CPME/AD/consultation/090408/068/EN

CPME adopted, on 9 April 2008, the following document "CPME answer to the European Commission's consultation document on a legal proposal on information to patients " (CPME 2008/068 EN)

CPME answer to the European Commission's consultation document on a legal proposal on information to patients

In the introduction to the consultation document CPME notes the broad declared intention that health care professionals should remain the principal source of health information to the patient. Regarding this matter CPME wants to stress that the prescribing doctor is a fundamental supplier of information to the patient within the context of the patient-doctor meeting. Both the doctor and the patient are key stakeholders with regard to patient information.

The primary objectives listed in the consultation paper are to:

- establish a framework which provides citizens of EU Member States with understandable, objective, high quality and non-promotional information about the benefits and risks of their medicines.
- maintain the ban on direct-to-consumer advertising of prescription medicines, and ensure that there is a clear distinction between advertising and non-promotional information.
- avoid unnecessary bureaucracy

CPME's response is to the examine the proposals in the consultation paper with reference to these objectives.

<u>A framework of understandable, objective, high quality and non-promotional information</u>

CPME is very much in favour of providing unbiased information about pharmaceuticals to patients, (as well as to doctors), whether by means of patient

information leaflets or ”soft pull” methods. CPME is concerned that there should be a better definition of ”pull” methods of information provision, since it is against the active and direct provision by the industry of information to patients on prescription drugs. CPME is not opposed to the provison of information on the websites of pharmaceutical companies[1], but does not think it appropriate to allow the industry to inform patients directly by any other means.

The paper states (page 6) that information should be compatible with approved summaries of product characteristics and patient information leaflets. CPME agrees with this principle, but believes that if information cannot go beyond product characteristics and existing patient information then a logical step is to refine the leaflets to meet the quality criteria (described on page 7) that all information should be objective and unbiased, patient-oriented, evidence-based, up-to date, accessible, transparent, and relevant.

In general, the dissemination of ”non-promotional information” on prescription-only medicines by pharmaceutical industries is accompanied by messages encouraging patients to go to their doctors and ask for these medicines. In particular, there is no separation between so-called "pull" and "push" Information provided on the internet.

<u>Maintaining the ban on direct-to-consumer advertising, and ensuring that there is a clear distinction between advertising and non-promotional information</u>

CPME welcomes the intention to maintain the ban on direct-to-consumer advertising of prescription medicines. However, what is still missing, and which must be considered further before legal instruments are framed, is how a legal definition between advertising and non-promotional information can be described.

[1] Article 86.2 directive 2001/83/EC as modified by Directive 2004/27/EC

“The following are not covered by this Title:
- the labelling and the accompanying package leaflets, which are subject to the provisions ofTitle V,
- correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product,
- factual, informative announcements and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general drug precautions, trade catalogues and price lists, provided they include no product claims,
- information relating to human health or diseases, provided that there is no reference, even indirect, to medicinal products.

CPME has very considerable doubts that this is possible, and would like to see the Commission develop further proposals on this question and is ready to contribute actively to the work.

In CPME's view, if the pharmaceutical industry is allowed to "inform" patients directly, the result will be that in patients' minds a specific pharmaceutical product will be connected to a specific pharmaceutical company. CPME considers that this would amount to indirect advertising, and interfere with the freedom for doctors to make prescribing decisions based on clinical judgement.

Avoiding unnecessary bureaucracy

The consultation paper proposes a complex structure for monitoring and imposing sanctions. The proposals reflect the many problems that will be met in this very delicate area. The proposed national mechanisms to ensure that the information providers inform the dedicated national co-regulatory bodies upfront about their activities will burden the member states with additional burdens. In CPME's view, this process simply provides a means to assist the industry in creating more direct contacts with patients.

Successful regulation in this area, in the view of CPME, should build on the processes already developed in the context of EMEA and the network of national competent authorities.

In conclusion, CPME believes that the current proposals from the Commission are likely to result in an undesirable and costly increase in the prescribing and consumption of prescription drugs.