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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 10.12.2008
COM(2008) 663 final

2008/0256 (COD)

Proposal 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

{SEC(2008) 2667}

{SEC(2008) 2668}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

1.1. Grounds for and objectives of the proposal

The general policy objectives of the proposals to amend Directive 2001/83/EC and Regulation (EC) No 726/2004 are in line with the overall objectives of the Community pharmaceutical legislation. These are intended to ensure the proper functioning of the internal market for medicinal products for human use and to better protect health of EU citizens. Following this line, the proposals aim specifically to:

- Provide for a clear framework for provision of information by marketing authorisation holders about their prescription-only medicines to the general public with a view to enhancing the rational use of these medicines, while ensuring that the legislative framework continues to prohibit direct-to-consumer advertising of prescription-only medicines.

This aim shall be achieved by:

- Ensuring the high quality of information provided by coherent application of clearly defined standards across the Community.
- Allowing information to be provided through channels addressing needs and capabilities of different types of patients.
- Allowing marketing authorization holders to provide in an understandable way objective and non-promotional information about the benefits and the risks of their medicines.
- Ensuring that monitoring and enforcement measures are in place to ensure that information providers comply with the quality criteria, while avoiding unnecessary bureaucracy.

1.2. General context

Directive 2001/83/EC on the Community code relating to medicinal products for human use¹ provides for a harmonised framework on advertising of medicines at Community level, the application of which remains a responsibility of Member States. This legislation prohibits the advertising to the general public of medicines subject to prescription.

However, neither the Directive nor Regulation (EC) No 726/2004 include detailed provisions on information on medicinal products, providing only that certain information supply activities are exempted from the advertising provisions. Therefore, Community legislation does not prevent Member States from establishing their own approaches regarding the provision of information on medicinal products as long as the above mentioned rules on advertising are respected. In addition, the boundaries between advertising and information, and therefore the field of application of the legislation's restrictions on advertising, are not interpreted consistently across the Community.

¹ OJ C L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2008/29/EC (OJ L 81, 20.3.2008, p. 51).

Article 88a of Directive 2001/83/EC, introduced by Directive 2004/27/EC², calls upon the Commission to present a report to the European Parliament and the Council in 2007 on “current practice with regard to information provision – particularly on the Internet – and its risks and benefits 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.”

On the basis of this provision, a Communication from the Commission to the European Parliament and the Council concerning the "Report on current practices with regard to the provision of information to patients on medicinal products"³ was adopted and submitted to the European Parliament and the Council on 20 December 2007.

It follows from the Report that rules and practices on what information can be available vary significantly among Member States. Certain Member States apply very restrictive rules, while others allow for several types of non-promotional information to be made available. Some Member States foresee a quite extensive role of public authorities, namely medicines regulatory agencies, in the provision of various kinds of information, while other Member States allow information activities performed under partnerships of public and private organisations, including health professionals’ associations, patients’ organisations and the pharmaceutical industry. This results in unequal access of patients, and the public at large, to information on medicinal products.

Moreover, divergences in terms of rules and practices on what information can be made available have a negative impact on legal certainty for marketing authorisation holders with cross-border activity.

1.3. Existing provisions in the area of the proposal

Directive 2001/83/EC

Directive 2001/83/EC does not contain detailed rules on information on prescription-only medicinal products by the marketing authorisation holder to the general public. However, Article 86(2) of Directive 2001/83/EC provides that certain information activities are not covered by the rules on advertising of medicinal products for human use that are currently contained in Titles VIII and VIIIa of Directive 2001/83/EC. The exemption concern cases where a marketing authorisation holder answers a specific question about a particular product (Art. 86(2) 2nd indent), where he makes factual, informative announcements (Art. 86(2) 3rd indent) or where general information relating to human health or diseases without reference to a particular product is given (Art. 86(2) 4th indent).

Experience has shown that the interface between the types of information excluded and the prohibition of advertising of prescription-only medicines is not interpreted uniformly across the Community.

² OJ L 136, 30.4.2004, p. 34.

³ COM(2007) 862. The Communication is supported by Commission Staff Working Document SEC(2007) 1740.

1.4. Consistency with the other policies and objectives of the Union

The proposals are consistent with the overall objective of the Community pharmaceutical legislation, which is to remove disparities between national provisions in order to ensure the proper functioning of the internal market for medicinal products, while at the same time safeguarding a high level of protection of public, human and animal health. The proposals also comply with Article 152(1) of the Treaty establishing the European Community, which provides that a high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities.

The proposals should be seen as part of a wider Community agenda on health information. This also includes initiatives such as the follow-up to the Pharmaceutical Forum's work on information to patients, the EU Health Strategy, the EU Health Portal, programmes funded under the EU Health Programme and initiatives concerning eHealth. These initiatives have a broader focus than information regarding prescription-only medicines, and are thus complementary to the proposals.

2. CONSULTATION OF INTERESTED PARTIES AND IMPACT ASSESSMENT

2.1. Consultation of interested parties

Consultation methods, main sectors targeted and general profile of respondents

As a first step, the Commission services conducted a survey in 2006 amongst Member States medicines regulatory agencies to gather information on their experience with the implementation and application at a national level of the legislation governing information on medicinal products, in particular related to the relevant provisions of Directive 2001/83/EC. This was complemented with information gathered by means of a questionnaire prepared for the Pharmaceutical Forum Information to Patients Working Group.

Between 19 April and 30 June 2007, a first public consultation was conducted on a Draft report on current practices with regard to the provision of information to patients on medicinal products, summarising the current state of play without presenting yet any political orientations or proposals.

