



Press Release

Companies researching and developing treatments for rare diseases welcome draft Commission guideline providing legal certainty on market exclusivity for Orphan Medicines

Brussels, 9 March 2007:

The industry, through the European Association of Bio-Industries (EuropaBio) and European Biopharmaceutical Enterprises (EBE), welcomes the draft Commission guideline on the review of the period of market exclusivity for orphan medicinal products. The draft guideline published on 7 March (1) confirms that ten years market exclusivity can only be reduced to 6 years if the initial designation criteria have significantly changed since the market authorisation of the orphan medicinal product.

This means that for prevalence-based designations, the overwhelming majority of orphan products designations to-date, the ten year market exclusivity remains a strong and predictable incentive. The draft Commission guideline, which provides guidance on how to interpret article 8.2 of the EU Orphan Medicinal Products Regulation EC 141/2000, now enters into a consultation period.

Orphan medicinal products are those developed for diseases or conditions that affect fewer than 5 people in every 10000 people. In the European Union ten years market exclusivity is given as an incentive to encourage developers of orphan medicines to invest in such rare diseases. This does not mean that a monopoly is being created as other medicines proving clinical superiority can break an original product's market exclusivity.

"The Commission has decided to give a strong message of support for the development of orphan medicines in Europe through various actions, including the Commission report from June 2006 on the five year experience of the Regulation and now this draft guideline", says Erik Tambuyzer, Chair of the Joint EuropaBio / EBE task force on Orphan Medicines. "This is very good news for patients, as it gives companies the certainty and stability needed for a long-term effort in this field. Provided that no major changes will emerge during the consultation period, the signal to our industry is to keep investing in medicines for rare disorders", he added.

There were almost no orphan products developed in the EU prior to the introduction of the Orphan Medicinal Product Regulation EC 141/2000, compared with 434 orphan

product designations granted and 34 approved orphan medicinal products with marketing authorization in the EU in the 6 years since the start of the system in 2000 (2).

ENDS

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NOTES TO EDITORS

(1) Proposed Guideline

http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2007/2007_03/draft_guideline_art8-2_200702.pdf

(2) EC Register of Orphan Medicinal Products

<http://ec.europa.eu/enterprise/pharmaceuticals/register/orphreg.htm>

About EuropaBio

EuropaBio, the European Association for Bioindustries, has 78 corporate members operating worldwide, 12 associate members, 5 BioRegions and 25 national biotechnology associations representing some 1800 small and medium sized enterprises involved in research and development, testing, manufacturing and distribution of biotechnology products. <http://www.europabio.org>

About EBE

EBE (European Biopharmaceutical Enterprises) is the European trade association that represents biopharmaceutical companies of all sizes operating in Europe. It has 62 member companies, which are engaged in research, development and marketing of new medicinal products using biotechnology. www.ebe-biopharma.org