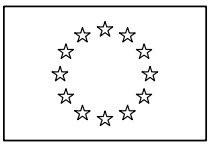

EUROPEAN COMMISSION

Brussels, 11.10.2011
COM(2011) 632 final

2008/0255 (COD)

Amended proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulation (EC) No 726/2004 as regards information to the general public on medicinal products for human use subject to medical prescription and as regards pharmacovigilance

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

The Commission presents an amended proposal for a Regulation of the European Parliament and of the Council on information to the general public on medicinal products subject to medical prescription. Incorporated within the amended proposal are amendments proposed by the European Parliament at its first reading which are acceptable to the Commission.

1. BACKGROUND

On 10 December 2008, the Commission adopted a proposal for a Regulation of the European Parliament and of the Council on information to the general public on medicinal products subject to medical prescription. This proposal was forwarded to the European Parliament and the Council on 10 December 2008.

The Economic and Social Committee gave its opinion on 10 June 2009 and the Committee of the Regions, 7 October 2009.

The European Parliament adopted a legislative resolution at its first reading on 24 November 2010.

2. OBJECTIVE OF THE COMMISSION'S 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 EU 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 EU.

- 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.

This amended proposal is in line with those objectives and further reinforces the rights of patients. In particular, the marketing authorisation holders will have the obligation, and no

longer the possibility, to make available certain information, such as the labelling and the package leaflet.

3. COMMISSION OPINION ON THE AMENDMENTS ADOPTED BY THE EUROPEAN PARLIAMENT:

On 24 November 2010, the European Parliament adopted 12 amendments on the proposal for a Regulation on information to the general public on medicinal products subject to medical prescription. The Commission considers that a majority of the European Parliament's amendments are acceptable in full, in principle, or in art, as they maintain the aims and overall scheme of the proposal.

The Commission therefore accepts in full or in part, the following amendments of the European Parliament:

Recital 1 is modified in accordance with amendment 1, which underlines that in the Commission Communication transmitted on 20 December 2007 concerning the "Report on current practices with regard to the provision of information to patients on medicinal products" the need for a more precise distinction between advertising and information was highlighted.

Amendment 2 specifies in recital 2 that the new Title introduced in Directive 2001/83/EC is intended to place emphasis on the rights and interests of patients.

In accordance with Amendment 6, it has been specified in Article 20b, paragraph 1, that although the pre-control of information is performed by the Agency for centrally approved medicinal products, the monitoring of the information rests with Member States. It is appropriate to ensure consistently that the Agency is also responsible for the control of the information made available through Internet websites registered in the Member States. Specific provisions are introduced to clarify the operation of this control mechanism in such case of information made available through Internet websites registered with the Member States. The Commission acknowledges that a number of Member States have expressed concerns in relation to the conformity with their national constitutions. The Commission is prepared to enter into a dialogue with those concerned to find suitable solutions while fully respecting the objectives of this Regulation.

Following Amendment 7, the word "disseminated" has been replaced by "made available" within Article 20b, paragraph 2.

Amendment 9 provides for the procedure regarding cases when the Agency requests for changes within the information submitted for control and for the fees applicable which should be proportionate to the additional work. Considering that the normal delay is 60 days, the subsequent delay should be of 30 days.

Amendment 10 modifies Article 57, paragraph 1, concerning the so-called EudraPharm database and provides that it should be available in all EU languages. Such a change has been introduced as regards the lay-out of the database; on the other hand, the information contained in the database will be available in the languages of Member States where the medicinal product is authorised. In another respect, it is not necessary to further specify that the information provided is designed for non-experts, as it is already provided that it should be worded in an appropriate and comprehensible manner in accordance with article 57.

Amendment 12 provides that EudraPharm should be actively promoted to European citizens. This should be done through the development of the European medicines web-portal established by Regulation (EU) No 1235/2010 as the central point of access to information about medicinal products. On the other hand, it is not appropriate that information available on marketing authorisation holder websites is reproduced on EudraPharm, which is a public database.

Pharmacovigilance

In addition to the changes introduced on the basis of the European Parliament resolutions regarding the Commission proposals on information to patients, the Commission considers that limited changes to Regulation 726/2004 in the area of pharmacovigilance should be introduced.

