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ЕВРОПЕЙСКА АСОЦИАЦИЯ НА СТАРШИТЕ БОЛНИЧНИ ЛЕКАРИ
ASOCIATIA EUROPEANA A MEDICILOR DIN SPITALE

Info-Document :	**AEMH 11-100**
Title:	**Revision of the Information to Patients Directive**
Author :	**EPHA & European Commission**
Purpose :	**Info-documents disseminated by the AEMH European Liaison Office do not necessarily reflect the opinion of the AEMH and its Board. Info-documents are meant to inform, to raise awareness, to alert, to launch a debate, to incite taking action,.....**
Distribution :	**AEMH Member Delegations**
Date :	**Sent by e-mail 11th October 2011**

To the AEMH Member Delegations

The commission released today a revision of the “Information to Patients Directive”. You can find the revised text here attached.

Here below the analysis by EPHA – the European Public Health Alliance – which they published in a Press Release.

Next steps: the revised proposal will now be debated in both in the European Parliament and the Council.

Best regards

Brigitte Jencik

AEMH-EU Liaison Officer

PRESS RELEASE - FOR IMMEDIATE RELEASE

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Finally: real progress on the Information to Patients Directive?

Brussels, 11 October 2011 – The European Commission released today its revised proposal on ‘Information to Patients’ which looks at different ways of providing information on prescribed medicines and the role of the pharmaceutical industry in providing such information on their products directly to people. The public health community cautiously welcomes this controversial and long awaited proposal.

“The previous proposal was just a disguised way of giving pharmaceutical companies enough flexibility to promote their products directly to the public, in order to boost the sector’s growth. EPHA welcomes the new tone of the proposal which has taken the public health perspective on board. We congratulate Commissioner Dalli for producing a revised version of the proposal. However we remain cautious of the man derogations and hope that this is resolved in discussions with the European Parliament and the Council.” Stated Monika Kosinska, Secretary General of EPHA.

EPHA – the European Public Health Alliance – Europe’s leading NGO advocating for better healthreleased its position earlier this week in which the Alliance highlights the impact the provision of information can have on Public Health as well as the obligations of the pharmaceutical industry.

Comparing the European Commission’s proposal with the recommendations of the public health community, Kosinska stressed that “we note with satisfaction that the pharmaceutical industry will have obligations to provide certain information after authorisation from competent authorities and not only the possibility to make available promotional materials of their choice. It is of utmost importance that this is regulated by law and not by the pharmaceutical industry themselves, despite the opt-outs that we can see built in to this draft.”

The internet has been a ’sticking point’ in the debates surrounding Information to Patients. EPHA agrees that the internet can be a useful place to provide information, however in the case of medicines information, this should be limited to the Patient Information Leaflet and other medicines safety information. This should be accessed though a portal or database with a single point of entry so as to avoid confusion and the proliferation

of misleading information. Unfortunately, this is not the approach chosen by the European Commission which still prefers 'information' to be provided by pharmaceutical companies directly on their website.

"The role of the internet should be limited to providing access to the Patient Information Leaflet and medicines' safety information from a single portal: providing it on pharmaceutical company websites would be misleading, confusing and inappropriate." Regrets Kosinska

The previously proposed directive did not meet the needs of people for reliable, objective, unbiased, user-friendly and comparative health information. In the coming months, EPHA will commit to further voice the concerns of patients, health professionals and other public health organizations on which information people should receive on prescription medicines.

END

Note to Editors:

1. EPHA is is the European Platform bringing together public health organisations representing health professionals, patients groups, health promotion and disease specific NGOs, academic groupings and other health associations. Our vision is of a Europe with universal good health and well-being, where all have access to a sustainable and high quality health system : A Europe whose policies and practices contribute to health, both within and beyond its borders.

2. EPHA position on Information to Patients is accessible at http://www.epha.org/a/4775 <http://my.epha.org/sites/all/modules/civicrm/extern/url.php?u=219&qid=158497>

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EUROPEAN COMMISSION - PRESS RELEASE

Empowering the patient: European Commission wants clearer rules for information on prescription medicines

Brussels, 11 October 2011 – Today, the European Commission adopted revised proposals clarifying the information that industry can supply to the public on prescription-only medicines.

Patients are increasingly interested in learning more about the medicines they take and want more of a say in how they are treated. At the same time, patients are confronted with a growing volume of information from various sources and often find it difficult to identify reliable information about medicines. The increased use of the internet over recent years makes the need for clarity even more important. Online information on medicines must be accurate and reliable.

In its revised proposals, the Commission amends its original proposals of 2008 and responds to requests from the European Parliament. The proposals maintain the current advertising ban on the prescription-only medicines and foresee that:

- **Only certain information** on prescription-only medicines would be allowed. For example, information on the label and on the packaging leaflets; information on prices; on clinical trials; or on instructions for use.
- Information on prescription-only medicines would only be allowed through **limited channels of communication**. For example, information on officially registered internet websites; or printed information made available when specifically requested by members of the public. A publication in general print media will not be permitted.
- The information must fulfil recognised **quality criteria**. For example, it must be unbiased; it must meet the needs and expectations of patients; it must be evidence-based, factually correct and not misleading; and it must be understandable.
- As a general principle, information which has not been approved before needs to be **verified by competent authorities prior** to its dessimination.

Revising these proposals has also been an opportune moment to further strengthen the current system for **monitoring the safety of medicines** (known as the *pharmacovigilance* system) in the European Union.

John Dalli, European Commissioner for Health and Consumer Policy , said: *"The revised proposals put rights, interests and safety of patients first. They oblige industry to provide certain key information to patients and set clear rules for additional, voluntary information on prescription medicines. In addition, they further strengthen the control of authorised medicines."*

Next steps

The revised proposals will now be debated by both the European Parliament and the Council of Ministers.

Further information:

http://ec.europa.eu/health/human-use/information-to-patient/legislative-developments_en.htm

http://ec.europa.eu/health/human-use/pharmacovigilance/index_en.htm

http://ec.europa.eu/health/human-use/index_en.htm

Text of the amended Directive:
http://ec.europa.eu/health/files/patients/ip_10-2011/dir_ip_2011_en.pdf