Biogen Idec Response to the Commission Consultation on a Legal Proposal on Information to Patients

Biogen Idec welcomes the opportunity to respond to the Commission's Consultation on Information to Patients.

Biogen Idec is a leading global biopharmaceutical company committed to improving the lives of patients by developing and marketing treatments currently in the areas of neurology, immunology and oncology.

We are a member of European Federation of Pharmaceutical Industries and Associations (EFPIA) and European Biopharmaceutical Enterprises (EBE).

General comments

Biogen Idec agrees that all patients in Europe must have the same right to access accurate and understandable information on diseases and treatment options independent of where they live and the language they speak. We therefore welcome initiatives and efforts to address today's inequality in terms of availability and accessibility of information with the aim to harmonize practices on information provision to patients in Europe. To that end, we support the Commission's forthcoming proposal for high quality, accessible, non-promotional information on diseases and available treatment options.

Knowledge and information play a key role in empowering patients and their families. No single stakeholder has the resources to provide all this information. Health professionals, patient organizations, public health institutes, and companies all have an important role to play in providing reliable and balanced information that contributes to understanding disease; increased awareness of the risk and benefits of treatments; and improved health outcomes.

Biogen Idec therefore agrees that there is a need to change the current regulatory framework in Europe to also allow industry to provide patients with high quality and non-promotional information about the disease and possible treatment options.

Information is at the centre of the biotechnology model and biopharmaceutical companies such as Biogen Idec have a particularly important role to play in the provision of information, as the area requires expert knowledge which resides often within the industry.

Finally, we also believe that accessible information will help manage demand for healthcare, improve health outcomes and mitigate some of the burden on already constrained healthcare systems and budgets.

Specific comments

Advertising & Information to Patients

We support the objective to maintain the current ban on advertising and agree with EFPIA that this would indeed not be an appropriate model for Europe. We also believe a clear distinction between advertising and information is of key importance to ensure that information can be trusted by patients and citizens in Europe. It therefore supports the patients' call for greater clarity regarding this distinction in the forthcoming proposal.

'Push' and 'pull' information

Biogen Idec also believes the proposed media, or channels, of information to patients should be very carefully considered, especially in the case of unsolicited or 'push' information. 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, prevention and health promotion. It agrees on the other hand that industry should be allowed to provide high-quality and non-promotional information on treatment options in the case of information searched for and requested by citizens, through internet sites and answering to questions from patients. This is important to provide accurate region specific information and also to counter-balance the information that is widely available on the internet that is posted in the United States.

Biogen Idec also believes there is a continued role for patient groups to act as intermediaries in the provision of relevant information to patients. It believes that patient groups are experienced in providing information in ways that patients can understand and find useful.

Quality criteria

Biogen Idec is committed to applying the highest quality standards and principles in the provision of information to patients and agrees to the general core principles set out in the Consultation document. It supports EFPIA's 'principles for quality information' of November 2005, setting out best practice for the content, review and approval of non-promotional information on prescription medicines. We believe that a self-regulatory approach [enforced by the industry association] and a form of governance and enforcement that will include external stakeholders would ensure that information can be trusted by patients and citizens alike. It furthermore believes

that it should be possible to include information on other treatments (including comparative information) as long as the information is objective (based on scientific sources) and non-promotional.

Proposed structure for Validation and Monitoring

Biogen Idec agrees that a well-functioning and trusted governance system should involve all relevant healthcare stakeholders. It is equally important that such a model would include clear and robust enforcement rules and procedures to ensure patient and citizens' trust and confidence. We share EFPIA's concerns however, that the proposed co-regulatory approach would potentially lead to a patchwork of different interpretations of information provision across Europe. We therefore support EFPIA's suggestion for a European-wide Code of Conduct and a form of ex-post governance and enforcement that will include external stakeholders.