COMMISSION REGULATION (EC) No 649/98

of 23 March 1998

amending the Annex to Council Regulation (EEC) No 2309/93

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products [1], and in particular Article 3(5) thereof,

Whereas for the purposes of animal health protection and given the specific nature of the market in veterinary medicinal products, encouragement should be given to pharmaceutical companies so that new and/or innovative medicinal products in the veterinary field are placed on the market as soon as possible;

Whereas pharmaceutical companies are bound by essential requirements for the development of medicinal products relating to, *inter alia*, clinical and toxicological studies; whereas these essential requirements vary according to whether the medicinal product is intended for domestic animals, animals producing food for human consumption or both categories of animal;

Whereas new and innovative veterinary medicinal products should be the subject of coherent and effective supervision by way of pharmacovigilance; whereas it is therefore preferable to entrust the supervision of a particular medicinal product to a single national or Community authority, regardless of its indications and target species;

Whereas it is also necessary to improve the transparency of and ease of access to the market in veterinary medicinal products by offering pharmaceutical companies the possibility, for a given new and/or innovative medicinal product, of a single type of national or Community authorisation whatever the target species for that product;

Whereas therefore it must be possible for the European Agency for the Evaluation of Medicinal Products to carry out an evaluation, at the request of a company, of any veterinary medicinal product containing a new active substance which, on the date of entry into force of this Regulation, was not authorised by any Member State for use in animals;

Whereas the measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products,

HAS ADOPTED THIS REGULATION:

Article 1

In the Annex to Regulation (EEC) No 2309/93, Part B, the last indent shall be replaced by the following text:

'Veterinary medicinal products containing a new active substance which, on the date of entry into force of this Regulation, was not authorised by any Member State for use in animals'.

Article 2

This Regulation shall enter into force on the day following its publication in the *Official Journal of the European Communities.*

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 23 March 1998.

For the Commission
Martin BANGEMANN
Member of the Commission

[1] OJ L 214, 24. 8. 1993, p. 1.