ANNEX II

REQUIREMENTS REFERRED TO IN POINT (B) OF ARTICLE 8(1)[(1)]

TITLE I

Requirements for veterinary medicinal products other than immunological veterinary medicinal products

PART 4

Pre-clinical and clinical trial

Chapter III

Particulars and documents

1. **Results of pre-clinical trials**

Wherever possible, particulars shall be given of the results of:

(a) tests demonstrating pharmacological actions;

(b) tests demonstrating the pharmacodynamic mechanisms underlying the therapeutic effect;

(c) tests demonstrating the main pharmacokinetic profile;

(d) tests demonstrating target animal safety;

(e) tests investigating resistance.

Should unexpected results occur during the course of the tests, these should be detailed.

Additionally, the following particulars shall be provided in all pre-clinical studies:

(a) a summary;

(b) a detailed experimental protocol giving a description of the methods, apparatus and materials used, details such as species, age, weight, sex, number, breed or strain of animals, identification of animals, dose, route and schedule of administration;

(c) a statistical analysis of the results, where relevant;

(d) an objective discussion of the results obtained, leading to conclusions on the efficacy and safety of the veterinary medicinal product.

Total or partial omission of any of these data shall be justified.

(**1**) This Annex will be amended by the Commission in accordance with Articles 146 and 153. All references to Articles or to 'this Directive' in this Annex, unless otherwise specified, are to be understood as references to Directive 2001/82/EC.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EU) 2019/6 of the European Parliament and of the Council, Division 1..