Regulation (EC) No 726/2004 has been recently amended by Regulation (EU) No 1235/2010 to revise the EU pharmacovigilance system. Regulation (EU) No 1235/2010 having as legal basis Article 168(4)(c) of TFUE; the amended proposal should also be based on Article 168(4)(c) of TFUE. Regulation (EU) No 1235/2010 substantially strengthens the legal framework for the surveillance of medicinal products in the EU. However, in view of recent pharmacovigilance events in the EU, the Commission has detected certain areas where the legislation could be further strengthened. Therefore:

– The new public list of medicinal products subject to additional monitoring introduced by Regulation (EU) No 1235/2010 will not necessarily include all medicinal products subject to post-authorisation safety conditions; competent authorities will have to decide on a case-by-case basis whether to make public the fact that products are subject to strengthened surveillance. For the sake of fuller transparency as regards products under special surveillance, Article 23 should be modified to systematically include medicinal products that are subject to conditions and requirements with regard to safety.

– Article 13 is modified and a new Article 14b is introduced to avoid that the voluntary withdrawal of a marketing authorisation or product by the holder could lead to safety issues not being addressed in the EU, by clarifying information obligations of the marketing authorisation holder.

– Article 20 is modified to clarify the respective scopes of this provision and the EU procedures foreseen in Directive 2001/83/EC.

4. CONCLUSION

Having regard to Article 293 of the Treaty on the functioning of the European Union, the Commission modifies its proposal as follows:

2008/0255 (COD)

Amended proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulation (EC) No 726/2004 as regards information to the general public on medicinal products for human use subject to medical prescription and as regards pharmacovigilance~~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~~ **on the Functioning of the European Union** ~~Community~~, and in particular Article ~~95~~ **114 and Article 168(4)(c)** thereof,

Having regard to the proposal from the **European** 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 **ordinary legislative** 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~~**Union** rules on advertising, and between national provisions on information**, highlighting the need for a more precise distinction between advertising and information.**

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1 OJ C , , p. .
2 OJ C , , p. .
3 OJ C , , p. .
4 OJ C , , p. .
5 COM(2007) 862.

(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 provisions intended to ensure the availability of good-quality, objective, reliable and non promotional information on medicinal products for human use subject to prescription **and to place emphasis on the rights and interests of patients**.

(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~~**Union**. Therefore Title VIIIa of Directive 2001/83/EC should also apply to those products.

(4) Directive 2001/83/EC provides**, with some exceptions,** that ~~certain types of~~ information ~~are~~ **is** subject to control by the Member States' national competent authorities prior to ~~their dissemination~~ **being made available**. ~~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~~ **this** information to be subject to prior vetting by the European Medicines Agency (hereinafter referred to as the 'Agency')**, and to clarify the operation of the control mechanism in the case of information made available through Internet websites registered with the Member States in accordance with Directive 2001/83/EC**.

(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) In order to ensure transparency on the surveillance of authorised medicinal products, the list of medicinal products subject to additional monitoring established by Regulation (EC) No 726/2004, as amended by Regulation (EU) No 1235/2010 of the European Parliament and of the Council should systematically include medicinal products that are subject to post-authorisation safety conditions.

(7) Information on medicinal products is already provided at Union level by several databases and portals managed by the Agency or the Commission concerning inter alia medicinal products and clinical trials, such as the Orphanet portal for rare diseases and orphan drugs[8]. It is appropriate to link these different sources of information to facilitate access by the public. The European medicines web portal created by Regulation (EC) No 726/2004, as amended by Regulation (EU)

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6 OJ L 311, 28.11.2001, p. 87.
7 OJ L 136, 30.4.2004, p. 1.
8 COM(2008) 679 final

No 1235/2010 should be the single point of reference for access to that information.

(8) As the prior vetting of information by the Agency will be financed by applicants' fees which are to be adjusted, it is appropriate to provide for a deferred application of the provisions on the pre-vetting of information by the Agency.

(~~6~~**9**) 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~~**Union** level, the ~~Community~~**Union** 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.

(**10**~~7~~) Regulation (EC) No 726/2004 should **therefore** be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

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

(1) In Article 13(4), the second subparagraph is replaced by the following:

"The holder shall also notify the Agency if the product ceases to be placed on the market of the Member State, either temporarily or permanently. Such notification shall, otherwise than in exceptional circumstances, be made no less than 2 months before the interruption in the placing on the market of the product. **The holder shall inform the Agency of the reasons for such action in accordance with Article 14b of this Regulation."**

(2) The following Article 14b is inserted:

"Article 14b

The marketing authorization holder shall notify the Agency forthwith of any action taken by him to suspend the marketing of a medicinal product, to withdraw a medicinal product from the market, to request the withdrawal of a marketing authorisation or not to apply for the renewal of a marketing authorisation, together with the reasons for such action. The marketing authorisation holder shall in particular declare if such action is linked to any of the grounds set out in Articles 116 and 117 of Directive 2001/83/EC. In such case, the Agency shall ensure that this information is brought to the attention of the Member States.

