The European Association for Bioindustries

Contribution to DG Enterprise's Public Consultation on a
Legal Proposal on Information to Patients

EuropaBio welcomes the opportunity to input into the above consultation and to express key ideas for a forthcoming draft legal proposal on information to patients that are of particular importance for the biotech industry.

I. Introduction

EuropaBio is the European Association for Bioindustries, solely and uniquely bringing together bioscience companies from all fields of research and development, testing, manufacturing and distribution of biotechnology products. It has 84 corporate 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

The biotech industry has developed more than 200 drugs and vaccines that have helped millions of people worldwide. It currently counts for approximately 20% of all marketed medicines, and represents 50% of all medicines in the pipeline. These figures are significantly higher again in the field of rare diseases - a field affecting some 25-30 million Europeans, where biotech therapies offer the best chance for addressing these diseases (for which 70-80% have a genetic component) and where diagnosis and treatment often come too late.

EuropaBio member companies are also 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); and pharmacogenomics (this new field of diagnostics means that people with gene defects, rather than disease, will seek access to therapies.

The significance of this industry and these emerging technologies has led to EuropaBio being an official stakeholder in the Pharmaceutical Forum, and an active participant in its three Working Groups, including the Working Group on Information to Patients. EuropaBio has therefore been closely engaged in, and closely followed the development of a legal proposal on information to patients.

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II. Comments on the public consultation

1. Purpose of Proposal: Need to revise the current legislative framework

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 as set out in the Lisbon Agenda.**

We therefore welcome the key ideas set out in the consultation paper and strongly support the need to adapt the current regulatory system in Europe in order to allow for the provision of objective and unbiased, patient oriented, evidence-based, up-to-date, accessible, transparent, relevant and reliable information to patients on available medicines from all pertinent sources, including the bio-healthcare industry. Patients should be able to access all relevant information relating to their treatment.

EuropaBio agrees with the Commission's finding that there is insufficient / unequal access by Europeans to quality health information on disease prevention and options of existing treatments available, and that legislative change is required in order to achieve a harmonized European practice based on quality standards.

Nowadays, healthcare biotechnology already has a tremendous impact on meeting the needs of patients and their families. And these new diagnostic tools and therapies will continue to represent the state-of-the-art evolution of science as applied to human medicine. They present novel approaches to diagnosis, patient disease management, and the technology itself is providing the biotech research sector with a better understanding on the course and mechanisms of disease.

Healthcare biotechnology is increasingly playing a role in conventional medicines discovery as well as opening new possibilities to prevent, treat and cure incurable diseases using novel methods of treatment and diagnosis. Healthcare biotech responds to patients' unmet needs. 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

Especially for patients with rare diseases, access to quality information is all that more difficult in that fewer resources are dedicated to providing credible background information on rare diseases and available treatments. The impact of rare diseases is huge both on the patient and their informal carers. Because the diseases in question are

rare, they are particularly isolating: there may be no other affected families nearby. Furthermore, the challenges faced with rare diseases may be both physical and mental and may require adjustment to both the educational setting and the home and society overall. For this reason, social and education support services resulting in more information and a better understanding about these conditions and treatments available are crucial.

Healthcare biotechnology innovators can offer a significant contribution and have an 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 companies. 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. Such models should definitely be considered in progressing and developing a European model.

2. Type of Proposal: Clear distinction between advertising and information/ legal definitions

It is recognised, also by the European Commission, that criteria need to be defined regarding what type of information to patients may be promotional and what type may be unbiased information strictly for "informational" purposes. It is therefore crucial that such criteria are elaborated. Since industry is an important stakeholder in this issue, it is suggested that the elaboration of these criteria is undertaken by the European Commission in close collaboration with relevant stakeholders including relevant and directly concerned patient groups, industry, including EuropaBio.

Within our industry, information drives the new strategic, organizational and business models on which 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 medicines 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 - 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 medicines, but also the way that technology and patient information transforms health innovation and ultimately positively affect healthcare budgets.

In this new 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

have enough resources to introduce a new therapy to practitioners on their own. Giving inventors more diverse opportunities to provide **high-quality and non-promotional information** about their innovations to 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.

