

## [<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 III

### REQUIREMENTS FOR SPECIFIC MARKETING AUTHORISATION APPLICATIONS

#### 6. Documentation for applications in exceptional circumstances

A marketing authorisation may be granted subject to certain specific obligations requiring the applicant to introduce specific procedures, in particular concerning the safety and efficacy of the veterinary medicinal product, when, as provided for in Article 26(3) of this Directive, the applicant can show that he is unable to provide comprehensive data on the efficacy and safety under normal conditions of use.

The identification of essential requirements for all applications mentioned in this section should be subject to guidelines which shall be adopted by the Agency.]