European Federation of Pharmaceutical Industries and Associations

EFPIA CONTRIBUTION TO THE

EUROPEAN COMMISSION PUBLIC CONSULTATION ON

A LEGAL PROPOSAL ON INFORMATION TO PATIENTS

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I. INTRODUCTION

The **European Federation of Pharmaceutical Industries and Associations** (EFPIA) represents the research-based pharmaceutical industry operating in Europe. Through its direct membership of 32 national associations and 43 leading pharmaceutical companies, EFPIA is the voice in the EU of over 2,200 companies committed to researching, developing and bringing to patients new medicines that improve health and the quality of life around the world.

EFPIA welcomes the European Commission's public consultation on a legal proposal on information to patients as an important opportunity to share its views on this topic. EFPIA's general views have been communicated at various occasions in past years, and most recently in the EFPIA response to the Commission's public consultation on a "draft report on current practice with regard to provision of information to patients on medicinal products" (June 2007)[1], which also included 7 recommendations for possible ways forward:

1. European citizens expect and deserve a modern and comprehensive EU information strategy that will truly benefit them and help to improve public health.
2. Access for all EU citizens and patients to non-promotional health and medicines information in their language must be improved. EFPIA does not consider US-style Direct-to-Consumer Advertising as an appropriate model for Europe.
3. Access to high quality medicines information from multiple sources is needed, including from the pharmaceutical industry, respecting the highest quality standards. Information should be judged by its actual quality, not the source providing it.
4. Availability of, and access to high-quality medicines information in all languages via the internet must be enhanced, while recognising the need for non-electronic tools for parts of the population and for improving access to such tools.
5. Public Private Partnerships, involving a range of healthcare stakeholders, could be one part of a comprehensive strategy.

[1] http://212.3.246.100/Objects/2/Files/infopatientscontribution0607.pdf

6. Legislative reform at EU level is needed with the primary goal of giving the same opportunities to all EU citizens, taking into account positive experiences gained at individual Member State level.
7. Self-regulatory schemes with efficient governance and enforcement procedures would be the most practical and beneficial way forward, provided that an adequate legislative frame is put in place allowing the provision of high quality information from multiple sources. We are convinced that this approach would help ensuring that information to patients on prevention, diagnosis, treatment and management of diseases meets the highest quality standards and provides the greatest benefits to citizens and patients.

At present, many Europeans are still disadvantaged in accessing health information they need. A European solution to this existing European challenge remains outstanding. The present consultation is an important step forward to develop a modern, truly European reform of health information provision in Europe, which should benefit public health in general and each individual citizen in particular.

As outlined in our specific comments below, EFPIA fully supports the general objectives of the Commission's consultation paper. **However, in order to meet these objectives, a number of clarifications are needed on certain key points in order to be fully able to assess their potential impact, and value for EU citizens, if they were put in the final legislative proposal and ultimately implemented in EU law.**

For instance, this applies to the proposed governance model ("structure for monitoring and sanctions"). It remains largely unclear how such a system (or systems) would operate in practice, and how it would help achieving the Commission's ***"fundamental objective of the legal proposal to provide rules that harmonise practices on information provision to patients."*** Although being aware that legislative proposals will be presented in form of a EU *Directive*, EFPIA is concerned that a model that leaves too much room for interpretation could potentially lead to a "patchwork" of very different interpretations and implementations in national laws (as it is currently the case) and thus fail to adequately address the European dimension of the current shortcomings (as stressed in last year's Commission's Communication on "current practice with regard to information provision on medicinal products"). Secondly, while recognising the need for providing health information to citizens through various channels (including also non-

electronic tools for large parts of the population), EFPIA considers that neither TV and radio nor print mass media would be appropriate ways for the industry to communicate information on specific prescription medicines to European citizens.

On both of these key points EFPIA proposes alternative approaches which are outlined below and which in our view would be more efficient to meet the current challenges and improve the EU framework for the provision of health information to EU citizens and patients in a sustainable manner.

II. SPECIFIC COMMENTS ON THE COMMISSION'S CONSULTATION PAPER[2]

2.2 Objectives

EFPIA welcomes the overall approach and objectives, i.e. to **put interests of patients first, to aim at reducing differences in access to information and to ensure the availability of good-quality, objective, reliable and non-promotional information on medicinal products**. While EFPIA also broadly agrees with the "key policy objectives" as outlined under this item (establish a new framework which maintains confidence, maintain the ban on direct-to-consumer advertising, avoid any unnecessary bureaucracy in line with Better Regulation principles), a number of clarifications are needed on certain key points contained in the consultation paper.

