ANNEX I

INFORMATION REFERRED TO IN POINT (A) OF ARTICLE 8(1)

1. Legal basis for the application for the marketing authorisation

2. Applicant

2.1. Name or company name and permanent address or registered place of business of the applicant

2.2. Name or company name and permanent address or registered place of business of manufacturer(s) or importer(s) of the finished veterinary medicinal product and name or company name and permanent address or registered place of business of the manufacturer of the active substance(s)

2.3. Name and address of the sites involved in the different stages of the manufacturing, importing, control and batch release

3. Identification of the veterinary medicinal product

3.1. Name of the veterinary medicinal product and Anatomical Therapeutic Chemical Veterinary code (ATCvet Code)

3.2. Active substance(s) and, if applicable, diluent(s)

3.3. Strength or, in case of immunological veterinary medicinal product, biological activity, potency or titre

3.4. Pharmaceutical form

3.5. Route of administration

3.6. Target species

4. Manufacturing and pharmacovigilance information

4.1. Proof of a manufacturing authorisation or certificate of good manufacturing practice

4.2. Reference number of pharmacovigilance system master file

5. Veterinary medicinal product information

5.1. Proposed summary of the product characteristics drawn up in accordance with Article 35

5.2. Description of the final presentation of the veterinary medicinal product, including packaging and labelling

5.3. Proposed text of the information to be provided on the immediate packaging, outer packaging and the package leaflet in accordance with Articles 10 to 16

6. Other information

6.1. List of countries in which a marketing authorisation has been granted or revoked for the veterinary medicinal product

6.2. Copies of all the summaries of product characteristics as included in the terms of marketing authorisations granted by Member States

6.3. List of countries in which an application has been submitted or refused

6.4. List of Member States in which the veterinary medicinal product is to be placed on the market

6.5. Critical expert reports on quality, safety and efficacy of the veterinary medicinal product.

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