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On 20 April 2010, CPME Executive Committee adopted the document "CPME comments on the EP draft report on info to patients on medicinal products subject to medical prescription" (CPME 2010/036 Final EN)

CPME comments on the EP draft report on info to patients on medicinal products subject to medical prescription

Draft report on the proposal for a Directive:

In general the draft report submitted by the rapporteur MEP C.Fjellner is a good initiative, moving in the right direction. The majority of the amendments can and should be supported by CPME. They reflect CPME's position as it has been repeatedly exposed and claimed at the successive Pharma Forums.

CPME welcomes the shift towards patients' rights

CPME supports the proposed amendments (e.g. amendment 3) insofar as they aim at shifting the Directive's focus on the patients and their rights and interests.

CPME believes that information to patients on pharmaceuticals is vital. Only the informed patient is an empowered and actively involved partner of the doctor. CPME therefore supports all efforts to improve information to patients.

CPME has consistently stated that Information to patients must be an instrument to safeguard public health, and not a means of promotion (cf. paradigm of Directive 2001/83). Information has to fulfill standards of objectivity, has to be transparent, independent and without any advertisement or commercial interest (cf. paradigm of Directive 2001/83).

Generally speaking, CPME believes that package leaflets and the summary of product characteristics (SPC) must be:

- easier to read and more patient friendly
- made available on the internet following the approval of the regulatory authority and with a link to the national regulatory authority
- available in all EU languages, stored in an European Medicines Agency or national regulatory authority database and accessible by all health care professionals

CPME also recommends that an additional pharmaceuticals/drugs factbox should be printed on top of the leaflet package (prepared on the basis of scientific standards, containing a

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realistic picture of desired and undesired effects and approved by the national regulatory body).

CPME would like to take this opportunity to reiterate that "information to patients" is a much broader issue than the current discussion that is being held on access to patients by the pharmaceutical industry.

Role of Health care professionals

CPME strongly supports the amendments (namely amendment 4) that underline the important role of healthcare professionals in general and doctors in particular in the provision of information on prescription-only medicines, and their involvement in the drawing up of guidelines (amendments 7 and 21). However, there is additional need in this regard: Information about prescription-only medicines that is made available to patients has direct implications on the patient-doctor relationship. On the one hand, the doctor, being the main source of information about rx medicinal products, will be confronted with patient requests for additional information and explanations regarding certain medicinal products. On the other hand, patients will actively demand to be prescribed certain medicinal products. For this reason, the Commission should not only consult patient organisations, but also doctor organisations, on issues relating to the implementation of the Directive and its application in the Member States. We strongly urge to change recital 15b (**Amendment 9**) and Article 100ka (**Amendment 24**) accordingly.

CPME supports the stance taken on information provided to patients versus advertising

The proposed reinforcement of information vs advertising and the proposed deletion of advertising through amendments 1 and 2 show that it is difficult to draw the line between the two concepts. To shift the focus away from advertising to strictly “pull” information procedures should be supported.

CPME supports the **the amendments 6, 15 and 16**, according to which information addressed to the general public about prescription-only medicines must not be disseminated via newspapers, magazines and similar publications. Only information actively "pulled" by the patient should be subject to Title VIIIa of the Directive. In this context, we regard **amendment 22** as absolutely crucial. If information published by the marketing authorisation holder on a registered website could subsequently be published on any other website, this would very probably lead to unsolicited information on medicinal products being published on a great number of general health related websites. Patients who consult those websites in search of general information on health related issues could thus be induced (e.g. by banners on those websites) to seemingly "pull" information on medicinal products.

CPME is concerned about the possibility for the Pharmaceutical industry to abuse patient organisations for advertising purposes

CPME recommends rejecting **amendments 5 and 13**, insofar as they refer to the “right of any other person or organisation, in particular the press or patients and patient organisations, to express their views on prescription-only medicinal products”.

