. While there is a general support for the Counterfeiting and Pharmacovigilance proposals from Member States, there is currently a strong political resistance and low interest from the Council to continue the work on the information on prescription medicines proposal.

Our position on the information on prescription medicines proposals outlines the positive aspect and some concerns. A broader issue, that EPF and its members have raised in previous consultations and will continue to do so is our disappointment in the limited scope of the proposal on Information on prescription medicines which focuses solely

on the role of industry in providing information on prescription medicines to the general public, rather than addressing the need for a comprehensive EU information to patients strategy. EPF has called for a tangible and swift action by the European Commission advancing on a comprehensive information to patients strategy, in the form of a concrete proposal incorporating the considerable wealth of recommendations put forward by EPF and other health stakeholder NGOs.

With regard to the legislative proposal on pharmacovigilance, EPF has been particularly interested in possibility for the public (patients) to request individual adverse reaction reports and will advocate for the provision of accessible information for patients about the procedure to request this reports.

In relation with the proposals on combating illegal distribution of medicines, EPF has highlighted that in addition to strategies to prevent counterfeit medical products reaching patients through legal measures, it is essential that a communications strategy is developed to inform patients organizations, patients and the general public about the risks of counterfeit medical products.

EPF will work closely with the European Parliament, particularly through the rapporteurs, shadows and secretariat of relevant committees, and the Council to make sure the patients' views are taken into account. In relation with our members, EPF will prepare a sample kit for patients organizations to be translated and used at national level (press release, template letters) and will encourage members to lobby the national governments and identify politicians who could champion this.

For further information, please contact the Secretariat.

4. THE DIRECTIVE ON PATIENTS' RIGHTS IN CROSS BORDER HEALTHCARE

After the EPSCO Council discussions on 9 July, based on the Czech EU Presidency progress report and questions suggested by the Presidency, the Swedish EU Presidency re-launched the discussions on the Commission's proposals, the amendments put forward by the European Parliament and Member States' positions. At a meeting of the Working Party in Public Health which will be held in Brussels on 30 September, Member States' representatives will examine the Presidency's compromise proposal and move forward the debate. A compromise agreement between the Council and the European Parliament will be discussed at the Health Council on 31 November 2009. If a compromise is reached, French MEP Françoise GROSSETÊTE (EPP) will take the Directive forward in a second reading in the European Parliament as a leading rapporteur. Dagmar ROTH-BEHRENDT (GE, S&D), Bas EICKHOUT (NL, GREENS) Antonyia PARVANOVA (BU, ALDE) and Tamara LIOTARD (NL, GUE) have been appointed shadow rapporteurs.

From EPF's perspective the Directive provides a bedrock to encourage and support Member States to cooperate on cross-border healthcare and to translate into reality the principles of quality and safety in healthcare that were endorsed by all EU governments in June 2006 in the Council Conclusions and strongly welcomed by the entire health community as a valiant and seemly way forward. EPF has prepared letters for the Member States Ministers and experts highlighting some core issues for patients and appealing to them, on behalf of patients in their country and on behalf of the European Patients' Movement to take these perspectives into account during the next few weeks while working on the Council's position on the Directive.

For further information, please contact the Secretariat.

5. PATIENT SAFETY AND QUALITY OF CARE WORKING GROUP

With its Working Group on Patient Safety and Quality of Care (PSQCWG), the Commission has moved forward in engaging representatives of Member States and stakeholders in a reflection on quality of health care and possible policy actions at EU level. A meeting took place in Brussels on 24 of September, at which EPF was represented by Roxana Radulescu.

Different aspects of healthcare quality have been addressed by the European Commission recently in a number of initiatives such as quality and safety of blood, tissues and organs, guidelines for high quality cancer.

Screening and quality indicators proposed by the Open Method of Coordination on Social Protection and Social Inclusion. However, an overarching approach, that addresses various aspects of healthcare quality in a comprehensive manner, has not yet been proposed.

At political level, the Council Conclusions of June 2006 highlight that access to good quality care, together with universality, equity and solidarity constitutes the overarching values on which EU health systems should be built. The current draft Directive on the application of patients' rights in cross-border healthcare refers to Member States defining clear quality and safety standards for healthcare provided on their territory and ensuring their implementation, while the Council Recommendation on patient safety and adopted in June this year represents also a cornerstone in this area. Moreover, about 80 research projects in the field of quality have been co-funded by the European Commission.

