



EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL
Consumer goods
Pharmaceuticals

PUBLIC CONSULTATION

LEGAL PROPOSAL ON INFORMATION TO PATIENTS

Deadline for Public Consultation: 7 April 2008

This document does not represent an official position of the European Commission. It is a tool to explore the views of interested parties on a preliminary proposal. The suggestions contained in this document do not prejudice the form and content of any future proposal by the European Commission.

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1. About the Consultation

1.1. The purpose of this consultation

The European Commission is preparing a legal proposal on information to patients to ensure good-quality, objective, reliable and non promotional information on prescription-only medicinal products to citizens and to harmonize the existing situation in Member States in this area. With this public consultation, the Directorate General Enterprise and Industry intends to consult all stakeholders and interested parties on the key ideas for a forthcoming draft legal proposal by the Commission. Feedback from this consultation as well as the ongoing assessment of the impact of the proposal will be carefully considered and used in the preparation of the legal proposal.

1.2. Who is consulted?

Contributions from all stakeholders and interested parties dealing with medicines or with provision of information on medicinal products to citizens are welcome. This covers for example information providers, healthcare providers and regulatory authorities. All citizens and organisations are also welcome to contribute to this consultation.

1.3. How can I contribute?

Contributions should be sent by e-mail to ulla.narhi@ec.europa.eu, **by 7 April 2008**. An acknowledgement of receipt will be issued for each contribution received, within five working days. Contributions will be made publicly available on the "Pharmaceuticals" website of Directorate General Enterprise and Industry (http://ec.europa.eu/enterprise/pharmaceuticals/index_en.htm) once the consultation period is over, unless a specific request for confidentiality is made, in which case only an indication of the contributor will be disclosed. If you do not wish for your contribution to be made public, please clearly indicate so.

1.4. What will happen next?

All contributions will be carefully analysed. A summary of the outcome of the consultation will be published on the "Pharmaceuticals" website of the Directorate General Enterprise and Industry.

1.5. Any questions? Please contact at the European Commission:

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2. Introduction

2.1. What are the reasons for the proposal?

Article 88a of Directive 2001/83/EC, introduced by Directive 2004/27/EC, called upon the Commission to present a report to the European Parliament and the Council in 2007 on current practices in Member States with regard to information provision for patients. Article 88a also provides that “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”.

In line with article 88a, the Commission adopted a Communication addressed to the European Parliament and the Council on the Report on current practices with regard to the provision of information to patients on medicinal products. The Report, published on the "Pharmaceuticals" website of Directorate General Enterprise and Industry (http://ec.europa.eu/enterprise/pharmaceuticals/index_en.htm) on 20 December 2007, concluded that evidence shows that the rules and practices on what information can be available still vary significantly among Member States, which results in unequal access of patients, and the public at large, to information on medicinal products. At the same time patients have become more empowered and proactive regarding the treatment of their illnesses. The quality of information is currently very variable, in particular in view of the Internet where the providers have no or limited accountability toward EU citizens.

The forthcoming proposal would amend Directive 2001/83/EC and, in keeping with the scope of this directive, would set rules on the provision of information by marketing authorisation holders. This would be without prejudice to the provision of information by other actors and the Commission's declared intention that healthcare professionals should remain as they are today, the primary source of health information.¹

¹ The Commission Staff Working Document SEC(2007)1740
http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2007/2007_12/comm_native_sec_2007_1740_1_en_documentdetavail.pdf

2.2. Objectives and impact assessment

The forthcoming proposal will put the interests of patients first and with this perspective should aim at reducing differences in access to information and should ensure the availability of good-quality, objective, reliable and non-promotional information on medicinal products.

The following main policy objectives are pursued:

1. Establishing a framework which provides citizens of EU Member States with understandable, objective, high-quality and non-promotional information about the benefits and the risks of their medicines, and which maintains the confidence of citizens, regulators and healthcare professionals.
2. Maintaining the ban on direct-to-consumer advertising of prescription medicines, making sure that there is a clear distinction between advertising and non-promotional information.
3. Avoiding unnecessary bureaucracy, in line with the principles of Better Regulation.

On the basis of these objectives, DG Enterprise and Industry is preparing an assessment of the possible impacts. This includes an analysis of the likely impacts of the main options and an examination of possible synergies and trade-offs. The results from the impact assessment and the public consultation together will be carefully considered and used in the preparation of the legal proposal on information to patients.

3. Key ideas of the forthcoming proposal

Key ideas under consideration for the forthcoming legal proposal on information to patients are explained below and summarised in the Table (at the end of the document).

