Authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

2001/0252(COD) - 29/03/2006 - Implementing legislative act

LEGISLATIVE ACT : Commission Regulation 507/2006/EC on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation 726/2004/EC of the European Parliament and of the Council.

CONTENT : this Regulation lays down rules on the granting of a marketing authorisation subject to specific obligations in accordance with Article 14(7) of Regulation 726/2004/EC ("conditional marketing authorisation").

In the case of certain categories of medicinal products, in order to meet unmet medical needs of patients and in the interests of public health, it may be necessary to grant marketing authorisations on the basis of less complete data than is normally the case and subject to specific obligations.

This Regulation applies to medicinal products for human use that fall under Article 3(1) and (2) of Regulation 726/2004/EC and belong to one of the following categories:

- medicinal products which aim at the treatment, the prevention or the medical diagnosis of seriously debilitating diseases or life-threatening diseases;

- medicinal products to be used in emergency situations, in response to public health threats duly recognised either by the World Health Organisation or by the Community in the framework of Decision 2119/98/EC;

- medicinal products designated as orphan medicinal products in accordance with Article 3 of Regulation 141/2000/EC.

ENTRY INTO FORCE: 02/04/2006.