



europeanpatients<sup>1</sup> forum

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Dear EPF members and friends,

Welcome to the EPF Mailing! Since our last issue in early May, the EPF Annual General Meeting has taken place, and we were delighted to welcome four new members and two new board members from France and Spain. Read more about the AGM and the key decisions in [section-1](#). We are also pleased to welcome Susanna Palkonen as EPF's new Vice President, following Jean Georges' decision to continue to be a board member but to stand down as Vice President. Warmest thanks go to Jean for his great and on-going contribution to EPF, since its foundation in 2003.

EPF has had the opportunity to attend a number of important meetings of other key health stakeholders over the last few weeks. We were represented by Anders Olauson at the Annual General Meeting of GIRP in Geneva (European Association of Pharmaceutical Wholesalers in Europe). Roxana Radulescu presented EPF at the Annual General Meeting of EFA (European Federation of Allergies and Airways Diseases Associations) in Bulgaria. We were represented by Nicola Bedlington at the Annual Symposium of PGEU (the European Organisation representing Community Pharmacists) in Vienna in mid – June. EPF was also invited to describe its work and opportunities for collaboration with patient advocates of the European Heart Network. Several other key meetings have also taken place since the last Mailing to which EPF was represented by the board and the secretariat - these are also reported in this issue.

A core topic for EPF continues to be "information to patients". Read our response to the European Commission consultation on its report on Information to Patients and, "hot off the press" a brief report on the high level Ministerial Pharmaceutical Forum, 26 June 2007, where we were represented by Anders Olauson. Our key message was the need for faster progress and stronger commitment at Member State level to the Pharmaceutical Forum, as we approach its final year of operations.

Finally, plans are underway for EPF's Autumn Advocacy and Campaign Seminar: Read more in [section-19](#). All EPF members are warmly invited to send a representative!

We take this opportunity to thank you again for your excellent and valued cooperation and wish you all the very best for the summer break. Please note that the EPF secretariat will be staffed throughout this period – and do not hesitate to contact us should you have a query.

Warmest regards,

Anders Olauson  
President

Nicola Bedlington  
EPF Director

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The next issue of the internal mailing will take place in mid- September 2007. The deadline for any contributions is 10 September 2007.

## Fact sheets

EPF is currently working on a wide variety of topics. For some of our very crucial working area, we have produced fact sheets for our members to keep you aware of the current status of discussion at the European level. Please contact the staff if you would like to get a copy of these (please also note that some of the fact sheets will be on our website soon):

1. Pharmaceutical Forum
2. Health Services
3. Information to patients
4. Health Strategy
5. Public Health Programme
6. Patient Safety

## 1. Highlights from EPF Annual General Meeting 9, 10 June 2007

EPF's Annual General Meeting took place over the weekend of 9, 10 June 2007 in Brussels. Delegates were delighted to welcome four new [full members](#): the European Section of the International Diabetes Federation, and National Patient Umbrella Organisations from France, Lithuania and Spain.

Two new board members were also voted in unanimously and given a warm welcome: Albert Jovell, President of the Spanish Patients' Forum and Christian Saout, Vice President of the National Patient Umbrella Organisation in France, and President of AIDES, a major national association of HIV-Aids Patients in France.



[Jean Georges](#) (Alzheimer Europe) stood down as Vice President of EPF, and will continue to serve as a board member, and [Susanna Palkonen](#) (European Federation of Allergies and Airways Diseases) became EPF's new Vice President.

The AGM also adopted the [EPF Annual Report 2006](#), the [EPF Strategic Plan](#), the [financial report for 2006](#) and [received the auditors report](#), and the [workplan](#)

and [budget for 2007](#).

An "Open Space" session for the members took place following the business session on consultation and communications within patient organisations, and key challenges and opportunities. A summary of the key outcomes of this meeting is available from [the secretariat](#).



## 2. New European movement for carers joins forces with the European Parliament

On 12th June, Nicolas Pradalié represented EPF at the joint launch of the “European Parliament Interest Group on carers and Eurocarers” by Baroness Jill Pitkeathly (President of Eurocarers) and Kathy Sinnott MEP (Acting Chair Interest Group on Carers).

