



European Commission  
Health and Consumer Protection Directorate-  
General  
Enterprise and Industry Directorate-General  
High Level Pharmaceutical Forum Directorates  
B232 8/102  
B-1049 Brussels  
Belgium

4 May 2007

**Re: High-Level Pharmaceutical Forum Public Consultation on Health-Related  
Information to Patients**

Dear Ms Lalis, Mr Fahy

EuropaBio is the European Association for Bioindustries, representing 78 direct members operating worldwide, 12 associate members and 5 bioregions, as well as 25 national biotechnology associations representing some 1800 small and medium sized enterprises involved in research and development, testing, manufacturing and distribution of biotechnology products.

As a member of the Pharmaceutical Forum's Working Group on Information to Patients, launched by the European Commission in 2005, EuropaBio has participated in the discussions and has regularly submitted comments throughout the process. However, we feel compelled to submit further comments during this consultation phase, as a number of points we have raised during the Working Group discussions continue to require further consideration.

*General Comments*

Biotechnology is delivering in Europe. Today more than 325 million patients have benefited from approved medicines manufactured through biotechnology. 418 new biotech medicines and vaccines are being tested for more than 100 diseases and 50% of all medicines in the pipeline are based on biotechnological research. The current health areas in which biotechnology is being used include medicines, vaccines, diagnostics, emerging cell and gene therapies. It is therefore crucial that information to patients addresses not only diseases, but also current and potential therapeutic options, including medicines.

Indeed, patients have a right and an increasing expectation to have access to good quality information about diseases and the medicines they take, and to be actively involved in decisions about their treatment. As an example, according to a research study commissioned by the Department of Health in the UK and conducted by MORI, 88% of patients would like to have access to more information in order to be in a position to make better choices about their treatment or care. Those same patients were also interested in having access to information on conditions and treatment options in unbiased and simple language.

This is even more the case in relation to biotech therapies, because these represent novel and innovative approaches to patient disease management. These therapies are:

- personalized and targeted;
- complex in their development and modes of action, with the highest level of knowledge sitting within biotech companies and little share heritage, as yet, within the scientific community;
- often aimed at treating rare diseases, therefore coming on to market with limited sets of evidences and information;
- providing society with a better understanding on the course and mechanisms of disease, rather than simply treating the symptoms; and
- dominated by SME research, further limiting the availability of information.

EuropaBio has therefore always supported the conclusions of the High Level Pharmaceutical Forum which gave the Working Group on Information to Patients a clear mandate to examine and develop proposals for high quality and easily accessible information on diseases and medicines (and other appropriate treatment options) for people in Europe. In addition, in order to avoid discrimination among patients, such information should be available on all disease areas, including rare diseases.

Such conclusions will benefit from the development of a variety of ways to disseminate information on diseases and medicines, across the communications spectrum (electronic/non-electronic formats), and from multiple sources. EuropaBio particularly endorses the statement of Commissioner Verheugen that “industry should have the right to produce non-promotional information for patients about their own medicines and diseases and to publish it”.

There is also the need for an appropriate oversight/governance mechanism to guarantee the quality of ALL such information provided to patients, and EuropaBio therefore calls for a common definition of standards for good quality information to be applied to all providers of information.

*A practical information model on a disease, including treatment options*

Having received a clear mandate from the High Level Pharmaceutical Forum, material produced by the Information to Patients Working Group should reflect the need to have high quality, objective information for diseases and treatments, including medicines, from all sources.

EuropaBio welcomes the decision to use diabetes as a case study for developing the model package of information, but want to stress that it is also important to recognise that different models will be required for different diseases. This is the only way to ensure that the diverse information needs of patients are met, including the needs of those suffering from rare diseases.

However, we believe that the current diabetes model, as proposed, does not provide such a comprehensive ‘package’, and fails to offer adequate information on the medicines available to treat diabetes. In developing a core set of information, it is essential that the available treatment options, including medicines, are included. Models such as the British Medical Journal’s ‘Best Treatments’ website ([www.besttreatments.co.uk](http://www.besttreatments.co.uk)) and Sweden’s ‘FASS’ ([www.fass.se](http://www.fass.se)), which already provide detailed information on all treatment options available to a patient, should be built upon to ensure patients have access to comprehensive health information.

Given that most of the information in the proposed “fact sheet” also exists in a number of other places and formats, the exact purpose, use and niche of this particular document also needs to be more fully developed. In addition, if this is to be translated into all European languages, it must be clear that this project will be able to be fit for purpose and will truly respond to patient needs around Europe.

*A set of core principles for patient information on diseases and treatment options*

It is important to recognise that in developing quality criteria such as these for the provision of information to patients, they must be applicable to ALL information providers, and across all channels of communication.

It is also essential that the criteria should go beyond websites of certified official bodies and should be used as a benchmark for all health information on diseases and medicines.

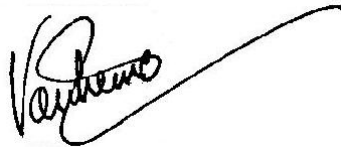
As such, while EuropaBio is supportive of this initiative, we would like to see more focus on “objective” information, rather than simply “unbiased” or “neutral”.

We also would call for information about treatment options (and not just diseases) to be covered by these criteria. This is becoming more and more necessary as biotech innovation and diagnostics continue to bridge the gap between a disease and its specific treatments through more personalized and targeted approaches.

We also suggest removing ‘[and appropriate]’ from the draft Principles. This does not add much, and in fact may detract from the information package a patient wants and needs to receive.

Thank you for the opportunity to comment on these documents and we look forward to active participation in, and a productive continuation of the Working Group.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Johan Vanhemelrijck', with a long, sweeping underline that extends to the right.

Johan Vanhemelrijck  
Secretary General