

[^{F1}ANNEX ICHEMICAL, PHARMACEUTICAL AND ANALYTICAL STANDARDS,
SAFETY AND RESIDUE TESTS, PRE-CLINICAL AND CLINICAL TRIALS
IN RESPECT OF TESTING OF VETERINARY MEDICINAL PRODUCTS**Textual Amendments**

- F1** Substituted by [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 \(Text with EEA relevance\)](#).

TITLE IV

**REQUIREMENTS FOR MARKETING AUTHORISATION APPLICATIONS
FOR PARTICULAR VETERINARY MEDICINAL PRODUCTS**

1. IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCTS
 - A. VACCINE ANTIGEN MASTER FILE

For particular immunological veterinary medicinal products and by derogation from the provisions of Title II, Part 2 Section C on active substances, the concept of a Vaccine Antigen Master File is introduced.

For the purpose of this Annex, a Vaccine Antigen Master File means a stand-alone part of the marketing authorisation application dossier for a vaccine, which contains all relevant information on quality concerning each of the active substances, which are part of this veterinary medicinal product. The stand-alone part may be common to one or more monovalent and/or combined vaccines presented by the same applicant or marketing authorisation holder.

Scientific guidelines for the submission and evaluation of a vaccine antigen master file shall be adopted by the Agency. The procedure for the submission and evaluation of a vaccine antigen master file shall follow the guidance published by the Commission in *The rules governing medicinal products in the European Union*, Volume 6B, Notice to Applicants.

- B. MULTI-STRAIN DOSSIER

For certain immunological veterinary medicinal products (foot-and-mouth disease, avian influenza and bluetongue) and by derogation from the provisions of Title II, Part 2 Section C on active substances the concept of the use of a multi-strain dossier is introduced.

A multi-strain dossier means a single dossier containing the relevant data for a unique and thorough scientific assessment of the different options of strains/combinations of strains permitting the authorisation of vaccines against antigenically variable viruses.

Scientific guidelines for the submission and evaluation of multi-strain dossiers shall be adopted by the Agency. The procedure for the submission and evaluation of multi-strain dossiers shall follow the guidance published by the Commission in *The rules governing medicinal products in the European Union*, Volume 6B, Notice to Applicants.]