### Issue

In the near future, 80% of the social and health care needed in Europe will be done by (family) carers and there is an urgent need for all EU Member States to address demographic challenges. Across Europe, there are millions of carers providing unpaid care by looking after an ill, frail or disabled family member, friend or partner. Therefore, it is time for the EU to consider the role and contribution of unpaid care to health and social care systems at all levels. Carers experience ill health, poverty and discrimination. If carers are to continue to care, measures will need to be taken to safeguard their rights and interests.

### The Interest Group on carers and Eurocarers

This is a new European organisation with representatives from different member states established with the overarching aim of representing carers’ interests at EU and national levels (putting amendments forward, making the carers more visible, etc.). Given the variety of current EU policy initiatives with a bearing on care, there is a need for a specific Interest Group addressing the issues stated above.

### Discussion

The Interest group was set up to face the difficulty of organising themselves, working together with other stakeholders like the Intergroup of family and children notably. The members of the Interest group believe that care should be available for everybody and should not be depending on income or wealth. Carers are facing challenges since care is not taken into account in GDP figures and carers’ work is not recognized. It happens also that when the people cared is working, the carer is not considered as such any longer. So, the generation of today’s carers will be the poor of the future. There was consensus on the fact that caring is an employment issue and not only a health issue. The Interest Group will make sure this reality is known at the European Union level. EPF is looking forward to cooperating closely with Eurocarers on common challenges.

### 3. Alliance for MRI scans and the Directive 2004/40/EC

On 13th June, Nicolas Pradalié represented EPF at the lunch on the implications of Physical Agents Directive 2004/40/EC (EMF) on the use of Magnetic Resonance Imaging scans in Europe. EPF has joined the Alliance launched by the European Society of Radiology (ESR) whose aim is to revise the Directive and to introduce derogation for MRI from the Directive.

#### Issue

The implementation of the directive, which is due to take effect in April 2008, could restrict the use of magnetic resonance imaging (MRI - eight million patients in Europe per year). The measures included in the directive were designed to protect employees from short term exposure to electromagnetic fields. Yet, it would limit the time that medical staff and operators could spend near the imaging machines, making it harder for health professionals to diagnose and support patients.

#### The Alliance's point of view

The Alliance for MRI says that the imaging machines should be totally excluded from the legislation and has proposed that the legislation should clearly state it would "not apply to the operation, manufacture, and servicing of magnetic resonance imaging."

#### EC acknowledges threat to use of MRI

Vladimir Spidla, the social affairs commissioner, informed member states at the ACHS (Advisory Committee for Health and safety) meeting in mid-June that it will propose an amendment to postpone the implementation date of the Physical Agents Directive (Electromagnetic Force). His concern is as follows: "We need a directive that makes full use of the great benefits of MRI and at the same time protects workers who are exposed to radiation."

The proposal was tabled at the meeting of Commissioners (Wednesday 27th June) and then subject to co-decision. However, to achieve derogation, Member States must also be involved and individually informed of the Directive and its potential impact on patient care.

#### EPF consultation

EPF is currently sending out a questionnaire to consult its members in order to understand how far they know about the issue and if they feel they would be concerned by this Directive on MRI scans.

#### Links

Directive 2004/40/EC (29 April 2004):

[http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l\\_159/l\\_15920040430en00010026.pdf](http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_159/l_15920040430en00010026.pdf)

Current status of the procedure:

<http://www.europarl.europa.eu/oeil/FindByProcnum.do?lang=en&procnum=COD/1992/0449C>

Alliance for MRI (ESR)

[http://www.myesr.org/cms/website.php?id=/en/newsTicker/ESR\\_launches\\_Alliance\\_for\\_MRI.htm](http://www.myesr.org/cms/website.php?id=/en/newsTicker/ESR_launches_Alliance_for_MRI.htm)

## 4. Round table on citizen's mobility and ehealth

On 14th June, Nicolas Pradalié represented EPF at the Round table on citizens' mobility - Accessibility of high quality health care as a condition to the free movement of people within the European Union" organised by Milan Cabrnoch, MEP.

