European Commission
Enterprise and Industry Directorate-General
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7 April 2008

Re: European Commission's Consultation on a Legal Proposal on Information to Patients

Dear Ms Närhi:

Pfizer welcomes the opportunity to respond to the European Commission's public consultation on a "legal proposal on information to patients".

The recent European Commission's report has revealed a recognised gap in European citizens' access to high quality health information and a lack of a harmonised EU-wide legal framework in the provision of such information to patients. In response to the increasing demand of Europeans to access quality information regarding available treatments, Pfizer supports the European Commission's intention to proceed with a legislative change on the current Directive 2001/83/EC as it relates to the provision of information to patients by marketing authorisation holders. We also welcome the Commission's recognition that the pharmaceutical industry is one of the many reliable expert sources of information on diseases and medicines. While a legislative reform is a necessary step for creating a modern European framework on health information, Pfizer believes that the European Commission should pay special attention to aspects of the forthcoming legislative proposal that demand extra clarity and those which may risk creating unnecessary bureaucracy.

We, at Pfizer, join other stakeholders in urging the European Commission to proceed with this initiative as quickly as possible and put forward a legislative proposal by October 2008 to ensure its review by the current mandate of the European Parliament and by the Council. Attached is a detailed contribution in response to the consultation. Please, do not hesitate to contact our office should you require any further information.

Sincerely,

Sylvie St. Laurent
Director, Public Affairs & Policy- Europe
Pfizer

Pfizer's Contribution to the European Commission's Public Consultation on a Legal Proposal on Information to Patients

Pfizer is the world's leading research-based pharmaceutical company, employing over 12,000 researchers worldwide. Established in 1849, our mission is to discover and develop innovative medicines that improve health and quality of life. In 2006, Pfizer invested globally over €5.5 billion on research across all major therapeutic areas. Pfizer is a member of the European Federation of Pharmaceutical Industries and Associations (EFPIA) and EuropaBio, and maintains Europe's largest pharmaceutical research centre in Sandwich, UK.

1.0 Introduction

First and foremost, Pfizer agrees with the Commission that access for all EU citizens and patients to non-promotional health and medicines information in their native language must be improved and that legislative reform at the EU level is needed to ensure that all EU citizens have the same access to high-quality information. We therefore support the Commission's initiative to amend Directive 2001/83 to meet these aims.

Pfizer welcomes the Commission's Public consultation *on a legal proposal to reform the current Directive 2001/83/EC as it relates to the provision of information to patients by marketing authorisation holders*. As highlighted in the Commission's Dec. 2007 "*Report on current practices with regard to the provision of information to patients on medicinal products*", the lack of a harmonized EU-wide legal framework and the different national interpretations of what is covered by the notion of "advertising" in Directive 2001/83 has contributed to unequal and insufficient access to quality medicines information by European patients and the public at large. This in turn has negatively impacted upon individual health and public health outcomes.

Pfizer also welcomes the Commission's recognition that the pharmaceutical industry is one of many expert sources of information on diseases and medicines. Pharmaceutical companies not only have expert knowledge of the medicines they develop, but have a wealth of disease knowledge drawn from years of research. We therefore support the Commission's initiative to amend the Directive in a way that will allow the pharmaceutical industry to act as a source of high quality, objective, reliable and non-promotional information on medicines.

Pfizer joins other stakeholders in saying that the time for change is now, and we therefore strongly urge the Commission to table its legal proposal as quickly as possible in 2008 so as to be able to complete a review by the Parliament and Council under the current mandate.

We have some detailed comments on different aspects of the Commission's proposal below.

2.0 Objectives of Forthcoming Proposal

Pfizer supports the view that the new legal framework must take as its starting point the needs of individual patients and citizens. Not only do health information needs vary with one's personal situation, they also vary according to linguistic, cultural, socio-economic circumstances.

Citizens are entitled to access quality information in their own language and in a format that they can easily access and understand. In certain member states like Sweden and the UK, the recognition of this right has already allowed for the provision of medicines information under certain conditions, and this situation should be considered a model to follow and not the subject of further EU restrictions. Adapting to patient needs also means recognizing that "information to patients" is a dynamic notion and its content should not be limited in advance. Patients should be allowed access to the latest relevant information, such as the results of recent clinical developments.