For the PSQCWG discussion, the Commission proposed a series of specific objectives that could contribute to improving the quality of healthcare for all EU citizens: to achieve a common understanding of quality in EU

Member States, to promote continuous healthcare quality improvements in all MS, to propose the collection of comparable data, and to establish a culture of mutual learning among Member States. At the next meeting the group will exchange views on the various policy options that are available at EU level such as an enhanced cooperation mechanism, a Council Recommendation on health care quality or possibly common quality standards for EU Member States.

EPF will keep you updated with the policy developments in this area. For further information, please contact Roxana Radulescu.

6. THE CLINICAL TRIALS DIRECTIVE

The European Commission has announced that it will make an assessment of the application of the Clinical Trials Directive, which will be followed by a public consultation. The Commission plans to make a new legislative proposal on the Directive by 2010. Issued in 2001, the Directive was created to regulate clinical research in a uniform way across Europe. Its basic aims were to speed up research and development, harmonise procedures, decrease bureaucracy, and enforce patients' protection. Key aspects of the directive include:

- A trial may only be started in a Member State of the EU if it has been authorised by the relevant competent authority in that Member State and has been given a positive opinion by an ethics committee.
- Each trial must have an identified sponsor who is responsible for the whole trial; this includes: initiation (including obtaining authorisation), management, conduct and pharmacovigilance.
- Informed consent must be obtained from patients and a specific procedure must be followed;

- Both the European Medicines Agency (EMEA) and national regulatory authorities conduct mandatory good clinical practice inspections and the findings from these inspections, together with details of each authorised trial are reflected in a new European database for clinical studies.

Since its implementation in 2004, the Directive has received much criticism from both commercial and non-commercial trial sponsors for allegedly hindering rather than assisting the establishment and conduct of clinical trials in the European Union. For patients, the Directive has been, in principle, a good step forward, as it puts forward procedures to require an informed consent, increased involvement of the ethics committee and stricter obligations of sponsors in the trials. However patients are not always provided with adequate and accessible information on the trials they are participating in. Moreover, the bureaucracy related to the implementation of the Directive has slowed down clinical trials within Europe, which ultimately led to decreased access for patients to new medicines. Another concern for patients has been around the Directive leaving the implementation mechanisms to the Member States that have taken very different approaches (including on the procedures of informed consent).

EPF plans to engage with its members and patients organisations allies to investigate patients groups' experiences and perceptions of clinical trials across EU, and therefore contribute to this policy process.
The Commission will convene a meeting on 13 November to consult key stakeholders. Those patient groups interested in this process should contact Nicola Bedlington.

For more general information, please contact the Secretariat.

7. MEDICAL DEVICES

EPF has been invited, alongside several other stakeholders, to a Commission exploratory exercise on the future of the medical devices sector, to map the existing industrial and public health challenges in the sector and investigate possible topics of reflections at European level. This will provide representatives of industry, users and consumers of medical technologies with an opportunity to put forward their perspective on the sector. The exercise should result in a series of suggested themes for future reflection, to be adopted by the members of exploratory exercise in early 2010.

Susanna Palkonen, EPF Vice President, will represent EPF at the launch meeting on 2 October 2009. The work has been divided into 3 streams:

Work stream 1: Medical Devices – Future challenges for public health and medical technologies developments

Work stream 2: Medical Devices – Balance between patients' needs and financial sustainability

Work stream 3: Medical Devices – Competitiveness and innovation of the medical devices industry

EPF has been invited to nominate experts for each of these areas. Any EPF member organisation that would be interested in being involved in this work is invited to contact the secretariat. More information on the specific process will be provided in the next issue of the EPF Mailing.

8. SURVEY ON MEDICAL PACKAGING

Non-concordance to prescribed medication and medication mismanagement are major problems in treating illness today. It is estimated that 30% to 50% of prescribed medication are not taken as recommended and that patient concordance (the degree or extent to which a patient follows or completes a prescribed diagnostic, treatment, or preventive procedure) drops to only 50% within the first three months of therapy. The WHO also assumes that one in four patients does not correctly follow the prescribed medical regime. This trend can have dire consequences for patients due to poor management of conditions as well as for healthcare systems due to poor management of resources.