### Aim of the meeting

Throughout the discussion the speakers and the panellists highlighted current problems regarding receiving health care services in other member states, introduced possible solutions, exchanged views of how to support cooperation in the field of eHealth, patient safety, ePrescription, electronic health records, some successful projects in the area of eHealth and gave an outlook to the future.

### Discussion: ehealth and patient mobility

It was highlighted that without effective hospitals decision-making, ehealth has no value: IT is not the solution. It is only a tool that can be useful to disseminate information provided there is trust between stakeholders. The debate on patient mobility applies not only about going abroad, but also about moving in a country or even in a region. Doctors should have swift access to patients' files. At the moment, they are reluctant to welcome new patients because of administrative costs. Patients need to know who is going to pay for the treatment and when the reimbursement would be made.

### Outcomes

Milan Cabrnoch is intending to organise a meeting with other MEP colleagues interested in ehealth so as to set up an informal group on the issue; there will also be public hearings on patient mobility and the cooperation between the European Commission and other stakeholders will be deepened.

## 5. IMI adopted by the European Commission

On 15 May, the European Commission adopted the Innovative Medicines Initiative (IMI) as a Joint Technology Initiative.

IMI seeks to overcome research bottlenecks in the drug development process. Its vision is to create real European leadership in biomedical research and development and thereby reinvigorate the European biopharmaceuticals sector as well as benefiting patients and society in general. IMI will embody a new approach to research financing at the European level, bringing together public and private funds, involving industry, SMEs, and non-profit research institutions.

Research will focus on 4 areas:

- Safety evaluation
- Efficacy evaluation
- Knowledge management
- Education and training

The Commission proposal will be presented to the Competitiveness Council of 21-22 May 2007, and it is hoped that the regulation can be adopted during the Portuguese Presidency, in time for IMI to start work in early 2008.

Commission press release and background information are available on the following website:

<http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/07/190&format=HTML&aged=0&language=EN&guiLanguage=en>

<http://europa.eu/rapid/pressReleasesAction.do?reference=IP/07/668&type=HTML&aged=0&language=EN&guiLanguage=fr>

<http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/07/191&format=HTML&aged=0&language=EN&guiLanguage=en>

## 6. DG SANCO – Stakeholder Involvement Conference

On 23rd May, Nicolas Pradalié was representing EPF at the Stakeholder Involvement Conference, organised by DG SANCO (EU Directorate-General for Health and Consumer Protection).

### Purpose of the conference

The purpose of the conference was to share and validate the findings and the recommendations made by DG SANCO Stakeholder Involvement Peer Review Group in the context of the Healthy Democracy Process. The basis for the discussion was the Synthesis Report, which forms the major substantive output of this process.

The conference was also intended to provide input to the follow-up of the Green Paper on European Transparency Initiative (COM(2006)194), by which the Commission launched a debate on its relations with interest groups and asked for external feedback on the application of the Minimum Standards for Consultation.

Consequently, the event was considered as a crucial stage in DG SANCO's "Health Democracy" debate, during which DG SANCO aimed at presenting widely its approach to improve stakeholder involvement and participation in health issues.

### Problems raised

Participants emphasised that time to answer consultations is often not long enough (legal minimum delay is 8 weeks). Other problems were highlighted such as: the use of one language (English), the updating of the websites which is not always done, the exclusive reliance on the internet tool (only 50% of the European citizen's have access to Internet) and the explanation on how to access documents. Participants reminded that they don't have enough resources (money and time) to answer to the consultations.

## Questions

Stakeholders who were present also reflected on how to influence on the legislative process, which the information used by the Commission and its civil servants to draft their legislative proposals are; who has influence and what is kept from the answers to consultations.

## DG SANCO

SANCO was said to be exemplary as to its consultations timeframes. For the European Commission, there is a need to identify best practices and to develop it in other DGs. DG SANCO is aware of some problems existing in the comitology procedure (15 committees for DG SANCO, 8 of which are regulatory) such as the minutes that are not available. For the Commission, the conference was a good way to take notes on the problems faced by the European Health and Consumer stakeholders.

