Shire plc Contribution to the Public Consultation on a Legal Proposal on Information to Patients

Shire plc (Shire) is grateful for the opportunity to contribute to the European Commission Consultation on a Legal Proposal on Information to Patients.

Shire is a leading global specialist biopharmaceutical company focusing on developing treatments for Attention Deficit and Hyperactivity Disorder (ADHD), Gastrointestinal (GI) disorders, Alzheimer's Disease, Renal Disease, and *very* rare genetic diseases such as Fabry Disease, Hunter Disease, Gaucher Disease and Pompe Disease[1].

Shire plc is a member of European Biopharmaceutical Enterprises (EBE) (Shire Pharmaceuticals) and EuropaBio (Shire Human Genetic Therapies).

General comments

Shire welcomes the current discussion on 'Information to Patients' and supports the Commission's forthcoming proposal for high quality, accessible, non-promotional information on diseases and available treatment options. In particular, it welcomes today's efforts and initiatives to harmonise information to patients practices in the EU.

Knowledge and information play a key role in empowering patients and their families. Indeed, patients increasingly expect to have access to high quality information about diseases, treatment and care. No one stakeholder has the resources to provide all this information. Healthcare professionals, health institutes, patient organisations and companies all have an important role to play in providing reliable information that contributes to understanding disease and treatment and enhanced health outcomes.

Shire therefore agrees that there is a need to change the regulatory framework in Europe to also allow industry to provide patients with good quality, fair, and non-promotional information about the disease and possible treatment options. It calls for information that is balanced, comprehensive and available for all disease types, including *very* rare diseases. We strongly believe that all patients in Europe should have the same right to accurate and understandable information on diseases and therapeutic options, including those suffering from *very* rare life-threatening and chronically debilitating diseases.

[1] Shire's strategic objective is to become the leading specialty biopharmaceutical company that focuses on meeting the needs of the specialist physician. Shire focuses its business on attention deficit and hyperactivity disorder (ADHD), human genetic therapies (HGT), gastrointestinal (GI), and renal diseases.

Especially for patients with *very* rare diseases, there are limited sources of support dedicated to providing credible and comprehensive information on rare diseases and available treatment options. Specialist biopharmaceutical companies such as Shire [and notably Shire Human Genetic Therapies] have a wealth of disease knowledge and expert knowledge of therapeutics drawn from researching, developing, and marketing innovative products against these *very* rare genetic diseases. They should play a role therefore in health information provision to both health professionals *and* patients and patient groups.

Finally, we also believe that enhanced, high-quality information will improve communications between patients and healthcare practitioners about health conditions and medicinal products and therapies.

Specific comments

3.1. We support the consultation document's bid to maintain the current ban on advertising. Shire agrees that this would indeed not be an appropriate model for Europe. We also support a clear distinction between advertising and non-promotional information with a clear definition of what constitutes advertising and information in a new legal framework. We generally support EuropaBio's suggestion that "advertising" should mean "unsolicited and direct communications by the industry on a specific prescription medicine."

3.3.1. Shire also believes the proposed media of information to patients and citizens should be carefully considered, especially in the case of information passively received by citizens. It agrees with EFPIA that television and radio are not appropriate information channels to provide information on medicines and supports its suggestion to limit unsolicited information to general health information on diseases that would include awareness and prevention.

3.3.2. Shire is committed to the highest quality standards and principles in the provision of information on prevention, diagnosis, treatment and management of disease. To that end it supports the principles and guidance notes EFPIA has issued on high quality information in November 2005, setting out best practice for the content, review and approval of non-promotional information on prescription medicines. We also support the development of a European health information code and a code of conduct by all relevant stakeholders. We believe that a self-regulatory approach [enforced by the industry association] and a form of vetting, governance and enforcement that will include external stakeholders would ensure that information can be trusted by patients and citizens alike.

4. Shire agrees with the proposed quality criteria in this section and believes that a set of common, specific criteria concerning the quality of the information will contribute to enhancing the consistency and quality of health information in Europe.

5. Shire agrees that public private partnerships, involving a range of healthcare stakeholders, are a very important part of a well-functioning and trusted governance model. It is important that such a model should include clear and robust quality assessment and enforcement rules and procedures to help to ensure the patients' and citizens' trust and confidence. We share industry's concerns however, that the proposed three-tier co-regulatory approach would lead to unnecessary bureaucracy and varied interpretations of information provision across Europe. We therefore favours the approach set out in its response to paragraph 3.3.2. (see above).