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On 18 November 2010, the CPME Executive Committee adopted the "CPME response to ENVI Committee vote on the 'Information to Patients' report by MEP Fjellner" (CPME 2010/116 Final EN)

CPME response to ENVI Committee vote on 'Information to Patients' report by MEP Fjellner

The Standing Committee of European Doctors (CPME) aims to promote the highest standards of medical training and medical practice in order to achieve the highest quality of health care for all patients in Europe.

CPME is also concerned with the promotion of public health, the relationship between patients and doctors and the free movement of doctors within the European Union.

CPME's members are the most representative National Medical Associations of 27 countries in Europe and works closely with the National Medical Associations of countries that have applied for EU membership as well as specialized European medical associations.

CPME's position on Amendments 119, 120 and 123

CPME is grateful for having been given the opportunity to provide comments on the amendments 119, 120 and 123.

Amendment 119
Amendment 119 is in line with CPME's policy

Amendment 120
As regards Amendment 120, given Article 100a par. 1, Title VIII.a applies to information provided by the marketing authorisation holder only – as opposed to information provided by health professionals to their patients - CPME agrees with the deletion of the exception for this kind of material.

The deletion of **Article 100a Para. 2 point a)** by **Amendment 120** is fine. General health related information without reference to medicinal products is subject to Art. 86 Para. 2 of the directive 2001/83/EC. Title VIIIa of the proposal exclusively deals with information to the general public by MAH with reference to medicinal products.

As for the deletion of **Article 100a Para. 2 point b)** by **Amendment 120**, possibly, the Commission wanted to cover pharmaceutical samples, which are governed by Art. 96 of the directive 2001/83/EC. Art. 96 is transposed into member states law. However, the formulation of the Commission's proposal can be misinterpreted as „material" can be anything. Instead of deleting the exception by **Amendment 120 and 123** the proposal could be clarified as follows:

"b) Material ***pursuant to Article 96*** provided by the marketing authorisation holder to healthcare professionals for distribution to patients"

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However, perhaps the deletion makes no difference as Art. 96 of the directive 2001/83/EC is applicable anyway - regardless of an extra reference in Article 100a Para. 2 point b).

Amendment 123
CPME's position is also in accordance with this amendment – please see above comments.

CPME comments on Compromise amendment 1 and on the consolidated amendments 1, 2 and 5 **as adopted on 28.09.2010**

CPME would like to outline some of its main concerns on the Compromise amendment 1 and on the consolidated amendments 1, 2 and 5. The latter amendments touch upon the relation of doctors and patients and raise ethical issues of relevance for the medical profession.

Compromise amendment 1

Article 100 1a (new)
Notwithstanding the provisions of this Title on information by the marketing authorisation holder, Member States shall ensure that objective, unbiased information is available to the general public and members thereof on

- *(a) medicinal products placed on the market on the territory of that Member State. Such information shall include, but shall not be limited to, the most recent summary of product characteristics and labelling and package leaflet of the medicinal product as approved by the competent authorities during the course of marketing authorisation and its renewal, and the most recent, publicly accessible version of the assessment report as drawn up by the competent authorities and its updates*
- *(b) (b) the diseases and health conditions which are to be treated with the medicinal product referred to in point (a); and*
- *(c) the prevention of such diseases*

Such information shall be made available in both electronic and printed form and in a format accessible for people with disabilities
The information shall be made available through the following channels:

- *(a) dedicated websites set up by the Member State or by a body assigned by the Member State and monitored by the competent national authority or by a body assigned by the competent national authority*
- *(b) (b) printed materials made available to the genera public*
- *(c) written answers to request for information of a member of the general public*

The Commission shall facilitate the sharing of best practices between Member States and shall adopt guidelines.
By [three years from the entry into force of the amending directive] the Commission shall present a report to the European Parliament and the Council on the practice of the Member States.

Concern: This amendment may establish the pharmaceutical industry as a provider of information on diseases. However, this should remain in the competence of the health care profession and the related official authorities. It also broadens the scope on info to patients on medicines by a tremendous new aspect: info on diseases.

