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 V

HOMEOPATHIC VETERINARY MEDICINAL PRODUCTS

Article 85

Homeopathic veterinary medicinal products

1 Homeopathic veterinary medicinal products that meet the conditions set out in Article 86 shall be registered in accordance with Article 87.

2 Homeopathic veterinary medicinal products that do not meet the conditions set out in Article 86 shall be subject to Article 5.

Article 86

Registration of homeopathic veterinary medicinal products

1 A homeopathic veterinary medicinal product that meets all of the following conditions shall be subject to a registration procedure:

a it is administered by a route described in the *European Pharmacopoeia* or, in the absence thereof, by the pharmacopoeias used officially in Member States;

b it has a sufficient degree of dilution to guarantee its safety, and shall not contain more than one part per 10 000 of the mother tincture;

c it has no therapeutic indication appearing on its labelling or in any information relating thereto.

2 Member States may lay down procedures for the registration of homeopathic veterinary medicinal products in addition to those laid down in this Chapter.

Article 87

Application and procedure for registration of homeopathic veterinary medicinal products

1 The following documents shall be included in the application for a registration of a homeopathic veterinary medicinal product:

a scientific name or other name given in a pharmacopoeia of the homeopathic stock or stocks, together with a statement of the route of administration, pharmaceutical form and degree of dilution to be registered;

b a dossier describing how the homeopathic stock or stocks are obtained and controlled, and justifying their homeopathic use, on the basis of an adequate bibliography; in the case of homeopathic veterinary medicinal products containing biological substances, a description of the measures taken to ensure the absence of pathogens;

c the manufacturing and control file for each pharmaceutical form and a description of the method of dilution and potentisation;

d the manufacturing authorisation for the homeopathic veterinary medicinal products concerned;

e copies of any registrations obtained for the same homeopathic veterinary medicinal products in other Member States;

f the text to appear on the package leaflet, outer packaging and immediate packaging of the homeopathic veterinary medicinal products to be registered;

g data concerning the stability of the homeopathic veterinary medicinal product;

h in the case of homeopathic veterinary medicinal products intended for food-producing animal species, the active substances shall be those pharmacologically active substances allowed in accordance with Regulation (EC) No 470/2009 and any acts adopted on the basis thereof.

2 An application for registration may cover a series of homeopathic veterinary medicinal products of the same pharmaceutical form and derived from the same homeopathic stock or stocks.

3 The competent authority may determine the conditions under which the registered homeopathic veterinary medicinal product may be made available.

4 The procedure of registration of a homeopathic veterinary medicinal product shall be completed within 90 days of the submission of a valid application.

5 A registration holder of homeopathic veterinary medicinal products shall have the same obligations as a marketing authorisation holder, subject to Article 2(5).

6 A registration for a homeopathic veterinary medicinal product shall only be granted to an applicant established in the Union. The requirement to be established in the Union shall also apply to registration holders.

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