Some functional limitations to taking the medication as prescribed are: poorly designed medication packs, inappropriate or misleading information, readability of labels, colour vision, use of child-resistant containers, short-term memory, and the interpretation of labelling. This can lead to medication errors, over or under dosing of medication and neglect of medication.

Packaging (alongside personalised patient counselling and well-written medication instructions) is seen as one tool to make it easier for patients to remember to take their medications correctly at home, especially if the design of medication packaging takes into account the different sensory, physical and mental capabilities of the patients. Currently manufactured drug packaging, however, very often significantly impedes access by patients to their medications.

In order to find out what patient leaders think about this subject, we conducted on occasion of EPF's Regional Autumn Advocacy Seminar 2009 a survey, asking representatives of patients' organisations from Bulgaria, Greece, Hungary, Rumania and Slovenia if they think that medical packaging can play a role in patient's concordance and help patients to take their medication on time, in the right dosage and for the prescribed period of time.

The analysis of responses will be made available soon, but some general trends can be stated. The majority of interviewees confirmed that medical packaging is an important issue for patients. Many wished for clearer information and instructions inside the packs, the packaging being after the doctor the most important source of information for patients. There was also strong agreement that medication is packed too complicatedly, with too much material.

9. INNOVATIVE MEDICINES INITIATIVE JOINT UNDERTAKING (IMI-JU) NEW CALL 2009 TOPICS PUBLISHED

The IMI is a unique partnership between the European Community and the European Federation of Pharmaceutical Industries and Associations (EFPIA).

The aim of IMI is to support the faster discovery and development of better medicines for patients and to enhance Europe's competitiveness by ensuring that its biopharmaceutical sector remains a dynamic high-technology sector. This will be achieved through funding major R&D projects. Half of the funding for IMI is made available through the European Commission's 7th Framework Programme on Research and Development (FP7). The other half will be provided by companies belonging to EFPIA's Research Directors Group.

EPF has appealed to both EFPIA and the European Commission to promote the involvement of relevant patients' organisations in the partnerships that coordinate IMI projects.

The IMI-JU announces, following approval by the Governing Board, the topics for the IMI-JU second Call for Proposals. These topics are based on IMI's research priorities for 2009 and include research in the two

strategic pillars: Predicitivity of Efficacy Evaluation, with focus on the therapeutic areas: oncology, diabetes, inflammation and infectious diseases, and knowledge management.

Please note that this announcement is to inform the scientific community about the topics that will be subject of the IMI-JU 2nd Call. The actual launch of the IMI-JU 2nd Call is foreseen for 30 October 2009 with an expected deadline in January 2010.

Should EPF members be interested in becoming involved in a project consortium in their disease area, or in relation to the more general thematic area of knowledge management, please read more here, also about opportunities regarding searching for partners.

10. EU CALLS FOR PROPOSALS

Following the recent call for proposals published on 30 July 2009 by DG Research within the 7th RTD Research programme, we would like to draw your attention to the following Call:

SSH.2010.2.1-4 Social Platform on Sustainable Lifestyles

One of the key tasks in the early twenty-first century is to reconcile the need to reduce the levels of energy and environmental resources and transport services we consume, while at the same time improving the quality of life for all in the context of an ageing society.

A social platform on 'sustainable lifestyle' will be supported to define a research agenda in the area driven by societal concerns. Taking into account previous research at national and EU level, the platform will involve societal stakeholders with a view to support the exchange of experiences and the development of structures

of analysis on current initiatives and practises that aim at new sustainable ways of living, moving, consuming, given current knowledge and economic, social, legal and cultural imperatives. Future perspectives about lifestyles will also be developed in order to better identify the issues to solve.

A large number of stakeholders including Civil Society Organisations (CSOs) will have to participate to this platform representing a wide variety of sectors from research and education to industry, services and society at large.

Please note that the **deadline for applications is 14 December 2009**. You can find all documents related to this call at:
http://cordis.europa.eu/fp7/dc/index.cfm?fuseaction=UserSite.CooperationDetailsCallPage&call_id=255

In case you need further information, please contact directly unit L2 in DG Research.