(3) Article 20(8) is replaced by the following:

'8. Where the procedure results from the evaluation of data relating to pharmacovigilance, the opinion of the Agency in accordance with paragraph 2

of this Article shall be adopted by the Committee for Medicinal Products for Human Use on the basis of a recommendation from the Pharmacovigilance Risk Assessment Committee and Article 107j(2) of Directive 2001/83/EC shall apply'.~~Notwithstanding paragraphs 1 to 7 of this Article, the Union procedures laid down in Article 31 and Article 107i of Directive 2001/83/EC shall apply, as appropriate, where the reason for the Member State or the Commission to consider taking decisions or measures referred to in this Article is based on the evaluation of data resulting from pharmacovigilance activities.~~

(~~1~~**4**) The following Articles 20a**,** ~~and~~ 20b **and 20c** are inserted:

"Article 20a

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 **concerning medicinal products for human use which have been authorised in accordance with this Regulation** shall be subject to vetting by the Agency prior to its **being made available** ~~dissemination~~.

This shall be without prejudice to Article 100j of Directive 2001/83/EC relating to the monitoring by the Member States of the information made available.

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~~**made available**.

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. Where the marketing authorisation holder resubmits to the Agency a mock-up of the information to be made available following objections by the Agency in application of paragraph 3, if the Agency does not object within 30 days, the revised information shall be deemed accepted and may be published.

5. The Agency may if appropriate collaborate with Member States when it performs the tasks set out in this Article.

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

Article 20c

1. By way of derogation from Article 100h(3) of Directive 2001/83/EC, the Agency shall be responsible for the prior vetting in accordance with Article 20b of this Regulation of information relating to medicinal products authorised in accordance with this Regulation which is contained in Internet websites registered with the national competent authorities of the Member States in accordance with Article 100h of Directive 2001/83/EC.

2. Where a marketing authorisation holder intends to include information on a medicinal product authorised in accordance with this Regulation in an Internet website registered in accordance with Article 100h of Directive 2001/83/EC, it shall submit the information to the Agency for the application of Article 20b of this Regulation prior to it being made available, and inform the Agency of the Member State where the Internet website is intended to be or is registered. The Agency shall inform the concerned Member State of the outcome of the procedure of Article 20b.

3. By way of derogation from point (c) of Article 100h(4) of Directive 2001/83/EC, if a Member State has reasons for doubts as to whether the information approved in accordance with Article 20b of this Regulation made available on a registered Internet website complies with the requirements of Title VIIIa of Directive 2001/83/EC, it shall inform the Agency of the reasons for its doubts. The Member State concerned and the Agency 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 Council Decision 75/320/EEC[9]. Any necessary measures may only be adopted after an opinion has been delivered by that Committee. Member States and the Agency 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) Article 23 is replaced by the following:

"Article 23

1. The Agency shall, in collaboration with the Member States, set up, maintain and make public a list of medicinal products that are subject to additional monitoring.

That list shall include the names and active substances of:

(a) medicinal products authorised in the Union that contain a new active substance which, on 1 January 2011, was not contained in any medicinal product authorised in the Union;

(b) any biological medicinal product not covered by point (a) that was authorised after 1 January 2011**;**~~.~~

[9] **OJ L 147, 9.6.1975, p. 23.**

(c) ~~2. At the request of the Commission, following consultation with the Pharmacovigilance Risk Assessment Committee,~~ medicinal products that are authorised pursuant to this Regulation subject to conditions referred to in points (c), (ca), (cb) and (cc) of Article 9(4), or in Articles 10a, Article 14(7) and (8) and in Article 21(2~~), may also be included in the list.~~**;**

(d) ~~At the request of a national competent authority, following consultation with the Pharmacovigilance Risk Assessment Committee,~~ medicinal products that are authorised pursuant to Directive 2001/83/EC, subject to the conditions referred to in Articles 21a, 22, 22a and 104a of that Directive~~, may also be included in the list~~.

~~3.~~**2.** The list **referred to in paragraph 1** shall include an electronic link to the product information and to the summary of the risk management plan.

~~4~~**3**. **In the cases referred to in points (a) and (b) of paragraph 1 of this Article,** the Agency shall remove a medicinal product from the list ~~5~~ **five** years after the Union reference date referred to in Article 107c(5) of Directive 2001/83/EC.

