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Issue 6: 31 January, 2007

Dear EPF members and friends,

Welcome to the first internal mailing of 2007. We hope you too have had a great start to the year.

In this issue, it is our pleasure to welcome warmly EPF's new policy officer Roxana Radulescu who joined us on 15th January – please see section 1

We are also very pleased to share with you EPF's work plan for 2007 that has been circulated to the EPF membership for comment and approved by the Board together with the strategic planning process (see section 2 and section 3). Key priorities in the next few months are the EPF Spring Conference (see section 14) and a proposal to the EU public health programme focussing on the effective involvement of patients in EU funded health projects (see section 15) Also in this issue you will find an overview of recent EU health developments in which EPF has been involved: this year is tremendously important for patients throughout Europe: Do read about our input to the health services consultation (section 5) , the health policy strategy (section 6), patient safety (section 7) and information to patients (section 12).

A summary of the main outcomes of the EPF board meeting on 29th January will be sent to EPF members in a few days time.

As ever, we look forward very much to your feedback or questions on this issue, and your input in the next issue is most welcome.

Very many thanks and warmest greetings,

Anders Olauson
President

Nicola Bedlington
EPF Director

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The next issue will be available on 28th February 2007. The deadline for articles/calendar additions is 25th February

1. *Introduction to our new Policy Officer*

Roxana Radulescu joined the EPF Secretariat on the 15th of January 2007. Previously, Roxana worked for the European Public Health Alliance (EPHA) where she managed several EC supported projects dealing with capacity building of health NGOs in new EU Member States, mental health, involvement of NGOs in public health research. Her tasks included developing new project and tender proposals and fundraising activities. Before joining EPHA, she worked for Mental Health Europe (MHE), where she coordinated two projects on mental health economics and suicide prevention policies.

Roxana holds a BA in Philology (English and French languages and literatures) and a MA in Public Policies from the University of Bucharest, with a thesis on the Romanian Ministry of Health's proposal for a national mental health plan. After her studies, she worked for the World Health Organization (WHO) in Bucharest and in Brussels. Roxana is committed to patients' rights and to a patient-centered health care approach and has a special interest in palliative care. She is very much looking forward to meeting the EPF members and to building fruitful collaboration.

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2. *EPF Five Years Strategic Plan*

During the Board meeting on 29 January, a draft five-year strategic plan was discussed and finalised. This is the outcome of 3 meetings of the EPF strategic planning working group during autumn 2006. The plan will then be sent to the EPF membership for consultation and adopted by written approval in May 2007 and published on the EPF website.

Should readers of the internal mailing be also interested in receiving the plan, contact the secretariat.

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3. *EPF Work Plan for 2007*

EPF's Work Plan for 2007 was adopted formally by the Board at its meeting on 29 January 2007. Please see below is the executive summary. All EPF members will receive a copy of the Work Plan. Should other readers be interested please contact the secretariat.

Executive Summary –EPF Work Plan

EPF objectives for 2007 are as follows:

- Building capacity within the secretariat, the governance structures and our relationship with the members
- Strengthening our policy impact
- Extending our membership base to ensure that EPF is a representative and as inclusive as possible
- Building powerful and effective communications and partnerships
- Diversifying the funding base

Governance and secretariat

Three major EPF meetings will take place in 2007: the EPF spring conference in March 2007, the Annual General Meeting in June 2007 and a capacity building seminar in November. The Board will meet 5 times.

A number of EPF working groups will also take place on specific policy areas.

In 2007, the secretariat will be composed of five staff, including a conference coordinator during the early part of the year. The secretariat will move to new larger premises.

Policy

EPF's policy work will be shaped by its over-arching goal of involvement of patients in all areas of EU policy, programmes and projects with an impact on health. An application will be submitted to the EU public health programme focused on this theme, and this will be a key dimension of its campaign work in the European Parliament.

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EPF will continue to invest in the high- level Pharmaceutical Forum, and in particular political developments surrounding information to patients. Other key policy interventions will include a patients' perspective on the EU health services consultation, the EU Health Policy Strategy White Paper, patient safety, the 7th Framework Programme on R and D, and in the EU Health Policy Forum

High-level meetings will take place with representatives of the German, Portuguese, and Slovenian EU Presidencies during the course of 2007.

EPF will continue to work with EMEA, and other health related agencies and think-tanks

EPF will engage in policy focused project in 2007 around the child and adolescent patient, the expert patient, and enhancing our evidence base and policy lines with patients' testimonies and case studies.