DG SANCO website for the Stakeholder Involvement Conference:

<http://www.sanco-stakeholderinvolvement.eu/>

For all documents:

<http://www.sanco-stakeholderinvolvement.eu/en/articles/stakeholder-involvement-conference/documents.cfm>

All the EU consultations:

<http://ec.europa.eu/yourvoice/>

All the consultations of the Commission in the health sector:

[http://ec.europa.eu/health/ph\\_consultations/consultations\\_en.htm](http://ec.europa.eu/health/ph_consultations/consultations_en.htm)

## 7. Information to patients Consultation – EPF's response; consultation with patient group allies

In response to the Commission's consultation on [its report on information to patients](#) – EPF has prepared a draft response on consultation with its membership and with patient group allies. A preparatory meeting took place on 5th June and an extensive discussion took place at the Annual General Meeting. The deadline for this consultation is 29th June 2007, in order to make a submission in line with the deadline of 30 June 2007. The response welcomes the consultation and the report as a good overview of the current state of play, but is critical of the lack of recognition of the role that can be played by patients' organisations themselves. The response puts forward a series of ideas of the way forward to ensure access to high quality, validated health information for patients throughout the European Union.

Draft version of the report [is available here](#).

## 8. Pharmaceutical Forum – briefing meeting 22 May, 26 June

Anders Olauson, represented EPF at the High Level Ministerial Pharmaceutical Forum meeting on 26 June 2007, and Nicola Bedlington attended the steering group meeting on 22 May to prepare this meeting. (A copy of the progress report submitted to the Pharmaceutical Forum [is available here](#)). This report was approved, with a reserve expressed by the European Social Insurance Platform (ESIP) and Association Internationale de La Mutualité regarding “information to patients”.

Key points from the Pharmaceutical Forum Ministerial meeting included:

- A presentation by Mme Schmidt, President of the EU Health Council on pharmaceuticals and innovation.
- Mr Zourek, Director General of the Commission Directorate on Enterprise and Industry presented the outcome of discussions on the value of innovation under the working group on pricing and reimbursement.
- Both Commissioners Kyprianou and Verheugen stressed the need for accelerated progress in the Pharmaceutical Forum.

Commissioner Kyprianou stated:

- The Pharmaceutical Forum was intended to focus on making concrete progress on three issues:
  - § Allowing patients' who seek it to have access to quality information
  - § Improving certainty and reliability of relative effectiveness assessments
  - § And ensuring that Member States limit their regulation of pharmaceutical prices to medicines the pay for.Despite the practical focus, it has become clear that we still have a basic lack of progress.
- On information to patients, the guidelines for information to patients that should be agreed are useful but still require a real mechanism for implementation if they are to be meaningful. On relative effectiveness, technical

progress is being made, but with no willingness yet to take concrete steps towards a more common approach in practice. And on pricing, again technical progress is being made but without real commitment to tackling the basic issues.

At the end of the meeting Commissioner Verheugen stated:

“The Forum process is difficult. This is not surprising given the tasks we have set ourselves. However I see evidence of progress, but we need to speed up. We have one more year in which to turn this work into more substantial and practical recommendations for us to consider next year. I would ask all of you to instruct those that represent you in different working groups to be prepared to take risks. Unless we are all prepared to take a collective step into the unknown and explore options that may be uncomfortable for us, we will not be able to make the breakthrough that our European citizens expect and deserve.”

Anders Olauson on behalf of the European Patients' Forum also highlighted the fact that “European patients are becoming impatient. We are acutely aware of the limited time left for the Pharmaceutical Forum and the significant tasks ahead of us to maximise the impact”. He also highlighted EPF's continued commitment to play our full part in moving forward. ([See attached statement](#)).

A full report on the Pharmaceutical Forum meeting will be made available on the Commission Website:

[http://ec.europa.eu/health/ph\\_overview/other\\_policies/pharma\\_forum\\_en.htm](http://ec.europa.eu/health/ph_overview/other_policies/pharma_forum_en.htm)

## 9. Advanced therapies: Regulation adopted in first reading in Council

On 31 May, the Council adopted the Regulation on advanced therapies (discussion in COREPER - Ambassadors of all Member States – on the 16th May), in first-reading. There is a first-reading agreement without/against the rapporteur (one of the first time in the EU history). All Member States supported the Regulation, including those who previously had some reservations (e.g. Spain).

