EU-Amendment Directive

# INFORMATION ON MEDICINAL PRODUCTS

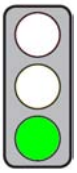
Status: 09.02.2009

Centrum für Europäische Politik

## MAIN ISSUES

**Objective of the Directive:** A harmonised legislative framework is to be established for the provision of information to the general public on medicinal products for human use subject to medical prescription.

**Groups Affected:** Pharmaceutical companies, patients, indirectly media.



**Pros:** (1) The boundaries between information provided by pharmaceutical companies and prohibited advertising are appropriate and sufficiently clear.

(2) The proposed monitoring measures allow for less bureaucratic practice.

**Cons:** It is not consistent to allow comparisons between medicinal products in information material distributed by pharmaceutical companies to patients through physicians and pharmacists.

## CONTENT

### Title

**Proposal COM(2008) 663** of 10. December 2008 for a **Directive** of the European Parliament and of the Council amending, as regards **information to the general public on medicinal products** subject to medical prescription, Directive 2001/83/EC on the Community code relating to medicinal products for human use

### Short Summary

References made refer to Directive 2001/83/EC to be amended, unless otherwise indicated.

- **Object**
  - A harmonised legislative framework is to be established for the provision of information through pharmaceutical companies to the general public on medicinal products subject to medical prescription for human use.
  - In particular, distinct boundaries are to be set between the admissible provision of information through medicinal products and prohibited advertising.

- **Prohibition of Public Advertising of Medicinal Products**
  - Public advertising of medicinal products subject to medical prescription remains prohibited. (Art. 88 (1) lit. a, Title VI).
  - "Advertising" includes "any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products" (Art. 86 (1)).

- **Authorised Medicinal Products Information to General Public**
  - The following types of information on medicinal products subject to medical prescription are not deemed advertising and may be disseminated to the general public by pharmaceutical companies and third parties authorised by them:
    - the summary of medicinal product characteristics,
    - labelling, package leaflets and prices,
    - publicly accessible assessment report drawn up by national authorities,
    - information on the environmental impact of the respective medicinal product,
    - informative announcements and reference material relating, for instance, to adverse-reaction warnings,
    - "medicinal product-related" information on certain scientific studies, or accompanying measures to prevention and medical treatment,
    - Information "which presents the medicinal product in the context of the condition to be prevented or treated" (new Art. 100a (1) and Art. 100b).
  - The provisions on authorised information on medicinal products do not apply to:
    - information relating to human health or diseases, provided there is no reference – direct or indirect – to medicinal products,
    - material provided by pharmaceutical companies to healthcare professionals for distribution to patients (new Art. 100a (2)).

- **Requirements for the Content and Presentation of Medicinal Product Information**
  - The content and presentation of information must be:
    - factually correct and up-to-date, based on verifiable evidence and must state the source of information,
    - objective and must state the benefits as well as the risks of a medicinal product,
    - "take into account" the general "needs and expectations" of patients and be "understandable for the general public" (new Art. 100d (1)).

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– Any information on medicinal products must include the following:
  - a statement that the medicinal product is available on prescription only,
  - a statement indicating that the information must not replace the relationship between patient and healthcare profession,
  - a mail address or e-mail address of the pharmaceutical company to ensure that anyone can contact them (new Art. 100d (2)).
– Information on medicinal products:
  - must not include comparisons between medicinal products,
  - must not give the impression that a medical consultation or surgery is unnecessary,
  - must not suggest that
    - the effect of taking the medicinal product is guaranteed without any side effects,
    - the effect of taking the medicinal product is equivalent to or better than that of another treatment or medicinal product,
    - that a "generally healthy" patient might enhance his or her health by taking the medicinal product (new Art. 100d (3), Art. 90).

► **Monitoring Measures**
– Before being disseminated medicinal products must, as a rule, be assessed as to whether or not they comply with statutory requirements. This does not apply if:
  - the content of the information has already been approved by competent authorities in another context
  - an equivalent monitoring is ensured through a "different mechanism", e.g. retroactive control. (new Art. 100g (1))
– Monitoring measures may be accomplished:
  - by Member States,
  - or by "self-regulatory or co-regulatory bodies" of the pharmaceutical industry, if an equivalent level of control is ensured (new Art. 100g (1)).
– The Commission may draw up guidelines on details of medicinal product information and a code of conduct for pharmaceutical companies regarding the dissemination of information (new Art. 100g (2)).

