EU adopts legislation to promote drug development for rare diseases

The European Union (EU) Executive Commission adopted legislation to stimulate the development of drugs for rare diseases on 27 April 2000. Pharmaceutical companies may now apply to the European Agency for the Evaluation of Medicinal Products (EMEA) to designate pharmaceuticals as “orphan medicinal products”. Under the new legislation, companies will be able to request reductions in the fees for market authorizations and for changes requested after registration has been granted. Companies whose products are granted orphan drug status will be entitled to a 10-year period of market exclusivity.

Fernand Sauer, Executive Director of the EMEA, comments: “The prospect of obtaining a 10-year period of market exclusivity for orphan medicinal products in the European Union will provide a strong incentive for sponsors to develop and market orphan medicinal products”. He added: “Pharmaceuticals intended to treat diseases which may have high prevalence in some developing countries, but which are classified as rare in the European Union, such as malaria, may also be designated as orphan medicinal products”.

Similar legislation was adopted in the United States in 1983, where the inclusion of tax incentives for companies proved to be effective. However, such incentives are not possible in the EU due to the absence of a centralized system of taxation. The Committee for Orphan Medicinal Products, which was established in 1999 and which is the first institutional committee of the EU to include representatives of patient organizations as full members, has been instrumental in introducing the new legislation. Sauer notes: “To date, the EMEA has received seven applications for orphan medicinal product designation. A further 35 sponsors have indicated their intention to submit applications”.

Barry Whyte, Bulletin