

## [<sup>F1</sup>ANNEX I

### CHEMICAL, 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

This part lays down specific requirements for identified veterinary medicinal products related to the nature of the active substances contained therein.

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.

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## 2. HOMEOPATHIC VETERINARY MEDICINAL PRODUCTS

This section sets out specific provisions on the application of Title I, Parts 2 and 3 to homeopathic veterinary medicinal products as defined in Article 1(8).

Part 2 The provisions of Part 2 shall apply to the documents submitted in accordance with Article 18 in the simplified registration of homeopathic veterinary medicinal products referred to in Article 17(1) as well as to the documents for authorisation of other homeopathic veterinary medicinal products referred to in Article 19(1) with the following modifications.

### (a) Terminology

The Latin name of the homeopathic stock described in the marketing authorisation application dossier shall be in accordance with the Latin title of the *European Pharmacopoeia* or, in absence thereof, of an official pharmacopoeia of a Member State. Where relevant the traditional name(s) used in each Member State shall be provided.

### (b) Control of starting materials

The particulars and documents on the starting materials, i.e. all of the materials used including raw materials and intermediates up to the final dilution to be incorporated into the finished homeopathic veterinary medicinal product, accompanying the application shall be supplemented by additional data on the homeopathic stock.

The general quality requirements shall apply to all of the starting and raw materials as well as intermediate steps of the manufacturing process up to the final dilution to be incorporated into the finished homeopathic product. Where a toxic component is present, this should be controlled if possible in the final dilution. However, if this is not possible because of the high dilution, the toxic component shall normally be controlled at an earlier stage. Every step of the manufacturing process from the starting materials up to the final dilution to be incorporated into the finished product must be fully described.

In case dilutions are involved, these dilution steps shall be done in accordance with the homeopathic manufacturing methods laid down in the relevant monograph of the *European Pharmacopoeia* or, in absence thereof, in an official pharmacopoeia of a Member State.

### (c) Control tests on the finished medicinal product

The general quality requirements shall apply to the homeopathic finished veterinary medicinal products. Any exception shall be duly justified by the applicant.

Identification and assay of all the toxicologically relevant constituents shall be carried out. If it can be justified that identification and/or an assay on all the toxicologically relevant constituents is not possible e.g. due to their dilution in the finished medicinal product the quality shall be demonstrated by complete validation of the manufacturing and dilution process.

### (d) Stability tests

The stability of the finished product shall be demonstrated. Stability data from the homeopathic stocks are generally transferable to dilutions/potentisations obtained thereof. If no identification or assay of the active substance is possible due to the degree of dilution, stability data of the pharmaceutical form may be considered.

Part 3 The provisions of Part 3 shall apply to the simplified registration of homeopathic veterinary medicinal products referred to in Article 17(1) of this Directive with the following specification, without prejudice to the provisions of Regulation (EEC) No

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2377/90 for substances included in the homeopathic stocks intended for administration to food-producing animal species.

Any missing information must be justified, e.g. justification must be given why demonstration of an acceptable level of safety can be supported although some studies are lacking.]