► **Authorised Information Channels**
– Medicinal product information may be disseminated through the following channels only:
  - "health-related publications" and internet-websites on medicinal products, unless unsolicited information material is distributed therewith,
  - and written answers to requests for information.
– The dissemination through television or radio is prohibited in order to protect patients from "unsolicited information" (new Art. 100c).

► **Website Requirements**
– Pharmaceutical companies must register their websites containing medicinal product information with the competent national authorities prior to being switched online (new Art. 100h (1)).
– The Member State where the website is registered is in charge of monitoring its content (new Art. 100h (3)).
– Upon registering a website pharmaceutical companies may provide the content of it on websites in other languages throughout other Member States (Art. 100h (1)).
– Websites may only contain links to other websites for medicinal products if they have been registered before (new Art. 100h (2)).

► **Language Rules**
– Registered websites of pharmaceutical companies must display the summary of characteristics and package leaflets of medicinal products subject to prescription in the official languages of all Member States where they are authorised (new Art. 100e (1)).
– Requests for information to pharmaceutical companies may be written in any official language of the Community, given the medicinal product is authorised there. Pharmaceutical companies are obliged to reply in the language of the request (new Art. 100e (2)).

► **Access to Information for Disabled Persons**
– Medicinal product information must be made accessible to disabled persons, unless such accessibility imposes "disproportionately" high burdens to pharmaceutical companies (new Art. 100f (1)).
– To this end, websites must conform to the "World Wide Web Consortium (W3C) Guidelines", which facilitates their processing through tools designed for e.g. visually handicapped persons (new Art. 100f (2)).

## Changes Compared to the Status Quo

To date EU legislation does not provide for clear rules regarding the form and extent to which pharmaceutical companies may provide information on medicinal products subject to medical prescription to the general public.

### Statement on Subsidiarity

According to the Commission, EU pharmaceutical law does not provide for a clear distinction between prohibited advertising for medicinal products and the authorised provision of information. It further holds the view that differing national rules impede pharmaceutical companies from providing adequate information to the general public. Moreover, strong deviations in national rules might infringe the free movement of goods pursuant to Art. 28 TEC and thus avert the implementation of the single market for medicinal products.

### Political Context

The Proposal for a Directive forms part of a "pharmaceutical package" published by the Commission on 10. December 2008 comprising a Proposal for a Regulation amending Regulation (EC) No. 726/2004 for the authorisation and supervision of medicinal products for human use ("Pharmacovigilance") [COM(2008) 664], a Communication on a renewed vision for the pharmaceutical sector [COM(2008) 666] as well as a Proposal for a Directive as regards the prevention of counterfeit medicinal products [COM(2008) 668 amending Directive 2001/83/EC, cp. CEP-Policy Brief].

### Legislative Procedure

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| 10.12.08 | Adoption by Commission |
| Open | Adoption by European Parliament and Council, publication in the Official Journal of the European Union and entry into force |

### Options for Influencing the Political Process

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| Leading Directorate General: | DG Enterprise and Industry |
| Committees of the European Parliament: | Environment, Public Health and Food Safety (in charge), rapporteur: Christofer Fjellner (EPP-ED Group, SE); Industry, Research and Energy; Internal Market and Consumer Protection |
| Committees of the German Bundestag: | Health |
| Decision Mode in the Council: | Qualified majority (approval by a majority of Member States and at least 255 out of 345 votes; Germany: 29 votes) |

### Formalities

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|---|---|
| Legal basis: | Art. 95 TEC (Internal Market) |
| Form of legislative competence: | Concurrent legislative competence |
| Legislative procedure: | Art. 251 TEC (Co-decision) |

## ASSESSMENT

### Economic Impact Assessment

#### Ordoliberal Assessment

The existing prohibition on the advertising of prescription-only drugs calls for **clear boundaries between the authorised provision of information and prohibited advertising** through pharmaceutical companies. This is true irrespective of how such a provision is interpreted. These boundaries **are clearly laid out by the proposed Directive** in principle, even though there may be room for interpretation in some individual cases.

