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**POSITION OF THE CPME ON THE REVISED ARTICLE 88 OF THE
COMMUNITY CODE RELATING TO MEDICINAL PRODUCTS FOR HUMAN
USE (COM (2001) 404 FINAL**

UEMO – PRESIDENCY

c/o Swedish Medical Association, P.O. Box 5610, Villagatan 5, SE-114 86 Stockholm
Tel: +46 8 790 34 52, Fax 46 8 20 57 18, E-mail: info@uemo.org



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TITLE / TITRE

Position of the CPME on the revised article 88 of the Community Code relating to medicinal products for human use

AUTHOR / AUTEUR

Dr Leth, Mrs Tiddens-Engwirda, Mrs Bonnamour

CONCERNING / CONCERNE

All delegations
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PURPOSE / OBJET

INFORMATION

DATE

20/03/2002

KEYWORDS / MOTS CLEFS

Pharmaceutical legislation

Review of the pharmaceutical legislation

Position of CPME on article 88

1. Text of the proposal of the European Commission¹

Article 88

1. Member States shall prohibit the advertising to the general public of medicinal products which:

- (a) are available on medical prescription only, in accordance with Title VI;
- (b) contain substances defined as psychotropic or narcotic by international convention, such as the United Nations Conventions of 1961 and 1971.

2. The communication of information on certain medicinal products is authorised under strict conditions in the interest of patients in order to respond to their legitimate needs. This provision applies to product information appended to the marketing authorisation as well as to additional related information.

By way of derogation from the prohibition in paragraph 1(a), Member States shall authorise the dissemination of information relating to certain medicinal products authorised in the framework of the affections set out below, in order to respond to the expectations expressed by the patients' groups:

This dissemination of information shall be carried out on the following conditions:

- (a) the medicinal product shall be authorised and prescribed for the treatment of any of the following conditions:
 - acquired immune deficiency syndrome;
 - asthma and chronic broncopulmonary disorders;
 - diabetes;
- (b) the information disseminated complies with the principles set out in this Title;
- (c) implementation of this paragraph shall be conditioned by the setting up of self-regulatory procedures by the pharmaceutical industry at Member State level;
- (d) the information and its dissemination shall be in conformity with the principles of good practice which are adopted, after consultation with interested parties, in conformity with the procedure set out in Article 121(2).
- (e) in order to monitor the implementation of the principles of good practice referred to above:
 - the additional information related to the medicinal products shall be notified to the Agency. If the Agency does not object within thirty days following this notification, the information shall be deemed to be accepted;

¹ CP Info 3/2002, COM (2001) 404 Final, 2001/0253 (COD)

- the Agency shall coordinate of the monitoring of the information on the medicinal products authorised in conformity with this Directive, in particular through the setting-up of a data base;
 - on a yearly basis, the Agency shall prepare a report on the application of these principles of good practice;
- (f) implementation of this paragraph shall be the subject of an evaluation and a detailed report no later than [date]. The Commission shall propose any changes required to improve its implementation.
3. Medicinal products may be advertised to the general public which, by virtue of their composition and purpose, are intended and designed for use without the intervention of a medical practitioner for diagnostic purposes or for the prescription or monitoring of treatment, with the advice of the pharmacist, if necessary.
4. Member States shall be able to ban, on their territory, advertising to the general public of medicinal products the cost of which may be reimbursed.
5. The prohibition contained in paragraph 1 shall not apply to vaccination campaigns carried out by the industry and approved by the competent authorities of the Member States.
6. The prohibition referred to in paragraph 1 shall apply without prejudice to Article 14 of Directive 89/552/EEC.
7. Member States shall prohibit the direct distribution of medicinal products to the public by the industry for promotional purposes."

2. Problems raised by this proposal

- The question of the definition: unclear distinction between information and advertising: risk to have so called information that would be in fact promotion.
- The definition of information raises also the question of the content of the information (Scope of the information that could be given directly to patients).
- The question of the procedure of control:
The European Commission proposes the set-up of self-regulatory procedures by the industry. Is it sufficient?
Should industry be the only source of information?
EMA will be in charge of the control of the information to be released. Is this procedure adequate and could it be improved?

