



THE PROVISION BY THE PHARMACEUTICAL INDUSTRY OF INFORMATION TO PATIENTS – KEY PRINCIPLES

Patients understand their bodies and illnesses – they should be equal partners in the payer-patient provider partnership. To do this, they need access to the information that will help them understand different treatment options, articulate preferences, and help physicians secure optimal outcomes.

Patient groups, the European Parliament, and the European Commission all recognise that better informed patients make a practical and efficient contribution towards reaching the objective of accessible, high quality and financially sustainable health care. Patient groups and individuals are increasingly calling on governments for better information provision, in terms of both quality of content and ease of access and use.

All patients and citizens in Europe should have the same right to objective, accessible, accurate and easily understandable information on health, healthcare, prevention, diseases and treatment availability. This should include information about medicinal products, including those available on prescription that enables them, in consultation with their doctors, to make well-informed choices about their health and treatment.

Initiatives to enable better patient access to high-quality health information should be a priority for governments and the EU institutions. Similar standards of access and availability of information should apply in all EU member states - the level of sophistication with which patient groups are able to access, gather and use information currently varies according to both therapeutic area and geographic origin.

Advertising of prescription medicines to the public is prohibited in Europe. GSK accepts that the cultural and socio-economic context in Europe is not suited to the introduction of direct-to-consumer advertising of prescription-only medicines by pharmaceutical companies. Nevertheless, the pharmaceutical industry clearly has an important role in enabling patients and citizens to have better understanding of medicines and their safe and appropriate use.

Disease education and vaccines information campaigns are an example of how responsible, approved information from the industry to the public can fulfil a number of objectives: raising public awareness of the existence of a safe and effective vaccine, educating the public of the risks attached to non-vaccination, allowing important savings to be achieved for healthcare systems by preventing disease, and contributing to the overall "wellness" of society. Because vaccinations target communicable diseases, it is essential that disease education and vaccination campaigns can take a pan-European dimension. Implementation of EU legislation and in particular the approval processes and conditions of individual disease education and vaccination campaigns at national level should therefore be dealt with in a more consistent and uniform manner.

The existing framework should be applied across Europe. Further regulatory barriers should not be imposed.



Key Principles

1. Enhanced access to health and medicines information is needed for all patients and citizens in Europe

Patients have a right to receive information about their disease. The provision of information should not be hampered by unnecessary control mechanisms and bureaucracy. The increased demand for information has been met by a proliferation of health-related websites and other type of media. This raises questions of how to ensure high levels of quality and reliability of information. The onus of regulation or guidelines should therefore lie in ensuring ease of access, accuracy and quality of content, regardless of the provider of the information. Individuals should be free to request and receive information from any source and channel they choose. Pharmaceutical companies should, like other sources, be free to supply accurate and balanced information about prescription medicines.

2. Quality medicines information should be provided from multiple sources

At present, the companies who research, develop and manufacture the medicines are prevented from contributing fully to the public's understanding of their products. Pharmaceutical companies have a valuable role to play in redressing this information deficit. They are heavily regulated and are legally responsible for any information they provide. It is not sensible, or in the interest of patients, that high quality communication on medicines is considered unacceptable or illegal if it is produced by a pharmaceutical company – but is acceptable and permitted legally if produced by anyone else.

Pharmaceutical companies should be given the possibility of answering specific queries from members of the public concerning the appropriate use of prescription-only medicines that they manufacture. In doing so, companies should be able to refer to the Summary of Product Characteristics (SmPC), the Patient Information Leaflet (PIL) and other objective, validated and balanced information.

3. Opportunities for Internet access to medicines information should be enhanced

Health-related websites are among the most sought after on the Internet. Many patients and citizens in Europe consult US websites where information about prescription medicines is freely available. This puts patients in Europe who do not understand English at a clear disadvantage. US web sites from pharmaceutical companies are highly controlled through internal review mechanisms as well as by the Food and Drug Administration (FDA). However, the information may not be appropriate for a European audience, e.g. it may concern unlicensed products or indications. Patients and citizens in Europe should have access to health information which is in their own languages and based on local European conditions.



4. Regulatory frameworks should reflect current best practice in Europe

Pharmaceutical companies support disease awareness activities and schemes to increase compliance. However, the current regulatory interpretation in some countries prevents citizens having the benefit of such information and services. Careful consideration should be given to appropriate ways to change current practice for the benefit of patients and citizens in Europe. Regulatory developments should enhance, not reduce, the amount of good quality information.

Existing EU legislation on direct-to-consumer communication by pharmaceutical companies¹ should be implemented in a more uniform manner across the whole of the EU. This would allow pharmaceutical companies to operate on a level-playing field and enable patients to access the same type of information regardless of their country of origin. Member states should look to current regulatory best practice, in particular the UK's ABPI² code of conduct and regulatory regime, in implementing current legislation.

Regarding the type of information that can be provided by a pharmaceutical company, the following principles should apply throughout the EU:

- information on prescription medicines should not encourage demand of an identifiable product, as this would be in breach of EU legislation, and it should refrain from using words such as 'safe' or raise hopes of successful treatment.
- a pharmaceutical company should be able to list the names of its approved products on its website, in addition to product-related information such as the product information leaflet as approved by the regulatory authorities and the SmPC. This is already possible in some, but not all, EU member states.
- further efforts are necessary to make PILs more understandable and user-friendly.
- a pharmaceutical company should be able to post validated third-party information on its website or provide a link to the sources of the information, such as regulatory authorities, health technology assessment bodies, or other governmental agencies.
- any information provided on the internet by a pharmaceutical company concerning its prescription-only medicines or more general information on health issues should conform to the pharmaceutical industry's Guidance on Internet Communications and any other national regulation or European guidelines concerning the provision of information over the internet.

5. Public Private Partnerships (PPP) should be part of a comprehensive strategy

¹ [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

[Directive 2004/27/EC](#) of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use.

² Association of British Pharmaceutical Industry



Pharmaceutical companies should be given the possibility to explore how they can work with non-commercial organisations as well as governments to provide the public as well as certain categories of healthcare professionals, such as nurses, with reliable and high-quality information on available therapies.

Voluntary establishment of public-private partnerships (PPP) between pharmaceutical companies, and government, patient, academic, scientific or health professional organizations, can be one approach to better respond to patients' and the general public's legitimate need for accurate and reliable health-related information. PPPs thus can contribute to the improvement of patient health education and continued professional development.

PPPs should be based on mutually agreed principles, which are sufficiently flexible to take account of patients' diverse needs, culture and language, and to adapt to changing environments and different healthcare systems. Participating parties in PPPs must have a recognised competence in their field of specialty and may be involved as planners and implementers, advisers and evaluators, collaboratively contributing to the improved quality of patient health information and education as well as continued professional development for the benefit of patients and society at large.

6. The public should enjoy access to clinical trial information via clinical trial registers and databases

Publicly available, internet-based registration of *ongoing* clinical trials³ can provide a stimulus for increased patient participation in clinical research. They also provide an important reference point tracking the subsequent disclosure of clinical trial results. Registration of *completed* clinical trials and their results helps to ensure that clinical trial information contributes to scientific knowledge and, for marketed pharmaceuticals, can provide the public with an important supplement to prescribing information and publications in scientific literature. A single international register would establish a complete, easily verified, continuum of clinical trial information, from study initiation to publication of results.

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³ Clinical trials are the investigations intended to determine the clinical pharmacological, pharmacokinetic, and/or other pharmacodynamic effects of an investigational agent, and/or to identify any adverse reactions to an investigational agent to assess the agent's safety and efficacy.