A second public consultation, conducted between 5 February and 7 April 2008, specifically addressed the key ideas of the forthcoming legal proposal on information to patients. Contributions were asked from all stakeholders and interested parties concerned by the provision of information on medicinal products to citizens.

Both public consultation documents were published on the website of Directorate General Enterprise and Industry.

Summary of responses and how they have been taken into account

As regards the first public consultation on a Draft report on current practices with regard to the provision of information to patients on medicinal products conducted in 2007, 73 responses were received from various sources. These include patients' organisations, consumer and citizen organisations, pharmaceutical industry organisations and companies, healthcare professionals, regulators, social insurance organisations, media organisations and individual citizens.

Concerning the public consultation conducted between 5 February and 7 April 2008 on the key ideas for a legal proposal, in total 193 contributions were received. These comprise 185 responses and eight supportive comments. The responses are available on http://ec.europa.eu/enterprise/pharmaceuticals/patients/patients_responses_200805.htm.

The results of the public consultation conducted in 2007 are contained in the Communication from the Commission to the European Parliament and the Council concerning the Report on current practice with regard to provision of information to patients on medicinal products and the accompanying Commission Staff Working Document submitted to the European Parliament and the Council on 20 December 2007.

The responses to the second public consultation conducted between 5 February and 7 April 2008 were analysed and were taken into account by the Commission when preparing this proposal.

2.2. Impact assessment

The details of the impact assessment are provided in the Commission Staff Working Document 'Impact Assessment' attached to this proposal.

Three basic policy-options were developed for the impact assessment:

1. Retention of the current legal framework (Option 1);
2. Revision of Directive 2001/83/EC to harmonize rules on what information industry is allowed to provide to patients combined with different enforcement mechanisms. This option includes four sub-options for the enforcement of the information provision (a. enforcement by national competent authorities (Option 2), b. self-regulation by pharmaceutical industry association with voluntary membership (Option 3), c. co-regulation involving a co-regulatory body and medicines regulatory authorities (Option 4), d. self-regulation via an industry body with compulsory membership);
3. Revision of Directive 2001/83/EC allowing specific types of advertising of prescription medicines within the EU.

The revision of Directive 2001/83/EC allowing specific types of advertising of prescription medicines within the EU and the sub-option foreseeing self-regulation via an industry body with compulsory membership were discarded at an early stage. The first was not considered to be appropriate as it would run counter the objective to maintain the current ban on direct-to-consumer advertising for prescription-only medicinal products. The latter was discarded as it was considered inappropriate on grounds of lack of legitimacy, duplication of structures and exceeds the policy scope.

It resulted from the impact assessment that harmonised provisions with regard to information to patients would have a benefit for patients. However, the differences between the various policy options (option 2, 3 and 4) relating to monitoring and enforcement were not significant.

3. LEGAL ELEMENTS OF THE PROPOSAL

3.1. Summary of the proposed action

The legal proposals to amend Directive 2001/83/EC and Regulation (EC) No 726/2004 address the gap in the current pharmaceutical legislation as regards the provision of information to the general public on prescription-only medicinal product for human use. The key elements of the proposals can be summarised as follows:

- Clarifying that the provision of information on prescription-only medicines directly to the public by marketing authorisation holders is allowed, without prejudice to the prohibition on advertising, provided that clearly defined conditions are respected.
- Establishing harmonised conditions on the content of information which marketing authorisation holders are allowed to disseminate (information approved by the competent authorities for granting marketing authorisation, whether used literally or presented in a different way, and other limited medicine-related information).
- Establishing harmonised quality standards for such information, to ensure that it is of high-quality and non-promotional.
- Determining the authorised channels of information provision, in order to exclude unsolicited means of dissemination.
- Introducing the obligation for Member States to establish a monitoring system to ensure that the mentioned provisions on content of information, quality standards and dissemination channels are complied with and ensure enforcement in case of non-compliance. The proposal leaves it up to the Member States to decide the most appropriate monitoring mechanisms, but lays down a general rule that monitoring should take place after dissemination of information, with certain exceptions (where prior approval would be necessary) in the case of certain modalities of information where the distinction between advertising and non-promotional information is more difficult to establish. For products authorised in accordance with Regulation (EC) No 726/2004, certain approval tasks are given to the European Medicines Agency.
- Establishing specific monitoring rules for information disseminated through websites, to take account of the cross-frontier nature of information provided over the Internet and to allow Member State cooperation and avoid duplication of monitoring.
- To ensure that the provision of information on prescription-only medicinal products for human use follows the same rules regardless of the procedure according to which these products have been authorised, it is appropriate to lay down the general rules in the Community code on medicinal products for human use (Directive 2001/83/EC), and to cross-refer to them in the regulation governing the centralised procedure (Regulation (EC) No 726/2004), with specific provisions for centrally authorised products as regards the role of the EMEA in a prior control of information on medicinal products to be disseminated.

3.2. Legal basis

The proposals are based on Article 95 of the Treaty, which provides for the use of the ‘co-decision’ procedure referred to in Article 251 of the Treaty. Article 95 is the main legal basis

of the whole Community pharmaceutical legislation, including Directive 2001/83/EC and Regulation (EC) No 726/2004 which these proposals seek to amend.

3.3. Subsidiarity principle

The proposals do not fall under the exclusive competence of the Community. Therefore the subsidiarity principle laid down in Article 5 of the Treaty applies. In this case, action should be taken at Community level and problems could not be adequately tackled at national level, for a number of reasons.

Today, restrictions on the possibilities of pharmaceutical companies to provide information result from the lack of clarity of the Community rules as regards the definition of advertising and, consequently, the distinction between advertising and information. The clarification of this distinction needs to be operated at the level of those Community rules.