Membership

EPF will endeavour to extend its membership in 2007, also to include representative national patient umbrellas/ platforms. It will also continue to build its relationship with the whole range of health stakeholders operating at EU level and undertake extensive representational work to promote the patients' perspective.

Communications

An EPF internal mailing will continue to be produced on a monthly basis for EPF members and allies, and regular communiqués to external partners. The EPF website will continue to be developed as EPF's flagship and central communication tool.

Funding Base

Significant efforts will be made in 2007 to diversify the EPF funding base. In addition to continuing to build sustainable relationships with pharmaceutical companies, EPF will extend its work with non-pharma companies, foundations in line with its transparency policy and code of ethics, and will also devote considerable energies in 2007 to obtain Commission funding for 2008. The aim is to ensure that 30% of EPF's income comes from non-pharma sources within the next 18 months.

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4. *IAPO Workshop on Biosimilar Medicines, a Meeting for Patient Groups, 4 December 2006*

On the 4th December 2006, a workshop on Biosimilars was organised by the International Alliance of Patients' Organizations (IAPO). There were around 30 participants. The day after, IAPO also organised the launch in the European Parliament of its Briefing Paper on this subject; Jules Maaten (MEP) was invited. EPF was represented in these two meetings by our Assistant Policy Officer, Mr. Nicolas Pradalié.

Definition

Biosimilars can be defined as the generic versions of the first generation of therapeutic proteins. So, a biosimilar product is a second or subsequent version of the original Biologic. Biosimilars are independently produced after the patent protecting the original Biological product has expired. The Biologics already treat conditions such as Cancer, infectious diseases like AIDS and Autoimmune disorders (Multiple Sclerosis, Motor Neuron Disease, etc) and Neurodegenerative diseases like Parkinson's disease, as well as rare genetic diseases.

Framework

By 2010, around 50% of all new approved medicines could be of biotechnological origin. Healthcare treatments will then be completely different from what it is now. Therefore, patients need to have the most transparent information on these new medicines, two of which are already on the market

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in Europe.

There are currently more than 150 biopharmaceuticals products marketed worldwide. Most of these first biotechnology medicines are now approaching the end of their patent life, which provides the opportunity for Biosimilars to be produced.

Regulation in the EU

The European Union is leading the way on the international regulatory stage, with a specific regulatory approvals process for biosimilars, which has led to the introduction of the two first biosimilars onto the European market this year, 2006.

Issues

Biosimilars are not identical to the Biotechnology medicinal products, but just similar since they are from biological origins and their molecular structure is far more complex than the one of traditional medicines and generics (molecular weigh for Biologics: 150,000 - molecular weigh for traditional medicines like Paracetamol: 150). Therefore, they are very fragile and need to be used very carefully (sensitiveness to heat and cold, etc). They also have to be delivered on an individual basis: each patient reacts differently to these medicines from a biological origin.

Price: there were great hopes as to the potential lower costs of Biosimilars. Though, the cost of manufacturing amounts to not less than 60%. The production of proteins is expensive and cells need to be fed. Also, to keep it safe, there is a need to regulate, which will even increase the price of

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Biosimilars. So, the price difference will not be so noteworthy.

Safety: there are concerns linked to Biosimilars' complex structure and manufacturing processes as well as to the different patients' reactions.

So, Information to patients and education are really needed and health professionals must systematically discuss the options of biosimilar therapies with the latter.

Outcome of the meeting

Part of the meetings' objectives was to assess the knowledge level of patient groups' and to provide them with information on this very technical issue. In the working group the need to cooperate and to build alliances between patient groups came out. The goal of this cooperation could be to advocate for information, education, traceability and access to biosimilars at a reasonable price. EPF and IAPO is currently exploring how we can best cooperate on this and other issues.

Attached Documents:

Questions and Answers on Biosimilars

Questions and Answers on Generic Medicine

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5. *The Health Services Consultation: CHES Roundtable/ EP Mini Audition/ EPF's Responce*

Health stakeholders' perspectives – Roundtable in the Madariaga Foundation

On the 6th December 2006, a roundtable was co-organised by the Centre for Health & Ethics in Society (CHES) and the Royal College of Physicians on the Health Services Consultation. EPF was represented by our Assistant Policy Officer, Nicolas Pradalié, please click here for the report.

Mini audition – European Parliament – Mrs. Bernadette Vergnaud MEP

On the 10th January 2007, Mrs Bernadette Vergnaud (MEP, Rapporteur for the Health Services) invited EPF to a Mini-Hearing on the Health Services Consultation. The attendees were: Mrs Anne-Claire Simon (University of Louvain), Mr Henri Lewalle (National Alliance of Christian Mutual Insurance), Mr Francis Montané and Mrs Olivia Uguen-Martin (from the French National Council of Doctors), Mrs Ilaria Passaroni (BEUC – European Consumers Organisation). Mrs Evelyne Gebhardt (MEP) was also present for the first part of the meeting. EPF was represented by our Assistant Policy Officer, Mr. Nicolas Pradalié who presented the draft EPF position (see above).