A fundamental objective of the legal proposal should be **to provide rules that harmonise practices on information provisions to patients** in Member States. A major part is to present a clear distinction between advertising of and information provided on prescription medicines. This distinction as well as the quality criteria, the content and means of the information provided, together with the proposed structure for the monitoring of

the quality of the information, **should create a framework for the industry to provide certain information on their medicines to the public**. The proposal should enable EU citizens to get objective information from reliable sources. The following key ideas for a legal proposal by the Commission are put forward for consultation:

3.1. Provisions on advertisement

The current rules ban advertisement of prescription medicines to the general public. At the same time they allow advertisement of over the counter medicines. These rules should not be changed.

3.2. Scope, content and general principles of the new legal provisions

The revision should clarify the rules on information provided by pharmaceutical companies on prescription-only medicines. Basically, communication not covered by the definition of advertisement, should be regarded as information. Clear criteria should distinguish the information that is allowed from the information that is not allowed.

Information should be compatible with approved summaries of product characteristics and patient information leaflets, and it should not contradict or go beyond the key elements specified in them. Other limited medicine-related information could also be given (information about scientific studies, prevention of diseases such as vaccines, accompanying measures to medical treatments, prices). In addition, specific quality criteria should be defined and respected.

3.3. Type of actions, content and monitoring of information

A distinction should be made between the cases where the patient is passively receiving the information ("push") or actively searching for the information ("pull") in terms of the monitoring mechanism.

3.3.1. Information passively received by citizens

Under the clear safeguard that all advertisement to the public is banned, it should be possible for the pharmaceutical industry to disseminate information on prescription-only medicines through TV and radio programmes, through printed material actively distributed, through information in printed media or through audiovisual and written material provided to patients by healthcare professionals.

To facilitate the monitoring of the information provided, a mechanism should be set up to ensure that the information providers inform national co-regulatory bodies about their activities before action is taken.

3.3.2. Information searched by citizens

Further, when industry disseminates information on prescription medicines through Internet websites or verbally, it should announce such information activities to a national co-regulatory body which should monitor the contents without validating ex-post or ex-ante specific actions.

3.3.3. Answering requests from citizens

Citizens often have questions to pharmaceutical companies. Replies by industry to enquiries from citizens through written solicited posting or e-mail should be monitored based on complaints.

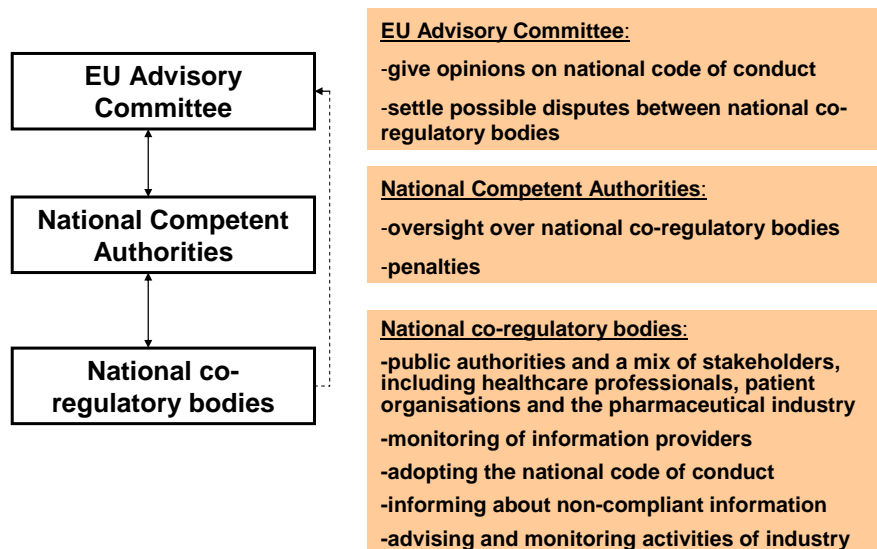
4. Quality criteria

All information provided to citizens should fulfil specific criteria concerning the quality of the information. The information provided should be objective and unbiased, patient-oriented, evidence-based, up-to-date, accessible, transparent, relevant and consistent with approved information. Comparisons between medicinal products should not be allowed.

5. Proposed structure for monitoring and sanctions

The structure of enforcement could take place on three different levels.

