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EUROPEAN FEDERATION OF PATIENTS' ASSOCIATIONS FOR ANTHROPOSOPHIC MEDICINE

European Commission
Directorate-General Enterprise and Industry
Consumer Goods - Pharmaceuticals
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Leidschendam (Netherlands), 7 April 2008

Subject: Public consultation on "Legal Proposal on Information to Patients"

This document is a response to the European Commission Directorate General 'Enterprise and Industry' consultation on a 'Legal proposal on Information to Patients' and was submitted to the Commission on 7 April 2008.

- EFPAM is very pleased to see that the European Commission earnestly wants to solve the asymmetry of information between providers and patients. However, we do not feel completely confident that the proposal will adequately deal with the problem.

- EFPAM is very worried that the present proposal does not serve the first of the main policy objectives (Providing "citizens of EU Member States with understandable, objective, high-quality and non-promotional information about the benefits and the risks of the medicines"), since it opens the possibility for more advertising on prescription-only medicines in an other, legally allowed, way under the cover of information provision.

- EPPAM strongly supports that healthcare professionals should remain the primary source of health information. Printed information or information provided through other information sources (e.g. Internet etc.) should be seen and treated as complementing the information given by health care professionals. Media-based information sources will never be able to replace human interaction, both in the field of content, understandibility, quality and individual needs of the patient and his or her health situation. Health care professionals are often involved by patients to help them to compare information, find alternatives for therapies and support patients in reaching health care related decisions.

- EFPAM believes that health information in general and information on OTC-medicines and prescription-only medicines should be seen as a whole, and although perhaps legally be treated in different ways, be part of an overall health information policy, although specific criteria may have to be formulated for each area.

- EFPAM would like to see the whole policy area of health information to be transferred from the competence of DG Enterprise to DG SANCO. Whereas DG Enterprise naturally has a focus on industry, DG Sanco is responsible for health and health information.

EFPAM would like to draw the attention of the European Commission to the following subjects:

## **Key ideas of the forthcoming proposal** (Chapter 3)

Provision of rules that harmonize practices on information provisions to patients in Member States (Introduction)

> The Commission aims to create a framework for industry to provide certain information on their products to the European public on the basis of making a distinction between 'advertising' and 'information'. By doing so the Commission believes that it is creating a framework that should enable EU citizens to get “objective information from reliable sources”.

- EPPAM believes that a distinction between advertisement and information providing is not easily defined.
  *E.g. If a doctor gives information to a patient on a certain medicine, is he than neutral enough, in other words: is he promoting a certain medicine (= advertisement) or is he giving information? Is the GP himself getting information from the pharmaceutical company in question or is he influenced by advertising-like approaches from the industry? In other words: information and advertising can not always to be distinguished clearly.*

- EFPAM believes that a conflict of interest could arise between the business interests of the pharmaceutical industry and health care providers and their ability to be primary actors in providing 'objective' information. This possible conflict of interest should be addressed properly.

- EFPAM would like see that information in advertisements should not use wording or lay claims that cannot be backed by the information given in the information provided on the prescription medicine in question.

- EFPAM is not sure what is meant by "reliable sources" in the introduction to chapter 3.

- Information and communication in general, very often is culturally and intellectually specific. Each Member State should be allowed to provide and communicate this information in the best method to suit the needs of its population. EFPAM appreciates the fact that the content of the information may be universal, but the methods of informing may have to be different in order to achieve the aims. Harmonisation of practices should allow sufficient freespace to member States.

- EFPAM does not consider the proposal be adequately dealing with the problem of “unequal access of patients and the public at large”. As stated already the citizens of the EU Member States are culturally and intellectually divers and no one solution will be able to solve the problem sufficiently.

Provisions on advertisement (Paragraph 3.1)

- EFPAM agrees that the present rules on banning advertisement of prescription medicines to the general public should be maintained.

Scope, content and general principles of the new legal provisions (Paragraph 3.2)

> The Commission states that communication not covered by the definition of advertisement should be regarded as information. Clear criteria should distinguish the information that is ‘allowed’ from the information that is ‘not allowed’.

- EFPAM finds it peculiar that information (in the definition that information is everything but

advertisements[1]) is to be compatible with approved summaries of product characteristics and patient information leaflets. We would like to see the opposite: information on prescription-only medicines should be the basic source and summaries, patient information leaflets and other related informational products should be compatible with the information on prescription-only medicines. Although the wording may be different in these spin-offs, the message should be in line with the said information. This information on prescription-only medicines deserves a proper workable definition.

- It remains unclear how the approved summaries and patients information leaflets are vetted. Who is responsible for approving summaries?

- Advertisements for prescriptions medicines are information sources and should be treated as such. This means that subjective and scientifically not proven, inaccurate or incomplete information etc. should not be allowed. Neither should anecdotes, testimonials from users and jubilant language should be forbidden.

Type of actions, content and monitoring of information (Paragraph 3.3)

***'Push' and 'Pull'***

The Commission states that "a distinction" should be made between the cases where the patient is passively receiving the information (push) or actively searching for the information (pull) in terms of the monitoring mechanism.

- EFPAM does not believe that this distinction is necessary. There is not one way of informing the public and surely this should be left to the pharmaceutical companies under the criteria to be formulated by the Commission. It would also overcomplicate the work of any national co-regularory body.

## Quality criteria (Chapter 4)

The Commission states that "all information provided to citizens should fulfil specific criteria" and that "comparisons between medical products should not be allowed".

- Does this mean that health care professionals cannot discuss various options in regard to medicines with their patients anymore? Clearly, this can not be the case. If this criterion has been included on purpose, than EFPAM is strongly against this.

- The proposals of the Commission do not include any reference as to the way the information is to be presented.
  From EFPAM's point of view this is of the utmost importance.

- EFPAM wonders what the Commission sees as "objective", "unbiased", but especially "patient-oriented". Information that can be understood by Professor X of the University of Y in Z-land does not necessarily have to be understood by Mrs A in a small village in rural B-land. Different target groups, sometimes need a different approach.
  EFPAM regrets that the Commission has not addressed this major problem.

- Of course EFPAM supports the Commission's criteria on accessibility, transparency, relevance, but wonders what the Commission means by "approved information". This is too vague to make sense.

- EFPAM strongly demands the provision of information on alternative therapies for the medical condition concerned to those citizens requiring this.

[1] This definition in itself is not without problems; advertisements can be seen as information as well, or would it mean that advertisements cannot include information?

## Proposed structure for monitoring and sanctions (Chapter 5)

- The proposed structure for monitoring is not without problems. EFPAM worries about the impartiality of the foreseen bodies. Because regulatory bodies and industry very often recruit from the same pool, objectivity, unbiased opinions etc. may come under stress.

- The pharmaceutical industry and medical lobby in Europe is very strong and EFPAM fears the sufficient independence and strength of these new regulatory bodies.

- The national regulatory bodies should also be able to oversee the addition of alternatives to the information about any prescription medicine they will have to control. Otherwise the whole purpose of information, namely that the patient will be enabled to form an unbiased complete judgment about his health situation, is impossible.
  EFPAM fears that these bodies will not be able to contribute in this field, due to the work load that would be involved with such a procedure.

- By giving an important role to “marketing authorisation holders” in the process of information provision EPPAM does believe strongly that the Commission will not be able to realise the proposed policy objectives. Furthermore, EFPAM is unclear of the fact how the proposal will avoid bureaucracy.

- Therefore EFPAM would welcome an Impact Assessment before moving forward with new legislation.