[F1 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).

INTRODUCTION AND GENERAL PRINCIPLES

1. The particulars and documents accompanying an application for marketing authorisation pursuant to Articles 12 to 13d shall be presented in accordance with the requirements set out in this Annex and shall take into account the guidance published by the Commission in *The rules governing medicinal products in the European Union*, Volume 6 B, Notice to applicants, Veterinary medicinal products, Presentation and Contents of the Dossier.

2. In assembling the dossier for application for marketing authorisation, applicants shall also take into account the current state of veterinary medicinal knowledge and the scientific guidelines relating to the quality, safety and efficacy of veterinary medicinal products published by the European Medicines Agency (Agency) and the other pharmaceutical Community guidelines published by the Commission in different volumes of *The rules governing medicinal products in the European Union*.

3. For veterinary medicinal products other than immunological veterinary medicinal products, with respect to the quality (pharmaceutical) part (physico-chemical, biological and microbiological tests) of the dossier, all relevant monographs including general monographs and the general chapters of the *European Pharmacopoeia* are applicable. For immunological veterinary medicinal products, with respect to the quality, safety and efficacy parts of the dossier, all relevant monographs including general monographs and the general chapters of the *European Pharmacopoeia* are applicable.

4. The manufacturing process shall comply with the requirements of Commission Directive 91/412/EEC[(1)] laying down the principles and guidelines for veterinary medicinal products and with the principles and guidelines on Good Manufacturing Practice (GMP), published by the Commission in *The rules governing medicinal products in the European Union*, Volume 4.

5. All information which is relevant to the evaluation of the veterinary medicinal product concerned shall be included in the application, whether favourable or unfavourable to the product. In particular, all relevant details shall be given of any incomplete or abandoned test or trial relating to the veterinary medicinal product.

6. Pharmacological, toxicological, residue and safety tests shall be carried out in conformity with the provisions related to Good Laboratory Practice (GLP) laid down in Directive 2004/10/EC of the European Parliament and of the Council[(2)] and Directive 2004/9/EC of the European Parliament and of the Council[(3)].

7. Member States shall ensure that all experiments on animals are conducted in accordance with Council Directive 86/609/EEC[(4)].

8. In order to monitor the risk/benefit assessment, any new information not in the original application and all pharmacovigilance information shall be submitted to the competent authority. After marketing authorisation has been granted, any change to the content of the dossier shall be submitted to the competent authorities in accordance with Commission Regulations (EC) No 1084/2003[(5)] or (EC) No 1085/2003[(6)] for veterinary medicinal products authorised as defined in Article 1 of those Regulations, respectively.

9. The environmental risk assessment connected with the release of veterinary medicinal products containing or consisting of Genetically Modified Organisms (GMOs) within the meaning of Article 2 of Directive 2001/18/EC of the European Parliament and of the Council[(7)] shall be provided in the dossier. The information shall be presented in accordance with the provisions of Directive 2001/18/EC and Regulation (EC) No 726/2004 of the European Parliament and of the Council[(8)], taking into account guidance documents published by the Commission.

10. In cases of applications for marketing authorisations for veterinary medicinal products indicated for animal species and indications representing smaller market sectors, a more flexible approach may be applicable. In such cases, relevant scientific guidelines and/or scientific advice should be taken into account.

This Annex is divided in four titles:

Title I describes the standardised requirements for applications for veterinary medicinal products other than immunological veterinary medicinal products.

Title II describes the standardised requirements for applications for immunological veterinary medicinal products.

Title III describes specific types of marketing authorisation dossiers and requirements.

Title IV describes the dossier requirements for particular types of veterinary medicinal products.**]**

(1) **[**[F1]OJ L 228, 17.8.1991, p. 70.**]**

(2) **[**[F1]OJ L 50, 20.2.2004, p. 44.**]**

(3) **[**[F1]OJ L 50, 20.2.2004, p. 28.**]**

(4) **[**[F1]OJ L 358, 18.12.1986, p. 1.**]**

(5) **[**[F1]OJ L 159, 27.6.2003, p. 1.**]**

(6) **[**[F1]OJ L 159, 27.6.2003, p. 24.**]**

(7) **[**[F1]OJ L 106, 17.4.2001, p. 1.**]**

(8) **[**[F1]OJ L 136, 30.4.2004, p. 1.**]**

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).