



europeanpatients' forum

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Issue 2: 24 August, 2006

Dear EPF members and friends,

Many thanks for the positive feedback from many of you regarding the first issue of the EPF internal mailing and for your input on the various policy themes. We look forward to hearing more from you in future with regard to dates of your key meeting to add to the EPF calendar.

There are a number of exciting developments over the coming months, both within EPF and externally. Our working groups will be meeting in early September, and we will report on developments in the next issue. Of particular importance right now is our strategic planning process (please see section 1 of this mailing). It would be very useful to get your initial views on EPF's strategic goals, at the very start of this work.

The Pharmaceutical Forum is a key milestone at the end of September, and we have chosen this time to launch the new EPF website (please see section 5 of this mailing for more information).

Over the coming weeks and months EPF will also be working vigorously with the European Parliament to address the draconian budgetary cuts to the EU Public Health programme, and you will be invited to get involved in an email campaign linked to this.

If you would like to contribute a specific article or section to this mailing, please contact the secretariat by Friday 22 September with a brief text and web links.

In the meantime, we wish you an excellent 'reentrée' and good luck in your current projects and ventures new.

Warmest greetings

Anders Olason
President

Nicola Bedlington
EPF Director

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Date of the next issue: Tuesday, 26 September, 2006

1. EPF strategic planning process –*ACTION*

As you are aware, EPF has set up a strategic planning working group and its first meeting will take place 7th September. The draft terms of reference for this group are available from the secretariat, should you be interested.

In order to help with the preparations of this first meeting, it would be very useful if your organisations could identify three strategic goals that you feel EPF should pursue during the next five years. We would need to have this by 6th September at the latest to feed your ideas into discussion on 7th. The planning process will build in an ongoing consultation with EPF members and you will receive further information on this after the first meeting. In the meantime, we look forward to your feedback on the above.

2. Re-launching the Patients' Interest Group in the European Parliament - *ACTION*

In order to pursue its work with the European Parliament, EPF will be re-launching the MEP patients' interest group in the European Parliament. A small group of committed MEPs is being identified. If you know, through your network, of MEPs who might be particularly interested in being involved in this work, please contact the secretariat. A launch meeting will be organised during the course of the autumn.

3. Date for the European Patients' Conference March 2007 – *INFO*

The European Patients Forum will be organising a Patients' Conference in spring next year to build on the achievements of previous events and to dialogue with a number of key external stakeholders on current health policy debates. The event will be supported by GSK and Pfizer. It will take place in Brussels on 21, 22 March 2007. Further details will be forwarded in the next issue of the EPF internal mailing, following the next planning meeting on 21 September.

4. EPF's response to the Transparency Directive - *INFO*

The Green Paper on Transparency initiative was **published on 3 May 2006**. However, the EU is not starting from scratch in this field: during the last 5 years different documents have also been trying to answer questions in order to improve transparency and facilitate a better communication policy between European institutions and civil society through:

- ❖ An "access to documents" legislation providing the framework for access to unpublished documents of the EU institutions and bodies
http://europa.eu.int/eurlex/pri/en/oj/dat/2001/l_145/l_14520010531en00430048.pdf
- ❖ Staff regulation:
http://ec.europa.eu/dgs/personnel_administration/statut/tocen100.pdf
- ❖ A Code of Conduct for Commissioners:
http://ec.europa.eu/commission_barroso/code_of_conduct/code_conduct_en.pdf
- ❖ A guide for the Commission staff in their relations with the public:
http://europa.eu.int/comm/secretariat_general/code/docs/code_en.pdf
- ❖ Minimum standards for consultation of interested parties:
http://europa.eu/eurlex/en/com/cnc/2002/com2002_0704en01.pdf

Background

The European Transparency Initiative aims to strengthen ethics rules for EU policy-makers and the estimated 15,000 lobbyists, NGOs and other pressure groups who seek to influence them in Brussels.

The publication of the 'Green Paper on European Transparency' officially started the public debate on lobbying, on the introduction of legal obligations for Member States to publish the information about the beneficiaries of funds under shared management, as well as on the Commission's consultation practices.

Transparency and accountability of the EU policy process are key elements to maintain and strengthen the trust of citizens. In order to ensure that the Union is "open to public scrutiny and accountable for its work", the Commission adopted and launched on November 2005 the Transparency Initiative:

http://europa.eu.int/comm/commission_barroso/kallas/doc/transp_report_en.pdf.

The launch of a Green Paper on the same topic in March 2006, and on 3rd May 2006 the Green paper on Transparency Initiative was launched:
http://europa.eu.int/comm/commission_barroso/kallas/doc/com2006_0194_4_en.pdf

EPF's Response: Green Paper Transparency

The European Patients' Forum with its members discussed the issue of transparency in relation to the Green Paper at its Annual General Assembly on the 22nd June 2006. Notes can be found on the web site along with the



EPF_Lettertranspare
ncy response.doc



TransparencyBriefjul
ydraft2.doc

full briefing and the full response.