3. Key ideas of the forthcoming proposal

As stated by the Commission in its recent Communication on current practice with regard to information provision on medicinal products (COM (2007) 862 final), EU citizens currently have unequal access to information, which may result in uninformed choices. Moreover, the lack of EU quality standards for information increases the risk of wrong, misleading or confusing information creating health risks (e.g. counterfeits), particularly since Europeans have become more proactive in seeking information as part of their willingness to be more responsible for their health.

A European solution to this existing European challenge remains outstanding. EFPIA therefore welcomes the Commission's "*fundamental objective of the [future] legal proposal to provide rules that harmonise practices on information provision to patients*" and to *"create a framework for the industry to provide certain information on their medicines to the public*." A modern reform of current restrictive rules for the benefit of EU citizens and patients should remain the overall goal of the future proposal.

[2] Numbering refers to paragraphs in the Commission's consultation document

3.1 Provisions on advertisement

EFPIA has repeatedly stated that US-style Direct-to-consumer advertising would not be an appropriate model for Europe. EU citizens and patients should have the possibility to access high-quality and non-promotional information from multiple sources, including pharmaceutical companies, who are legally liable for their products. At present, many Member States prevent pharmaceutical companies from communicating even basic and legally authorised information about their medicines to the public (e.g. the patient information leaflet or other approved information through company websites), ironically whilst allowing anyone else to do so in a completely unregulated way. EFPIA firmly believes that information should be deemed "acceptable" depending on its quality rather than the source providing it. To that end, EFPIA has issued its own principles for high quality information in 2005, which also served as a basis for discussions with members of the EU High-Level Pharmaceutical Forum[3].

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

- "Communication not covered by definition of advertising should be regarded as information"

EFPIA agrees that under a revised legal framework it should be clearly defined what would be considered to constitute *information* and what *advertising.* Assuming that the current definition of advertising in article 86(1) would be maintained, the revised Directive should clearly state what is defined as information and therefore should be exempted from the ban of advertising. A separate section should be created for the information part.

However, it should be absolutely clear that certain information must remain exempted from this categorization (and thus also not fall under a system of "monitoring and sanctions" as outlined under point 5 of the consultation paper), e.g. information made available by pharmaceutical companies in order to inform shareholders, Stock Exchanges and the like by way of annual reports and announcements etc, as well as

[3] http://212.3.246.100/Objects/2/Files/infoprescirponlymed11052.doc

business-orientated medicines information provided to current or prospective employees.

Information on medicines can come from many sources. EFPIA understands that the proposals seek to control outputs from only one source, i.e. the medicines manufacturer. Other sources may produce high quality information, but also information that may be misleading and potentially harmful to patients. In some cases negative communications on prescription medicines are linked to non-medicinal remedies of doubtful efficacy and/or safety. It is thus important that manufacturers should also be able to provide information to counter false and misleading information on their medicines issued by others.

- *"Information should be compatible with approved summaries of product characteristics and patient information leaflets, and it should not contradict or go beyond the key elements specified in them."*

As indicated earlier, many Member States currently prevent pharmaceutical companies from communicating even basic and legally authorised information about their medicines to the public (e.g. the patient information leaflet or other approved information through company websites). EFPIA agrees with the Commission that in a future system, product information provided by companies should be based on already approved documents such as the SmPC (Summary of Product Characteristics) and PIL (Patient Information Leaflet). However, information must be made more understandable to be useful for the intended audience. It is therefore important to present information in a more user-friendly language, **provided it is in line with already approved information and pre-defined quality criteria.**

- *"Other limited medicine-related information could also be given (information about scientific studies, prevention of diseases such as vaccines, accompanying measures to medical treatments, prices). In addition, specific quality criteria should be defined and respected."*

EFPIA agrees that it is important to put product information in a broader context to improve health literacy and the understanding of the public. The higher the level of health literacy, the better information can contribute to disease **prevention and early diagnosis**, help ensuring the use of the most **appropriate treatment** (whether this

concerns administering a medicinal product or not) for the individual patient at an earlier stage of a disease and improve the management of a disease and **concordance** with the prescribed treatment ("patient journey"). All these factors support a beneficial understanding between doctors, other approved healthcare professionals, payers and patients and will lead to more successful health outcomes, a more efficient use of healthcare resources (e.g. through reducing the need for expensive hospitalisation and long-term care as well as days taken off work) and ultimately to **healthier societies**.

