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 III

PROCEDURES FOR MARKETING AUTHORISATIONS

Section 3

Marketing authorisations valid in several Member States ('decentralised marketing authorisations')

Article 48

Scope of decentralised marketing authorisation

1 Decentralised marketing authorisations shall be granted by the competent authorities in the Member States in which the applicant seeks to obtain a marketing authorisation ('Member States concerned') in accordance with this Section. Such decentralised marketing authorisations shall be valid in those Member States.

2 Decentralised marketing authorisations shall not be granted in respect of veterinary medicinal products for which a national marketing authorisation has been granted, or for which an application for a marketing authorisation is pending at the time of the application for a decentralised marketing authorisation, or which fall within the scope of Article 42(2).