The European Association for Bioindustries

European Commission
Health and Consumer Protection Directorate-General
Health Services Consultation
B232 8/102
B-1049 Brussels

Brussels, 30 January 2007

Re: Consultation Regarding Community Action on Health Services

To whom it may concern

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

EuropaBio is the European Association for Bioindustries, representing 70 direct members operating worldwide, 12 associate members and 5 bioregions, as well as 24 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 general point, it is clear that the right for cross-border healthcare in Europe has been upheld by several judgements by the European Court of Justice. However, we do support the Commission's consideration of a specific (potentially legislative) action to lay down clearly and transparently the rights, roles and responsibilities of the actors in this process.

For EuropaBio and its members, there is particular value in such a consideration as it applies to the introduction and application of orphan medicines, and the treatment of rare diseases, within the European Union. We believe that any action taken by the Commission in relation to cross-border healthcare should take this area of medical research/treatment into account. As such, we propose to list a few points that are relevant to such a consideration.

BACKGROUND

Thousands of diseases and conditions affect so few people that without special support it would be unlikely that any company could afford to develop a treatment or cure for them. Lacking a company to sponsor development, drugs for these diseases or conditions are called "orphan medicines". Each "orphan" disease or condition may affect only a few thousand patients around the world, but there are some 8,000 rare diseases, most of them lacking effective medical treatments. Although individually rare, collectively they affect some 20 to 30 million Europeans and their families. Between 70 to 80 per cent of these rare diseases have a genetic origin, so biotechnology is an important tool for developing treatments for them.

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QUESTION 1: What is the current impact of cross-border healthcare on accessibility, quality and financial sustainability of healthcare systems, and how might this evolve?

- There is a need to develop centralised groupings of Orphan specialists as these are very specific areas. Often expertise does not exist in every Member State.
- Once diagnosis of a rare disease is made, treatment, when available, is needed. Centres of expertise will assist here in the case of rare diseases. However, a mechanism needs to be found to encourage countries to host these Centres. National governments may be discouraged if they have to pay for the treatment.

QUESTION 2: The need for legal certainty

- Despite a centralized approval for Orphan Medicinal Products, reimbursement and availability differ strongly between Member States. Legal certainty is needed for cases where the patient would purchase a treatment or care in another country that is not covered by his or her own country.

QUESTION 3: Which issues (e.g., clinical oversight, financial responsibility) should be the responsibility of the authorities in which country? Are these different for the different kinds of cross-border healthcare described in 2.2 [of the document]?

- Although EuropaBio supports the establishment of specialised centres of diagnosis and treatment where they are needed (to assure expertise is shared where such expertise might be limited), continuity of such treatment may become problematic where Member States are not committed to it because of the cost. This is especially the case for rare diseases. Consideration should therefore be given to the need for centralized funding and reimbursement in specialist areas of treatment such as Orphan Medical Products.

QUESTION 4: Who should be responsible for ensuring safety in the case of cross-border healthcare? If patients suffer harm, how should redress for patient be ensured?

- A centralized system for addressing this issue should also be considered in the case of rare disease treatment, where specialized centres of treatment are established in order to pool expertise. Member states may be more willing to support ongoing cross-border treatment under these circumstances.

QUESTION 5: What action is needed to ensure that treating patients from other Member States is compatible with the provision of a balanced medical and hospital services accessible to all (for example, by means of financial compensation for their treatment in "receiving" countries)?

- Certainly treatment using orphan medicinal products should form part of any consideration of financial compensation for treatment in "receiving" countries, especially where patients are required to move across borders because of the lack of specialists in their own country.

QUESTION 8: In what ways should European action help support the health systems of the Member States and the different actors within them? Are there areas not identified [above]?

- As stated earlier, we agree with the statement in the Consultation Paper that some types of health services require a particular concentration of resources or expertise, and the use of rare diseases as an example. As such, we support establishing European networking for such centres to ensure the highest quality of care for patients. Centralised financial support for Member States hosting the expertise and, as a result, patients is the main way European action can help in this regard.

QUESTION 9: What [legislative] tools would be appropriate to tackle the different issues related to health services at EU level? What issues should be addressed through Community legislation what though non-legislative means?

- It may be appropriate, given the specialized circumstances associated with rare diseases, to consider the introduction of Community legislation implementing a centralized procedure for supporting their treatment. Member states will need to see certainty in this process (in terms of financial support for ongoing treatment and compensation costs) before they commit to significant resources of their own.

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

Johan Vanhemelrijck
Secretary General