3.3. Type of actions, content and monitoring of information (push versus pull)

In this context, the distinction of "push versus pull" could be a workable categorization (see also EFPIA comments on 3.3.1)

3.3.1. Information passively received by citizens

- *"It should be possible for the pharmaceutical industry to disseminate 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."*

- *- "To facilitate the monitoring of the information provided, a mechanism should be set up to ensure that the information providers inform national co-regulatory bodies about their activities before action is taken".*

It is not entirely clear what types of communication are envisaged by mentioning the various channels for dissemination of product information.

As it is presented, EFPIA does not consider that television, radio and print mass media would be appropriate ways for the industry to communicate information on specific prescription medicines to European citizens.

Instead, EFPIA proposes the following categorization of non-promotional information provision:

1. "**Pro-active information" ("Push"),** which is provided unsolicited to the public, should be limited to general information on diseases, e.g. covering awareness, prevention etc. but not mentioning specific medicines.

2. "Reference information" on diseases and medicines ("Pull"), which is sought by patients and citizens as in a library, e.g. through the Internet.

3. "**Reactive Information" on medicines,** which is supplied in response to spontaneous enquiries received from patients and citizens.

4. "**Support information",** which is supplied with or subsequent to a prescription for a specific medicine, e.g. to support concordance with the prescribed medicine.

Under this model, the information provided should be based on authorised information (e.g. patient leaflet, summary of product characteristics) and comply with clearly defined standards for high-quality information ("quality criteria"). Application of these could be monitored through a European-wide industry "health information" code of conduct, including effective quality assessment procedures for the information and ex-post control mechanisms (with involvement of third/independent parties) as well as robust enforcement procedures in case of breaches (sanctions, fines).

The pharmaceutical industry (and EFPIA in particular) has a long experience with self-regulation (cf. the EFPIA "Code on the Promotion of prescription-only medicines to, and interactions with, healthcare professionals"[4]), which could be built upon (see more detailed comments on point 5). As pointed out by the Commission, one of the objectives of the future legal proposal should be "*to avoid any unnecessary bureaucracy, in line with the principles of Better Regulation*". EFPIA believes that a system based on self-regulatory elements (but with independent involvement in the governance structure) would be best suited to meet the original Commission's objectives for the future proposal and achieve the greatest benefit for public health and each individual patient.

3.3.2. Information searched by citizens

- "When industry disseminates information on prescription medicines through Internet websites or verbally, it should announce such information activities to a national co-regulatory body, which should monitor the contents without validating ex-post or ex-ante "specific actions.

To meet the demands of certain parts of the population (e.g. the elderly), it should also be possible to provide information through other appropriate tools, including printed material such as books, booklets and brochures. Moreover, under this point, EFPIA

[4] http://www.efpia.eu/content/Default.asp?PageID=366

would request further clarification about the envisaged "notification" procedures, i.e. how to "announce" (or "inform" as mentioned above) would actually work in practice. Again, unnecessary bureaucracy and delays should be avoided. For instance, regular minor updates of a website, which are necessary but do not change the general content of the available information, should not be subject to notification. It is also unclear what is meant by "verbally" and how such information should be "announced" prior to "dissemination".

3.3.3. Answering requests from citizens

- "Replies by industry to enquiries from citizens through written solicited posting or e-mail should be monitored based on complaints."

EFPIA agrees with this approach, but phone or other verbal inquiries by citizens should also be taken into account. EFPIA would request further clarification as regards the envisaged procedures for handling potential complaints. In EFPIA's view, this would be best done by a system based on self-regulatory elements including multi-stakeholder involvement as described under point 5.

4. Quality criteria

- All information provided to citizens should fulfil specific criteria concerning the quality of the information. The information provided should be objective and unbiased, patient oriented, evidence-based, up-to-date, accessible, transparent, relevant and consistent with approved information. Comparisons between medicinal products should not be allowed".

See previous comments. Criteria for high-quality information are an essential element of any future proposals. EFPIA's comprehensive "principles and guidance for high-quality information" issued in 2005 set out best practice for the content, review and approval of non-promotional information on prescription medicines, which should be applied by all providers of information.