Next steps: the Regulation now needs to be translated in all EU official languages, checked by the 'linguistic revisers' of the Council/European Parliament, and formally adopted/signed/published. According to the Council Secretariat, this purely formal and administrative procedure will take it to September. The implementation work has now started in the Commission and in the European Medicines Agency.

Whole procedure:

<http://www.europarl.europa.eu/oeil/FindByProcnum.do?lang=2&procnum=COD/2005/0227>

Reminder - adoption in Parliament (25 April):

[http://www.europarl.europa.eu/news/expert/infopress\\_page/066-5722-113-04-17-911-20070420IPR05538-23-04-2007-2007-false/default\\_en.htm](http://www.europarl.europa.eu/news/expert/infopress_page/066-5722-113-04-17-911-20070420IPR05538-23-04-2007-2007-false/default_en.htm)

Commission welcomes Member States' text approval:

<http://europa.eu/rapid/pressReleasesAction.do?reference=IP/07/741&format=HTML&aged=&language=en&guiLanguage=en>

More information:

<http://www.euractiv.com/en/health/advanced-therapies/article-117507>

## 10. Patient Safety – International Association of Patients' Organisations (IAPO) addresses the World Health Organization

Myrl Weinberg, IAPO Chair Elect presented on the views and role of patients' organizations regarding combating counterfeit medicines at the World Health Professions Alliance Luncheon on Monday 14 May. She outlined IAPO's strategic and practical approach to patient safety issues generally and specifically relating to counterfeit medicines. The audience included high-level WHO representatives, heads of delegations and international health organizations.

IAPO and Save the Children UK, in collaboration with the WHO World Alliance for Patient Safety, convened an Informal Forum on Patient Safety at the 60th World Health Assembly on 15 May. The forum informed civil society organizations of the patient safety agenda and highlighted some positive contributions of civil society to patient safety initiatives.

Presentations were given by representatives from Save the Children, UK, the World Health Professions Alliance, the World Alliance for Patient Safety, Alzheimer's Pakistan and IAPO.

More information on the IAPO website:

<http://www.patientsorganizations.org/showarticle.pl?id=797&n=210>

## 11. Information to patients - CHES

Nicola Bedlington attended a meeting on "information to patients" organised by CHES (Centre for Health, Ethics and Society) on 2nd May 2007. [Please contact the secretariat](#) for a copy of this report.

## 12. Information to patients - Meeting in Paris (legislation in France and in Europe)

On Thursday 24th May 2007, Nicolas Pradalié was representing EPF at a meeting ("le Cercle des Associations") with around 15 French patients' organisations in Paris. The subject of the meeting was the Information to patients both in France and at the European level.

## 13. Information to patients - EPHA consultation with stakeholders

Roxana Radulescu represented EPF at a consultation meeting with health-related organizations (EPHA members, members of the Pharmaceutical Forum, health professional organizations) on the Commission report on information to patients on medicinal products, organised by the European Public Health Alliance (EPHA) on 30 May.

The discussion looked at the various positions participants have on the EC report and explored ways of agreement on certain general principles and recommendations and discussed on alternative proposals to put forward in order to meet the need for more quality information, without opening the door to Direct to Consumer Advertisement.

A follow-up meeting was organized on 21 June. Roxana Radulescu and Susanna Palkonen – EPF's Vice-president - attended it. It was decided to set up an informal Working Group on Information to Patients among the NGOs present to explore further the topic and share knowledge and experiences.

#### 14. EFPIA Think Tank meeting - 5 June 2007

Nicola Bedlington chaired the EFPIA Think Tank Meeting on 5th June. A presentation on measuring quality of health care services, given by Jim Attridge (Health Management Centre, Imperial College, London) at the [Think-Tank meeting](#) on 5 June 2007. Other discussion items included an update on progress in the Pharmaceutical Forum, an update on the Advanced Therapies Regulation, and an update on Animal Testing. On the latter issue, EPF has prepared a draft position paper approved by the board that will be circulated to the wider membership before the summer for their approval. It was noted at the meeting that the joint position paper by EFPIA, PhRMA, IFPMA, JPMA on disclosure of clinical trial information is available on the following webpage:

<http://clinicaltrials-dev.ifpma.org/>

#### 15. Meeting in Prague of Johnson and Johnson

Anders Olauson represented EPF at a major meeting of Johnson and Johnson in Prague, on 19th June on the Challenges of the Pharmaceutical Industry. Anders was invited to present a patients' perspective.