11. CONFERENCE – ASSESSING DRUG EFFECTIVENESS, STOCKHOLM, JULY 2009

The Swedish Ministry of Health and Social Affairs, working in cooperation with the Dental and Pharmaceutical Benefits Agency and the Medical Products Agency, held a conference on Assessing Drug Effectiveness on 29 July 2009.

The aim of the conference was to find ways of cooperating across Europe on the collection and sharing of data on the effectiveness of drugs. A better understanding of how well drug treatments work in everyday clinical use benefits patients, medical professionals, industry, government agencies and society as a whole.

The one-day conference combined a plenary session that highlighted different perspectives on European collaboration in connection with the follow-up of drug effectiveness and discussion workshops. These workshops focusing on biologic agents for chronic inflammatory diseases, orphan drugs or cancer drugs covered three core areas i) setting up a pilot project on collective gathering and sharing of data on drug effectiveness, and ii) the potential for long term collaboration.

Some of the most influential medicinal stakeholders in Europe were in Stockholm to address the importance of collecting and sharing data on the effectiveness of drugs and to explore opportunities for future European collaboration on this issue.

EPF President Anders Olauson was involved in the steering group planning the conference and also gave a presentation at the plenary session.

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Anders highlighted: “The most important way to improve effectiveness assessments is to involve patients. Only patients can provide information about living with a disease and should be treated as stakeholders with equal standing as other stakeholders. New thinking and flexibility can be achieved by risk sharing and conditional pricing. This is welcomed by patients and gives an opportunity for early access to new drugs. It will also give early rewards for innovation, funding authorities will have control over spending and it will give the opportunity to collect valuable experience about how the innovative medicine works in real life settings. Working together at EU level gives added value, i.e. coordinated post marketing requirements through EU level studies and registries, better targeting of patients with right treatment regimens and doses, and finally better value for money.”

Anders Olauson gave one example of strong patient involvement, i.e. Alzheimer’s disease where dialogue between the UK’s Alzheimer’s Society and NICE (the National Institute for Clinical Excellence) in the UK created some change and concessions.

EPF is moving forward on this issue and on the agenda in 2010 is a European workshop on health technology assessment, compilation of accessible patient oriented materials on HTA information, and a joint event with HTA experts and patient leaders.

Anders will represent EPF at a follow-up event also organised by the Swedish Presidency on the 13 November 2009 in Brussels, to look at collective gathering and sharing of data.

For a full copy of Anders’ presentation please contact the EPF secretariat.

12. CONFERENCE ON YOUTH AND HEALTH, BRUSSELS, 9-10 JULY 2009

On 9-10 July 2009, DG Sanco organised together with the European Youth Forum and the World Health Organisation the conference "Be healthy, be yourself" under the patronage of the Commissioner for Health Androulla Vassiliou. The conference targeted young people and health related problems of their age groups. A group of 100 young people (age 18 to 25) had been invited to actively participate in the conference and to elaborate the European Youth's position on some acute health issues like Sexual and Reproductive Health and Rights, Mental Health, Nutrition and Healthy Lifestyles, Health and Safety at Work in a two days Youth Camp before the conference.

Many diseases have their roots in the youth and the lifestyle young people adopt. The importance of literacy to enable and empower young people to take responsible decisions for their health was emphasised again and again, as was mentioned the problem of exclusion through poverty, disease and discrimination that heavily weighs on people's and especially young people's health.

The role of youth organisations and youth workers in prevention, policy-making, and awareness rising was underlined as well as their active role in social inclusion, confidence building to make healthy choices, and in providing safe spaces irrespective of illness or disability.

The focus of the conference was, however, solely on prevention. There was no mention of young patients, chronically ill young people or the problem of handling and living with illness.

The main statements in this conference were that young people accept peer-to-peer education more easily than formal education provided by adults, that negative myths have to be dropped and positive messages found instead (especially in the context of smoking/drugs/alcohol), that uncomfortable truths and issues have to be addressed openly (notably concerning sexual health). There is need for sustainably funded, long-term

youth-adult partnerships, a cross-sectoral approach in youth and health related problems, young people in determining positions and the active involvement of parents and everybody who is in contact with young people.