5. Update with regard to the new EPF website - *INFORMATION*

At the end of July EPF ordered a new domain name, www.eu-patient.org, and new host server, which allows increased flexibility, creativity and much improved access than the current EPF's website.

At the beginning of August an additional European domain name www.eu-patient.eu was ordered. Both domains are now active and ready to use.

The new website presently under construction will be available by the end of September 2006 and currently much work is under way on developing the architecture and design. At the moment we are concentrating on simple, innovative menu, preparing subscription and contact forms (which will allow visitors to subscribe for EPF news and to contact the secretariat directly from the website), logos, website search engine, etc.

From September, the first online version of the website will be available, new email accounts (addresses) will be created, with an active SPAM filter, there will be a "Restricted Area" developed, which will allow security and password protection to the online document library for EPF members

6. EU consultation on drugs policy - *ACTION*

Green Paper on the role of Civil Society in Drugs Policy in the European Union Action

The European Commission has launched a wide consultation, by means of a Green Paper, to explore how best to organise a continuous dialogue with civil society organisations **active in the drugs field** to ensure their knowledge and expertise is taken account in the EU policy-making process, in particular the implementation of the **EU Action Plan on**

Drugs 2005-2008 http://eur-lex.europa.eu/LexUriServ/site/en/com/2006/com2006_0316en01.pdf

Interested parties should submit their comments by 30 September 2006.

The European Patients draft response can be viewed in the briefing paper [Green Paper on the role of Civil Society in Drugs Policy in the European Union \(Action\)](#).
([briefingcivil...](#))

If you would like to contribute to this response, please send your comments to the secretariat by 20 September.

7. Report on GRIP conference, Budapest, June 2006 - *INFO*

47th Annual General Meeting of the European Association of Pharmaceutical Full-line Wholesalers (GIRP), Budapest, June 2006

EPF President, Anders Olauson represented EPF at the 47th Annual General Meeting of the European Association of Pharmaceutical Full-line Wholesalers (GIRP), Budapest, June 2006. GIRP's president, M René Jenny highlighted at the meeting that 'Advancing the single market for medicines in Europe is our core goal. It would result in immediate market access for all EU citizens to the most innovative medicines.'

Anders presented EPF's vision and raison d'être and stressed the importance of partnership between EPF, GIRP and other stakeholders in promoting health equalities across Europe.

Anders said 'This meeting provided the opportunity to meet key players in the wholesalers field, and enhance their understanding about the patients' perspective and their potential contribution..... [Anders please complete](#)

For a copy of Anders' presentation, please contact the secretariat. For more information about GIRP and the outcomes of the Budapest meeting please visit www.girp.org

8. Report on AEGSP conference, Athens, June 2006 - *INFO*

Conference of the European Association of the Self Medication Industry (AESPG), 7-9 June, Athens 2006

Anders Olauson also represented EPF at the AESPG Conference 'European Self Care – Realising the Vision.

The main themes dominating this year's conference were:

- Innovation in self-care and how this is (or can be) supported by the various stakeholders; and
- The development of a truly European self-care market through the removal of barriers holding back this development.

These debates focused in particular on:

- the simplification of the regulatory burden for pharmaceutical companies – many of which are and small and medium-sized enterprises (SMEs),
- the shortening of regulatory timelines,
- the use of trade names for non-prescription medicines and
- the lifting of controls on the manufacturer prices of non-reimbursed medicines.

In his presentation, Anders highlighted a number of fundamental questions for the European patient community in relation to self-care

- Is the move of medicines from prescription to non-prescription good?
- What about reimbursement?
- Is the provision of more choices/treatment options good from a patients perspective?
- Has the move towards self-care a positive impact on people's attitude towards health?
- Does it make them more responsible?
- Can the information to patients via health professionals, media, government bodies, industry be improved?
- Could medical doctors and pharmacists do more to support people wishing to practise self-care?

EPF will continue dialogue with AESPG and other stakeholders in developing an appropriate response to these questions.

For a copy of Anders' presentation, please contact the EPF

secretariat; For a copy of the conference report please visit the AESPG web-site www.aespg.be

9. Feedback from a meeting with the Finnish Presidency - *INFO*

Nicola Bedlington met with Arno Koho of the Finnish Permanent Representation to present EPF short- term policy goals and to learn more about the Finnish Presidency's work on mainstreaming health into all policy areas. A publication on health mainstreaming will be launched at an EU Presidency event on 20, 21 September. EPF will present a review of the publication from the perspective of EPF's member organisations and including our recommendations in the context of mainstreaming to be fed in to later discussions under the presidency.

Anders Olauson will also have the opportunity to meet Finnish Health Minister, Liisa Hyssälä at the informal lunch hosted by the Presidency on the day of the European Pharmaceutical Forum 29 September 2006

10. Medical Devices Update - *INFO*

Latest info and next steps

- The Parliament's ENVI committee is set to adopt its report on 4 October 2006 (see [draft report](#)) and the Parliament's first reading is set to take place on 14 November 2006.
- The Council is expected to reach a political agreement on the proposal on 30 November 2006.
- The Commission [published](#) a [proposal](#) for a directive amending the three medical devices directives in December 2005.
- The Commission held a [public consultation](#) (in May-June 2005) on its [draft proposal](#) modifying the directives on implantable medical devices, medical devices and in-vitro diagnostic medical devices.