The goal of improving access to quality medicines information should be to allow European citizens to be more involved and responsible for their health, as well as enable them to have a more informed dialogue with their healthcare professional. We recognize that having access to good quality, objective, reliable and non-promotion information is only part of the larger challenge of health literacy, but it is the essential starting point, and one that is currently lacking in Europe.

Comments on Key Ideas of Forthcoming Proposal

3.0 Clear distinction between Advertising and Information

As a basis for the Commission's legal proposal, Pfizer supports the recommended approach to introduce a clear distinction between advertising and information on prescription medicines. The current lack of a clear distinction is one of the causes of a patchwork of interpretations across Europe. We believe that a useful distinction would be on the "push" vs. "pull" mechanisms, or from a citizen's perspective; "unsolicited" vs. "on-demand" information. This distinction could be summed up by the following principles:

1. Advertising designates communication activities that are essentially "unsolicited" or "push" in nature, and involve the direct mention of a prescription medicine.
2. When an individual actively seeks out medicines information, i.e. by searching a company website, or requesting a medicines brochure or other information, it should not be considered advertising, but an expression of that individual's right to access and know where to access health and treatment information if he/she seeks it.
3. Pfizer is committed to providing easily understood, objective information that helps Europeans make healthy choices in partnership with their doctor. As part of this commitment, medicines information will not contain superiority or comparative claims.

3.1 Provisions of advertisement

Pfizer supports the Commission's position that the current ban on advertisement of prescription medicines should be maintained.

3.2 Scope, content and general principles of the new legal provisions

Pfizer agrees that the information provided to European citizens on its medicines should be compatible and not exceed the scientific and medical claims of the approved summaries of product characteristics and that additional information of interest and value (such as clinical trials, adherence advice, proper usage, prices) should be accessible. The format of this information should correspond to previously defined quality criteria.

3.3 Type of actions, content and monitoring of information

As per our comments under 3.1, Pfizer generally agrees with the distinction regarding "push" vs. "pull" information as a means for distinguishing advertising from information. However, Pfizer believes that it is not the type of media that should determine the nature of the information but rather whether the information is actively solicited or not by patients.

3.3.1 Information passively received by citizens

The section on television and radio seems somewhat contradictory to the principle of "push" vs. "pull" and therefore Pfizer would simply reiterate that unsolicited or push information should be limited to health promotion and disease awareness. To accommodate the needs and access preferences/opportunities of different citizens, "pulled" or "on-demand" information on prescription should be available through various media and channels.

3.3.2 and 3.3.3 Information searched by citizens / Answering requests from citizens

Under these sections, the Commission has introduced the notions of "announcing" activities to a "national co-regulatory" body without providing any detail. As a result, it is difficult to provide any meaningful feedback to this section. What we can say is that based on an eventual legislative reform, Pfizer supports EFPIA's on-going work on a governance code for information to patients, designed to ensure that quality health information is provided in a responsible way. It is envisaged that such a system would be based on a self-regulatory approach, with multiple outside stakeholders, and take into account existing best practices in Europe, such as in Sweden or the UK.

4.0 Quality Criteria

Pfizer agrees with the Commission that medicines information should adhere to quality criteria and should be evaluated on that basis.

All those providing such information should adhere to the same quality standards. However, Pfizer believes that such quality criteria could be set in advance, either in an Annex to the Directive or in a European-wide Code of Conduct, and that there should be no prior approval or authorization of information by third parties. The goal of the Commission's proposal should be to facilitate the provision of information to patients, not imposing additional regulatory burdens on the industry that will make it difficult to provide patients with the information they seek.

5.0 Proposed structure for monitoring and sanctions

We note that the Commission's proposal contains three options related to governance – government regulation, co-regulation and self-regulation but only the "co-regulation" model is detailed, while the other two are simply foot-noted.