In the cases referred to in points (c) and (d) of paragraph 1, the Agency shall remove a medicinal product from the list ~~However, the Commission or the national competent authority, as appropriate, may, following a recommendation of the Pharmacovigilance Risk Assessment Committee, extend that period~~ **once** ~~until such time as they conclude that~~ the conditions ~~referred to in Article 14a and Article 21(2) of this Regulation or referred to in Articles 22b and 104a of Directive 2001/83/EC~~ have been fulfilled.

~~5.~~**4.** For medicinal products included in that list, the summary of product characteristics and the package leaflet shall include the statement “This medicinal product is subject to additional monitoring”. That statement shall be preceded by a black symbol which shall be selected by the Commission following a recommendation of the Pharmacovigilance Risk Assessment Committee by 2 January 2012, and shall be followed by an appropriate standardised explanatory sentence."

(6) In Article 26 the following paragraph 3 is added:

"3. The European medicines web-portal shall contain at least links to the following:

(a) the database on medicinal products referred to in point (l) of Article 57(1) of this Regulation,

(b) the Eudravigilance database referred to in Article 24(1) and point (d) of Article 57(1) of this Regulation,

(c) the database referred to in Article 111(6) of Directive 2001/83/EC,

(d) the Orphanet portal for rare diseases and orphan drugs,

(e) the Health Portal referred to in Decision 1350/2007/EC of the European Parliament and Council[10]."

(7) In Article 57(1), point (l) is replaced by the following:

"(l) creating a database on medicinal products, to be accessible to the general public **and allowing searches in all official languages of the Union,** and ensuring that it is updated, and managed independently **of the commercial interests** of pharmaceutical companies; the database shall facilitate the search for information already authorised for package leaflets; it shall include a section on medicinal products authorised for the treatment of children; the information provided to the public shall be worded in an appropriate and comprehensible manner.

(~~2~~**8**) In Article 57(1), the following point (u) is added:

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

(9) In Article 57(2), the first subparagraph is replaced by the following:

"2. The database provided for in paragraph 1(l) shall include the summaries of product characteristics, the patient or user package leaflet and the information shown on the labelling. The database shall be developed in stages, priority being given to medicinal products authorised under this Regulation and those authorised under Chapter 4 of Title III of Directive 2001/83/EC and of Directive 2001/82/EC respectively. The database shall subsequently be extended to include any medicinal product placed on the market within the ~~E~~U**nion**. **That database shall be actively promoted to European Union citizens".**

Article 2

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

2. It shall apply from [OJ: insert date of entry into force] with the exception of Article 1 (4) and (8) which shall apply from [OJ: insert date of publication + 4 years].

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

Done at Brussels,

For the European Parliament
The President

For the Council
The President

[10] **OJ L301, 20.11.2007, p. 3.**

LEGISLATIVE FINANCIAL STATEMENT FOR PROPOSALS

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative:

1.2. Policy area(s) concerned in the ABM/ABB structure

1.3. Nature of the proposal/initiative

1.4. Objective(s)

1.5. Grounds for the proposal/initiative

1.6. Duration and financial impact

1.7. Management method(s) envisaged

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

2.2. Management and control system

2.3. Measures to prevent fraud and irregularities

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

3.2. Estimated impact on expenditure

3.2.1. Summary of estimated impact on expenditure

3.2.2. Estimated impact on operational appropriations

3.2.3. Estimated impact on appropriations of an administrative nature

3.2.4. Compatibility with the current multiannual financial framework

3.2.5. Third-party participation in financing

3.3. Estimated impact on revenue

LEGISLATIVE FINANCIAL STATEMENT FOR PROPOSALS

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

Amended proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC, as regards information to the general public on medical products for human use subject to medical prescription and as regards pharmacovigilance

Amended proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 726/2004, as regards information to the general public on medical products for human use subject to medical prescription and as regards pharmacovigilance

This Legislative Financial Statement covers the two above-mentioned legal proposals

1.2. Policy area(s) concerned in the ABM/ABB structure[11]

Public Health

1.3. Nature of the proposal/initiative

x The proposal/initiative relates to **a new action**

☐ The proposal/initiative relates to **a new action following a pilot project/preparatory action**[12]

☐ The proposal/initiative relates to **the extension of an existing action**

☐ The proposal/initiative relates to **an action redirected towards a new action**

1.4. Objectives

1.4.1. The Commission's multiannual strategic objective(s) targeted by the proposal/initiative

Within heading 1A, Competitiveness for Growth and Employment, the proposal aims to promote public health across the EU 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.

