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

Post Authorisation Assessments

Effipro 2.5mg/ml Cutaneous Spray, Solution for Cats and Dogs Vm 05653/3031

Approval of mock ups.
Change in shape or dimensions of the container or
closure (immediate packaging).
Change in the contact details of the QPPV of an
existing pharmacovigilance system as described in the
DDPS.
Change of specifications of a former non
Pharmacopoeial active substance to comply with the
Ph. Eur. monograph 2869.
Change in RMS from UK to FR.
Addition of pictograms and explanatory text to the
product literature, for the correct application of the
product.
Deletion of manufacturing site for the finished product.
Change in the name and address of a manufacturer
used in the manufacture of the active substance.
Addition of a manufacturer of the active substance.
Change in shape or dimensions of the container or
closure (immediate packaging) x6
Addition of an active substance manufacturer.
Changes to the specification limits.
Renewal procedure – UK as RMS.
Change in dimension of immediate packaging.
Minor change to the purification process of the active
substance. Deletion of a non-significant specification
parameter. Increase in the batch size range of the
active substance.
To change the shelf life of the veterinary medicinal
product as packaged for sale from 2 years to 3 years.
To change the batch size of the finished product.