The need for Community action is furthermore supported by the objective of preserving the effectiveness of the Community pharmaceutical acquis as regards advertising. As the pharmaceutical legislation lays down detailed restrictions on advertising and excludes certain types of information from these restrictions, any national rules prohibiting or unduly restricting such information could alter the balance introduced by the directive.

Moreover, in a system where the rules on key product information (summary of products characteristics and package leaflet) are fully harmonised to ensure the same level of protection of public health across the Community, this objective is undermined if widely divergent national rules on the dissemination of such key information are allowed.

The need for action at Community level is also linked to the evolution of Community internal market rules on marketing authorisations for medicines. Medicinal products authorised by the Commission enjoy a Community-wide marketing authorisation, circulate freely within the Community and have the same summary of product characteristics and package leaflet for the whole Community. Similar considerations apply to products authorised by the Member States under the mutual recognition framework, leading to a Community harmonised summary of product characteristics and package leaflet.

Moreover, national rules and practices on information may lead to restrictions to the free movement of goods in violation of Article 28 of the Treaty, impacting negatively on the completion of a single market of pharmaceuticals which the harmonised legal framework on medicinal products tries to achieve. The European Court of Justice has already found certain national provisions on information on medicinal products to be contrary to Article 28 of the Treaty (case C-143/06, Juers-Pharma).

3.4. Proportionality principle

The proposals comply with the proportionality principle as laid down in Article 5 of the Treaty for the following reasons, as the proposed action by the Community does not go beyond what is necessary to achieve the objectives of the proposal.

The proposals are limited in scope to medicinal products subject to medical prescription. Current Community rules allow the advertising to the general public of medicinal products not subject to prescription, subject to certain conditions; thus, pharmaceutical industry may engage in any kind of dissemination of information for such products.

The proposals introduce a harmonised set of quality standards and rules with regard to the provision of non-promotional information on prescription-only medicines. However, it leaves it up to Member States to establish their own monitoring and enforcement system or to make use of existing structures, and simply lays down certain general principles. This is in keeping with the system currently in place as regards advertising.

3.5. Choice of instruments

The proposals aim at introducing a harmonised framework for the provision of information on prescription-only medicinal products for human use into Directive 2001/83/EC and making this framework applicable to prescription-only medicinal products for human use authorised following Regulation (EC) No 726/2004. An amending directive and an amending regulation are therefore considered the most appropriate legal instruments.

4. BUDGETARY IMPLICATION

The proposals have no implications for the Community budget.

5. ADDITIONAL INFORMATION

5.1. Simplification

The project is referenced in the Commission Agenda Planning as 2008/ENTR/024. It is part of the Commission Legislative and Work Programme for 2008, under Annex I (Priority Initiatives)⁴.

This proposals aim at filling a gap in the existing legal framework by introducing a harmonised set of rules for information provision to be complied with throughout the Community. Currently Member States have adopted divergent rules relating to information provision. Thus, marketing authorisation holders have to abide to different rules according to the Member State where the information is to be disseminated. In this regard simplification is expected as marketing authorisation holders will be subject to the same rules for the provision of information in their prescription-only medicinal products in all Member States. Competent bodies in turn will be able to apply harmonised rules when monitoring information provided and, if necessary, when enforcing. In general a clarification of rules is expected to lead to a simplification of the provision of information for all operators.

5.2. European Economic Area

The proposed act is of relevance to the EEA.

⁴ http://ec.europa.eu/atwork/programmes/docs/clwp2008_en.pdf (see page 20)

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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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission⁵,

Having regard to the opinion of the European Economic and Social Committee⁶,

Acting in accordance with the procedure laid down in Article 251 of the Treaty⁷,

Whereas:

- (1) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use⁸ establishes harmonised rules on the advertising of medicinal products for human use. In particular, it prohibits the advertising to the general public of medicinal products subject to medical prescription.
- (2) In the area of information, Directive 2001/83/EC lays down detailed rules on the documents to be annexed to the marketing authorisation and intended for information purposes: the summary of product characteristics (distributed to health-care professionals) and the package leaflet (inserted in the product's packaging when it is dispensed to the patient). On the other hand, as regards the dissemination of information from the marketing authorisation holder to the general public, the Directive only provides that certain information activities are not covered by the rules on advertising, without providing for a harmonised framework on the contents and the quality of non promotional information on medicinal products or on the channels through which this information may be disseminated.

⁵ OJ C , , p. .

⁶ OJ C , , p. .

⁷ OJ C , , p. .

⁸ OJ L 311, 28.11.2001, p. 87.

- (3) On the basis of Article 88a of Directive 2001/83/EC, on 20 December 2007 the Commission submitted a Communication to the European Parliament and the Council on a "Report on current practices with regard to the provision of information to patients on medicinal products"⁹. The report concludes that Member States have adopted divergent rules and practices with regard to the provision of information, resulting in a situation where patients and the public at large have unequal access to information on medicinal products.
- (4) Experience gained from the application of the current legal framework has also shown that certain restrictions on the possibilities of pharmaceutical companies to provide information result from the fact that the distinction between the notions of advertising and information is not interpreted consistently across the Community.
- (5) Those disparities in the interpretation of the Community rules on advertising, and between national provisions on information have a negative impact on the uniform application of Community rules on advertising, and on the effectiveness of the provisions on product information contained in the summary of products characteristics and the package leaflet. Although those rules are fully harmonised to ensure the same level of protection of public health across the Community, this objective is undermined if widely divergent national rules on the dissemination of such key information are allowed.
- (6) The different national measures are also likely to have an impact on the proper functioning of the internal market for medicinal products, as the possibility for marketing authorisation holders to disseminate information on medicinal products is not the same across Member States, while information disseminated in one Member State is likely to have effects in other Member States. This impact will be greater in the case of medicinal products whose product information (summary of product characteristics and package leaflet) is harmonised at Community level. This includes medicinal products authorised by the Member States under the mutual recognition framework of Chapter IV of Title III of Directive 2001/83/EC.
- (7) In the light of the above and taking into account technological progress with regard to modern communication tools and the fact that patients throughout the European Union have become increasingly active as regards healthcare, it is necessary to amend the existing legislation in order to reduce differences in access to information and to allow for the availability of good-quality, objective, reliable and non promotional information on medicinal products.
- (8) National competent authorities and health care professionals should remain important sources of information on medicinal products for the general public. Member States should facilitate the access of citizens to high-quality information through appropriate channels. Marketing authorisation holders may be a valuable source of non promotional information on their medicinal products. This Directive should therefore establish a legal framework for the dissemination of specific information on medicinal products by marketing authorisation holders to the general public. The ban on advertising to the general public for prescription-only medicinal products should be maintained.