It is not enough to join the youth and health agenda – health has to be an integral part of ALL policies. All political sectors CAN take care of the social determinants of health. Since January 2009, it is therefore obligatory in the Commission to assess the possible impact of every initiative on health. It is, however, the responsibility of the health community to deliver good tools to assess and understand health indicators for these proceedings to be fruitful. In this vein, the Commissioner announced her intention to start an initiative on health inequalities in autumn, together with the Commissioner for Employment, Social Affairs and Equal Opportunities Vladimir Spidla.

For a copy of EPF's report on a pilot in Sweden on young patients and how they perceive their health environment please contact the EPF secretariat.

13. EFPIA PATIENT THINK TANK, BRUSSELS, 22 SEPTEMBER 2009

The EFPIA Patient Think Tank met on 22 September 2009. Items on the agenda included an overview of the new European Parliament, and update and exchange of views on the Pharmaceutical Package of proposals on Information to Patients, Pharmacovigilance, and Counterfeiting. There was a discussion on a Code of Practice between patient organisations and the healthcare industry and an update on other EU healthcare developments such as cross border healthcare, animal research, rare diseases and the new call for the Innovative Medicines Initiative (see section 9).

For more information, or a copy of the presentations made at the Think Tank, please contact the EPF secretariat.

14. NANOMED ROUND TABLE, LONDON, 3 SEPTEMBER 2009

On 3 September 2009, EPF participated in a meeting of the Patients Needs Working Group of the Nanomed Round Table in London. The Nanomed Round Table is a project financed in the European Commission's Seventh Framework Programme (FP7) Nanosciences. Its aim is to explore possible ethical and socio-economical issues that could arise in the wake of nanomedical innovations and their employment in medical treatment. The Round Table is a forum where all stakeholders (patients, industry and society) can express their needs and requirements and aims to develop a set of recommendations to support decision-making in regard to nanomedical innovations. The work is implemented in five working groups: "ethics and societal impact"; "economic impact"; "regulation"; "communication"; and "patient needs" which tries to assess what patients expect from developments in the nanomedical field and what possible issues for them might be. EPF is involved in this last group.

In this third meeting of the Patients Needs Working Group, the draft report on key findings and recommendations was discussed. A pilot study with online survey, telephone interviews and a focus group had come to following preliminary conclusions:

- There is a low level of awareness and knowledge among patients and patient organisations of nanomedicine and its uses.
- The majority of patients would like to receive more information on nanomedicine, ideally via the internet, and it should include information in lay terms on current research and the advantages and disadvantages of nanomedicine. Most patients would like to receive this information from patient organisations and/or clinicians.

The Working Group will recommend inter alia that the European Technology Platform (ETP) Nanomedicine and EPF should develop ways of actively including patient organisations into the work of ETP; that the European Commission should produce information material on nanomedicine similar to that already existing on nanotechnology as well as encourage and support patient organisations to research whether nanomedicine is potentially useful in the treatment of their condition and if so, to provide adequate information to patients and carers; that national strategies in nanomedicine should be coordinated on European level; that the European Commission should gauge the awareness of clinicians and healthcare professionals in regard to nanomedicine and determine whether frameworks for continuous medical education (CME) and continuous professional development (CPD) are capable of responding to the novel possibilities and accompanying challenges.

The fourth and last meeting of the Patients Needs Working Group will be in November 2009.

15. NOVO NORDISK MEETING, BRUSSELS, 3 SEPTEMBER 2009

Roxana Radulescu gave a presentation about EPF and our advocacy work with the European institutions at a meeting organized by Novo Nordisk on EU health Advocacy. She took part in a panel discussion with representatives from other health NGOs and explained how EPF works with the European Parliament, the Commission and the Council and what the major health policy topics are currently under debate and what European project EPF is involved in. She also shared with the participants EPF's policy of diversity of funding - from both public and private sources - and the way EPF works with healthcare industry partners, who provide unrestricted sustainable funding to contribute to EPF's strategic plan and annual work programme. Key documents are EPF's Code of Ethics and EPF's Framework of working with funding partners which highlight key principles that underpin EPF's acceptance of industry funding: transparency, mutual respect,

independence, unrestricted, sustainable, no single company, proportionality and timelines.

