

Post Authorisation Assessments

Tilmodil 300 mg/ml Solution for Injection for Cattle and Sheep Vm 34534/5008

Change in address of the manufacturer of the active substance.
Change in address details of an active substance master file holder.
Change in address details of the manufacturer of the active substance. Change in address details of the ASMF holder.
C hanges to the labelling and package leaflet. Change in distributor details from Animalcare Limited, 10 Great North Way, York, YO26 6RB to DUGV (UK) LIMITED, Union House, 111 New Union Street, Coventry, CV1 2NT.
Changes to the active substance master file.
Change in the name of a manufacturer used in the manufacture of the active substance. Minor change to the restricted part of an Active Substance Master File.
Change of RMS from the UK to IE.
Deletion of manufacturing site for an active substance.
Change(s) to a DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH.
Renewal – UK as RMS
Changes to the SPC and product literature following an EU Directive.
Change of distributor.