In order to prevent industry-financed third parties, like patient organisations, from being used as an instrument to circumvent the restrictions applicable to information made available by

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marketing authorisation holders, we propose the following amendments to Recitals 9 (**amendment 5**) and 12 (**amendment 6**):

- Proposed new wording for **Amendment 5**: In accordance with the principle of proportionality, it is appropriate to limit the scope of this Directive to the making available of information on prescription-only medicinal products by the marketing authorisation holder**, or a third party acting on behalf of or sponsored by the marketing auhorisation holder**, as current Community rules allow the advertising to the general public of medicinal products not subject to prescription, under certain conditions.

- Proposed new wording for **Amendment 6**: Information to the general public on prescription-only medicinal products should only be made available by the marketing authorisation holder**, or a third party acting on behalf of or sponsored by the marketing auhorisation holder**, through specific channels of communication to avoid that the effectiveness of the prohibition on advertising is undermined by unsolicited provision of information to the public. Where information is made available by the marketing authorization holder**, or a third party acting on behalf of or sponsored by the marketing auhorisation holder**, via television, radio, or newspapers, magazines and similar publications, patients are not protected against such unsolicited information and such making available of information should therefore not be allowed.

In the light of recent case law and pending procedures according to which information provided by third parties, like journalists or healthcare authorities, can be classified as advertising, we support those amendments that explicitly address the provisions on information about rx medicinal products to information made available by the marketing authorisation holder or somebody cooperating with or financed by him. This particularly applies to the amendments 5 (first sentence), 6 and 12.

CPME is concerned about Amendment 11 on information campaigns

Amendment 11: There have been some bad examples of this principle being abused in the past. CPME therefore proposes to replace "**approved** " by the competent authorities of the Member States by "**in close collaboration with**" the competent....

Types of information on prescription-only medicinal products to be made available by the marketing authorisation holder

CPME would like to propose the following significant changes to **Article 100b (amendment 14)**:

According to **Article 100b § 2 (a)** the marketing authorisation holder is entitled to present the contents of the SPC or package leaflet in a different manner. The amendment proposed by the rapporteur aims at guaranteeing that the quality and reliability of the information is not affected in those cases. However, in order to make sure that this Article is not abused in order to highlight a medicinal product's benefits and minimise its risks, this Article should be supplemented by a provision corresponding with Article 100d (a), according to which "if the information refers to the benefits of a medicinal product, its risks shall also be stated".

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Finally, we propose to clarify Article **100b § 2 (c)** in order to make clear that information about ongoing scientific studies shall by no means be communicated to the public, as they are likely to create massive uncertainty in patients.
CPME also considers that it is paramount that industry should not be able to make clinical trials and tests available on a selective basis. They should also be forced to publish unfavourable test results. Information is also about completeness.

Methods of monitoring

Regarding article 100g §1 second indent, CPME would like to propose the following alternative wording:

"Member States shall ensure that there are adequate and effective methods of monitoring to avoid misuse when information on authorised medicinal products subject to medical prescription is disseminated by the marketing authorisation holder to the general public or members thereof.

Such methods shall be based on the control of information prior to its dissemination, unless
- the content of the information has already been approved by the competent authorities; or
- an equivalent level of adequate and effective monitoring is ensured through a different mechanism.

The methods may include the voluntary control of information on medicinal products by self-regulatory or co-regulatory bodies **under the supervision of an independent national authority** and recourse to such bodies, if proceedings before such bodies are possible in addition to the judicial or administrative proceedings available in the Member States."

Draft report on the proposal for a regulation amending Regulation (EC) No 726/2004

CPME strongly opposes amendment 2, reducing the deadline for the Agency to object to information submitted by a marketing authorisation holder to 20 days. This provision is directed at information that does not comply with the provisions of Title VIIIa of the Directive and therefore should be banned from publication in the best interest of patients. If the deadline for the Agency is reduced to 20 days, it will not be in a position to examine all requests in time. As a consequence, information that may not comply with the criteria laid down in Title VIIIa of the Directive will be deemed accepted and allowed to publish. This would seriously undermine the application of the Directive. One must not forget that the restrictions to the publication of information about rx medicinal products applies to information made available by the marketing authorisation holder only. Information necessary to preserve patient safety, such as product alerts, is primarily published by other organisations, such as health care authorities. For this reason, a longer period for the Agency to examine information submitted by marketing authorisation holders would not have any detrimental effects on patient safety, but rather serve patients' interests.

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