Around 65 Novo Nordisk representatives from a wide range of national affiliates, as well as the company's headquarters in Copenhagen were present at the meeting.

For further information, please contact Roxana Radulescu.

16. EMEA MEETING ON CLINICAL TRIALS OUTSIDE EU, LONDON, SEPTEMBER

Roxana Radulescu participated in a ad-hoc working group meeting at EMEA on clinical trials outside EU which took place in London on 7 September. The group discussed on practical steps to be undertaken during the provision of guidance and advice in the drug development phase and in the Marketing Authorisation phase, as well as on the practical application of ethical standards for clinical trials in the context of EMEA activities. The newly published report "Biomedical Research in Developing Countries: the Promotion of Ethics, Human Rights and Justice" prepared by UNICRI and the Italian Medicine Agency was also presented and discussed. From the patients' perspective, concerns raise particularly around the need for consistent and continuous provision of information to patients, in an understandable and accessible way, about the steps of a clinical trial procedure (recruitment, participation, follow up trials). Building a level of trust with health professionals and informed consent guidance is also crucial.

EMEA plans to organise a workshop in spring 2010 on this topic to stimulate the debate and to which patients' representatives will be invited. EPF and the International Alliance o Patients Organisations (IAPO) will follow-up on this issue to ensure a good patients' representation.

For further information, please contact Roxana Radulescu.

17. BREAST HEALTH DAY 2009

"ACTIVE TODAY FOR YOUR BREAST HEALTH TOMORROW"

On 15 October 2009, Europa Donna, the European Breast Cancer Coalition, organises the annual Breast Health Day. The aim is to disseminate information, raise awareness and encourage prevention as well as further the early detection of breast cancer which is the most common cancer suffered by women and girls in Europe (over 430,000 new cases every year).

This year's overarching theme is "More active for your breast health tomorrow" and strives to remind women across Europe of the important influence of lifestyle factors on their breast health. The International Agency for Research on Cancer estimates, for example, that excess body weight and physical inactivity account for approximately 25-33% of breast cancer cases.

For this reason, Europa Donna has teamed up with sport celebrities and international scientifics as to raise awareness and demonstrate the scientifically proven positive influence of physical activity on breast health.

For further information please visit www.breasthealthday.org

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18. EPF MANIFESTO IN ACTION-"TOGETHER WE CAN DO MORE" – A NEW PROJECT IN POLAND PROMOTING THE EPF MANIFESTO "150 MILLION REASONS TO ACT"

"Together We Can Do More" is a new project led by the Federation of Polish Patients and financed by the Ministry of Labour and Social Affairs from Funds for Public Initiatives. The main goal of the project is to meet with representatives of patients' organisations around Poland and share examples and ideas around participation and involvement of patients while at the same time get an insight on patients' issues in these regions. Two major publications were promoted: "Vademecum" created by NHF – a guide for patients about the Public Healthcare System, and the EPF Patients' Manifesto that has been translated into Polish.

A series of seminars in 16 major Polish cities is a key element of the project. Our partnership with the National Health Fund (NHF) during this tour gave us a unique opportunity to gain immediate recognition in the regions. During each event we usually meet around 20 patients' organisations' representatives and other guests (local stakeholders). Each meeting has full media coverage. There are always all major regional media present. Here is a list of those that we have been interviewed by so far (after visiting 10 out of 16 cities):

<table>
<tr>
<td>Regional TV stations:
TVP Rzeszów
TVS Kraków
TVP Opole
TVP Szczecin
TVP Bydgoszcz</td>
<td rowspan="2">Regional newspapers:
Kurier Szczeciński
Gazeta Pomorska
Gazeta Wyborcza- Bydgoszcz
Express Bydgoski
Nowa Trybuna Opolska
PAP Katowice
Dziennik Polski Kraków
Super Nowości Rzeszów
Gazeta Wyborcza Rzeszów</td>
</tr>
<tr>
<td>Regional radio stations:
Polskie Radio Lublin
Radio Opole
Radio Merkury</td>
</tr>
</table>

We estimate that this news coverage has reached 5 million listeners and viewers around regions so far. At the end of the tour, the number of informed people will exceed 10 million.

