

European Commission
DG Enterprise and Industry -
Pharmaceuticals
B-1049 Brussels

entr-pharmaceuticals@ec.europa.eu

29 June 2007

Re: Comments on draft report on current practices with regard to the provision of information to patients on medicinal products

Dear Sir or Madam,

Thank you very much for the opportunity to input into the above Consultation.

EuropaBio is the political voice of the biotechnology industry in Europe. Our association of bioindustries has 89 corporate members operating worldwide, 12 associate members and 5 bioregions, as well as 25 national biotechnology associations, representing 1800 small and medium sized enterprises in Europe. Members of EuropaBio are involved in research, development, testing, manufacturing and commercialisation of biotechnology products and processes.

Biotechnology leads innovation in healthcare

Healthcare biotechnology already has a tremendous impact on meeting the needs of patients and their families. And these therapies will continue to represent the state-of-the-art evolution of science as applied to human medicine. They present novel approaches to patient disease management, and the technology itself is providing us with a better understanding on the course and mechanisms of disease. These types of therapies are:

- personalized and targeted;
- often aimed at treating serious illness and rare diseases;
- dominated by SME research; and
- complex in their development and modes of action, meaning that the highest level of knowledge sits within biotech companies, with little share heritage within the scientific community.

Innovative European biotechnology companies are now defining diseases at a molecular level, distinguishing between different disease states, and connecting genomics identified targets with particular disease pathologies. Examples of these specialized areas include:

- Monoclonal antibody therapies – which represent a new approach to treating diseases, and introduce a new paradigm into patient/physician relationships.
- Pharmacogenomics – this new field of diagnostics means that people with gene defects, rather than disease, will seek access to therapies.
- Rare diseases (orphan drugs) – biotech therapies offer the best chance for addressing these diseases affecting some 25-30 million Europeans, for which 70-80% have a genetic component and whose diagnosis and treatment often come too late.

Information is at the centre of the biotechnology model

Information drives the new strategic, organizational and business models on which these biotechnology advances depend. In fact, biotechnology may be the ultimate information-based and information-intensive sector. It provides a new “toolkit” of health technologies, diagnostics and drugs that allows movement from diagnosis and discrete medical interventions to a longer-term focus on health through prediction, prevention and targeted therapies throughout a person’s life.

These business models - based on integrating information and open innovation - are truly new models that increasingly will create novel and different possibilities in healthcare. They improve not only the way that innovation can deliver health technologies, diagnostics and drugs, but also the way that technology and patient information transforms health innovation. In this new “open innovation” paradigm, biotech firms are restructuring themselves to exploit information, knowledge and technology from multiple sources (including universities, public research organizations, SMEs, patients groups and patients).

In addition, for all medicines, market registration is only the beginning of a long process before a medicine reaches the patient. Biotech firms are affected disproportionately in this field, as the majority is too small to fund the cost of introducing a new therapy to practitioners on their own. This is why they require partnerships with larger companies to remain solvent, even when their initial investments in the science pay off. Giving inventors more diverse opportunities to communicate with patients can help to level the playing field and allow more of the smaller biotech firms to remain independent – and become the European champions of tomorrow.

Healthcare biotechnology innovators, in particular, have an even more important role to play in the dissemination of information, as the area of biotech is new, and most of the expertise relating to its applications actually sits within the industry.

Bio-healthcare companies already provide information resources to healthcare professionals and to consumers in areas such as vaccines and medical devices. In certain Member States, EuropaBio members also provide prevention, early diagnosis, and information about appropriate treatments and tools to manage patient compliance, as well as run a number of disease prevention programs.

Yet easily accessible and understandable information on these specialized therapies is often not being made available to all patients and healthcare professionals throughout the EU, depending on how Member States interpret the current Directive prohibiting advertising to the public for prescription-only medicines.

EuropaBio Position

EuropaBio considers that better informed patients will be better users of innovative treatments, better judges of the quality of information, and better users of healthcare resources. Overall, more and better information to patients will contribute to improved health outcomes for citizens, optimizing the management of healthcare budgets, which in turn will have a positive impact on the European economy and promote the EU's competitiveness agenda.

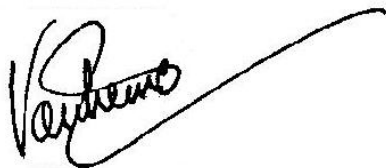
We therefore welcome the conclusions of the draft report on current practices with regard to the provision of information to patients on medicinal products. EuropaBio believes that there is a need to change the current regulatory system in Europe in order to allow for the provision of objective and reliable information to patients on biotech medicines from all pertinent sources, including the bio-healthcare industry, based on a robust governance system. Patients should be able to access all relevant information relating to their treatment.

In addition, the particularity of bio-healthcare leads us to believe that it is crucial that such a new regime for information made available to European patients addresses not only diseases but also, where applicable, current and potential therapeutic options, including biotech medicines. Moreover, it is important that the supplied information does not lead to discrimination of patients because of disease type, rarity or availability of therapy. As such, information must be comprehensive and available for all disease types, including rare diseases.

EuropaBio therefore asks that Directive 2001/83 on the Community code relating to medicinal products for human use be amended to include appropriate provisions explicitly confirming that the dissemination of information on therapeutic medicines is allowed, including by the bio-healthcare industry.

Thank you very much again for the opportunity to comment, and we look forward to the Commission coming forward with a concrete regulatory proposal by the end of the year.

Yours faithfully,

A handwritten signature in black ink, appearing to read 'Johan Vanhemelrijck', with a long, sweeping horizontal line extending to the right.

Johan Vanhemelrijck
Secretary General