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Post Authorisation Assessments

Comfortan 10 mg/ml, Solution for Injection for Dogs and Cats $$\rm Vm\ 16849/3005$$

Alignment with the latest version of the QRD.
Repeat Use to add one CMS
Update of the Summary of Product Characteristics packaging information to reflect the latest QRD template.
Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
Change in ATC Vet Code from QN02AC52 to QN02AC90
To introduce joint labelling.
Change in distributor details.
Repeat Use to add 6 new Member States.
Submission of an updated certificate of suitability.
Renewal – UK as CMS
Deletion of a manufacturing site of the active substance.
Changes to the product literature, not connected with the SPC.
Change of QPPV and QPPV contact details for an existing pharmacovigilance system.
Variation to add cats as a new target species.