

Brussels, 30 January 2009

Dear Sir or Madam,

Re: EuropaBio comments for the European Commission stakeholder consultation on the Pharmaceutical Sector Inquiry Preliminary Report (ref 39514)

We would like to thank the European Commission's services for the opportunity to comment on the preliminary report about the pharmaceutical sector inquiry – we are pleased to be able to share with you our observations and reservations about this important document and thereby contribute towards a final report that more adequately reflects the views of all relevant stakeholders, including the originator healthcare biotechnology industry, and contains a more detailed and complete description of the inefficiencies within the healthcare sector.

EuropaBio, the European Association for Bioindustries¹, which brings together 79 corporate members and, through 25 national biotechnology associations, some 1800 small and medium sized enterprises involved in research. agrees with the European Commission's services' statement that the pharmaceutical sector is "vital to the health of Europe's citizens". We welcome the Commission's recognition of the essential nature of intellectual property protection for investment and innovation. We do, however, regret that the report adopts what could be perceived to be an accusatory tone against the innovator industry that risks creating major damage to the reputation of the entire sector, including the biotechnology-based companies and the innovation process. We believe our concerns in relation to the report's views on the patent system would be shared by other innovation lead industry sectors that rely on secure intellectual property protection as the foundation for their investments in bringing new products to market.

Impact of Healthcare Systems on Innovation

We are surprised that this exercise does not address the major challenges and inefficiencies within the healthcare sector and as such is a missed opportunity to give a strong signal to all stakeholders involved, not least the Member States, that all is not going well in Europe when it comes to, first, stimulating innovation in healthcare, and, then, ensuring access to new treatments for patients. EuropaBio believes that the most important sources of inefficiencies are the national healthcare systems, a belief that was even echoed by the President of the European Generics Association (EGA) at the public presentation of the report on 28 November 2008.²

By creating a high degree of uncertainty for developers with regard to the future of their medicines and by impeding innovative medicines from being available in a timely manner, these policies and practices penalise originator companies, patients and ultimately society. They are much more appropriately described as a restraint on innovation and contribute to "the decline of new chemical entities reaching the market" which the preliminary report suggests. The same is true for biological entities. EuropaBio believes that the preliminary report has missed the opportunity to highlight how some practices and policies of regulators and payers distort markets

¹ 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 79 corporate members operating worldwide, 5 associate members, 6 BioRegions and 25 national biotechnology associations representing some 1800 small and medium sized enterprises involved in research. Its mission is to promote an innovative and dynamic biotechnology-based industry in Europe.

² Rory O'Riordan, Vice-President European Generics Association, Presentation to Pharmaceutical Sector Inquiry Hearing, 28 November 2008

which greatly depend on reimbursement by governmental bodies. This environment makes it difficult for companies large and small to bring products to market, but is particularly difficult for SMEs who do not have a broad differentiated portfolio over which to spread the risk and, for whom, the uncertainty of state price controls can call into question the viability of their business model. We hope that the Commission will address this omission by including in the final report a detailed analysis of the impact of the healthcare systems and their pricing and reimbursement procedures, on competitive dynamics, market entry and innovation. We hope also that it will explore potential remedies to these issues and take into account the competence of the Member States in this area.

The European Commission can draw inspiration from the conclusions of the High Level Pharmaceutical Forum that studied the difficulties faced by the pharmaceutical industry as a whole and highlighted the anti-competitive consequences of regulatory measures that resulted in market access delays.³

Reward for Innovation

EuropaBio would like to suggest that another important reason for the difficulties faced by the pharmaceutical industry in relation to new molecular entities being submitted for approval is the lack of incentives for their development, as well as the increasingly onerous safety requirements which seem to require a utopian 'zero risk' standard. As the Commission's services have rightly noted, research and development, clinical trials, and, for biotech products, manufacturing, are major cost components for medicines, whatever the technology used to make them.

In addition, the development of a completely new indication for a product that has been on the market for more than 10 years and which requires an entire clinical development programme for approval, might only be rewarded with one year additional data exclusivity. This is clearly not sufficient reward for a company to undertake such a huge investment, which could represent a substantial portion of the total medicine development costs. A more appropriate framework for the reward of such innovative efforts and the associated risks would therefore also be very much welcomed by EuropaBio. In its Final Report of the High Level Pharmaceutical Forum, the Commission clearly stated that "...pricing and reimbursement policies need to balance (1) timely and equitable access to pharmaceuticals for patients all in the EU, (2) control of pharmaceutical expenditure for Member States, and (3) reward for valuable innovation within a competitive and dynamic market that also encourages Research & Development."

On the issue of pricing, EuropaBio would like to highlight that the costs of medicines are only a relatively moderate part of the overall expenditures for healthcare. For biotech medicines, it is an even smaller percentage. Thus, to truly address inefficiencies in the healthcare system we would suggest one might also want to focus on the other cost components, such as the margins for wholesalers and pharmacists.

Access to Capital and Financial Means

Given the current global financial crisis, we urge European regulators and policy makers to seize all opportunities, including this sector inquiry, to propose concrete and short-term measures to ensure that there is a favorable and stimulating environment in Europe for innovation in healthcare, including by the biotechnology-based sector. In this respect, particular attention should be paid to the vital and urgent need for biotechnology-based companies, especially Small and Medium Size Enterprises (SMEs), to access capital and the necessary financial means to be able to continue their operations, especially when access to credit is restricted

Patents and Protection

³ High Level Pharmaceutical Forum 2005 – 2008, Final Conclusions and Recommendations, 2 October 2008.