Patients are already able to find a variety of information on prescription-only drugs on the internet. For instance, there are numerous websites from pharmaceutical companies designed for the US-American market on which even advertising is allowed, as well as web forums where users exchange information on medicinal products. That patients have incomplete, inaccurate or even misleading information can therefore not be excluded. **In this context the provision of information by pharmaceutical companies can enrich the information available to patients**, provided pharmaceutical companies are obliged to present information in a factually correct and appropriate way as the proposed Directive requires.

The fact that authorised information must not contain any comparative statements as to the effects of medicinal products is justifiable, since the results of comparative studies need expert interpretation which can normally neither be rendered nor comprehended by patients. Therefore, it is very possible that advertising could influence.

**However, the proposed Directive does allow comparisons to be made** between medicinal products **in information material that is distributed by pharmaceutical companies to physicians** and pharmacists **to be made available to patients, for example by** displaying it in the waiting room or through a consultation. Disseminating information material through physicians and pharmacists does not ensure though that the knowledge of patients is fully taken account of. Moreover, there is a danger that information material is deemed more important than it actually is if provided by healthcare professionals. This is exacerbated by the fact that because the publication of comparative studies is prohibited, patients have little opportunity to refer to comparative studies from other companies and thus to make up their own minds. Thus, in this respect **the exception is inconsistent and should be waived**.

Whether or not a statement is merely informative or of an advertising nature also depends on the context in which it is presented. Therefore, it is reasonable to restrict the dissemination of information to health-related publications and medical products websites, especially as it is well-nigh impossible to filter the target audience of radio and television in such a way that listeners and viewers can be expected to pay the degree of attention required to follow a balanced presentation of information. Besides, information which fully complies with the requirements of the proposed Directive might adopt an advertising nature if repeated often enough on radio or television. Therefore, it is justified to prohibit their dissemination through these media channels.

### Impact on Efficiency and Individual Freedom of Choice

It is to be welcomed that information already authorised for publication on websites – translated websites in particular - no longer have to be authorised for a second time when being reissued. In addition, **it is appropriate that Member States may delegate monitoring to self-regulatory or co-regulatory bodies and may allow for retroactive control**, if such control is equivalent in quality. When transposing said requirements into national law this option should be expressly taken account of, as this allows costs to be saved and administrative burdens lowered without Member States losing essential monitoring rights.

### Impact on Growth and Employment

Not evident.

### Impact on Europe as a Business Location

Unproblematic.

## Legal Assessment

### Legislative Competence

Art. 95 Abs. 1 TEC allows for an adjustment of national requirements for the provision of information on medicinal products to the general public, provided it promotes the functionality of the single market.

### Subsidiarity

Unproblematic.

### Proportionality

Since medicinal products subject to prescription require an enhanced due diligence, the proposed regulations on dissemination are appropriate.

### Compatibility with EU Law

Unproblematic.

### Compatibility with German Law

The German Medicines Law (*Arzneimittelgesetz AMG*) contains rules on the direction for use in package leaflets for patients (§ 11 AMG) and for expert groups (§ 11a AMG). The German Law on Advertising in the Healthcare Sector (*Heilmittelwerbegesetz HWG*) regulates the admissibility of advertising medicinal products.
Neither the German Pharmaceutical Law nor the German Law on Advertising in the Healthcare Sector contain any final definition of the "advertising of medicinal products" or of the boundaries to be set between advertising and disseminating information or comprehensive requirements for informing the general public on medicinal products subject to prescription. To this end, the German Pharmaceutical Law would have to be amended.

## Alternatives Policy Options

The prohibition of comparisons between medicinal products should also apply to information material of pharmaceutical companies distributed to patients through healthcare professionals.

## Possible Future EU Action

Currently not evident.

## Conclusion

Since patients already have access to a variety of information of differing quality through the internet, it is to be welcomed that from now on pharmaceutical companies are entitled to provide information EU-wide. The requirements for the presentation of information are in principal appropriate. However, the prohibition of comparisons between medicinal products should also apply to information material from pharmaceutical companies which is distributed by healthcare professionals.