The European Agency for the Evaluation of Medicinal Products

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PRESS RELEASE
EMEA publishes first Summaries of Opinions for designated orphan medicines

The EMEA has today published the first Summaries of Opinion for designated orphan medicines. The summaries outline the basis on which a medicine for a rare disease has been granted an orphan medicines designation in the European Union.

This is the latest phase in EMEA initiatives to improve regulatory transparency, and follows the introduction in 2001 of summaries of opinions for marketing authorisations for medicines for human and veterinary use.

Orphan medicines are those intended for rare and serious or life-threatening diseases affecting less than 5 in 10,000 persons in the European Union or medicines that are unlikely to be developed under normal market conditions.

Orphan designation is given by the European Commission on the recommendation of the Agency's Committee for Orphan Medicinal Products (COMP). As of March 2002 over 165 applications for designation have been made and the COMP has adopted opinions on almost 100 of these. Summaries of opinion will be published only after the designation has been approved by the European Commission.

European Union orphan medicines legislation was introduced in 2000 and gives a number of incentives for the development of medicines for rare diseases. The designation procedure identifies 'orphans' eligible for such incentives, which include 10-year market exclusivity in the designated indication once the medicinal product is authorised.

As of March 2002 the Agency has given positive opinions for authorisation for 5 designated orphan drugs: Fabrazyme (authorised), Glivec (authorised), Replagal (authorised), Tracleer (authorisation pending) and Trisenox (authorised).

More than 50 % of designations granted to date are for rare diseases in oncology and more than 65 % of designations are for diseases which affect children.

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