Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (Text with EEA relevance)

CHAPTER II

MARKETING AUTHORISATIONS – GENERAL PROVISIONS AND RULES ON APPLICATIONS

Section 7

Examination of applications and basis for granting marketing authorisations

Article 35

Summary of the product characteristics

1 The summary of the product characteristics referred to in point (a) of Article 33(1) shall contain, in the order indicated below, the following information:

a name of the veterinary medicinal product followed by its strength and pharmaceutical form and, where applicable, a list of the names of the veterinary medicinal product, as authorised in different Member States;

b qualitative and quantitative composition of the active substance or substances and qualitative composition of excipients and other constituents stating their common name or their chemical description and their quantitative composition, if that information is essential for proper administration of the veterinary medicinal product;

c clinical information:

(i) target species;

(ii) indications for use for each target species;

(iii) contra-indications;

(iv) special warnings;

(v) special precautions for use, including in particular special precautions for safe use in the target species, special precautions to be taken by the person administering the veterinary medicinal product to the animals and special precautions for the protection of the environment;

(vi) frequency and seriousness of adverse events;

(vii) use during pregnancy, lactation or lay;

(viii) interaction with other medicinal products and other forms of interaction;

(ix) administration route and dosage;

(x) symptoms of overdose and, where applicable, emergency procedures and antidotes in the event of overdose;

(xi) special restrictions for use;

(xii) special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance;

(xiii) if applicable, withdrawal periods, even if such periods are zero;

d pharmacological information:

(i) Anatomical Therapeutic Chemical Veterinary Code ('ATCvet Code');

(ii) pharmacodynamics;

(iii) pharmacokinetics.

In case of an immunological veterinary medicinal product, instead of points (i), (ii) and (iii), immunological information;

e pharmaceutical particulars:

(i) major incompatibilities;

(ii) shelf life, where applicable after reconstitution of the medicinal product or after the immediate packaging has been opened for the first time;

(iii) special precautions for storage;

(iv) nature and composition of immediate packaging;

(v) requirement to use take-back schemes for veterinary medicinal products for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products and, if appropriate, additional precautions regarding hazardous waste disposal of unused veterinary medicinal products or waste materials derived from the use of such products;

f name of the marketing authorisation holder;

g marketing authorisation number or numbers;

h date of the first marketing authorisation;

i date of the last revision of the summary of the product characteristics;

j if applicable, for veterinary medicinal products referred to in Article 23 or 25, the statement:

(i) 'marketing authorisation granted for a limited market and therefore assessment based on customised requirements for documentation'; or

(ii) 'marketing authorisation in exceptional circumstances and therefore assessment based on customised requirements for documentation';

k information on the collection systems referred to in Article 117 applicable to the veterinary medicinal product concerned;

l classification of the veterinary medicinal product as referred to in Article 34 for each Member State in which it is authorised.

2 In the case of generic veterinary medicinal products, the parts of the summary of the product characteristics of the reference veterinary medicinal product that refer to indications or pharmaceutical forms which are protected by patent law in a Member State at the time of placing of the generic veterinary medicinal product on the market may be omitted.