- As Member States will be obliged to publish information linking medicines with diseases, patients may feel comforted in the idea that they can request a certain type of medicine for their treatment which could pressure onto the doctor to deliver the requested medication. This could also put pressure on the Social Health Systems as patients could demand a more extensive availability of medicines.
- "CPME has argued repeatedly that the inclusion of information on diseases would represent a task of herculian proportions" (CPME 2009/112 FINAL). Only information that is complete constitutes qualitative good information. Providing objective and verifiable information on diseases is perhaps a nice idealistic concept, but it is unobtainable in practice.
- CPME maintains that even though patient autonomy calls for diverse sources of information coming from industry or national competent authorities, amongst many others, the main source of information

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remains the health care professional through the privileged patient-doctor relationship. It is through this individual, intimate and confidential contact that available information can be transformed into patient knowledge. In these times of information surplus the invidualisation of information, tailored to the needs and requests of the individual patient is of foremost importance.

Concern: This amendment may increase the role of the pharmaceutical sector in a domain for which it is not competent.

- The information facilitated by Member States could also be provided and controlled through **an aggregated body.** This could imply that Member States could eventually delegate this task to the Pharmaceutical Industry without ensuring the accurateness of information or taking responsibility for the outcome of this delegation.

Consolidated amendment 1:

Article 1 – point 2
Amendment
4. The prohibition set out in paragraph 1 shall not apply to vaccination campaigns carried out by the industry and approved by the competent authorities of the Member States.

Such campaigns shall be approved by the competent authorities of the Member States only if it is ensured that objective, non-biased information is provided in the frame of the campaign by the industry on the causes of the disease, the efficacy of the vaccine, the suspected adverse reactions and the contra-indications of the vaccination.

Concern: direct advertisement from pharmaceutical industry

- Generally speaking, CPME has seen through numerous past examples how industry bypasses direct-to-consumer advertising by so-called public interest campaigns which tend to put pressure on health care officials, health care professionals and patients alike. For example, without advertising a specific product, the campaigns promoting the use and reimbursement of HPV (human papilloma virus) vaccines have proven that industry can very well go into advertising mode on prescription medicines. For these cases CPME has recommended (CPME 2009/112 FINAL) that a European Agency should be able to intervene. Prior to an intervention an ethical board should be convened by the European Agency in order to treat complaints about these types of advertisement (such as the Pharmaceutical Committee in decision 75/320/EEC). This power of intervention should also comprise sanctions.

Consolidated amendment 2:

Article 1 – point 5
2. This title shall not cover *materials on medicinal products subject to medical prescription* provided by the marketing authorisation holder to healthcare professionals for distribution to patients. *The healthcare professional may only actively give such material to the patient. The material shall state that the information is provided by the market authorisation holder.*

Concern: The pharmaceutical industry should not use the doctor's office as a means for promoting their products. The same "pull" versus "push" principles, as outlined before, have to apply in these circumstances. Information should be remitted upon request only and the information remitted should be validated by accepted sources. On the other hand it has to be stressed that remitting info alone does not provide knowledge about medicines or the correlating disease or diseases. The doctor, by customizing this information to the patient's particular case, shall provide the added value of individual information tailoring.
This should also apply for medicines or products handed out as samples (for social indications for instance).

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Consolidated amendment 5:

Article 1 – point 5
Amendment

Information on authorised medicinal products subject to medical prescription *made available* by the marketing authorisation holder to the general public or members thereof shall not be made available on television, radio *or newspapers, magazines and similar publications*. It shall only be made available through the following channels:

(a) deleted
(b): internet websites on medicinal products *registered and managed in accordance with Article 100h*, to the exclusion of unsolicited material actively distributed to the general public or members thereof;
(c) answers to specific requests for information *about a medicinal product* of a member of the general public
(ca) printed materials about a medicinal product prepared by the marketing authorisation holder pursuant to Article 100b upon specific request by a member of the general public

Concern:
- By addressing the provision of information (primarily) through the internet though, this might prove contrary to the goal of equal access of all citizens. In order to obtain health literacy, citizens have to become internet literate first and preferably in the English language. Is the aim then solely a declared one, or is there a policy of access for all citizens behind it? Furthermore, even if the internet is good platform it must be ensured that information is distributed evenly by age, gender, language, social status etc. Caveat: this could have the unwanted effect that even more channels for the distribution of information material to patients would be opened up to the pharmaceutical industry.
- Monitoring and enforcement measures destined to ensure that the information providers (market authorisation holders) comply with the established quality criteria, should primarily guarantee that the very thin line between objective information and promotional advertising is clearly identified and that the existing and future ban on direct-to-consumer advertising is vigorously enforced. CPME wishes to emphasize once more its' absolute opposition to direct-to-consumer advertising, be it in individual, generalised, direct or indirect formats.

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