⁹ COM(2007) 862 final.

- (9) In accordance with the principle of proportionality, it is appropriate to limit the scope of this Directive to prescription-only medicinal products, as current Community rules allow the advertising to the general public of medicinal products not subject to prescription, under certain conditions.
- (10) Provisions should be established to ensure that only high-quality non-promotional information about the benefits and the risks of medicinal products subject to medical prescription may be disseminated. The information should take into account patients needs and expectations in order to empower patients, allow informed choices and enhance the rational use of medicinal products. Therefore, any information to the general public on prescription-only medicinal products should comply with a set of quality criteria.
- (11) In order to further ensure that marketing authorisation holders disseminate only high-quality information and to distinguish non-promotional information from advertising, the types of information which may be disseminated should be defined. It is appropriate to allow marketing authorisation holders to disseminate the contents of the approved summaries of product characteristics and package leaflet, information that is compatible with those documents without going beyond their key elements, and other well-defined medicinal product-related information.
- (12) Information to the general public on prescription-only medicinal products should only be provided through specific channels of communication, including Internet and health-related publications, to avoid that the effectiveness of the prohibition on advertising is undermined by unsolicited provision of information to the public. Where information is disseminated via television or radio, patients are not protected against such unsolicited information and such dissemination should therefore not be allowed.
- (13) The Internet is of major importance with regard to the provision of information to patients and its importance is increasing. The Internet allows almost unlimited access to information disregarding national boundaries. Specific rules on the monitoring of websites should be established to take account of the cross-border nature of information provided over the Internet and to allow cooperation between the Member States.
- (14) Monitoring of information on prescription-only medicinal products should ensure that marketing authorisation holders only disseminate information which is in compliance with Directive 2001/83/EC. Member States should adopt rules establishing effective monitoring mechanisms and allowing effective enforcement in cases of non-compliance. Monitoring should be based on the control of information prior to its dissemination, unless the substance of the information has already been agreed by the competent authorities or if there is a different mechanism in place to ensure an equivalent level of adequate and effective monitoring.
- (15) As this Directive introduces for the first time harmonised rules on the provision of information on medicinal products subject to medical prescription to the general public, the Commission should assess its operation and the necessity for a review five years after its entry into force. Provision should also be made for the drawing up of guidelines by the Commission based on Member States' experience in the monitoring of information.

- (16) Since the objective of this Directive to harmonise the rules on information on medicinal products subject to prescription across the Community cannot be sufficiently achieved by the Member States and can therefore be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve this objective.
- (17) Directive 2001/83/EC should be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 2001/83/EC is amended as follows:

- (1) Article 86(2) is replaced by the following:
- "2. The following are not covered by this Title:
- the labelling and the accompanying package leaflets, which are subject to the provisions of Title V;
 - 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;
 - information relating to human health or diseases, provided that there is no reference, even indirect, to medicinal products;
 - 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 VIIIa."
- (2) Article 88(4) is replaced by the following:
- "4. The prohibition set out 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.";
- (3) The heading "TITLE VIIIa "Information and advertising" is deleted;
- (4) Article 88a is deleted;

(5) The following Title VIIIa is inserted after Article 100:

“Title VIIIa – Information to the general public on medicinal products subject to medical prescription

Article 100a

1. Member States shall allow the marketing authorisation holder to disseminate, either directly or indirectly through a third party, information to the general public or members thereof on authorised medicinal products subject to medical prescription provided that it is in accordance with the provisions of this Title. Such information shall not be considered advertising for the purposes of the application of Title VIII.

2. This Title shall not cover the following:

(a) information relating to human health or diseases, provided that there is no reference, even indirect, to medicinal products;

(b) material provided by the marketing authorisation holder to healthcare professionals for distribution to patients.

Article 100b

The following types of information on authorised medicinal products subject to medical prescription may be disseminated by the marketing authorisation holder to the general public or members thereof:

(a) the summary of product characteristics, labelling and package leaflet of the medicinal product, as approved by the competent authorities, and the publicly accessible version of the assessment report drawn up by the competent authorities;

(b) information which does not go beyond the elements of the summary of product characteristics, labelling and the package leaflet of the medicinal product, and the publicly accessible version of the assessment report drawn up by the competent authorities, but presents them in a different way;

(c) information on the environmental impact of the medicinal product, prices and factual, informative announcements and reference material relating, for example, to pack changes or adverse-reaction warnings;

(d) medicinal product-related information about non-interventional scientific studies, or accompanying measures to prevention and medical treatment, or information which presents the medicinal product in the context of the condition to be prevented or treated.

