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Post Authorisation Assessments

HIPRAGUMBORO-G97 lyophilisate for oral suspension for chickens Vm 17533/3008

Variation to update product information in line with EU QRD text version 9.
Deletion of a specification parameter of the finished product.
Change in the safety database of an existing
pharmacovigilance system as described in the DDPS.
Change in RMS from UK to FR.
Repeat use MRP to add 3 new member states
Change in the name of the local UK representative.
Addition of two presentations - one vial of 1000 doses and
one vial of 5000 doses
Change of distributor
Changes to comply with Ph. Eur.
Renewal
Change of shelf life of the finished product from 12 months to
24 months
Change of distributor
Repeat Use
Mutual Recognition procedure, UK as RMS