

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS Telephone +44 (0)1932 336911

Post Authorisation Assessments

Bovex 2.265% w/v Oral Suspension for Cattle and Sheep Vm 11990/4008

Substantial changes in the updated version of the ASMF or the active substance part of the dossier.
Deletion of a manufacturing site for an active substance. Deletion of a manufacturing site for an active substance. Updated certificate of suitability from an already approved manufacturer.
Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
Changes to the licence wording for the immediate packaging.
Change to the manufacturing process of the finished product.
Addition of a manufacturer of an active substance.
Addition of warning 'Do not mix with other products' to the SPC and labelling.
Approval of previously unseen mock-ups.
Changes to bring the SPC and Product Literature in line with new legislation and change of legal category from PML to POM-VPS.
Renewal.
Renewal.
Minor change to the manufacturing process of the active substance.
Renewal.
Change to the manufacturing process.
Change manufacturer and batch size of finished product.
Change of shelf life to 36 months.