Article 100c

Information on authorised medicinal products subject to medical prescription disseminated by the marketing authorisation holder to the general public or members

thereof shall not be made available on television or radio. It shall only be made available through the following channels:

- (a) health-related publications as defined by the Member State of publication, to the exclusion of unsolicited material actively distributed to the general public or members thereof;
- (b) internet websites on medicinal products, to the exclusion of unsolicited material actively distributed to the general public or members thereof;
- (c) written answers to requests for information of a member of the general public.

Article 100d

1. The content and presentation of information on authorised medicinal products subject to medical prescription disseminated by the marketing authorisation holder to the general public or members thereof shall fulfil the following conditions:

- (a) it must be objective and unbiased; in this regard, if the information refers to the benefits of a medicinal product, its risks shall also be stated;
- (b) it must take into account the general needs and expectations of patients;
- (c) it must be based on evidence, be verifiable and include a statement on the level of evidence;
- (d) it must be up-to-date and include the date of publication or last revision of the information;
- (e) it must be reliable, factually correct and not misleading;
- (f) it must be understandable for the general public or members thereof;
- (g) it must clearly state the source of the information indicating its author and giving references to any documentation that the information is based on;
- (h) it must not contradict the summary of product characteristics, labelling and package leaflet of the medicinal product, as approved by the competent authorities.

2. Any information shall include:

- (a) a statement that the medicinal product concerned is available on prescription only and that instructions for use appear on the package leaflet or on the outer packaging, as the case may be;
- (b) a statement indicating that the information is intended to support, not to replace, the relationship between patient and health professionals and that a health professional should be contacted if the patient requires clarification on the information provided;

- (c) a statement indicating that the information is disseminated by a marketing authorisation holder;
 - (d) a mail address or e-mail address allowing members of the general public to send comments to the marketing authorisation holder.
3. The information shall not include:
- (a) comparisons between medicinal products;
 - (b) any of the material referred to in Article 90.
4. The Commission shall adopt the measures necessary for the implementation of paragraphs 1, 2 and 3.

Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 121(2a).

Article 100e

1. Member States shall ensure that marketing authorisation holders' Internet websites for the dissemination of information on medicinal products subject to medical prescription reproduce the summary of product characteristics and the package leaflet of the medicinal products concerned in the official languages of the Member States where they are authorised.
2. Member States shall ensure that requests for information to a marketing authorisation holder on a medicinal product subject to medical prescription by a member of the general public may be drafted in any of the official languages of the Community which are official languages in the Member States where the medicinal product is authorised. The reply shall be drafted in the language of the request.

Article 100f

1. Member States shall, without creating a disproportionate burden for the marketing authorisation holder, ensure that marketing authorisation holders make information provided in accordance with this Title accessible to persons with disabilities.
2. To ensure accessibility of information on a medicinal product provided by marketing authorisation holders through the Internet, the websites concerned shall conform to the World Wide Web Consortium's (W3C) Web Content Accessibility Guidelines version 1.0, Level A. The Commission shall make those guidelines publicly available.

The Commission may amend this paragraph to take account of technical progress. This measure, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 121(2a).

Article 100g

1. 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 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.

2. After consulting the Member States, the Commission shall draw up guidelines concerning information allowed under this Title and containing a code of conduct for marketing authorisation holders providing information to the general public or members thereof on authorised medicinal products subject to medical prescription. The Commission shall draw up these guidelines on the entry into force of this directive and update them regularly on the basis of the experience gained.

Article 100h

1. Member States shall ensure that marketing authorisation holders register Internet websites containing information on medicinal products with the national competent authorities of the Member State of the country code Top Level Domain used by the website concerned, prior to making it available to the general public. Where the website does not use a country code Top Level Domain, the marketing authorisation holder shall select the Member State of registration.

After registration of the Internet website, the information on a medicinal product contained therein may be provided by the marketing authorisation holder on other Internet websites throughout the Community if the contents are identical.

2. Internet websites registered in accordance with paragraph 1 shall not contain links to other marketing authorisation holder websites unless they have also been registered in accordance with that paragraph. Those websites shall identify the competent authority which granted the marketing authorisation and its website address.

Internet websites registered in accordance with paragraph 1 shall not allow the identification of members of the general public which have access to those websites or the appearance therein of unsolicited material actively distributed to the general public or members thereof. Those websites shall not contain web-TV.

3. The Member State where the Internet website has been registered shall be responsible for the monitoring of the contents disseminated on that website.
4. A Member State shall not adopt any measure with regard to the content of an Internet website which reproduces an Internet website registered with the national competent authorities of another Member State, except on the following grounds:
 - (a) If a Member State has reasons for doubts as to whether the translation of the reproduced information is correct, it may require a marketing authorisation holder to provide for a certified translation of the information disseminated on the Internet website registered with the national competent authority of another Member State.
 - (b) If a Member State has reasons for doubts as to whether the information disseminated on an Internet website registered with the national competent authorities of another Member State complies with the requirements of this Title, it shall inform that Member State of the reasons for its doubts. The Member States concerned shall use their best endeavours to reach agreement on the action to be taken. If they fail to reach an agreement within two months, the case shall be referred to the Pharmaceutical Committee set up by Decision 75/320/EEC. Any necessary measures may only be adopted after an opinion has been delivered by that Committee. Member States shall take account of opinions delivered by the Pharmaceutical Committee and shall inform the Committee of how its opinion has been taken into account.
5. Member States shall allow marketing authorisation holders which have registered Internet websites in accordance with paragraphs 1 to 4 to include a statement therein to the effect that the site has been registered and is subject to monitoring in accordance with this Directive. The statement shall identify the national competent authority monitoring the website concerned. It shall also specify that the fact that the website is monitored does not necessarily mean that all the information on the website has been subject to prior approval.