All innovators, across all industries, seek to protect and market their products. Innovative academic institutions and SMEs also commonly rely on patent portfolios, and if needed litigations, settlements, agreements, marketing strategies and second generation products for their operations. These are lawful and pro-competitive practices, often stimulated by regional and national development agencies. The general usage of pejorative terms such as 'toolkits' or 'delaying tactics' creates a false impression of illegal or suspicious conduct. It unfairly damages the reputation of the entire industry. It places us in a defensive position towards our key stakeholders - European governments, scientists and patients. EuropaBio therefore hopes that the final report will refrain from using such terms and provide the legal certainty needed for innovators' activities.

Marketing versus Research Costs

EuropaBio believes that the issue of marketing versus research cost is presented in a somewhat simplistic way in the report. Stating that originator companies spend "about one third more [on marketing and promotional activities] than they spent on R&D as a whole" without further analyzing the reasons behind this difference is, in our opinion, not adequate. If the report had elaborated on this point, it would have found that a large proportion of what is termed 'marketing costs' is in actual fact doctors' education in the relevant area (as in several Member States, doctors have no incentive to continue their education) – which we believe is vital for the good health of European citizens and very much in the interest of patients. This point on education is particularly true for biotech-based products which are newer (certainly older physicians will not have seen them during their education), more innovative and highly complex. We feel strongly that the public interest objectives covered at least partly by such educational efforts by the pharmaceutical and biopharmaceutical industries should be properly reflected in the final report. Furthermore, we would like to see the final report highlight the fact that the provision of information on medicinal products by industry is part of the regulatory obligations upon innovators.

Generics versus Biosimilars

A further concern is the way the preliminary report covers generics and biosimilars. We understand that, for historical reasons linked to the way the questionnaires were drafted, the report is structured in such a manner that the term 'generic' also includes the term 'biosimilar', unless otherwise specified. However, both science and the EU's own regulatory and legal system make a difference between the two categories. While the overall concepts (e.g. marketing application, market mechanisms) are equally relevant for generics and biosimilars, EuropaBio has identified a number of cases where the detailed information contained in the preliminary report do not identically apply to biosimilars (e.g. substitution at pharmacy level), or have not been seen during the period the report covers and therefore merit clearer distinction (e.g. in §148, § 92).

EuropaBio respectfully requests that the European Commission's services identify these paragraphs⁴ and clearly specifies where they are only applicable to or relevant for generics and not biosimilars. This could be done in the final report, for instance, by way of the addition of a footnote after the term 'generic' or, alternatively and preferably, a change to the definition of the term 'generic', as not including the term 'biosimilar', unless otherwise specified. EuropaBio believes that the principle differences between small molecules and biologics resulting in the mentioned need to make such requested distinction have been brought to the attention of the European Commission's services during our meeting on November 18, 2008, which we believe took place after the preliminary report was finalized for the so-called inter-service consultation.

We do understand and accept that information relating to our research, development and

⁴ Section D.3.2nd paragraph of the executive summary and the following paragraphs of the preliminary report: 92, 148, 297 (after the third word "generic" used in that paragraph), 306, 367, 703, 724, 757 (because the 16 intervention cases regarding reference pricing were not related to biosimilars), 893 (provided that no patent litigation was reported during the inquiry period as being related to biosimilar entry) and 921.

marketing is gathered and included in the preliminary report but we would appreciate if the European Commission's services could use all opportunities to distinguish between the very different context of chemical and biological substances to avoid any inappropriate confusion and to ensure that the information collected is reported accurately.

SMEs and Administrative Burden

As the representative of over 1800 biotech SMEs through our network of national associations, EuropaBio would like to make one final point about the importance of SMEs, and the interdependence between SMEs and large pharma companies – both groups need to be encouraged in equal measure if we are to maintain a truly innovative Europe.

A major burden for SMEs is the very high administrative burden which hinders them from accessing markets in a timely fashion. Therefore, the Commission's services statement that "significant cost and efficiency improvements could be achieved by creating a Community patent and a unified patent judiciary" is a most welcome one and one that EuropaBio would strongly recommend that the Commission takes further. We truly believe that the creation of a European-wide single patent would make a real difference, especially for SMEs, and support any plans the Commission has in this area.

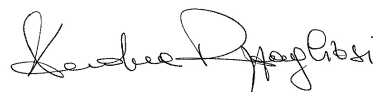
EuropaBio realizes that this preliminary report addresses certain issues that are not (or not exclusively) within the competence of the EU. We nevertheless understand that the findings of the final report may be integrated in a Commission Communication and discussed at the levels of the Council and the European Parliament. This makes it even more crucial to ensure that the final report correctly and adequately reflects the views of all relevant stakeholders, including the originator biopharmaceutical industry, and contains a more detailed and complete description of the inefficiencies within the healthcare sector. We would mostly appreciate having the opportunity to comment on the final report and/or the Communication before their adoption by the Commission.

As the representatives of the biotechnology-based sector, we therefore very much hope that you will take our comments on the above into consideration, and are of course at your disposal, should you require further information on this or other issues.

Yours sincerely,



Willy de Greef
Secretary General, EuropaBio



Andrea Rappagliosi
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