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 U.K.

MARKETING AUTHORISATIONS – GENERAL PROVISIONS AND RULES ON APPLICATIONS

Section 3 U.K.

Clinical trials

Article 9 *U.K.*

Clinical trials

1 An application for the approval of a clinical trial shall be submitted in accordance with the applicable national law to a competent authority of the Member State in which the clinical trial is to take place.

2 Approvals of clinical trials shall be granted on condition that food-producing animals used in the clinical trials or their produce do not enter the food chain unless an appropriate withdrawal period has been set by the competent authority.

3 The competent authority shall issue a decision to approve or refuse a clinical trial within 60 days of the receipt of a valid application.

4 The clinical trials shall be carried out taking due account of the international guidelines on good clinical practice of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products ('VICH').

5 Data stemming from clinical trials shall be submitted with the application for a marketing authorisation for the purposes of providing the documentation referred to in point (b) of Article 8(1).

6 Data stemming from clinical trials conducted outside the Union may be taken into consideration for the assessment of an application for a marketing authorisation only if those trials were designed, implemented and reported in accordance with the international guidelines on good clinical practice of the VICH.

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Point in time view as at 11/12/2018.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 3.