

Commission takes measures to help rare disease patients

The European Commission has adopted a regulation laying down rules for implementing the European Parliament and Council Regulation 141/2000, on Orphan Medicinal Products, which opens up new treatment opportunities for patients with rare, or "orphan" diseases. These rules will encourage the pharmaceutical industry to invest in developing treatments for rare and/or "uneconomic" diseases, which affect fewer than 5 patients in every 10,000 of the EU population.

From tomorrow morning, companies may apply to the European Agency for the Evaluation of Medicinal Products (EMA) to designate their candidate medicines as "orphan medicinal products". These medicines could benefit patients not only in Europe, but also in developing countries, as diseases such as malaria or sleeping sickness would also be eligible.

The Regulation, which sets out a series of incentives, including market exclusivity and the possibility for fee exemptions for marketing authorisation activities, came into force on 22 January 2000. However, these measures could not be implemented until the Commission adopted the necessary definitions and implementing criteria.

The Regulation 141/2000 also creates the *Committee for Orphan Medicinal Products* - the first European scientific committee where patients' representatives participate fully in decisions on whether a potential medicine meets the 5 in 10,000 criterion, or is unlikely to be profitable enough to justify the investment needed. This Committee held its inaugural meeting on 17 April 2000.

Further information on the Regulation, its implementing regulation, and the Committee for Orphan Medicinal Products is available on <http://pharmacos.eudra.org> and the EMA web site (<http://www.eudra.org>).

Since the Commission's first legislative proposal, in July 1998, the progress of the Regulation on Orphan Medicinal Products has been actively supported by both the European Parliament and the Council of Ministers. Modelled on legislation in place in the US since 1983, which was subsequently introduced in Japan, Australia and Singapore, it creates the first Community-wide rules specifically for these treatments.