First of all, Mrs. Vergnaud introduced the topic of the discussion presenting to us some areas of uncertainty and some existing problems that she had identified: reimbursements, patient and professional mobility, risk of different speeds in the EU as to the access to healthcare and reasonable

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delays and costs.

As far as Mrs. Simon was concerned, although the Consultation from the Commission is not going as far as it could do, it is asking the right questions and it is tackling ambitiously the conciliation between a European legal framework and a national organisation of healthcare. To her, the issue should not be left to the only European Court of Justice (ECJ).

The second speaker, Mr. Lewalle, suggested the cross-border care issue is vital: liberalisation must be carefully looked after but is needed in these areas as it will help to diminish the waiting lists for care access. An inter-hospital Convention would be useful to enhance safety of patients and an an overview on cross-border care.

Mr. Montané recalled that sometimes Doctors also face a lack of information as to patient mobility possibilities: in France for instance, 90% of doctors are not confident about the European Health Insurance Card (how to get it, which rights it allows, etc). Also, Doctors are really concerned about redress to patients in a European context and they stressed on the necessity of differentiating medical risk from medical errors. They believe the authorisation to go abroad for care must be a medical rather then an administrative decision.

Mrs. Passaroni insisted on the fact patients need to understand their rights when they go across border: they currently face a lack of information. There are different kinds of Patient Mobility; some patients are willing to go abroad for care and can afford it anyway - others cannot. So, the inequality issues need to be tackled so that this situation disappears. Prioritisation between local patients and wealthy foreigners sometimes becomes an issue. The EU has definitely a role to play on that. Also, BEUC would push for a binding instrument especially to tackle the reimbursement issues.

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EPF's Response

EPF has drafted a response to the Health Services Consultation and it is now with EPF members for final consultation before being submitted to the Commission on 31 January 2007.

In summary EPF believes action should be threefold:

1) A **binding legal instrument** to offer clarity on cross-border healthcare that builds on existing jurisprudence.
2) A political tool such as a **Patients' Charter** that will serve to encourage public awareness and confidence
3) **Robust and compatible management systems** to ensure patient –centred high quality delivery in practice that is not hindered by complex bureaucracy.

To complement these actions, EPF feels it would be useful to explore whether initiatives in the framework the Open Method of Coordination, the Structural Funds and the EC Public Health Programme and eventually the Seventh Framework Programme on Research and Development could contribute towards knowledge building and information exchange in relation to cross border health services and to monitor future application and utility.

If you are interested in receiving a copy of EPF's response, please contact the secretariat.

Attached links:
- Please find the conference programme, the background papers and the report at the following here.
- Please click here to find more information on the Consultation on Health services.

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6. *European Health Policy Strategy*

EPF has formulated a draft response to the discussion document for a European Health Strategy 'Health in Europe: a strategic approach' on the basis of informal consultation with the EPF membership. This was then circulated to the EPF board for their comments and circulated to the wider EPF membership for their input. A final response was submitted to the Commission on 12 February 2007.

In the response, which deals with the patients' perspective, EPF welcomes the Commission's initiative to consult stakeholders, supports many aspects of the discussion document and welcomes the fact that the EU is committed to provide, for the first time, an **overarching strategic framework**, which aims to set clear objectives to guide future work on health at the European level, and to put in place implementation mechanisms, while working in partnership with Member States. The response proposes mechanisms to involve effectively patients organisations at European and member state level in this work.

If readers would like to receive a copy of EPFs final response in mid February, please contact the secretariat.

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7. *Report on the Patient Safety Group Meeting at the offices of Haute Autorite de Sante (HAS), Paris, 18 December, 2006*

The meeting was effectively a workshop to explore how best to take forward the Patient Safety initiative on a pan-European basis aimed at reducing the burden of disease linked to medical error. It was pointed out that 10% of patients experience some form of medical error yet 50% of these incidents are avoidable. There is an urgent need to change attitudes on this topic and openly admit the extent of the problem so that rectification measures may be put in place. We should be ready to learn from past errors and avoid repeating them in the future. This will require a change both in the practice and culture of health professionals.

Please read full report by Rodney Elgie here.