Article 100i

1. Member States shall take appropriate measures to ensure that the provisions of this Title are applied and that adequate and effective measures are adopted to sanction non-compliance with those provisions. Such measures shall include the following:
 - (a) the determination of the penalties which shall be imposed should the provisions adopted for the implementation of this Title be infringed;
 - (b) the obligation to sanction cases of non-compliance;
 - (c) the conferment of powers on the courts or administrative authorities enabling them to order the cessation of dissemination of information that does not comply with this Title or, if such information has not been disseminated but dissemination is imminent, to order prohibition of such dissemination.

2. Member States shall make provision for the measures referred to in paragraph 1 to be taken under an accelerated procedure either with interim effect or with definitive effect.

Article 100j

Member States shall ensure that marketing authorisation holders, through the scientific service referred to in Article 98(1):

- (a) keep available for the authorities or bodies responsible for monitoring information on medicinal products, a sample of all information disseminated in accordance with this Title and information on its volume of dissemination, together with a statement indicating the persons to whom it is addressed, the method of dissemination and the date of first dissemination,
- (b) ensure that information on medicinal products by their undertaking complies with the requirements of this Title;
- (c) supply the authorities or bodies responsible for monitoring information on medicinal products with the information and assistance they require to carry out their responsibilities;
- (d) ensure that the decisions taken by the authorities or bodies responsible for monitoring information on medicinal products are immediately and fully complied with.

Article 100k

Information on homeopathic medicinal products referred to in Article 14(1) that have been classified as prescription-only shall be subject to the provisions of this Title.

Article 100l

By [insert specific date *five years from the entry into force of amending directive*] at the latest, the Commission shall publish a report on the experience acquired in the implementation of this Title and shall also assess the need for a review thereof. The Commission shall submit this report to the European Parliament and to the Council."

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [*12 months after publication in the Official Journal; exact date inserted at time of publication*] at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

LEGISLATIVE FINANCIAL STATEMENT

1. NAME OF THE PROPOSAL:

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, and a Directive amending, as regards information to the general public on medicinal products subject to medical prescription, Directive 2001/83/EC (CLWP Item 2008/ENTR/024 and is part of the Commission Legislative and Work Programme for 2008, under Annex 1 Strategic and Priority initiatives)¹⁰.

Note:

The Legislative Financial Statement is proposed based on the fact that the legislative proposal, if adopted, foresees that specific information activities of marketing authorization holders for centrally authorized medicinal products subject to medical prescription will be subject of fees charged by the European Medicines Agency (EMA). The legislative proposal foresees the insertion of new articles 20a and 20b to the existing Regulation (EC) No 726/2004 laying down in one of its paragraphs that the “submission of information to the Agency in accordance with this Article shall be subject to a fee payable in accordance with Regulation (EC) No 297/95.”

The EMA shall be charged with delivering opinions on information to the general public on medicinal products subject to medical prescription. In this regard Article 57(1) of Regulation (EC) No 726/2004 shall be amended.

The Legislative Financial Statement proposes that all costs relating to activities resulting from the legislative proposal will be recuperated through fees. On this basis, the calculation made leads to the conclusion that the proposals are not expected to have a significant financial impact on the Community budget (see the Annex to this Legislative Financial Statement).

2. ABM / ABB FRAMEWORK

Policy Area(s) concerned and associated Activity/Activities:

Policy area(s): Internal Market (Article 95 of the EC Treaty).

Activities:

- Promoting public health across the Community through providing for harmonized rules on information on medicinal products subject to medical prescription;
- Supporting the achievement of the internal market in the pharmaceutical sector;

¹⁰ http://ec.europa.eu/atwork/programmes/docs/clwp2008_en.pdf (see page 20).

3. BUDGET LINES

3.1. Budget lines including headings:

02.030201 – European Medicines Agency — Subsidy under Titles 1 and 2

02.030202 – European Medicines Agency — Subsidy under Title 3

3.2. Duration of the action and of the financial impact:

The assumption is that the proposals on information to the general public on medicinal products subject to medical prescription would apply from late 2011 (year "n"). The calculation in the Annex has been calculated for 2011-2016.

3.3. Budgetary characteristics:

Budget line	Type of expenditure		New	EFTA contribution	Contributions from applicant countries	Heading in financial perspective
02.030201	Non-comp	Differentiated	NO	YES	NO	No 1a
02.030202	Non-comp	Differentiated	NO	YES	NO	No 1a

4. SUMMARY OF RESOURCES

4.1. Financial Resources

4.1.1. Summary of commitment appropriations (CA) and payment appropriations (PA)

EUR million (to 3 decimal places)

Expenditure type	Section no.		Year n	n + 1	n + 2	n + 3	n + 4	n + 5 and later	Total
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Operational expenditure¹¹

Commitment Appropriations (CA)	N.A.	a							
Payment Appropriations (PA)	N.A.	b							

¹¹ Expenditure that does not fall under Chapter xx 01 of the Title xx concerned.

Administrative expenditure within reference amount¹²

Technical & administrative assistance (NDA)	N.A.	c							
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TOTAL REFERENCE AMOUNT

Commitment Appropriations	N.A.	a+c							
Payment Appropriations	N.A.	b+c							

Administrative expenditure not included in reference amount¹³

Human resources and associated expenditure (NDA)	N.A.	d							
Administrative costs, other than human resources and associated costs, not included in reference amount (NDA)	N.A.	e							

Total indicative financial cost of intervention

TOTAL CA including cost of Human Resources	N.A.	a+c +d +e							
TOTAL PA including cost of Human Resources	N.A.	b+c +d +e							

4.1.2. Compatibility with Financial Programming

- Proposal is compatible with existing financial programming.

