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COMMISSION STAFF WORKING DOCUMENT

Accompanying document to the

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

and

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending, as regards information to the general public on medicinal products subject to medical prescription, Directive 2001/83/EC on the Community code relating to medicinal products for human use

SUMMARY OF THE IMPACT ASSESSMENT

{COM(2008) 662 final}
{COM(2008) 663 final}
{SEC(2008) 2667}

1. INTRODUCTION

Medicines contribute considerably to the health of EU citizens. The discovery, development and effective use of medicines have improved many people's quality of life, reduced the need for surgical intervention and the length of time spent in hospital and saved many lives. Consumption of medicines is high and is increasing, with pharmaceutical market value reaching €196.5 billion (retail prices) in the EU in 2006.

The EU citizens, patients, their relatives and consumers have expectations to have access to information on existing medicines and treatments and to be more actively involved in making decisions regarding their treatments. They have become more empowered and proactive consumers of healthcare, increasingly seeking information about medicines and treatments. With the increased use of the internet over recent years, ensuring reliable and good quality information available, particularly on websites, has become essential.

2. PROBLEM DEFINITION

Since 1992 Community legislation has differentiated between advertisement and information on medicines. While EU rules banned advertisement on medicines subject to prescription to the public and allowed advertising for other medicines under certain conditions, a lack of detail on information provision has led to the current situation in which different Member States interpret the EU regulatory framework in very different ways, leading to legal uncertainty for potential information providers, namely the pharmaceutical industry. The different rules on information provision across the EU create inequalities in the information available to citizens, patients, their relatives and consumers in different EU Member States, potentially leaving some patients in the EU without access to information they may need or want. An impact on human health can be expected.

This situation could be seen as especially inappropriate for an increasing range of pharmaceuticals authorised centrally by the Commission for distribution under the same name in all Member States, for which other aspects of drug approval are dealt with at an EU-level, and for information provided through media which cross national boundaries. In particular, the internet has revolutionised the distribution of and access to information. More than 60 percent of EU citizens have today access to the internet and can search information on pharmaceuticals available worldwide based on the active substance. Therefore, neither different national practices of Member States, nor EU-wide prohibitions will be able to stop the search by patients.

Nevertheless, reliable sources of good quality information could result in the search being successful and supporting rational use of medicines. Some gaps in the information available may be filled as time proceeds by private or public sector information provision initiatives. For example, Member States may also introduce their own initiatives to facilitate information provision by industry. However, such national and intergovernmental initiatives have a limited character and would not lead to sufficient harmonisation of rules and practices at the EU level, so that the above described deficiencies would persist.

3. OBJECTIVES

Taking into consideration the outcome of the broad public consultation, the 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 was adopted by the College on 20 December 2007 and transmitted to the European Parliament and the Council.¹ The Communication announced a legal proposal by the Commission.

The Commission proposal on provision of information about medicines to the general public should be fully in line with overall objectives of the Community pharmaceutical legislation:

- to ensure proper functioning of the internal market for medicinal products;
- to better protect health of the EU citizens;

and should 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 medicines.

The specific policy objective has been translated into four operational objectives::

- (1) Ensuring the high quality of information provided by coherent application of clearly defined standards across the Community.
- (2) Allowing information to be provided through channels addressing needs and capabilities of different types of patients.
- (3) 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.
- (4) Ensuring that monitoring and enforcement measures are in place to ensure that information providers comply with the quality criteria, while avoiding unnecessary bureaucracy.

¹

http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2007/2007_12/inf_to_patients_com_2007_862_en.pdf

4. POLICY OPTIONS

There is a range of policy options relating to information provision by industry which could be considered in order to meet the policy objectives. These include:

- a) Retention of the current legislative framework (referred as Option 1 in the further text);
- b) Revision of Directive 2001/83/EC to harmonize rules on what information industry is allowed to provide to patients combined with different enforcement mechanisms. Communication to patients by marketing authorisation holders would be permitted where it was not covered by the definition of advertising, and provided that it met certain quality standards, used specific information channels and respected a degree of restriction on information content. Sub-options for enforcing such information provision would include:
 - Enforcement by national medicines regulatory authorities (Option 2);
 - Self-regulation by pharmaceutical industry associations, with membership of such associations continuing to be voluntary (Option 3);
 - Co-regulation, in which some regulatory responsibilities are given to a co-regulatory body while others are given to medicines regulatory authorities (Option 4).
 - A self-regulatory model in which all marketing authorisation holders are required to belong to the industry body responsible for self-regulation;
- c) Revision of Directive 2001/83/EC allowing specific types of advertising of prescription medicines within the EU.

Two of these options were discarded at an early stage:

- Revision of Directive 2001/83/EC allowing specific types of advertising of prescription medicines within the EU.
- A self-regulatory model in which all marketing authorisation holders are required to belong to the industry body responsible for self-regulation.

All other options have been subject to more detailed analysis as a part of the impact assessment.

Two categories of information channels were considered varying in their extent to which information was “pushed” by the marketing authorisation holder or “pulled” by patients taking the initiative in seeking information:

- a) Information passively received by citizens (or “push” information) when a marketing authorisation holder disseminates information on prescription-only medicines through TV and radio programmes, through printed material actively

distributed, through information in printed media or through audiovisual and written material provided to patients by healthcare professionals.

- b) Information searched by citizens (a type of “pull” information). This category would include:
- Information disseminated through internet websites or verbally;
 - Answering requests from citizens - Information which the industry provides to patients through the post or by email in reply to their enquiries.

