Commission Directive 2009/9/EC of 10 February 2009 amending Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to medicinal products for veterinary use (Text with EEA relevance)

COMMISSION DIRECTIVE 2009/9/EC

of 10 February 2009

amending Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to medicinal products for veterinary use

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products[(1)], and in particular Article 88 thereof,

Whereas:

(1) In order to be placed on the European Community market, a veterinary medicinal product must be granted a marketing authorisation by a competent authority. For this purpose, an application dossier containing particulars and documents relating to the results of tests and trials carried out on the veterinary medicinal product must be submitted.

(2) The purpose of Annex I to Directive 2001/82/EC is to lay down detailed scientific and technical requirements regarding the testing of veterinary medicinal products against which the quality, safety and efficacy of the veterinary medicinal product should be assessed. It also gives instructions concerning the presentation and content of the application dossier.

(3) The detailed scientific and technical requirements of Annex I to Directive 2001/82/EC need to be adapted to take account of scientific and technical progress and in particular of a set of new requirements resulting from recent legislation. The presentation and content of the marketing authorisation application dossier should be improved in order to facilitate the assessment and the better use of certain parts of the dossier which are common to several veterinary medicinal products.

(4) In order to simplify current procedures for the assessment of veterinary vaccines, both for the granting of a first marketing authorisation and for the subsequent changes to it due to modifications to the manufacturing process and testing of individual antigens involved in combined vaccines, a new system based on the concept of a master file (Vaccine Antigen Master File, VAMF) should be introduced for vaccines which involve several antigens.

(5) To permit authorisation of vaccines against antigenically variable viruses in a way that ensures that the most effective measures can be taken swiftly by the Community against the incursion or spread of epizootic diseases, the concept of multi-strain dossier should be introduced. This will at the same time ensure that marketing authorisations are granted on the basis of objective scientific criteria of quality, safety and efficacy.

(6) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee for Veterinary Medicinal Products,

HAS ADOPTED THIS DIRECTIVE:

(**1**) OJ L 311, 28.11.2001, p. 1.