EuropaBio considers the **finding of a workable distinction between information and advertising as the best approach**, as opposed to creating exceptions to the advertising Directive - as this approach is fully consistent with judging information based on its quality criteria and not the source. The European proposal relating to information to patients should not introduce additional regulation in fields which are already exempt from the definition of advertising and therefore permissible under the Directive eg, responses to specific enquiries. We suggest that "advertising" should be limited to mean promotional unsolicited and direct communication by the industry on a specific prescription medicine, and fully agree with the way forward set out in the consultation paper to establish a European framework that enables greater access to quality information sources, maintains the ban on direct-to-consumer advertising, and where the physician remains the primary source of personal health information.

3. Interests of Patients First

EuropaBio also agrees that the starting point for such a framework, and of the European Commission's proposal, needs to be based on the goal of ensuring the availability of **good quality, objective, reliable and non-promotional information on medicines for all Europeans**.

4. Important key objectives for EuropaBio members

Bioindustries are often small and medium size undertakings and it is vitally important for them that the Community regulatory framework ensures a **harmonized framework,** as these companies only have limited resources and therefore are not able to allocate resources to investigate and adapt to different standards across Europe.

In addition to harmonized legal provisions on the provision of information we consider the European Commission objective to avoid any unnecessary bureaucracy as vital for our member companies, since small and medium size enterprises do not have the capacity to deal with excessive bureaucracy due to their limited financial and administrative resources. It is important that the quality principles regarding the provision of information to patients dovetail with the quality criteria developed in the Better Regulation policy of the Commission.

A proposal that would impose excessive controls on reliable sources would go against this policy and be absolutely unproductive and would mean that unreliable sources will continue to dominate the European information landscape. We think it will be more important to create workable standards of excellence and ensure that these apply to and are respected by all sources.

5. Specific Comments

3.3.1 Information passively received by citizens
As this section is drafted, we agree with other submissions that it is not entirely clear what type of communications are envisaged by mentioning the various channels for dissemination of product information.

EuropaBio believes that, as it is currently presented in the Consultation Paper, the communication of information when provided unsolicited to the public , on specific medicines, through television, radio and print by the industry should not, in general, be part of the communication practices to be included in the new framework. .On the other hand, when information is "pulled" by the patient, industry should be able to provide high-quality product information, e.g. on internet sites, in response to enquiries from patients and in the context of compliance programs.

3.3.2 Information Search by Citizens
EuropaBio members are committed to adhering to standards of excellence and quality principles in the provision of information, under a self-regulatory approach. Such an approach could include the active participation of external stakeholders on an advisory board. Under this approach, the industry association would oversee the good practice of its members. The proposed 'co-regulatory body' and the notification process of verbal and internet dissemination appears overly bureaucratic and unnecessary, and may cause unnecessary delays in the dissemination of information.

4 Quality Criteria
EuropaBio fully agrees with this clause. However, it should remain possible to discuss a range of treatments, or class of products in a balanced, non-promotional manner.

5 Proposed Structure for monitoring / sanctions
EuropaBio agrees that a well-functioning governance structure should involve multiple stakeholders. We also believe that a governance structure should respect the key policy objectives outlined by the Commission: namely:

- establishment of a harmonized framework across Europe;
- distinction between information and advertising; and
- no unnecessary bureaucracy.

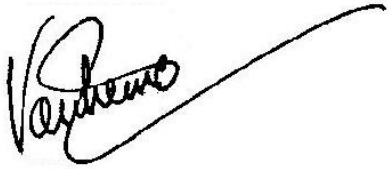
The proposed co-regulatory approach raises many issues with respect to achieving these objectives. On the one hand, the approval and monitoring of codes by national authorities would leave open the possibility of creating once again varied interpretations of information provision across Europe. Additionally, the direct involvement of national authorities on an advisory board would give it official legal status and therefore make any decisions legally binding in nature. On appeals process, this would lead to such possibilities as legal challenges in a Court of Law. On this point, we believe that

involving national authorities is inconsistent with the objective of the Commission to avoid unnecessary and excessive bureaucracy.

EuropaBio supports an approach by which its members would adhere to strict quality standards consistent with those outlined by the Commission, and enforced by the trade association through a process that would involve outside, independent stakeholders. We note that the Swedish industry association has for many years successfully used this approach in the provision of information to Swedish citizens.

Thank you very much again for the opportunity to comment, and we look forward to being involved in the next stages of this process.

Yours sincerely



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