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8. Report on a conference – "Continuing professional development – Improving healthcare quality, ensuring patient safety", Luxembourg, 14 December 2006

EPF board member, Astrid Sharpantegen represented EPF at a European Conference organised by the European Standing Committee of Doctors (CPME).

A Consensus Statement was agreed at this meeting in which EPF stressed the importance of patient empowerment, and the role of Doctors in enhancing this through information and through communications.

Attached Document: Consensus Statement

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9. STEP: a Strategy for The EuroPhysiome

EPF and its members has been invited to comment on a description of the virtual physiological human, as part of a strategy for the EuroPhsiome, a project funded under the EU sixth framework programme on research and development.

This description of the Virtual Physiological Human explains why, when completed, it is expected to change the face of biomedical research, clinical practice and of the industrial development of drugs and medical devices.

The scope of the document is *to provide organizations, such as the European Patients' Forum, with the tools to properly disseminate the VPH concept and, in doing so, to inform and gather opinion from the public at large with respect to this new grand challenge of biomedical research.*

Please send any comments you may have on this document to the EPF secretariat by 24 February 2007.

Attached link: www.europhysiome.org

Attached document: What is Virtual Physiological Human?

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10. *Update on Advanced Therapies*

The Commission proposal for a Regulation on "**advanced therapies**" is currently in discussion in the European Parliament and Council. This proposal, which builds on the existing pharmaceutical legislation, aims at harmonising the legal framework for medicinal products based on genes (**gene therapy**), cells (**cell therapy**) and tissues (**tissue engineering**). The current lack of such harmonisation is seen to hinder patients' access to these innovative, often life-saving treatments. In certain countries today, patients cannot get advanced therapy products because no proper legislation is in place; in other countries, patients are prescribed products which are not safe.

The main objective of this proposal is therefore to make sure that all European patients can get easier and uniform access to products that are demonstrated to be of high quality, safe and effective. All stakeholders, including patients and the industry, have been calling for a Regulation in this field for a number of years already. After three open rounds of public consultation, the Commission submitted its proposal in November 2005.

Because advanced therapy products are based on human or animal genes, cells or tissues, they can raise important ethical questions. In this proposal, the Commission position on this matter is that:

- The scientific evaluation of advanced therapy products is complex. Expertise in this area is scarce. Such evaluation should therefore be carried out centrally according to one set of rules, to avoid double standards.
- However, authorisations granted under this Regulation should fully respect and be without prejudice to national legislations on ethics, which may, in certain countries, prohibit the use of certain products/technologies (e.g. embryonic stem cells).

In other words, this Regulation should only be about science and making sure that products on the market are safe and effective. This Regulation should not seek to harmonise ethics and should

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recognise that those ethical aspects are better addressed at national level.

This approach has been fully supported by the Council so far.

Some Members of the European Parliament seek to promote a different line on those ethical aspects, by prohibiting marketing authorisations for products which are derived from ethically-controversial technologies (*e.g.* use of embryonic stem cells, modification of the germline, hybrids and chimeras).

The Regulation is currently in the first reading of the so-called 'co-decision' procedure (*i.e.* discussions in Council and European Parliament).

Rapporteur M. Mikolasik's report will be voted on 30-31 January. The plenary vote, involving the whole Parliament, should take place in March 2007.

A number of EPF members are actively involved in trying to ensure that this legislation achieves its intended objectives: to ensure that advanced therapy products marketed in Europe are safe and effective, while respecting Europe's diversity of views towards ethics. Should you be interested in being kept updated, or being involved in this work, please contact the EPF secretariat.

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11. *Reminder: questionnaire on innovation from the Pharmacuetical Forum Working Group on Pricing and Reimbursement*

Stefaann van der Spiegel, Commission official responsible for this working group sent a questionnaire to EPF members and patient group allies, on the issue of innovation last year with the deadline of 26 January 2007. There are many different perspectives on what is valuable innovation, and this exercise aims to capture the variation in these perspectives.

For your information and interest we attach another copy of the questionnaire and explanatory note and encourage you to reply directly to the Commission as soon as possible.

Should you have any further questions, please contact Mr. Christoph Thalheim, EPF representative on the Pricing and Reimbursement Working Group.

In the last internal mailing, Mr. Christoph Thalheim also made an appeal for more information for EPF members on access to drugs for their respective disease areas in different member states and where there were particular barriers. We remind you to send any comments on this issue to christoph.thalheim@emsp.org

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12. *Pharmaceutical Forum Information to Patients*

EPF attended the last 'information to patients' working group in Brussels on 7 December 2006, and presented an overview of the interim results of EPF's consultation with its members and allies on information to patients. Please see attached power-point presentation.

