GlaxoSmithKline

Government Affairs
Europe and Corporate

GlaxoSmithKline
Park Leopold
Rue Wiertz 50
1050 Brussels
Belgium

Tel. 32 2 280 41 61
Fax. 32 2 230 99 35
www.gsk.com

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European Commission
DG Enterprise and Industry – Pharmaceuticals
entr-pharmaceuticals@ec.europe.eu

GLAXOSMITHKLINE (GSK) RESPONSE TO THE EUROPEAN COMMISSION CONSULTATION ON A LEGAL PROPOSAL ON INFORMATION TO PATIENTS

GSK welcomes the European Commission's public consultation on a legal proposal on information to patients. European citizens expect and deserve a modern and comprehensive EU information strategy that will truly benefit them and help to improve public health.

Context

Patients understand their bodies and illnesses. They should act as equal partners in the payer-patient-provider partnership. In order 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 and other stakeholders recognise that better informed patients make a practical and efficient contribution towards reaching the objective of accessible, high quality and financially sustainable healthcare.

Information on medicines can come from many sources. The Commission's proposals seek to control outputs from only one source, the medicine's 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.

However, 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). Ironically, anyone else is allowed to provide information in a completely unregulated way.

GSK therefore welcomes the Commission's objective to "create a framework for the industry to provide certain information on their medicines to the public." It is critical to put the interests of patients first, to reduce differences in access to information, and to ensure the availability of good quality, objective, reliable and non-promotional information on medicinal products.

R.C. Nivelles
65945

T.V.A. BE
440.872.918

Fortis Banque S.A.
271-0518333-94

Direct to Consumer Advertising

GSK accepts that the cultural and socio-economic context in Europe is not suited to the introduction of direct-to-consumer advertising (DTCA) of prescription-only medicines by pharmaceutical companies. However GSK believes strongly that industry does have a role in providing non-promotional information to patients so that they have an understanding of the medicines they are taking and so that use is safe, appropriate and optimally improves patients' quality of life.

GSK's comments on DTCA specifically address the proposal with respect to communications to EU citizens, including the legal and regulatory boundaries defining the types of communications and tools used to disseminate these communications to EU citizens. In other, non-EU settings, different laws and regulations govern such communications. Within the boundaries of a given venue's legal and regulatory framework, GSK supports accurate and truthful communications concerning the effectiveness and safety profile of its prescription medicines, regardless of medium used, provided communications are delivered in a responsible and appropriate manner.

Vaccines

The comments in the main body of this document relate to medicines as opposed to vaccines, as it is prescription-only medicines that are the focus of the Commission's consultation. GSK agrees with article 88(4) of Directive 2001/83/EC of 6 November 2001, which states that the prohibition of advertising to the general public of prescription-only medicinal products shall not apply to vaccination campaigns carried out by the industry and approved by the competent authorities of the Member States.

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 Importance of a Harmonised Approach

GSK believes that there should be equality of access to high quality non-promotional information on medicines and vaccines across all twenty seven EU countries. There should be no barriers due to geographical location, disease areas, language, socio-economic class, levels of health literacy, or technological competence. A modern reform of the current restrictive rules for the benefit of EU citizens and patients should remain the overall goal of the future proposal. Access for all EU citizens and patients to non-promotional health and medicines information in their language must be improved.

GSK therefore welcomes the Commission's objective "to provide rules that harmonise practices on information provision to patients". 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 individual citizens in particular.

Sources of Information – the importance of quality

As stated above, GSK supports the Commission's objective to "create a framework for the industry to provide certain information on their medicines to the public." Pharmaceutical companies seek to support 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. They should therefore be recognised as important contributors to health information, alongside other key providers such as healthcare professionals, patient groups and regulatory agencies.

Information should be judged by its quality, not the source providing it. It is important to focus on the content of the information, and criteria for high-quality information should be an essential element of any future proposals. As the Commission document states, "all information provided to citizens should fulfill 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". 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.

The rules governing advertising and information should apply to all persons, and not only to pharmaceutical companies and their agents. This is a logical consequence of the public health considerations that are the justification of the prohibition of direct-to-consumer advertising for prescription products. It is also required under general principles of non-discrimination.

What Kind of Information?

GSK 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 understandable to be useful for the intended audience. It is therefore important to present information in a user-friendly language, provided it is in line with already approved information and pre-defined quality criteria. GSK suggests that patient groups should play a role in advising on the appropriate language.

The Commission proposal also states that "other limited medicine-related information could also be given (information about scientific studies, prevention of diseases such as vaccines, accompanying measures to medical treatments). In addition, specific quality criteria should be defined and respected." GSK supports this proposal and believes additional information could include general disease management information, details on and assistance with therapy compliance, general dietary recommendations, ongoing clinical research and the like.

GSK agrees that it is important to put product information in a broader context to improve health literacy and public understanding. The higher the level of health literacy, the better information can contribute to disease prevention and early diagnosis, help ensure the use of the most appropriate treatment 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 an improved understanding between doctor and patient 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.