## 16. Value+

As explained in previous Internal Mailings, EPF has prepared a project proposal on promoting patients' involvement in EU supported health-related projects (VALUE+). The proposal was submitted to the Public Health Executive Agency on 21st of May. A response is expected by October 2007.

8 associate partners are involved: Alzheimer Europe, Spanish Patients' Forum, European Network of (ex-) Users and Survivors of Psychiatry, Health Policy Center of Lithuania, European Men's Health Forum, Bulgarian Confederation "Health Protection", European Institute of Womens' Health, Empirica (a Bonn-based research center). 3 collaborative partners have also agreed to support the project: European Multiple Sclerosis Platform, the European Federation of Allergy and Airways Diseases Patients Associations and Agrenska Foundation.

## 17. EUNETPAS

EPF has also become involved as an associated partner in a European Union Patient Safety Project (EUNETPAS), which aims to set up an umbrella European network to improve cooperation between EU Member States in the field of Patient Safety (culture, reporting and learning systems, education). This was also submitted in the framework of the 2007 public health call for proposals.

## 18. EUROHEALTH, RESPECT

Within FP7 Call for proposal on Health 19 April 2007, EPF joined two major projects:

- EUROHEALTH (Mapping European Health Research Area Accessible) – led by Karolinska Institute - which aims to disseminate information about ongoing FP6 funded projects and their results, by making it easily accessible to the general public.
- RESPECT (Relating Expectations and needs to the Participation and Empowerment of children in Clinical Trials), led by the University of Göteborg – which aims to identify the needs of children and their families as related to outcomes in clinical trials.

## 19. Communication with members – Save the Date – Autumn Seminar

It was highlighted during EPF's AGM (9/10 June 2007) that for better communication between EPF and its members, it would be very useful to enhance cooperation between staff and share newsletters policy papers etc in a more systematic way - EPF will be sending specific correspondence to the members on this issue in the next couple of weeks

Save the Date!

Please also note that EPF is organizing its "Autumn Seminar" next November (26-28). It will be a good time for our members' representatives to get the latest information the EU legislative process and current EU health policy work, and to enhance advocacy or media skills. A programme and registration form will be sent to all members before the summer break.

## 20. Preliminary Diary for second half of 2007

DATE	EVENT	PLACE	ATTENDANCE
30 June	Cancer meeting 30 June	Frankfurt	Nicola Bedlington
30 June	Information to Patients Consultation deadline		
5 July	Meeting for the preparation of EPF next Spring Conference (2008)	Brussels	Nicola Bedlington Roxana Radulescu
6 July	American French Pharmaceutical Conference	Brussels	Nicola Bedlington
9 July	GSK Advisory Board	London	Nicola Bedlington
10 July	Meeting with CEO of IAPO	London	Nicola Bedlington
10 September	EFPIA Think Tank Meeting	Brussels	Anders Olauson, Roxana Radulescu
12 September	Evening meeting with EPF funders	Brussels	EPF BOARD

13 September	Joint Board Meeting with CPME board meeting	all day	Brussels	EPF BOARD
25 September	FP7 High Level Advisory Meeting		Brussels	Anders Olauson
26 September	Federation of Nursing Regulators		Dubrovnik	Nicola Bedlington
4-6 October	European Health Forum Gastein		Gastein	Nicola Bedlington
11-12 October	EPF Board Meeting		Brussels	EPF BOARD
18 October	EPOSSI Meeting		Copenhagen	Anders Olauson
8 November	HCPC Meeting		Copenhagen	Anders Olauson, Nicola Bedlington
9 November	EFPIA Think Tank			Anders Olauson, Nicola Bedlington
26-28 November	Autumn Advocacy Seminar		Brussels	
28 November	EPF Board Meeting		Brussels	EPF BOARD