1.4.2. Specific objective(s) and ABM/ABB activity(ies) concerned

Specific objective No..

[11] ABM: Activity-Based Management – ABB: Activity-Based Budgeting.

[12] As referred to in Article 49(6)(a) or (b) of the Financial Regulation.

Pre-control of the information for centrally authorised medicinal products.

ABM/ABB activity(ies) concerned

Public Health

1.4.3. Expected result(s) and impact

Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.

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 EU.

- 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.

1.4.4. Indicators of results and impact

Specify the indicators for monitoring implementation of the proposal/initiative.

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.

1.5. Grounds for the proposal/initiative

1.5.1. Requirement(s) to be met in the short or long term

Articles 114 and 168(4)(c) of the Treaty on the Functioning of the European Union.

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 EU 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, EU legislation does not prevent Member States from establishing their own approaches.

Divergent interpretations of EU 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.

1.5.2. Added value of EU involvement

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 34 EU, impacting negatively on the completion of a single market in pharmaceuticals which the harmonised legal framework on medicinal products tries to achieve.

1.5.3. Lessons learned from similar experiences in the past

N/A

1.5.4. Coherence and possible synergy with other relevant instruments

N/A

1.6. Duration and financial impact

☐ Proposal/initiative of **limited duration**

– ☐ Proposal/initiative in effect from [DD/MM]YYYY to [DD/MM]YYYY

– ☐ Financial impact from YYYY to YYYY

X Proposal/initiative of **unlimited duration**

– Implementation with a start-up period from 2016 to 2021,

– followed by full-scale operation.

1.7. Management mode(s) envisaged[13]

☐ **Centralised direct management** by the Commission

X **Centralised indirect management** with the delegation of implementation tasks to:

– ☐ executive agencies

– X bodies set up by the Communities[14] : European Medicines Agency

– ☐ national public-sector bodies/bodies with public-service mission

– ☐ persons entrusted with the implementation of specific actions pursuant to Title V of the Treaty on European Union and identified in the relevant basic act within the meaning of Article 49 of the Financial Regulation

☐ **Shared management** with the Member States

☐ **Decentralised management** with third countries

☐ **Joint management** with international organisations ***(to be specified)***

If more than one management mode is indicated, please provide details in the "Comments" section.

Comments

The EU 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).

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 34 EU, impacting negatively on the completion of a single market in pharmaceuticals which the harmonised legal framework on medicinal products tries to achieve.

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13 Details of management modes and references to the Financial Regulation may be found on the BudgWeb site: http://www.cc.cec/budg/man/budgmanag/budgmanag_en.html

14 As referred to in Article 185 of the Financial Regulation.

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

Specify frequency and conditions.

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.

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.

2.2. Management and control system

2.2.1. Risk(s) identified

Main risk is the incorrect or incomplete transposition of EU legislation by the Member States.

2.2.2. Control method(s) envisaged

The Commission has established the Pharmaceutical Committee which allows for the exchange of information between Member States and the Commission on the state-of play- of implementation of EU legislation

2.3. Measures to prevent fraud and irregularities

Specify existing or envisaged prevention and protection 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 EMA 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.

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

- Existing expenditure budget lines

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number [Description……...…….]	DA/NDA (15)	from EFTA[16] countries	from candidate countries[17]	from third countries	within the meaning of Article 18(1)(aa) of the Financial Regulation
1A	17.031001 - European Medicines Agency — Subsidy under Titles 1 and 2	DA	YES	NO	NO	NO
	17.031002 - European Medicines Agency — Subsidy under Title 3	DA	YES	NO	NO	NO

- New budget lines requested

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number [Heading……..]	Diff./non-diff.	from EFTA countries	from candidate countries	from third countries	within the meaning of Article 18(1)(aa) of the Financial Regulation
	[XX.YY.YY.YY]		YES/NO	YES/NO	YES/NO	YES/NO

15 DA= Differentiated appropriations / DNA= Non-Differentiated Appropriations

16 EFTA: European Free Trade Association.

17 Candidate countries and, where applicable, potential candidate countries from the Western Balkans.

3.2. Estimated impact on expenditure

3.2.1. Summary of estimated impact on expenditure

EUR million (to 3 decimal places)

Heading of multiannual financial framework:	Number	[.]