It was agreed that a final EPF document would be submitted in advance of the next working group meeting in March 2007 to feed into the debates. May we remind those organizations that have not yet sent comments and examples based on their respective experience and expertise on information to patients to do so by 16 February. We attach again the explanatory note and reference document.

It was agreed on 7th December that a series of documents developed by the working group in relation to information to patients would be circulated for wider consultation. A draft version of the Commission's report on Information to Patients will also be sent out for consultation.

These consultations should be launched in the coming few days, and EPF will send on these immediately to all EPF members and allies to ensure that those interested receive the papers with minimal delay.

EPF will be preparing a response, and the process and timeline to input on this will be sent out with the papers.

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13. *German EU Presidency priorities on Health*

The programme for the German EU Presidency is based on the 18-month programme drawn up by the three Presidencies Germany, Portugal and Slovenia. It builds on the work of the Finnish Presidency and takes account of the Commission's strategic work programme for 2007.

Its priorities will include continuation of the constitutional process, the viability of the European economic and social model, the area of freedom, security and justice and expansion of the European area of security and stability. The European Council meetings (summits) will focus on shaping Europe's economic and social future (8 and 9 March) and on the future of the Treaty Establishing a Constitution for Europe (21 and 22 June).

The Presidency acknowledges that the health sector has a considerable growth potential and will drive forward and possibly conclude work on the draft regulation on advanced therapies and the revision of the medical devices directive.
Regarding prevention and promotion of a healthy lifestyle, the Presidency will focus especially on prevention of new HIV infections. A ministerial conference will examine ways to involve and mobilize civil society more effectively in HIV/AIDS prevention measures. In addition, it will conduct a more in-depth analysis of preventive health using exercise and diet-related examples.

As for the Community framework for healthcare services which the Commission has announced for 2007, the goal of the Presidency is to establish greater legal certainty in the interpretation and application of internal market regulations in the area of health policy.

For further information open EU Presidency Programme.

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14. EPF Spring Conference

Readers of the recent mailings will know that European Patients' Forum is hosting a third EU conference on 20th-21st March 2007 in Brussels. The themes for this year's meeting include: the empowerment of patients and their role at EU level; 'the Informed Patient'; and 'the sustainability of patient organisations into the future'.

High level speakers with a wide range of EU expertise and experience will stimulate discussion and result a call for action at various levels to enhance the patients' opportunity to be heard and impact in the policy debate.

EPF has invited all its member organisations and patient group allies, together with national patient representatives from a representative platform or coalition from all 27 Member States. Crucially, other health stakeholder allies and partners with whom we work together in Brussels, including representatives from the EU Institutions health professional organisations, industry federations, health NGOs,agencies and think-tanks will participate and contribute their views and ideas on how patients group can be most effective.

A comprehensive report will be made available shortly after the conference on the EPF website. In the meantime, should you have any queries about the meeting, please contact the conference coordinator conference2007@eu-patient.eu

Attached link:
www.eu-patient.eu/conference2007

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15. *Call for proposals EU Public Health Programme*

Recent communication with the European Commission indicates that the Call for Proposals and Guidelines will be made available by mid February and the Open information day in Luxembourg will take place on 28th February. The timeframe for submitting proposals is likely to be similar to last year. EPF will send a note out to all members as soon as the call becomes available on the Commission website.

You will recall that EPF will submit a proposal linked to the involvement of patients in all EU health related projects, drawing on good practice in various fields, including the public health programme itself, Rand D and the structural funds, and developing tools to enhance meaningful involvement at both policy and programme levels.

More detailed information will be sent to EPF members and allies in the coming weeks, however, should your organization be interested in being involved in this project, do please contact the secretariat.

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16. Photos from the 3rd EPF/EFPIA Seminar

Please download [full EPF/EFPIA photo album] from our website.

17. EPF Calendar for February-March-April 2007

Date	Event
5 February 2007	***KNAPPE Project meeting (Knowledge and Need Assessment on Pharmaceutical Products in Environement Waters)*** Representative: Policy Officer Roxana Radulescu
7-8 February 2007	***High Level Health Finance Conference*** Representative : Susanna Palkonen
12 February 2007	***Meeting of EFPIA think-tank***
13 February 2007	***Meeting with the Director and President of CPME (Standing Committee of European Doctors), Luxembourg*** Representatives: President Anders Olauson Director Nicola Bedlington
19-20 March 2007	**European Voice Health Conference** Representative: President Anders Olauson
20-21 March 2007	***EPF Spring Conference (www.eu-patient.eu/conference2007)***
9-10 April 2007	***EPF Annual General Assembly***

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