5. Proposed structure for monitoring and sanctions

National Co-regulatory bodies

It should be clear that proposed structures in whatever form must not contradict the Commission's general objectives of the future legal proposal as set out on page 5 of the

consultation document, including the "**fundamental objective of the legal proposal […] to provide rules that harmonise practices on information to patients in Member States**." EFPIA is concerned that the proposed model with 27 different national approaches and procedures, codes of conducts etc could actually lead to a "patchwork" of very different interpretations and implementations of future provisions in national laws (as it is currently the case) and thus fail to adequately address the European dimension of the current shortcomings.

EFPIA would be in favour of multi-stakeholder involvement in future governance models for the provision of high-quality information. However, the envisaged role and responsibilities of "public authorities" in the proposed "co-regulatory body" remain unclear. EFPIA would also request further clarification about the envisaged structures and processes for the actual monitoring of "information providers" within the proposed "co-regulatory bodies", which, to be effective, should avoid any unnecessary bureaucracy and potentially related delays in dissemination of information. Moreover, it remains unclear whether the "co-regulatory" bodies and its members would actually carry out the "monitoring" of information provided by industry, and how that would work in practice.

An **"EU Advisory Committee"** chaired by the Commission could be useful in terms of setting high and consistent standards, provided it ensures multi-stakeholder involvement (including healthcare professionals, patient groups, the pharmaceutical industry) and avoids additional bureaucracy.

Alternative model

The pharmaceutical industry, and particularly EFPIA, has a long experience with self-regulation, e.g. in the field of interactions with healthcare professionals. Self-regulation by the pharmaceutical industry has proven to be highly efficient and valuable, including the opportunity to quickly adapt to changing needs in an un-bureaucratic manner.

EFPIA currently develops a draft European "health information code", based on self-regulatory principles, with efficient governance structures (incl. balanced third party involvement) and robust enforcement procedures. Such a code could work alongside and complement any legislative change as envisaged by the Commission. The Code would set out minimum standards, which EFPIA considers must apply. In full respect of

applicable national laws and regulations, EFPIA's national member associations would be obliged, at a minimum, to adopt in their national codes provisions no less rigorous than the provisions set out in such an EFPIA Code. Adherence to and compliance with such a code of conduct would be a requirement for EFPIA membership.

Multi-stakeholder involvement

Each EFPIA member association would be required to establish national procedures and structures to receive and process complaints, to determine sanctions and to publish appropriate details regarding the same, including, at a minimum, a **national body** of the member association that is designated to handle complaints and **consists of a non-industry chairman (e.g. an independent judge) and, besides any industry members, membership from other stakeholders including healthcare professionals and patient representatives.**

Effective enforcement of a "health information" code of conduct (including efficient processing of complaints by national multi-stakeholder bodies, sanctions and fines in case of breach) would be the backbone of the model proposed by EFPIA.

This model would also contain a European **standing advisory panel** to advise on the content and interpretation of such a code, to develop advice for companies on good information practice and to highlight examples of good practice. **This panel could also include different stakeholders, e.g. patient representatives, independent health care professionals and representatives from EFPIA member associations and companies.**

"Regulation", as mentioned in footnote 2 of the consultation paper, would be appropriate to support and back up self-regulation or to step in in cases where it may fail for some reason (e.g. if a marketing authorisation holder is not member of an industry association or if information is provided by others than marketing authorisation holders). This should generally be restricted to determining whether promotion of prescription-only medicines has occurred and take necessary action where required. It would not be an appropriate system for the dissemination of information and maintenance of the highest quality in information to patients' communications.

III. CONCLUSIONS

Pharmaceutical companies' aim is to improve the appropriate and effective use of their medicines for the benefit of the patient. They know their products better than anyone else: having researched and developed their medicines over a long time-period (average 10-12 years per approved product), companies have not only unique product expertise but also considerable knowledge concerning diseases, and thus should be recognized as important contributors to health information alongside other key providers such as healthcare professionals, patient groups and regulatory agencies.

Existing partnerships in certain Member States demonstrate the **value that the industry can bring to improve citizens' understanding of its products.** The UK "Medicines Information Partnership" and the Swedish "FASS" system (including a trusted website with 4 million hits per month) are two successful models, which could be a starting point for the ongoing European debate on how to improve the legal framework on information to patients. EFPIA would be happy to discuss its ideas and different available options with policy makers and interested parties in more detail, and looks forward to contributing to the development of a modern, truly European reform of health information provision in Europe without further delay. Meeting European citizens' growing demands for accessing high-quality information concerning their health should be the common goal.