DG: <>			Year **2016**[18]	Year **2017**	Year **2018**	Year **2019**	… enter as many years as necessary to show the duration of the impact (see point 1.6)			**TOTAL**
• Operational appropriations										
Number of budget line – 17.031001	Commitments	(1)								
	Payments	(2)								
Number of budget line – 17.031002	Commitments	(1a)								
	Payments	(2a)								
Appropriations of an administrative nature financed from the envelop of specific programs[19]										
Number of budget line		(3)								
TOTAL appropriations for DG <.>	Commitments	=1+1a +3								
	Payments	=2+2a +3								

[18] Year N is the year in which implementation of the proposal/initiative starts.

[19] Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former "BA" lines), indirect research, direct research.

• TOTAL operational appropriations	Commitments	(4)								
	Payments	(5)								
• TOTAL appropriations of an administrative nature financed from the envelop of specific programs		(6)								
TOTAL appropriations under HEADING <1A.> of the multiannual financial framework	Commitments	=4+ 6								
	Payments	=5+ 6								

If more than one heading is affected by the proposal / initiative:

• TOTAL operational appropriations	Commitments	(4)								
	Payments	(5)								
• TOTAL appropriations of an administrative nature financed from the envelop of specific programs		(6)								
TOTAL appropriations under HEADINGS 1 to 4 of the multiannual financial framework (Reference amount)	Commitments	=4+ 6								
	Payments	=5+ 6								

Heading of multiannual financial framework:	**5**	" Administrative expenditure "

EUR million (to 3 decimal places)

		Year **2016**	Year **2017**	Year **2018**	Year **2019**	… enter as many years as necessary to show the duration of the impact (see point 1.6)			**TOTAL**
DG: <…….>									
• Human resources									
• Other administrative expenditure									
TOTAL DG <…….>	Appropriations								

TOTAL appropriations under HEADING 5 of the multiannual financial framework	(Total commitments = Total payments)								

EUR million (to 3 decimal places)

		Year **2016**[20]	Year **2017**	Year **2018**	Year **2019**	… enter as many years as necessary to show the duration of the impact (see point 1.6)			**TOTAL**
TOTAL appropriations under HEADINGS 1 to 5 of the multiannual financial framework	Commitments								
	Payments								

[20] Year N is the year in which implementation of the proposal/initiative starts.

3.2.2. Estimated impact on operational appropriations

– ☐ The proposal/initiative does not require the use of operational appropriations

– x The proposal/initiative requires the use of operational appropriations, as explained below:

Commitment appropriations in EUR million (to 3 decimal places)

Indicate objectives and outputs ⇩			Year **2016**		Year **2017**		Year **2018**		Year **2019**		… enter as many years as necessary to show the duration of the impact (see point 1.6)						**TOTAL**	
	OUTPUTS																	
	Type of output[21]	Average cost of the ouput	Number of ouputs	Cost	Number of ouputs	Cost	Number of ouputs	Cost	Number of ouputs	Cost	Number of ouputs	Cost	Number of ouputs	Cost	Number of ouputs	Cost	Total number of ouputs	Total cost
SPECIFIC OBJECTIVE No 1[22]…																		
- Output																		
- Output																		
- Output																		
Sub-total for specific objective N°1																		
SPECIFIC OBJECTIVE No 2…																		
- Output																		
Sub-total for specific objective N°2																		
TOTAL COST																		

[21] Outputs are products and services to be supplied (e.g.: number of student exchanges financed, number of km of roads built, etc.).

[22] As described in Section 1.4.2. "Specific objective(s)…"

Impact on EMA budget

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 demonstrate that costs relating to activities resulting from the legislative proposal will be recuperated through fees. On this basis, the calculation leads to the conclusion that the proposals on information to the general public on medicinal products subject to medical prescription would not have a financial impact on the Union budget.

The EMA budget is €208,9 million in 2011. The EU contribution has increased from €15,3 million in 2000 to € 38,4 million in 2011. 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 85% of total income in 2011 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. 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 2010 the surplus was superior to €10 million.

The legislative proposal foresees that the EMA shall be charged with the pre-control of the information for centrally authorised medicinal products.

The request for pre-control 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 will only concern pre-control of the information and that subsequent monitoring will be undertaken by Member States, administrative procedures within the Agency will not be burdensome. However, as some of the information will not have been already assessed by EMA in the context of the marketing authorisation process, for example information on the disposal and collection system of the product as well as information on prices which is under the exclusive competence of the Member States, this pre-control will demand coordination with the Member States and the impact of this work should be considered.