At our final event (the national conference) at the end of this tour, we will present a final report outlining all of the issues from regions highlighted by patients. We hope to have the opportunity to invite representatives of EPF, Polish authorities and decision-makers to this occasion. We also intend to organise an event bringing together as many Polish MEPs as possible from across the European Parliament's Groupings, to once again promote the EPF Manifesto and share the outcomes of our patients' tour across Poland.

For further information, please, contact Tomasz Szelagowski.

EPF and the Secretariat

19. SUMMARY OF FUNDERS' MEETING, BRUSSELS, 22 SEPTEMBER 2009

On the 22 September 2009, EPF held a funders' briefing in order to bring together current sustainable funders and future supporters to explore EPF's key achievements and challenges in 2008/2009 and likely major themes in 2010. It was also an opportunity for EPF's new board and staff to meet company Federations and companies interested in supporting EPF in line with our framework for funding and code of ethics.
For a copy of the presentation made at the meeting, please contact the Secretariat.

20. SUMMARY OF THE BOARD MEETING, BRUSSELS, 23 SEPTEMBER 2009

7 members of the EPF board met in Brussels on 23 September 2009. Key items on the agenda were the revision of the Constitution regarding Associate Membership. The revised Constitution and By Laws will be sent to all members in advance of the next Annual General Meeting 2010. The board meeting was also an important opportunity to build the EPF work plan and budget 2010 and our activities in the framework of the Spanish and Belgian Presidencies. Other items on the agenda included the Terms of reference of EPF's new set-up Policy Advisory Group that will be launched formally at a meeting in autumn.

For more information please contact Nicola Bedlington.

21. UPDATES ON CALLIOPE PROJECT

CALLIOPE project – Interoperability: Creating a European coordination network for e-health interoperability implementation-calliope meetings and CALLepSO workshop, Brussels, 1-2 September 2009.

The primary aim of the project CALLIOPE is to create a network of experts to support member states in identifying and implementing e-Health interoperability solutions.

At the beginning of September CALLIOPE's partners met to discuss the progress of the two working groups in charge of reviewing the EC Recommendation on e-Health Interoperability and of formulating a Roadmap on e-Health Interoperability. The second day the first workshop of CALLepSO - formal partnership between CALLIOPE and the epSOS project – was held.

Participants discussed in groups their views on the strengths and weaknesses of the Recommendation as well as expectations from this review. The outcome of this exchange fed into the successive sessions related to the Road Map where we discussed in particular objectives, timeframe, key areas and stakeholders.

In the context of the CALLepSO workshop, representatives from epSOS presented the achievements to date in relation to the patient summary – to be used in cross border health care provision – and to e-prescription. Case studies that will be piloted in selected regions of a number of Member States were discussed in depth. The progress to date seems very positive for patients as well as health professionals. There are certainly questions and doubts on certain functionalities and these were raised during the workshop.

It became apparent following these meetings that EPF needs to consult its membership to have a clearer position on some of the aspects related to the Recommendation, the Road Map, the patient summary and e-prescription.

EPF will soon launch this consultation with the aim of feeding back at the next meetings of the working groups in mid-November.

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

22. UPDATES ON EUNETPAS PROJECT

At the meeting of the Patient Safety and Quality Working Group on 24 September, Jean Bacou, the coordinator of the EUNetPaS project gave an update on the latest project developments and also initiated a debate on the life of the EUNetPas network after the end of the project in 2010 and possible options to continue the work of this unique Network.

The aim of the project is to produce European added value of Member States collaboration in patient safety by mutual support, and exchange of ideas and materials for accelerating progress in this field. The project facilitated the setting up of a pan European Network for patient safety involving 46 organisations, representing Member States, stakeholders and international organization. It is structured around national coordinators (National platforms) with the objective to pilot tools to reduce medication errors as a first step, promote education, a change in culture and a learning environment and propose a basis for research projects for better safety. For example, Austria has recently established a Patient Safety Platform and shared with the project partners their experience of embarking in this process.

