

ANNEX

PROPOSAL FOR A DIRECTIVE AMENDING, AS REGARDS INFORMATION TO THE GENERAL PUBLIC ON MEDICINAL PRODUCTS SUBJECT TO MEDICAL PRESCRIPTION, DIRECTIVE 2001/83/EC

The draft proposal focuses on information as to the:

- **Content:** Summary of product characteristics (SPC), package information leaflet and information which is compatible with these documents and other well defined product related information (art. 100 b)
- **Quality** (art. 100 d)
- **Communication channels:** Internet and health related publications. Television or radio should not be allowed (art. 100 c + art. E)
- **Monitoring process:** It is left up to Member States (MS) to establish national structures for monitoring and enforcement. As general rule, monitoring should be based on a posterior control (recital 14) + art. 100 g/100 h

Article 86(2) of Directive 2001/83/EC amended as:

- “the labelling and the accompanying package leaflets, which are subject to the provisions of Title 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,
- New: information by the marketing authorisation holder to the general public on medicinal
- products subject to medical prescription, which is subject to the provisions of Title VIII a.
- ~~statements relating to human health or diseases, provided there is no reference, even indirect, to medicinal products.”~~

Article 88

1. Member States shall prohibit the advertising to the general public of medicinal products which:
 - are available on medical prescription only, in accordance with Title VI,
 - contain psychotropic or narcotic substances, such as the United Nations Conventions of 1961 and 1971,
 - may not be advertised to the general public in accordance with the second subparagraph of paragraph 2.
2. 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.

Member States shall prohibit the mentioning in advertising to the general public of therapeutic indications such as:

- tuberculosis,
 - sexually transmitted diseases,
 - other serious infectious diseases,
 - cancer and other tumoral diseases,
 - chronic insomnia,
 - diabetes and other metabolic illnesses.
3. 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.

4. The prohibition set out referred to in paragraph 1 shall not apply to vaccination campaigns and other campaigns in the interest of public health carried out by the industry and approved by the competent authorities of the Member States.
5. The prohibition referred to in paragraph 1 shall apply without prejudice to Article 14 of Directive 89/552/EEC.
6. Member States shall prohibit the direct distribution of medicinal products to the public by the industry for promotional purposes; they may, however, authorize such distribution in special cases for other purposes.

New from Directive 2004/27/EC

The following text is inserted after Article 88:

~~TITLE VIII a~~

~~INFORMATION AND ADVERTISING~~

~~Article 88a~~

~~Within three years of the entry into force of Directive 2004/726/EC, the Commission shall, following consultations with patients' and consumers' organisations, doctors' and pharmacists' organisations, Member States and other interested parties, present to the European Parliament and the Council a report on current practice with regard to information provision — particularly on the Internet — and its risks and benefits for patients.~~

~~Following analysis of the above data, the Commission shall, if appropriate, put forward proposals setting out an information strategy to ensure good quality, objective, reliable and non-promotional information on medicinal products and other treatments and shall address the question of the information source's liability.';~~

New: Title VIII a – Information to the general public on medicinal products subject to medical prescription. Addition of Articles 100 a to 100 l

Article 100 a: authorisation for marketing authorisation holder to disseminate either directly or indirectly through a third party information to general public on prescription-only medicines.

Article 100 b: content

- a. SPC, labelling and package leaflet as approved by competent authorities + publicly accessible assessment report.
- b. Information which does not go beyond the above mentioned documents but presented in a different way.
- c. Prices, information on pack changes or adverse-reaction warnings.
- d. Product related Information on non-interventional scientific studies or accompanying measures to prevention and medical treatment.

Article 100 c: channels

- Health-related publications as defined by the Member State of publication.
- Internet websites
- Correspondence answering in writing requests
→ NO TV or RADIO

Article 100 d: quality criteria to be respected for content and presentation:

Objective – unbiased – evidence-based – reliable – understandable – source of information – in conformity with SPC + package leaflet → NO COMPARATIVE INFORMATION

Article 100 e: company websites

Any marketing authorisation holders' Internet site for the dissemination of information shall contain the SPC and package leaflet, in language of the Member State

[Article 100 f](#): access to patients with disabilities

[Article 100 g](#): Member states should establish adequate monitoring mechanisms to avoid misuse which should be based on a control prior to the dissemination. This may be done through self-regulation or co-regulation;

Commission will provide guidelines including a code of conduct.

[Article 100 h](#): Registration of company websites prior to dissemination in Member State of registration. There is the possibility to disseminate information on other Internet websites if contents are identical. → **NO WEB-TV**. The Member States where the Internet site is registered is responsible for the monitoring. In case of divergent appraisal of a website's among Member States, the case should be submitted to the Pharmaceutical Committee.

[Article 100 i](#): Member States should take effective measures to adopt sanctions in case of non-compliance with these rules.

[Article 100 j](#): Marketing authorisation holder should keep available a sample of all information disseminated, for Member States' authorities.

[Article 100 k](#): homeopathic prescription-only medicines fall under the scope of this Directive.

[Article 100 l](#): The Commission should publish a report on the experience with this Directive after 5 years of entering into force.

PROPOSAL FOR A REGULATION AMENDING, AS REGARDS INFORMATION TO THE GENERAL PUBLIC ON MEDICINAL PRODUCTS FOR HUMAN USE SUBJECT TO MEDICAL PRESCRIPTION, REGULATION (EC) No 726/2004

[Article 20 b](#): Principal of prior authorisation before dissemination. The Agency should receive a mock-up of the information to be disseminated. If the Agency does not object within 60 days, the information shall be deemed accepted.

The submission of information shall be subject to a fee.