The overall objective of the Commission's initiative is to improve access to quality health and medicines "information" in Europe, and to avoid unnecessary bureaucracy in setting up the framework to achieve this objective. In that regard, Pfizer believes that it is important that the quality principles regarding the provision of information to patients should dovetail with the quality criteria developed in the Better Regulation field. As stated in the 2005 Communication of the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - Implementing the Community Lisbon programme, emphasis was put on the fact that:

"the EU should only regulate if a proposed action can be better achieved at EU level. Any such action should not go beyond what is necessary to achieve the policy objectives pursued. It needs to be cost efficient and take the lightest form of regulation called for".

By contrast, a regulatory model would be the least efficient and most costly system since it would require review and approval of all materials by national authorities. Under this scenario, the burden would be on authorities to "control" quality, and not on producers to "adhere" to standards. However, the objective of the Commission is not to introduce more control, but rather to improve the access and the quality of the information to Europeans, the governance model needs to look at how this can be achieved in the most efficient way possible.

This is why Pfizer has serious concerns about how co-regulatory model as currently set out in the Commission's document. It appears this model not only involves but is directed by national authorities with the secondary participation of non-government individuals. Additionally, there are many aspects about this proposed model that are simply not clear. The consultation paper states that national co-regulatory bodies should be charged with adopting national codes of practice, with the EU advisory committee giving opinions on these codes. However, this risks creating an uneven playing field across the EU, with different national co-regulatory bodies adopting different codes of conduct.

Instead, Pfizer suggests that the industry would require all member companies to adhere to a European-wide code of practice that would include strict enforcement, sanctions for transgressions and the involvement of external third parties, such as health professionals and patient groups. Moreover, the industry would commit to having an outside stakeholder as head of its advisory board. However, this board would not include national authorities as their participation would automatically give an official regulatory dimension to the work of this body, and introduce the associated bureaucracy.

The EU code of practice could be adopted in the following way:

a) first, the adoption by the European Federation of Pharmaceutical Industries and Associations ("EFPIA"), of a European code of practice which would set out both the practical conditions for the delivery of information to patients by the industry and also a framework for how monitoring and sanctions will take place;

b) in addition to the basic legal requirement that the European Code comply with all provisions of the Treaty (in particular the internal market rules) as well as

with the international engagements of the Community, including multilateral trade rules of the WTO, the envisaged Directive could include in an Annex a list of criteria to ensure that the European Code is sufficiently stringent to achieve the Directive's aims;

c) the European Code would then be evaluated and endorsed by an independent, external body, in light of the requirements of the Annex. This body may be the European Commission;

d) the European Code would then serve as the benchmark for individual national codes of practice by pharmaceutical associations.

This will ensure greater uniformity of national codes of practice, while reducing the regulatory burden on the industry and ensuring greater flexibility if ever the European and/or national codes need to be amended.

6.0 Monitoring and sanctions based on self-regulation

Pfizer believes that the system of monitoring and sanctions should be based on robust self-regulation, with multiple stakeholder involvement. Indeed, the Community institutions have twice previously accepted that self-regulation can be a viable alternative to legislative measures contained a Directive:

- Directive 2005/32/EC of the European Parliament and of the Council of 6 July 2005 establishing a framework for the setting of eco-design requirements for energy-using products[1] accepts "*the admissibility of self-regulatory initiatives as an alternative*" to measures contained in that Directive (Annex VIII), provided that, among other things, the *self-regulatory initiatives* "*contain a well-designed monitoring system, with clearly identified responsibilities for industry and independent inspectors.*"

- Commission Directive 2003/125/EC of 22 December 2003 implementing Directive 2003/6/EC of the European Parliament and of the Council as regards the fair presentation of investment recommendations and the disclosure of conflicts of interest provides that certain requirements in the Directive may not apply if an industry adopts self-regulation measures which ensures "*equivalent appropriate self-regulation*."

In conclusion, Pfizer welcomes the Commission's legislative initiative to improve the accessibility, quality and reliability of health and medicines information in Europe, and we look forward to the Commission's progress on this important topic.

[1] OJ L 191, 22.7.2005, pp. 29–58.