5. IMPACT ASSESSMENT METHODOLOGY

Possible positive and negative impacts which the policy might have on patient health have been analysed by looking at the ways in which additional information on medicinal products and the diseases they treat might affect patient behaviour. In particular, more information could lead people to:

- a) Take action to prevent disease (e.g. by changing their lifestyle or diet).
- b) Become aware of their disease and seek treatment, in circumstances when this either would not have happened without the information or would not have happened at such an early stage.
- c) Become anxious about diseases which they do not in fact have.
- d) Interact better with doctors during consultations (e.g. by sharing more relevant information on their symptoms) so as to improve the doctor’s prescription decision.
- e) Distort prescription decisions by asking for a specific drug when it is not actually the best available treatment.
- f) Comply better with their prescription (e.g. due to greater understanding of how the drug should be taken or the benefits of compliance).
- g) Comply worse with their prescription (e.g. due to more information on possible side-effects).

In addition to these health impacts, there would be a number of costs associated with the policy, namely:

- a) The cost to healthcare systems across the EU of any increase in expenditure on pharmaceutical drugs, less any reduction in other healthcare costs (e.g. the costs of hospitalisations).
- b) The cost to marketing authorisation holders of the additional information provision.
- c) The cost of regulating this information provision.

- d) The administrative costs to companies of notifying the regulatory body of information provision and assisting with any investigations arising from complaints.

This impact assessment provides monetary estimates of these various costs and benefits. However, these estimates are based on a large number of assumptions and should be treated with caution. The estimates are summarised as follows:

- The impact of changing current legislation to allow greater information provision by industry, including by allowing companies to choose which Member State's regulatory body to notify. These are presented by showing the impact of Option 2 relative to the counterfactual of Option 1. However, this should not be interpreted as meaning that Option 2 is the preferred option.
- Estimates how the impact of the policy may change depending on whether or not "push" information is allowed to be provided.
- The different enforcement approaches are compared by presenting calculations of the incremental benefit of self-regulation (Option 3) and co-regulation (Option 4) relative to enforcement by medicines regulatory authorities (Option 2).

No substantial environmental impacts have been identified.

6. RESULTS OF THE IMPACT ANALYSIS

Taking all of the impacts listed above into account, indicative calculations suggest that Options 2, 3 and 4 would all yield a net benefit in the medium scenario (see Tables 1 and 3), which indicates a positive impact of a clear framework for provision of information by marketing authorisation holders about their prescription-only medicines to the general public. However, the impact of the policy is rather uncertain: for example, when push information is included the estimated net benefit of Option 2 ranges from - €88 billion (i.e. a net cost of €88 billion) in the pessimistic scenario to +€329 billion in the optimistic scenario.

Table 1: Net benefit of new rules on information provision (for Option 2)

(NPV over 10 years in billions of euros)

	Pessimistic	Medium	Optimistic
Impact of moving from Option 1 (current regime) to Option 2 (direct regulation)	-88	44	329

Note: the figures in this table assume regulation by medicines regulatory authorities. This is simply a choice made for presentational purposes, and should not be interpreted as meaning that this is a preferred option. The incremental impacts of moving to self-regulation and co-regulation are discussed below.

Source: Europe Economics calculations

While a majority of stakeholders accepts the need to act in areas of regulatory gaps, a number of respondents in the public consultation expressed their concerns on possible misuse of some “push” information channels, notably TV and radio, provided to the general public. A key area of concern with the proposed policy is the risk of a significant negative impact (i.e. if the pessimistic scenario shown in the tables were to materialise). The possibility of negative impacts appears to be particularly associated with “push” information.

Assuming enforcement by medicines regulatory authorities, Table 2 shows the effect of restricting the policy to the provision of “pull” information actively sought by citizens. Although this slightly reduces the net benefit of the policy in the medium scenario, it also substantially reduces the risk of negative impacts (shown by the pessimistic scenario).

Table 2: Impact of inclusion or exclusion of push information

(NPV over 10 years in billions of euros)

	Pessimistic	Medium	Optimistic
Pull information only	-26	39	277
Pull and push information	-88	44	329

Source: Europe Economics calculations

In order to reduce the risk of “pushed” information (related to anxiety factor), the legal proposal should not generally allow mass media to distribute information on prescription medicines to the general public. Hence, the recommended approach is to restrict information provision to “pull” information provided to patients who actively seek it (including information disseminated through internet websites), to patients who already have a prescription for the drug and certain printed information having a clear positive public health impact.

The calculations also suggest that switching from enforcement by medicines regulatory authorities to self-regulation or co-regulation would lead to worse outcomes under all scenarios, as shown in Table 3.

Table 3: Incremental benefit of adopting self- or co-regulation

(NPV over 10 years in billions of euros)

		Pessimistic	Medium	Optimistic
Impact of moving from Option 2 (direct regulation) to	Option 3 (self-regulation)	-40	-14	-38
	Option 4 (co-regulation)	-16	-7	-28

Note: the optimistic scenario gives the highest estimate for the net benefit from Options 2, 3 and 4 when they are compared to Option 1, but not necessarily when they are compared to each other. Similarly, the pessimistic scenario gives the lowest estimate for the net benefit from Options 2, 3 and 4 when they are compared to Option 1, but not necessarily when they are compared to each other.

Source: Europe Economics calculations

As regards centrally authorised innovative products, the European Medicines Agency should be given certain tasks as concerns the verification of specific information. While there is no need to check information reproducing the package leaflet, it would be a clear advantage if specific information going beyond be subject to scrutiny by EMEA. This should cover medicinal product-related information about non-interventional 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.

Member States have better oversight of what information is provided on their national territory. Thus, enforcement could be left to Member States as they have better possibilities to detect infringements and to react accordingly without delay. Under such circumstances, fees should finance activities and the existing national enforcement structure should be maintained.