# 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 8*

### *Protection of technical documentation*

*Article 38*

#### Protection of technical documentation

1 Without prejudice to the requirements and obligations laid down in Directive 2010/63/EU, technical documentation on quality, safety and efficacy originally submitted with a view to obtaining a marketing authorisation or a variation thereof shall not be referred to by other applicants for a marketing authorisation or a variation of the terms of a marketing authorisation for a veterinary medicinal product unless:

a the period of the protection of technical documentation as set out in Articles 39 and 40 of this Regulation has elapsed, or is due to elapse in less than two years;

b the applicants have obtained written agreement in the form of a letter of access with regard to that documentation.

2 The protection of the technical documentation as set out to in paragraph 1 ('the protection of technical documentation') shall also apply in Member States where the veterinary medicinal product is not authorised or is no longer authorised.

3 A marketing authorisation or a variation to the terms of a marketing authorisation differing from the marketing authorisation previously granted to the same marketing authorisation holder only with regard to target species, strengths, pharmaceutical forms, administration routes or presentations shall be regarded as the same marketing authorisation as the one previously granted to the same marketing authorisation holder for the purpose of applying the rules of the protection of technical documentation.

*Article 39*

#### Periods of the protection of technical documentation

1 The period of the protection of technical documentation shall be:

a 10 years for veterinary medicinal products for cattle, sheep for meat production, pigs, chickens, dogs and cats;

b 14 years for antimicrobial veterinary medicinal products for cattle, sheep for meat production, pigs, chickens, dogs and cats containing an antimicrobial active substance

which has not been an active substance in a veterinary medicinal product authorised within the Union on the date of the submission of the application;

c 18 years for veterinary medicinal products for bees;

d 14 years for veterinary medicinal products for animal species other than those referred to in points (a) and (c).

2 The protection of technical documentation shall apply from the day when the marketing authorisation for the veterinary medicinal product was granted in accordance with Article 5(1).

*Article 40*

**Prolongation and additional periods of the protection of technical documentation**

1 Where the first marketing authorisation is granted for more than one animal species referred to in point (a) or (b) of Article 39(1) or a variation is approved in accordance with Article 67 extending the marketing authorisation to another species referred to in point (a) or (b) of Article 39(1), the period of the protection provided for in Article 39 shall be prolonged by one year for each additional target species, provided that, in the case of a variation, the application has been submitted at least three years before the expiration of the protection period laid down in point (a) or (b) of Article 39(1).

2 Where the first marketing authorisation is granted for more than one animal species referred to in point (d) of Article 39(1), or a variation is approved in accordance with Article 67 extending the marketing authorisation to another animal species not referred to in point (a) of Article 39(1), the period of the protection provided for in Article 39 shall be prolonged by four years, provided that, in the case of a variation, the application has been submitted at least three years before the expiration of the protection period laid down in point (d) of Article 39(1).

3 The period of the protection of technical documentation provided for in Article 39 of the first marketing authorisation, prolonged by any additional periods of protection due to any variations or new authorisations belonging to the same marketing authorisation, shall not exceed 18 years.

4 Where an applicant for a marketing authorisation for a veterinary medicinal product or for a variation to the terms of a marketing authorisation submits an application in accordance with Regulation (EC) No 470/2009 for the establishment of a maximum residue limit, together with safety and residues tests and pre-clinical studies and clinical trials during the application procedure, other applicants shall not refer to results of those tests, studies and trials for a period of five years from the granting of the marketing authorisation for which they were carried out. The prohibition on using those results shall not apply, insofar as the other applicants have obtained a letter of access with regard to those tests, studies and trials.

5 If a variation to the terms of the marketing authorisation approved in accordance with Article 67 involves a change to the pharmaceutical form, administration route or dosage, which is assessed by the Agency or the competent authorities referred to in Article 66 to have demonstrated:

a a reduction in the antimicrobial or antiparasitic resistance; or

b an improvement of the benefit-risk balance of the veterinary medicinal product,

the results of the concerned pre-clinical studies or clinical trials shall benefit from four years protection.

The prohibition on using those results shall not apply, insofar as the other applicants have obtained a letter of access with regard to those studies and trials.

*Article 41*

**Patent-related rights**

Conducting the necessary tests, studies and trials with a view to applying for a marketing authorisation in accordance with Article 18 shall not be regarded as contrary to patent-related rights or to supplementary-protection certificates for veterinary medicinal products and medicinal products for human use.

**Status:**
Point in time view as at 11/12/2018.

**Changes to legislation:**
There are currently no known outstanding effects for the Regulation (EU) 2019/6 of the European Parliament and of the Council, Section 8.