Figure. Proposed structure for monitoring



a) Each Member State could set-up a **national co-regulatory body**, consisting of public authorities and a mix of stakeholders, including healthcare professionals, patient organisations and the pharmaceutical industry. These co-regulatory bodies could be responsible for

- adopting a code of conduct on information to patients
- monitoring and following up of all information activities by the industry.

b) Each Member State could charge its competent authorities to act in the case of repeated and severe cases of non-compliance and apply sanctions.

c) On the EU level, an **Advisory Committee with no Comitology powers**, chaired by **the Commission**, could be given the task to oversee the work of national co-regulatory bodies and authorities. The Committee would have to be consulted before adoption of any national code of conduct and would deal with all questions on information to patients with a Community dimension. The existing Pharmaceutical Committee could be tasked with this role. While the EMEA could contribute to the work of the committee, the

Agency should not have any further role as no scientific assessment of information will be necessary².

² The following other options are taken into consideration in the impact assessment:

Alternative 1: regulation by medicines regulatory authorities. Under Alternative 1, those responsible for the regulation of this initiative would be the national competent authorities in Member States currently responsible for the monitoring of information provision.

Alternative 2: regulation on a self-regulatory basis. Under Alternative 2, the responsibility for regulation would rest with existing pharmaceutical industry associations. In other words, this option would involve industry self-regulation. Membership of the industry associations would continue to be on a voluntary basis.

6. Table: Key ideas of the forthcoming proposal on information to patients

Type of action by providers ¹	Type of action by the general public	Monitoring	Content of medicines information	Accessibility: languages, specific patient groups	Competent authority/body	Sanctions/ Responsibilities	Quality criteria of provided information ²
Advertising³ e.g. - unsolicited posting for citizens, e-mails, telephone calls/messages - TV and radio (short slots, not linked to the content of the programme) - Internet (automatic pop-ups) - communicating by motion-related material	Passive				National competent authorities	Sanctions (national rules) → penalties	
		Maintain Status quo PROHIBITION					
"Pushed" information - TV and radio (programmes with factual content) - printed material actively distributed to citizens - written information in printed media - audiovisual and written material about prescription medicines provided to patients by healthcare professionals	Passive	"Tell and do"	1. SPCs and PILs <i>per se</i> 2. Information that is compatible with approved SPCs and PILs, not contradicting or going beyond the key elements on them 3. Other limited medicine-related information (information about scientific studies, prevention of diseases e.g. by vaccination, accompanying measures to medicine treatment, prices)	All information about medicinal products should include a reference where to find SPC and PIL in official language of the Member State where the information is provided	National competent authorities National co-regulatory body → public authorities and a mix of stakeholders, including healthcare professionals, patient organisations and the pharmaceutical industry	National competent authorities are responsible for sanctions National co-regulatory bodies are responsible for: → monitoring of all information activities by the industry → "name and shame" → insisting providers to change illegal informing → for repeat and severe cases reporting to competent authorities	Objective and unbiased → <i>based on facts and not influenced by prejudices or personal perceptions</i> Patient oriented → <i>patient-centred and taking into account patients' needs and expectations in order to empower patients</i> Evidence-based → <i>the evidence base for any information resource needs to be clearly stated, including making clear the level of evidence</i> Up-to-date → <i>factually correct and not misleading</i> Understandable Accessible → <i>via different mechanisms</i> Transparent → <i>clear clarification of the source</i> Relevant → <i>include issues of relevance and importance to patients' decision-making</i> Consistent with approved product information Non-promotional → <i>focus on informing and guiding patients to correct and safe use of the medicine</i> Information should not include any comparative sections between medicinal products
Information searched by citizens - registered Internet sites - oral information (presentations, seminars)	Soft pull	Monitoring		Essential information shall be provided on request in patient's own language, if this is an official EU language and the product is authorised in that Member State			
Answering on request - written solicited information (e.g. posting, e-mails)	Active pull	Monitoring based on complaints					

¹ Marketing authorisation holders (MAHs) or any organisations in which MAHs have an influence on the substance and quality of information they produce

² All the information provided to citizens shall fulfil these criteria

³ The full definition of advertising Article 86 of Directive 2001/83/EC: **For the purposes of this Title, ‘advertising of medicinal products’ shall include any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products; it shall include in particular:**
- the advertising of medicinal products to the general public,
- advertising of medicinal products to persons qualified to prescribe or supply them,
- visits by medical sales representatives to persons qualified to prescribe medicinal products,
- the supply of samples,
- the provision of inducements to prescribe or supply medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in kind, except when their intrinsic value is minimal,
- sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products,- sponsorship of scientific congresses attended by persons qualified to prescribe or supply medicinal products and in particular payment of their travelling and accommodation expenses in connection therewith.