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## **EU-Council Presidency plans no discussions of European Commission's proposal on information to patients on medicines**

It seems that the current Spanish Presidency of the EU Council has no interest in promoting the European Commission's proposal aiming at providing the public with more information about prescription medicines. The Presidency has not provided in fact for any discussions of the European Commission's proposal on 'pharma-package' – now more than a year old – during its term of office (January 2010 – June 2010).

As you remember, the 10/12/08, the European Commission has published a communication including three legislative proposals (so-called the '[Pharma-package](#)'), with the objective:

- a) to revise the regulation on pharmacovigilance (medicine safety and monitoring) in order to protect public health and improve the working of the internal market;
- b) to revise the regulation on information to patients, in order to set harmonised rules on information that drug companies can give to patients in the internet age,
- c) to examine the possibilities for drafting a Directive on counterfeit medicines with the objective to improve traceability of products and crack down on counterfeiting.

Last week, a Spanish health ministry spokesman said it was not proper for information on such medicines to go direct to patients without the filter of a health professional. The spokesperson confirmed that the subject does not figure in the agenda of the Presidency, adding that no Member-State have asked for it to be discussed.

The European Commission presents its proposal as a response to the spread of information on the internet – mostly unofficial and frequently misleading. One of its main aims is to create a regulatory framework in which authorized information on products can be provided – including information from drug firms.

But health campaign groups have accused the European Commission of offering pharmaceutical manufacturers an open road to advertising.



At the European Parliament's level, the discussion was scheduled to begin on the 27 January on this issue within the committee on industry and research, but this has now been postponed. **Christofer Fjellner**, a Swedish centre-right MEP who is responsible for the report of the EP environment and public health (ENVI) committee on the same subject, underlined however his wish to produce a draft report in February.

By contrast, the Spanish Presidency is moving ahead rapidly with the two other elements of the pharma package – measures to improve monitoring of medicines on the market (known as pharmacovigilance), and combat against counterfeiting. 17 meetings of the Council working party have already been scheduled, in order for Member-States officials to examine these proposals.

Draft reports on both these proposals were discussed for the first time in the European Parliament's environment and public health (ENVI) committee on 26 January, and both are scheduled for a committee vote in April. Signs of compromise are already emerging on some of the points that have proved contentious until now amongst MEP's.

*You may consult the documents discussed in this article at the following e-sites.*

Communication of the European Commission (Pharma-package): <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0666:FIN:en:PDF>.

Draft report of MEP Linda McAvan on the 'pharmacovigilance':  
[http://www.europarl.europa.eu/meetdocs/2009\\_2014/documents/envi/pr/798/798819/798819en.pdf](http://www.europarl.europa.eu/meetdocs/2009_2014/documents/envi/pr/798/798819/798819en.pdf)

Draft report of MEP Marisa Matias on counterfeit medicines:  
[http://www.europarl.europa.eu/meetdocs/2009\\_2014/documents/envi/pr/800/800835/800835en.pdf](http://www.europarl.europa.eu/meetdocs/2009_2014/documents/envi/pr/800/800835/800835en.pdf)

All the documents mentioned in this article are also available at the FEPI Secretariat, both in electronic and hard copy.

### **Conferences and Events to come**

- **European Voice Health-check debate:** [‘The right to know: Should information to patients be restricted?’](#)
  - o Once again the Brussels weekly newspaper on EU affairs is organizing its roundtable on health-related issues. This time the topic of the debate will focus on info to patients.
  - o **Where?** Stockholm Region Representation, Avenue Marnix 28, B-1000 Brussels
  - o **When?** Wednesday 24 February 2010 - 12.00-15.00
  - o FEPI will be represented by Mr. Laurent Louette, Policy and Press Officer
  
- **CEPLIS Health Working Group.**
  - o The CEPLIS Working Group on Health, chaired by FEPI Vice-president Prof. Sasso will tackle the current issues related to health at the EU level.
  - o **Where?** CEPLIS' premises, 70 Coudenberg, B-1000 Brussels
  - o **When?** Wednesday 10 February 2010 – 09.30 – 11.00
  
- **eHealth Ministerial Conference & eHealth Week 2010**
  - o The conference's theme – "eHealth for Sustainable Healthcare Delivery: global challenges through local actions" – acknowledges the pressing perspective of a rapidly ageing European society, where the progressively extended life expectancy and the consequent increase in the prevalence of chronic diseases are globally posing serious challenges to the sustainability of national

health systems. The conference will present how and why eHealth can make the difference in facing such a global challenge.

- **When?** 15/03/10 – 18/03/10
- **Where?** Barcelona, Spain

- **World Health Professions Conference on Regulation**

- The aim of the WHPCR 2010 will be to shape the future of health professional regulation within the context of global health systems' redesign and evolving roles, always keeping in mind that public protection is the primary objective of health professional regulation.
  - **Where?** Centre International de Conférence de Genève (CICG), Geneva, Switzerland.
  - **When ?** 18 & 19 February 2010
  - FEPI will be represented by Dr. Theodoros Koutroubas, Senior Policy Adviser.
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