Lessons from National Models

Existing partnerships in certain Member States demonstrate the value that the industry can bring in improving citizens' understanding of its products. There are excellent examples of provision of information on disease and medicines in some EU countries. The FASS model in Sweden and the Medicines Guides in the UK are impressive examples of high quality, comprehensive and easily accessible information. The FASS model, developed by the

Swedish Association of the Pharmaceutical Industry (LIF), in close collaboration with public bodies, provides information on medicines to healthcare professionals, patients and the general public. It includes information on medicines and clinical trials, and continues to receive excellent feedback from its users, numbering over four million a month. The UK Medicines Guides, with significant input from the pharmaceutical industry, has information on medicines and disease and has seen a very substantial rise in numbers of people accessing this user-friendly information repository. Both of these models are entirely non-promotional. They provide factual information on medicines based on the SPC with no claims or comparisons with other medicines. The aim of amending the current legal restriction must be to bring all countries up to the level of these best practice models.

Push and Pull of Information

GSK supports the following categorisation 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. Examples of this category would include information on disease in leaflets available in General Practice and secondary care settings.

2. **"Reference information" on diseases and medicines ("Pull"),** which is sought by patients and citizens as in a library for example through the Internet. Examples of this category would include disease information and information on prescription only medicines (based on information in the SPC) on websites.

3. **"Reactive Information" on medicines (Pull"),** which is supplied in response to spontaneous enquiries received from patients and citizens. Examples of this category would include information on disease and medicines in leaflets which the public could request from pharmaceutical companies.

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

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 improved access to such tools. To meet the demands of certain parts of the population (e.g. the elderly), it should be possible to provide information through printed material such as books, booklets and brochures.

The Commission has proposed that "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." While recognising the need to provide health information to citizens through various channels, GSK considers that neither TV and radio programmes nor print media would be appropriate ways to communicate information on specific prescription medicines to European citizens. Again, this reflects the cultural and socio-economic context in Europe specifically.

Regulatory Framework - proposed structure for monitoring and sanctions

Proposed structures for monitoring and sanctions, 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. These include the "**fundamental objective of the legal proposal [...] to provide rules that harmonise practices on information to patients in Member States**." GSK is concerned that the proposed model, with 27 different national approaches and procedures, codes of conducts etc, could lead to a 'patchwork' of very different interpretations and implementations of future provisions in national laws (as it is currently the case). This would undermine the goal of improved harmonisation.

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. This approach would help ensure that information to patients on prevention, diagnosis, treatment and management of diseases meets the highest quality standards and provides the greatest benefits to patients. GSK therefore supports a self-regulatory framework, as proposed in alternative 2 of the consultation document.

The pharmaceutical industry, and particularly EFPIA, has long experience with self-regulation, for example in the field of interactions with healthcare professionals. Self-regulation by the pharmaceutical industry has proven to be highly efficient and valuable, as it offers the opportunity to quickly adapt to changing needs in an unbureaucratic manner.

EFPIA is currently developing a draft European "health information code", based on self-regulatory principles, with efficient governance structures (including 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 an EFPIA Code. Adherence to, and compliance with, such a code of conduct would be requirements for EFPIA membership.

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.

The EFPIA approach 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.

The Commission consultation document suggests patient group involvement in the process to regulate the information being provided. GSK is in favour of multi-stakeholder involvement in future governance models for the provision of high-quality information, and welcomes proposals to maximise the involvement of patient groups in order to ensure truly patient-centric information.

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

The monitoring framework should not be considered separately from the development of concrete standards. Quality will be achieved through a constant interaction between the monitoring framework and development of the rules.

Regulation is appropriate to back up self-regulation or to step in where it may fail for some reason, for example if a marketing authorisation holder is not member of an industry association, or if information is provided by others than marketing authorisation holders. Regulation should generally be restricted to determining whether promotion of prescription-only medicines has occurred and taking necessary action where required.

Conclusion

GSK welcomes the Commission's proposal to harmonize the provision of high quality non-promotional information on medicines to the public. Across the EU, there is a large disparity in what information patients are able to receive on medicines. Those able to speak English and access the internet have a clear advantage (although being able to read English on the internet may, of course, cause problems for a European patient if there are differences between the EU and US SPC/PIL.) GSK agrees with the Commission and the majority of

stakeholders in this area that all patients across the EU have the right to equal access to high quality health-related information. Improved access to health-related information should encompass information on treatments, prevention, healthy lifestyles, and healthcare systems.

As researcher, developer and manufacturer, the pharmaceutical industry possesses key information on its medicines and vaccines, and thus should be one source of information. GSK wholeheartedly supports the Commission's proposal that this information should be appropriately regulated and of the highest standard.

Sincerely,

C Strutt

Chris Strutt
Vice President, Government Affairs Europe and Corporate
GlaxoSmithKline