Finnish Presidency and Medical Devices Directive

In addition to promoting 'Health in all Policies', the Finnish Presidency is expected to hammer out political agreements on Health programme 2007-2013, medical devices and advanced therapies.

The main EU legislative proposals on the table during the second half of the 2006 are the [Health programme 2007-2013](#), the revision of legislation on [medical devices](#) and a proposal for a Directive on [advanced therapies](#); on all of which the Council is expected to reach a political agreement on 30 November 2006. (Finnish Presidency [Health in all policies - background leaflet](#) (1 August 2006).

Medical Devices Directive Amendments (Draft Opinion Document)



MedDevopinion.doc

The European Patients' Forum comments of the 14th July 2006 concerning the proposal reviewing the Directive 93/42/EEC which is intended to establish a harmonised regulatory framework for marketing medical devices in the European Union are as follows. For the [full briefing Opinion Document, EPF letter on medical devices](#)



Medical
Devisesletter.doc

[\(briefing medical devices2aug\)](#)

11. Structural Funds – EPF briefing and position on involvement of patients' groups – *ACTION & INFO*

EPF has prepared a **briefing** [Zil we need a link here to Don's doc](#) on the



EPFStructural

structural funds ([FundsAugdraft1.doc](#)) that we hope you find useful. You will be aware from previous papers, that EPF will be striving towards ensuring that a criterion for funding on health related projects should be the involvement of a representative patients organisation and appropriate budgetary allocation to resource their involvement. EPF is in the process of organising meetings with the Commission and member states to advance this work. We would be very interested in knowing if your organisation is working specifically on the EU structural funds, and examples of good practice on patient involvement.

12. 7th Framework Programme on Research and Development – EPF briefing and position on involvement on patient groups - *ACTION & INFO*

EPF has also prepared a **briefing** [Zil we need a link here to Don's doc](#) on



EPFBriefing Seventh
Framework briefing A

the 7th Framework programme ([Framework briefing A](#)). Again from a patients' perspective, we are arguing in favour of the involvement of patients organisations in all health related projects, and the resources to facilitate their meaningful participation.

To develop this work, it would be very helpful to get information from your organisation on good and bad experiences in relation to previous Framework Programmes.

13. Review of EU Pharmaceutical Legislation & Information on medicines from pharmaceutical companies to consumers – *ACTION & INFO*

EPF has prepared a **briefing** [Zil we need a link here to Don's doc \(EPF briefing info patients.doc\)](#) on the Review of EU Pharmaceutical Legislation & Information on medicines from pharmaceutical companies to consumers. This briefing gives an outline of the development of the pharmaceutical directive on information to patients, and contains a summary of research into patient needs for information and its sourcing. From a patients' perspective, we are arguing in favour of the involvement of patients' organisations in all health related projects concerning information to patients.

14. EPF calendar for September/October 2006

Date	Event
7 September	Second Workshop on Health Democracy Briefing Notes (Sanco) .
7 September	EPF working group on strategic planning.
8 September	EPF board meeting.
12 September	Inaugural Meeting of the European High Level Forum on Pharmaceuticals – European Parliament Life Science Circle , Invitation to EPF to represent EPF on discussions with MEP's Commissioners and stakeholders about Life Sciences, reform and legislative impacts within the EU.
14-15 September	Conference under the EU Finnish Presidency Nanotechnology, Helsinki, Finland. EPF representative: Susanne Palkonen
18-19 September	Conference " Building a Strategy for Patient Safety in Europe " which will be held under the auspices of the European Commission in Luxembourg. EPF representative: to be decided
20-21 September	Finish Presidency Meeting on Mainstreaming Health in all areas of EU policy.
20 September	Friends of Europe's Café Crossfire lunch debate " EU policymakers' options on patient information " in Brussels. EPF representative: Nicola Bedlington
21 September	EFPIA – EPF Think Tank. EPF representative: Nicola Bedlington

29 September	High level Pharmaceutical Forum meeting. EPF representative: President Anders Olauson
30 September –1 October	EPF board meeting in Brussels
4-7 October	“European Health Forum Gastein” Salzburg, Austria. Exchanging of experience and networking. EPF representative: Nicola Bedlington
11 October	EMA workshop in London, UK. “Neonates Workshop” – Issues related to the investigation of medicinal products intended for neonatal use. EPF representative: Vice President Jean Georges
18-19 October	Conference “New legislation – the right impact?” The conference will look at how the legislator’s original objectives compare with reality on the ground. This will facilitate the debate on areas where further guidance might be appropriate. It will also be the basis for developing concrete steps towards “better regulation” for non-prescription medicines in Europe. EPF representative: Member of EPF board