All partners involved in various Work Packages are currently working towards recommendations and common tools to be used by all Member States such as: a patient safety culture measurement tool, Guidelines for education on patient safety, a library of methods for reporting and learning systems implementation and an inventory of rapid response mechanism for sharing high priority patient safety issues and solutions. For example, regarding medication safety, several practices were selected for testing: the safety vest (do not disturb during medicine preparation in wards), the sleep card (guideline to reduce unnecessary treatment by sleeping pills), bed dispensation practice (preparation and administration of medicines by the same person reduces the risk of confusion), medication reconciliation at discharge (written discharge medication given to the patient and sent to the GP and community pharmacist) and at admission.

EPF is particularly active in the Work Package (WP) on education for patient safety, promoting the support of health literacy for patients and patients' education in areas that involve their own safety during the medical journey. A meeting of the partners involved in this WP will be held in Brussels on 9 October and we will keep you informed with the main developments.

For further information, please contact Roxana Radulescu.

23. SECRETARIAT NEWS

New EPF Staff Member-Communication Officer

On October 5th Efstathia Megas will join EPF in the position of Communication Officer. Although of Greek origin, Efstathia has studied and worked in the US for a long time. She is now back to Europe, and very keen to contribute to EPF by combining her academic background in Health policy with her professional skills in Communication, Public Relations and Marketing.

New Look Website

EPF continues website development. At the end of year 2009, visitors will be able to surf on the newly designed eu-patient.eu. We are concentrating on the accessibility, more frequent and efficient handling of the content, search functionality, improved structure, etc. Read more in the next issue of the EPF Mailing or contact Žilvinas Gavėnas.

24. DIARY

Wed, Sep 30		**Anders Olauson Meets Minister of Health at the Inauguration of Burgos** Place: Spain Attendance: Anders Olauson
Wed, Sep 30 -- Thu, Oct 1		**Gastein Health Forum** Place: Gastein Attendance: Nicola Bedlington (speaker), Roxana Radulescu
Fri, Oct 2		**Medical Devices meeting** Attendance: Susanna Palkonen
Wed, Oct 7		**ITU TELECOM World 2009 Forum** Place: Geneva Attendance: Anders Olauson (speaker)
Thu, Oct 8		**Med-e Tech** Place: Brussels Attendance: Nicola Bedlington (speaker)
Fri, Oct 9		**EUNETPAS project meeting - WPE (Education on patient safety)** Attendance: Roxana Radulescu
Sun, Oct 11		**Conference on Patient Safety in Intensive Care Settings** Place: Vienna Attendance: Anders Olauson (speaker)
Tue, Oct 13		**ETP Conference 2009 Gearing R&I to address societal challenges** Attendance: Liuska Sanna
Fri, Oct 16		**European Union Health Policy Forum** Attendance: Nicola Bedlington
Wed, Oct 21		**EHTEL Anniversary Symposium** Attendance: Roxana Radulescu
Thu, Oct 22		**CALLIOPE Open Session in Brussels in association with the EHTEL 10th anniversary event** Attendance: Liuska Sanna

Sat, Oct 24 -- Tue, Oct 27		**ISPOR 12th Annual European Congress** Health Care Decision Making in Europe: From Patients to Populations Attendance: Nicola Bedlington www.ispor.org/congresses/paris1009/p102709.asp#ThirdPlenary
Thu, Oct 29		**Swedish Regional Conference** Attendance: Anders Olauson
Fri, Nov 6		**Health Technology Assessment Program (HTA) Meeting** Attendance: Nicola Bedlington
Mon, Nov 9 -- Tue, Nov 10		**Medical Devices** Attendance: EPF Represnetatives to be confirmed
Thu, Nov 12 -- Sat, Nov 14		**CALLIOPE meeting** Attendance: Liuska Sanna
Thu, Nov 12		**EMEA meeting on clinical trials outside EU** Attendance: Roxana Radulescu
Thu, Nov 12		**Zuerich Health Compliance Packaging Council** Attendance: Nicola Bedlington
Fri, Nov 13		**Follow up to the Swedish Conference on Drug Effectiveness** Place: Brussels Attendance: Anders Olauson
Fri, Nov 13		**Clincal Trials Meeting, European Commission** Attendance: Nicola Bedlington and other colleagues to be agreed
Tue, Nov 24 -- Wed, Nov 25		**EPF Board Meeting** Place: Brussels Attendance: EPF Board Members
Wed, Dec 9 -- Thu, Dec 10		**Value+ Swedish Presidency Conference** Place: Gothenburg