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

2001/0252(COD) - 15/12/2005 - Implementing legislative act

ACT : Commission Regulation 2049/2005/EC laying down, pursuant to Regulation 726/2004/EC of the European Parliament and of the Council, rules regarding the payment of fees to, and the receipt of administrative assistance from, the European Medicines Agency by micro, small and medium-sized enterprises.

CONTENT : Regulation 726/2004/EC provides that the revenue of the European Medicines Agency must consist of a contribution from the Community and fees paid by companies, and states that the situation of micro, small and medium-sized enterprises (SMEs) has to be considered separately. This Regulation establishes the circumstances in which, by derogation from the relevant provisions of Regulation 297/95 /EC, SMEs may pay reduced fees, defer payment of fees, or receive administrative assistance when submitting applications under Regulation 726/2004/EC to the Agency. The Regulation applies both to applications concerning medicinal products for human use and to applications concerning veterinary medicinal products.

Fee deferrals and reductions: The payment of certain fees is deferred until the notification of the final decision on the marketing authorisation is issued, or the application is withdrawn:

- the fee for an application for a marketing authorisation of a medicinal product;

- the fee for inspections undertaken for the purpose of assessing a marketing authorisation application for a medicinal product.

These fees are payable within 45 days of the date of the notification of the final decision on the marketing authorisation, or within 45 days of the date of the notification of withdrawal of the application.

The Regulation makes provision for a conditional fee exemption, where an application for marketing authorisation is submitted for a medicinal product on which scientific advice has already been given by the Agency. The fee payable to the Agency for the examination of that application will be due only if a marketing authorisation is granted.

Fee reductions:

- in the case of inspections a 90 % reduction to the inspection fee;

- in the case of scientific advice a 90 % reduction to the scientific advice fee;

- in the case of scientific services a 90 % reduction to the scientific service fee;

- scientific advice and scientific services for designated orphan medicinal products as referred to in Regulation 141/2000/EC shall be provided free of charge;

- a 90 % reduction to the full and additional maximum residue limits (MRL) fees, as referred to in Regulation 297/95/EC;

- there are provisions on multiple fee reductions.

SME Office: The Executive Director of the Agency shall set up dedicated administrative structures and specific procedures for the establishment of an SME Office, which will have the following tasks:

- to give advice to applicants on the administrative and procedural steps necessary to comply with the requirements laid down in Regulation 726/2004/EC;

- to ensure the appropriate monitoring of all requests and applications submitted by the same applicant and related to a particular medicinal product;

- to organise workshops and training sessions for applicants on the administrative and procedural steps necessary to comply with the requirements laid down in Regulation 726/2004/EC.

The Agency will publish a detailed User Guide on the administrative and procedural aspects of the provisions laid down in Regulation 726/2004/EC, which are of particular relevance for SMEs.

ENTRY INTO FORCE : 16/12/2005. The Regulation shall not apply to valid applications pending at the date of its entry into force.