Furthermore, applications might be submitted in other languages than EN, the usual working language of the Agency. Therefore either translations will need to be done or Staff Members will have to be able to work in several EU languages.

The average cost of 1 full time equivalent (FTE) AD Staff Member for the EMA in London has been provided by the EMA (beginning 2011) as: Salary €161 708/year for AD and €90 091/year for AST, 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 566 centrally authorised medicinal products exist. As per the EMA annual report 2009, there were 2577 variations, 708 out of them referred to type II clinical variations, which implied a substantial change in the product information. These procedures to change the initial marketing authorisation will also lead to new information on medicinal products to be pre-controlled. It can be estimated that during the first year of application of the proposed regulation approximately 700 submissions of information to be disseminated to the general public will be submitted to the Agency for a pre-control. For the following years, an increase in submissions to the Agency can be expected. The average estimated fee charged to the pharmaceutical industry is € 3 650.

Cost to the EMA

As explained above, it can be estimated that 700 submissions about information to patients on centrally authorised products will need to be checked by the Agency in the first years (2016-2021). An increase of this number is to be expected to 800 submissions once pharmaceutical companies have got familiar with the new procedure (as from 2019).

It can be estimated that total costs for EMA is made up by:

1. the annual salary of the staff, comprising 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,

– contacts with Member States in order to have information which is under their competence and to ensure consistency, in particular with regard to information on clinical trials;

– internal discussions,

– administrative processing of the submission (incl. drafting of the conclusion)

There will be no extra costs for literature screening by EMA, because the information to patients shall be based on the documentation that the pharmaceutical companies provide in their application.

2. translations: applications might be submitted in other languages than EN, the usual working language of the Agency. Therefore the application will have to be translated into EN in order to be checked by EMA and then its assessment will have to be translated back into the language of the applicant.

3. IT: the pharmaceutical industry will provide information through channels addressing needs and capabilities of different types of patients. This will include video, audio and written materials. In order to review, track and store this variety of communication media, the EMA will need to put in place appropriate infrastructure with compatible IT software. EMA foresees the development of the IT tool over 12 months for a total cost of €1,5 million. Maintenance of the IT tool would cost €225 000 for the 1st year of its functioning (n+1) and €300 000 per year for the following years.

The total impact of the legislative proposal on EMA budget has been presented in the Tables below.

Table: Impact on EMA budget – establishment plan[23]

	Year 2016	Year 2017	Year 2018	Year 2019	Year 2020	Year 2021
FTE for core activity + for management overhead (10% of core activity)						
AD - €161 708/year	4.4	4.4	4.4	5.5	5.5	5.5
AST - €90 091/year	1.1	1.1	1.1	1.1	2.2	2.2
Contractual Agent	0	0	0	0	0	0
SNE	0	0	0	0	0	0
TOTAL staff	5.5	5.5	5.5	6.6	6.6	6.6

Table: Impact on EMA budget – Statement of income and expenditure (€)

EMA costs	Year 2016	Year 2017	Year 2018	Year 2019	Year 2020	Year 2021
Total annual staff costs (=Annual salary)	810 615	810 615	810 615	988 494	1 087 594	1 087 594

[23] Assumption: there will be an increase in applications and no impact on EMA costs.

Cost of translation into English[24]	569 100	569 100	569 100	650 400	650 400	650 400
Cost of translation back into submission language[24]	569 100	569 100	569 100	650 400	650 400	650 400
IT cost (development)	1 125 000	375 000				
IT cost (maintenance)		225 000	300 000	300 000	300 000	300 000
Total costs[25]	**3 073 815**	**2 548 815**	**2 248 815**	**2 589 294**	**2 688 394**	**2 688 394**
Income fees[26]	2 555 000	2 555 000	2 555 000	2 920 000	2 920 000	2 920 000
Balance	-518 815	6 185	306 185	330 706	231 606	231 606

The table shows that the EMA budget might run a negative balance in the first year (2016). This deficit would be covered by other income to the EMA budget.

The calculation made in the table above is based on the model where EMA works in English, and therefore translates into EN applications submitted by applicants and translates into the original language the EMA pre-control position before sending it to the applicant. However reality may demonstrate that another model should be followed in order to ensure more efficiency in working directly in original languages, with the use of in-house resources for the pre-control of the information and therefore not using translation. The staff allocation would have to be revised to a total of 15 AD, with a concomitant reduction of translation costs.

[24] For 7 pages

[25] **An inflation rate of 2% should be taken into consideration.**

[26] The fee for the pharmaceutical company will be €3 650.