4.1.3. Financial impact on Revenue

- Proposal has no financial implications on revenue (see details of calculation in the Annex)

4.2. Human Resources FTE (including officials, temporary and external staff) – see detail under point 8.2.1.

Annual requirements	Year 2011	2012	2013	2014	2015	2016 and later
Total number of human resources						

¹² Expenditure within article xx 01 04 of Title xx.

¹³ Expenditure within chapter xx 01 other than Articles xx 01 04 or xx 01 05.

5. CHARACTERISTICS AND OBJECTIVES

5.1. Need to be met in the short or long term

Patients have become more empowered and proactive consumers of healthcare, increasingly seeking information about medicines and treatments. While Directive 2001/83/EC provides for a harmonised framework on advertising of medicines at Community level, the application of which remains a responsibility of Member States, neither Directive 2001/83/EC nor Regulation (EC) No 726/2004 include detailed provisions on information on medicinal products. Therefore, Community legislation does not prevent Member States from establishing their own approaches.

Divergent interpretations of Community rules and different national rules and practices on information are creating obstacles to patients' access to high quality information and to the operation of the internal market.

5.2. Value-added of Community involvement and coherence of the proposal with other financial instruments and possible synergy

Considering the existing harmonised EU legislation on the authorisation and supervision of medicinal products a common approach on information provision has to be taken. Harmonised provisions would allow that citizens in all Member States have access to the same type of information. If this matter continues to be left for national rules, it will almost inevitably lead to the adoption of national rules running counter to the spirit of the existing pharmaceutical legislation.

National rules and practices on information may lead to restrictions to the free movement of goods in violation of Art 28 EC, impacting negatively on the completion of a single market in pharmaceuticals which the harmonised legal framework on medicinal products tries to achieve.

5.3. Objectives, expected results and related indicators of the proposal in the context of the ABM framework

The high level objective of the proposal is to improve the protection of health of EU citizens and to ensure the proper functioning of the internal market for medicinal products for human use. Following this line, the proposal aims specifically to:

- Provide for a clear framework for provision on information by marketing authorisation holders about their prescription-only medicines to the general public with a view to enhancing the rational use of these medicines, while ensuring that the legislative framework continues to prohibit direct-to-consumer advertising of prescription-only medicines.

This aim shall be achieved by:

- Ensuring the high quality of information provided by coherent application of clearly defined standards across the Community.
- Allowing information to be provided through channels addressing needs and capabilities of different types of patients.

- Not inappropriately restricting the ability of marketing authorization holders to provide in an understandable way objective and non-promotional information about the benefits and the risks of their medicines.
- Ensuring that monitoring and enforcement measures are in place to ensure that information providers comply with the quality criteria, while avoiding unnecessary bureaucracy.

5.4. Method of Implementation (indicative)

Centralised Management

indirectly by delegation to:

bodies set up by the Communities as referred to in art. 185 of the Financial Regulation

Shared or decentralised management

with Member states

Joint management with international organisations (please specify)

Relevant comments: The Community system for regulating medicinal products operates as a network between the Commission, the European Medicines Agency (EMA) and the National competent authorities for medicinal products. Responsibilities are frequently shared with the exact split depending on whether a medicine is centrally authorised (with the Commission as competent authority) or nationally authorised (with the Member States providing the competent authorities).

6. MONITORING AND EVALUATION

6.1. Monitoring system

The Commission has established mechanisms for working with the Member States to monitor transposition and in the pharmaceutical sector the Commission's Pharmaceutical Committee is a key forum for exchanging information in this regard.

The EMA should contribute to the implementation, although no scientific assessment of information will be necessary.

With regard to *ex-post* evaluation of the operational objectives, these can be evaluated by:

- Extent of compliance with rules
- Information provision by industry
- Indicators of use of this information
- Patient awareness of this information
- Measuring the effect of information on patient behaviour and on health outcomes.

6.2. Evaluation

6.2.1. Ex-ante evaluation

Within the framework of the impact assessment process the Commission services extensively consulted all relevant stakeholders using a wide range of communication means. Two general web-based public consultations, carried out according to the Commission's general principles and minimum standards for consultation, were supplemented by questionnaire surveys and interviews with representatives of key stakeholder groups. Comments of the Commission services raised during the inter-service steering group meetings were fully taken into consideration.

The first formal public consultation was conducted between April and June 2007 on a Draft report on current practices without presenting yet any political orientations or proposals.

The second public consultation, conducted between February and April 2008, specifically addressed the key ideas of the forthcoming legal proposal on information to patients.

6.2.2. Measures taken following an intermediate/ex-post evaluation

Experience in the area of information to patients exists on a Member State level. In 2006, the Commission conducted a survey amongst medicines regulatory agencies to gather information about their practises, in particular related to the relevant provisions of Directive 2001/83/EC. This was complemented with information gathered by means of a questionnaire prepared for the Pharmaceutical Forum Information to Patients Working Group.

The report concluded that Member States have adopted divergent rules and practices with regard to the provision of information. This shall be changed by providing a clear framework on what information may be disseminated, through which channels and by establishing a set of quality criteria which have to be respected.

Experience with the current legal framework has also shown that the notions of advertising and information are not interpreted consistently throughout the Community, thus restricting possibilities of pharmaceutical companies to provide information.

6.2.3. Terms and frequency of future evaluation

The overall objectives of the Community pharmaceutical legislation are to ensure proper functioning of the internal market for medicinal products and to better protect health of the EU citizens. Given that the Directive 2001/83/EC contains existing general review clauses which will apply to the new provisions, any *ex-post* evaluation should therefore include these general reviews and any external study should be conducted in this context.

