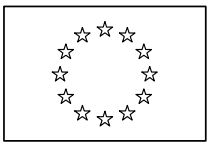

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 10.12.2008
COM(2008) 662 final

2008/0255 (COD)

Proposal for a

# REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

**amending, as regards information to the general public on medicinal products for human use subject to medical prescription, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency**

{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 use[1] 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.

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[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/EC[2], 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.

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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)

2008/0255 (COD)

Proposal for a

**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**amending, as regards information to the general public on medicinal products for human use subject to medical prescription, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency**

**(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 Commission[1],

Having regard to the opinion of the European Economic and Social Committee[2],

Having regard to the opinion of the Committee of the Regions[3],

Acting in accordance with the procedure laid down in Article 251 of the Treaty[4],

Whereas:

(1) On 20 December 2007, the Commission submitted a Communication 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"[5] . 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. Experience gained from the application of the current legal framework has also shown disparities in the interpretation of the Community rules on advertising, and between national provisions on information.

(2) The introduction of a new Title VIIIa in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on a Community code relating to medicinal products for human use[6] addresses those concerns through various

1 OJ C , , p. .
2 OJ C , , p. .
3 OJ C , , p. .
4 OJ C , , p. .
5 COM(2007) 862.
6 OJ L 311, 28.11.2001, p. 87.

provisions intended to ensure the availability of good-quality, objective, reliable and non promotional information on medicinal products for human use subject to prescription.

(3) Disparities in the provision of information on medicinal products for human use are not justified in the case of medicinal products authorised pursuant to Title II of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[7] for which a single summary of the products characteristics and package leaflet are approved for the whole Community. Therefore Title VIIIa of Directive 2001/83/EC should also apply to those products.

(4) Directive 2001/83/EC provides that certain types of information are subject to control by the Member States' national competent authorities prior to their dissemination. This concerns 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. In the case of medicinal products for human use authorised pursuant to Title II of Regulation (EC) No 726/2004, provision should also be made for certain types of information to be subject to prior vetting by the European Medicines Agency (hereinafter referred to as the 'Agency').

(5) To ensure the adequate funding of these activities related to information, provision should be made for the collection of fees charged to marketing authorisation holders by the Agency.

(6) Since the objective of this Regulation, namely to provide for specific rules on information on medicinal products for human use subject to prescription authorised pursuant to Regulation (EC) No 726/2004 cannot be sufficiently achieved by Member States and can 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 Regulation does not go beyond what is necessary in order to achieve this objective.

(7) Regulation (EC) No 726/2004 should be amended accordingly,

HAVE ADOPTED THIS REGULATION:

*Article 1*

Regulation (EC) No 726/2004 is amended as follows:

(1) The following Articles 20a and 20b are inserted:

"Article 20a

[7] OJ L 136, 30.4.2004, p. 1.

1. Title VIIIa of Directive 2001/83/EC shall apply to medicinal products which are authorised under this Title and are subject to medical prescription.

Article 20b

1. By way of derogation from Article 100g(1) of Directive 2001/83/EC, medicinal product-related information referred to in Article 100b(d) of that Directive shall be subject to vetting by the Agency prior to its dissemination.

2. For the purposes of paragraph 1, the marketing authorisation holder shall submit to the Agency a mock-up of the information to be disseminated.

3. The Agency may object to the information submitted or parts thereof on grounds related to non-compliance with the provisions of Title VIIIa of Directive 2001/83/EC within 60 days after receipt of the notification. If the Agency does not object within 60 days, the information shall be deemed accepted and may be published.

4. The submission of information to the Agency in accordance with paragraphs 1, 2 and 3 shall be subject to a fee payable in accordance with Regulation (EC) No 297/95."

(2) In Article 57(1), the following point (u) is added:

"(u) delivering opinions on information to the general public on medicinal products for human use subject to medical prescription."

*Article 2*

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

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

| | |
|---|---|
| *For the European Parliament* | *For the Council* |
| *The President* | *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)[8].

*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 (EMEA). 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 EMEA 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;

[8] 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 |
|---|---|---|---|---|---|---|---|---|---|
| **Operational expenditure**[9] | | | | | | | | | |
| Commitment Appropriations (CA) | N.A. | a | | | | | | | |
| Payment Appropriations (PA) | N.A. | b | | | | | | | |
| **Administrative expenditure within reference amount**[10] | | | | | | | | | |
| Technical & administrative assistance (NDA) | N.A. | c | | | | | | | |

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

10 Expenditure within article xx 01 04 of Title xx.

**TOTAL REFERENCE AMOUNT**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Commitment Appropriations** | N.A. | a+c | | | | | | | |
| **Payment Appropriations** | N.A. | b+c | | | | | | | |

**Administrative expenditure not included in reference amount**[11]

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 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 | | | | | | |

## 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 Direcitve 2001/83/EC nor Regulation (EC) No 726/2004 include detailed provisions on information on medicinal

[11] Expenditure within chapter xx 01 other than articles xx 01 04 or xx 01 05.

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 (EMEA) 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 EMEA 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 (EMEA).

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 EMEA 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 EMEA 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 EMEA 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 EMEA 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 EMEA 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 EMEA staff. Due to the fact that EMEA 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 EMEA in London has been provided by the EMEA (draft 2007 costs) as: Salary: €112.113 and Salary and overheads: €161.708 and these are the staff costs used for the calculations below.

**Fees charged by the EMEA to the pharmaceutical industry**

Regarding EMEA 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: €112.113 and Salary and overheads: €161.708 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 budget[16]

| 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) (€)**[17] | 242,562 | 323,416 | 323,416 | 323,416 | 323,416 | 323,416 |
| **Income fees**[18] | 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*** |

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

17 Covers salary and overheads, €161,708/year.

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