3.2.3. Estimated impact on appropriations of an administrative nature

3.2.3.1. Summary

– ☒ The proposal/initiative does not require the use of administrative appropriations

– ☐ The proposal/initiative requires the use of administrative appropriations, as explained below:

EUR million (to 3 decimal places)

	Year **N** [27]	Year **N+1**	Year **N+2**	Year **N+3**	… enter as many years as necessary to show the duration of the impact (see point 1.6)	**TOTAL**
HEADING 5 of the multiannual financial framework						
Human resources						
Other administrative expenditure						
Subtotal HEADING 5 of the multiannual financial framework						

Outside HEADING 5[28] of the multiannual financial framework								
Human resources								
Other expenditure of an administrative nature								
Subtotal outside HEADING 5 of the multiannual financial framework								

TOTAL								

[27] Year N is the year in which implementation of the proposal/initiative starts.

[28] Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former "BA" lines), indirect research, direct research.

3.2.3.2. Estimated requirements of human resources

– ☐ The proposal/initiative does not require the use of human resources

– ☐ The proposal/initiative requires the use of human resources, as explained below:

Estimate to be expressed in full amounts (or at most to one decimal place)

		Year **N**	Year **N+1**	Year **N+2**	Year **N+3**	… enter as many years as necessary to show the duration of the impact (see point 1.6)		
• Establishment plan posts (officials and temporary agents)								
XX 01 01 01 (Headquarters and Commission's Representation Offices)								
XX 01 01 02 (Delegations)								
XX 01 05 01 (Indirect research)								
10 01 05 01 (Direct research)								
• External personnel (in Full Time Equivalent unit: FTE)[29]								
XX 01 02 01 (CA, INT, SNE from the "global envelope")								
XX 01 02 02 (CA, INT, JED, LA and SNE in the delegations)								
XX 01 04 ***yy*** [30]	- at Headquarters[31]							
	- in delegations							
XX 01 05 02 (CA, INT, SNE - Indirect research)								
10 01 05 02 (CA, INT, SNE - Direct research)								
Other budget lines (specify)								
TOTAL								

XX is the policy area or budget title concerned.

The human resources required will be met by staff from the DG who are already assigned to management of the action and/or have been redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

Description of tasks to be carried out:

Officials and temporary agents	
External personnel	

29 CA= Contract Agent; INT= agency staff ("*Intérimaire")*; JED= "*Jeune Expert en Délégation"* (Young Experts in Delegations); LA= Local Agent; SNE= Seconded National Expert;

30 Under the ceiling for external personnel from operational appropriations (former "BA" lines).

31 Essentially for Structural Funds, European Agricultural Fund for Rural Development (EAFRD) and European Fisheries Fund (EFF).

3.2.4. Compatibility with the current multiannual financial framework

– X Proposal/initiative is compatible with the multiannual financial framework starting 2014.

– ☐ Proposal/initiative will entail reprogramming of the relevant heading in the multiannual financial framework.

Explain what reprogramming is required, specifying the budget lines concerned and the corresponding amounts.

– ☐ Proposal/initiative requires application of the flexibility instrument or revision of the multiannual financial framework[32].

Explain what is required, specifying the headings and budget lines concerned and the corresponding amounts.

3.2.5. Third-party contributions

– The proposal/initiative does not provide for co-financing by third parties

– The proposal/initiative provides for the co-financing estimated below:

Appropriations in EUR million (to 3 decimal places)

	Year **N**	Year **N+1**	Year **N+2**	Year **N+3**	… enter as many years as necessary to show the duration of the impact (see point 1.6)			Total
Specify the co-financing body								
TOTAL appropriations cofinanced								

[32] See points 19 and 24 of the Interinstitutional Agreement.

3.3. Estimated impact on revenue

– X Proposal/initiative has no financial impact on revenue.

– ☐ Proposal/initiative has the following financial impact:

– ☐ on own resources

– ☐ on miscellaneous revenue

EUR million (to 3 decimal places)

Budget revenue line:	Appropriations available for the ongoing budget exercise	Impact of the proposal/initiative[33]						
		Year **N**	Year **N+1**	Year **N+2**	Year **N+3**	… insert as many columns as necessary in order to reflect the duration of the impact (see point 1.6)		
Article …….								

For miscellaneous assigned revenue, specify the budget expenditure line(s) affected.

…

Specify the method for calculating the impact on revenue.

…

[33] As regards traditional own resources (customs duties, sugar levies), the amounts indicated must be net amounts, i.e. gross amounts after deduction of 25% for collection costs.