7. ANTI-FRAUD MEASURES

The European Medicines Agency has specific budgetary control mechanisms and procedures. The Management Board, which comprises representatives of the Member States, the Commission and the European Parliament, adopts the budget, as well as the internal financial provisions. The European Court of Auditors examines the execution of the budget each year.

Regarding fraud, corruption and other unlawful activities, the provisions of Regulation (EC) No 1073/1999 of the European Parliament and of the Council of 25 May 1999 concerning investigations conducted by the European Anti-Fraud Office (OLAF) apply to the EMEA without restriction. Besides, a decision concerning co-operation with the OLAF was already adopted on 1 June 1999 (EMEA/D/15007/99).

Finally, the Quality Management System applied by the Agency supports a continuous review. Several internal audits are undertaken each year as part of this process.

Annex: details of calculation

Introduction

The Legislative Financial Statement is proposed based on the fact that the legislative proposal foresees that specific information activities of marketing authorization holders for centrally authorized medicinal products subject to medical prescription will be subject to fees charged by the European Medicines Agency (EMA).

The Legislative Financial Statement and the calculations in this annex demonstrate that all costs relating to activities resulting from the legislative proposal will be recuperated through fees. On this basis, the calculation in this Annex leads to the conclusion that the proposals on information to the general public on medicinal products subject to medical prescription are not expected to have a financial impact on the Community budget.

The EMA budget was €163 million in 2007. The Community contribution has increased from €15.3 million in 2000 to €41 million in 2007. The remainder of the increase of the budget over time has been covered by fees charged by the EMA to the pharmaceutical industry (estimated at 77% of total income in 2008 and based on Council Regulation (EC) No 297/95 as amended by Commission Regulation No 312/2008 of 3 April 2008). Fee revenues are anticipated to further increase in the coming years in line with the general increase in the number of centrally authorised products. It should be noted that based on fee income the EMA budget has run at a surplus in recent years and use has been made of the carry-over facility. Indeed, in 2006 the surplus was superior to €8 million.

The legal proposal foresees that the EMA shall be charged with supervision of specific pieces of information on centrally authorised products: Medicinal product-related information about non-interventional scientific studies or accompanying measures to prevention and medical treatment, or information which presents the medicinal product in the context of the condition to be prevented or treated shall be notified to the EMA prior to publication in health-related publications or in an Internet site.

The notification shall be subject to a fee payable in accordance with Regulation (EC) No 297/95. The assessment of the information submitted shall be fully conducted by EMA staff. Due to the fact that EMA activities only have an opinion giving character and that subsequent monitoring will be undertaken by Member States, administrative procedures within the Agency will not be burdensome.

The average cost of 1 full time equivalent (FTE) AD Staff Member for the EMA in London has been provided by the EMA (draft 2007 costs) as: Salary: €12.113 and Salary and overheads: €61.708 and these are the staff costs used for the calculations below.

Fees charged by the EMA to the pharmaceutical industry

Regarding EMA fees, the following estimates can be made:

At the moment approx. 400 centrally authorised medicinal products exist. It can be estimated that during the first year after entry into force of the proposed directive approximately 100 submissions of information to be disseminated to the general public will be submitted to the Agency for an opinion. For following years an increase in submissions to the Agency can be expected. The estimated fee charged to the pharmaceutical industry is €2,300. Based on these

estimates the additional income to the EMEA from patient information fee revenue will be in the first year €230,000 and €345,000 in the following years.

Cost to the EMEA

As explained above, it can be estimated that 100 submissions for an opinion about information to patient on centrally authorised products will need to be checked by the Agency in the first year. An increase of this number is to be expected to 150 submissions once pharmaceutical companies have got familiar with the new procedure.

It can be estimated that total costs for EMEA is made up by the annual salary of the staff.

On the basis of the following tasks:

- checking the information on the basis of the documentation that has been provided by the pharmaceutical company and on the basis of other scientific information,
- contacts with pharmaceutical companies if there is a need for extra information;
- internal discussions,
- administrative processing of the submission (incl. drafting of the opinion),

it can be assumed that it takes 2.5 working days to check one application.

If there are 200 working days per year and one application takes 2.5 days, there will be 80 submissions handled by one person in a year. This will mean a need for 1.5 administrators for the first year (number of submissions is 100) and a need for 2 administrators in other years (150 submissions).

The average cost of 1 full time equivalent (FTE) AD Staff Member for the EMEA in London has been provided by the EMEA (draft 2007 costs) as: Salary: €12.113 and Salary and overheads: €61.708 and these are the staff costs used for the calculations below.

There will be no extra costs for literature screening by EMEA, because the information to patients shall be based on the documentation that the pharmaceutical companies provide in their application. It can also be assumed that there is no need for one-off costs; since EMEA already disposes information sources (i.e. scientific journals and databases) existing IT-systems can be used when checking the content of the information provided.

Impact on EMEA budget

The total impact of the legal proposal on EMEA budget has been presented in the Table below. Based on a need for 1.5 or 2 extra vacancies, a slight negative balance in the first year followed by a slight positive balance in subsequent years are to be expected.

Table: Impact on EMEA budget¹⁴

EMEA costs	Year 2011	Year 2012	Year 2013	Year 2014	Year 2015	Year 2016
Number of applications submitted	100	150	150	150	150	150
FTA	1.5	2	2	2	2	2
Total costs (=Annual salary) (€)¹⁵	242,562	323,416	323,416	323,416	323,416	323,416
Income fees¹⁶	230,000	345,000	345,000	345,000	345,000	345,000
Balance	-12,562	21,584	21,584	21,584	21,584	21,584

¹⁴ Assumption: there will be an increase in applications and no impact on EMEA costs.

¹⁵ ² Covers salary and overheads, €161,708/year.

¹⁶ The fee for the pharmaceutical company will be €2,300.