

“The Informed Patient – What the European Union has to do”

European Parliament, 6 December 2007

EFPIA statement

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 44 leading pharmaceutical companies, EFPIA is the voice in the EU of 2,100 companies committed to researching, developing and bringing to patients new medicines that improve health and the quality of life around the world.

For many years now there seems to be widespread agreement among EU institutions, healthcare stakeholders and EU citizens that communication with patients and the general public on health issues and prescription medicines should be improved with the objective of having better informed patients. **EFPIA firmly believes that after years of debate, European citizens and patients expect, and deserve, that the debate now turns into action.**

II. Current situation

EFPIA welcomed the European Commission’s recent draft report on “current practice with regard to provision on information to patients on medicinal products”¹. Its conclusions summarise well the current situation and demonstrate why there is a need for substantial reform. Basically, **the current lack of a modern and comprehensive Community framework for information about health and medicinal products clearly hampers EU citizens’ equal access to information.**

While societal behaviour (e.g. the “empowered” patient) has evolved and new technologies (e.g. internet) emerged and spread, the current legal situation in Europe has basically remained unchanged over the past 15 years. Consequently, there are today huge inequalities in terms of availability and accessibility of information among different population groups and among EU Member States (e.g. depending on where you live, whether you speak English and whether you have internet access).

III. The value of health-literate patients

As confirmed by recent studies, a high level of health literacy can contribute to disease prevention and early diagnosis, help ensuring the use of the most appropriate treatment for the individual patient at an earlier stage of a disease and improve concordance with the prescribed treatment. **Improved health literacy**, which aims at supporting the crucial relationship between the patient and the doctor, 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.

Patients may currently receive information from different sources including the package leaflet, the health professional prescribing medication, the dispensing pharmacist, carers, newspapers, the Internet and – to a limited extent in a few countries – from pharmaceutical companies. It is clear however that no single source can provide all the available information, and no single source should have an exclusive right to do so.

¹ http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2007/2007_04/draft_infopatients2007_04.pdf

IV. The value of the research-based pharmaceutical industry

Pharmaceutical companies have unique product expertise and disease knowledge, having researched and developed their medicines over a long time-period (average 10-12 years per approved product). They are thus important contributors to health information alongside other key providers such as healthcare professionals, patient groups and regulatory agencies.

We believe 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 and guidance notes on high quality information in November 2005², setting out best practice for the content, review and approval of non-promotional information on prescription medicines.

Allegations, voiced by certain stakeholders, that the industry would seek introducing Direct-to-consumer advertising in Europe are taken seriously, because these risk hampering a serious, open and mature public debate between all stakeholders about possible solutions to overcome the current information deficit and improve the situation in Europe.

EFPIA has repeatedly stated that we do not advocate US-style Direct-to-consumer advertising as an appropriate model for Europe. We call for industry to be enabled, among other information providers, to supply non-promotional, high-quality health-related, disease and treatment information to EU citizens. Pharmaceutical companies’ aim is first and foremost to improve the appropriate and effective use of their medicines for the benefit of the patient.

Existing partnerships in certain Member States demonstrate the value that the industry can bring in the provision of information to patients, such as in the UK (“Medicines Information Partnership”) and Sweden (“FASS”, a trusted website with 5 million hits per month).

V. The way forward

In summary, we believe the following principles and objectives are key in the current debate about reforming current rules on information to patients³:

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.
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 (EFPIA principles for high quality information).
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.
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 legal system is put in place allowing the provision of high quality information from multiple sources. This approach would help ensuring that information to patients on prevention, diagnosis and treatment of diseases meets the highest quality standards and provides the greatest benefits to patients.

The industry stands ready to play its role in the provision of high quality health information and thus respond to citizens’ legitimate right to benefit from such information.

² <http://www.efpia.eu/Objects/2/Files/infoprescirponlymed11052.doc>

³ For more: <http://www.efpia.eu/Content/Default.asp?PageID=172>