3. Proposed amendments

- 1) Amendments of title VIII “Advertising” of the Community Code relating to medicinal products for human use

As the new provision allows information on medicinal products, the title creates confusion on what is information. The two concepts of information and advertising should be clearly separated.

Proposal :

New title VIII “Advertising and information”

- 2) Amendments of article 88, paragraph 2 as proposed by the European Commission

In order to distinguish very clearly between advertising and information, it would be better to have a **new provision** in the title VIII dealing exclusively with information, instead of having a mixed article 88 in which some paragraphs concern advertising and one information.

Proposal:

New article in Title VIII dealing exclusively with information

3) Definition of medicinal information on medicinal products

The European Commission proposes the following criteria: information is what patients ask for and advertising is what patients receive without any request. This criterion is of course essential but is not sufficient to guarantee the good content of the information.

The definition of information should therefore include:

- at the request of patients
- reliable
- objective (with no hidden incentives for the sales/prescription of products)
- subject to a validation mechanism
- scientifically sound (evidence based medicine)
- complete
- neutral and balanced
- understandable (written if possible in a user friendly way)
- restricted to medicinal products

It should also contain warnings on the need to go to health care providers.

Proposal:

To elaborate a clear definition of medical information

4) Set-up of an appropriate procedure for the control of information to patients

The European Commission proposes the set-up of self-regulatory procedures at national level and an “a priori” control of the EMEA (if not reaction within 30 days, it is considered as approved).

This procedure is contradictory and not fully satisfactory because:

- Member states shall authorise this new information but with no control on it from their side.
- Codes of conducts are produced at national level by the industry and the control is centralised.
- Some medicinal products are not authorised via the centralised procedure, which does not cover all medicines. How EMEA will control the information on these products that were authorised at national level?
- Is 30 days a sufficient period?
- Should the silence mean approval or would it be better to have a formal approval?
- How will EMEA deal with this new competency? Via the staff of EMEA or via a committee composed of national experts in which representation of patients and health professionals should be requested?

The elaboration of self-regulatory procedures is normal, especially for Internet commercial communications. But medicinal products, especially for prescription products for three severe conditions are not ordinary products. The use of stricter rules and controls seems to be a public health requirement.

Proposal:

CPME considers that the origin of the self-regulatory rules and the validation mechanism of information are essential issues of public health. Therefore, the maximum guarantees should be taken for the set-up of a neutral and effective system of control.

Firstly, CPME recommends that the elaboration of guidelines should not only involve industry. The elaboration of guidelines should not be performed at national level but at European level in order to get a harmonised approach at EU level. These guidelines should be produced by a committee of the European Commission composed of independent medical personalities representing their member states and interested parties like the industry and consumers.

Secondly, CPME supports the procedure proposed by the proposal. It is essential that the control is a priori. However, the control should be performed within EMEA by a committee that would include representatives of consumer organisations and of the medical professions (and industry).

Annex :

Recommendation X of the G10 Medicines (High Level Group on Innovation and Provision of medicines) Report – 26 February 2002

Recommendation X

- a) The restriction on advertising of prescription medicines to the general public should continue;
- b) There should be no restrictions on advertising of non-prescription medicines, which are not reimbursed, in line with existing requirements for advertising to encourage the rational use of the product and not to be misleading. There should be sharing of information and development of common approaches to regulation of such advertising;
- c) Consideration should be given by the European Institutions, as part of their current review of the pharmaceutical legislation, to:
 - in co-operation with all stakeholders to produce a workable distinction between advertising and information that would allow patients actively seeking information to be able to do so, and to develop standards to ensure the quality of such information; and
 - to the establishment of a collaborative public-private partnership involving a range of interested parties. The information should be carefully piloted and evaluated to assess the extent to which it meets the needs of patients.