Veterinary Medicines Directorate

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Post Authorisation Assessments

Duphacort Q 0.2% w/v Solution for Injection

•	25 March 2022	Changes in the SPC, Labelling or Package Leaflet intended to implement the outcome of a procedure concerning PSUR.
•	13 August 2021	Submission of a new Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	28 July 2021	Increase in batch size of the finished product. Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions. Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions. Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions. Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions. Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions.
•	12 March 2020	Minor changes to an approved test procedure of the finished product. Update of the test procedure to comply with the updated general Ph. Eur monograph.
•	30 July 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	11 November 2014	Change of distributor.
•	17 December 2009	Renewal.
•	02 December 2009	Change of withdrawal period for milk from 72 hours to 84 hours.
•	14 January 2009	Changes to the SPC and Product Literature to bring in line with new legislation.
•	20 March 2007	Change of legal category from POM to POM-V.
•	17 November 2005	Addition of a manufacturing site of assembly.
•	28 January 2005	Addition of a manufacturing site of the active substance.