Veterinary Medicines Directorate

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Post Authorisation Assessments

Dexa-ject 2 mg/ml Solution for Injection for Cattle, Horses, Pigs, Dogs and Cats

Vm 28365/5003

•	11 May 2024	Approval of mock-ups.
•	22 September 2023	One-off alignment of the product information with version 9.0* of the QRD templates.
•	04 September 2020	Submission of a new certificate of suitability for an active substance.
•	24 December 2018	Change in the batch size of the finished product
•	07 August 2018	Addition of a test procedure for the finished product.
•	28 February 2018	Repeat Use application to add 8 new member states.
•	20 December 2017	Changes to the labelling or package leaflet.
•	27 July 2017	Renewal – UK as CMS
•	02 August 2016	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer
•	03 December 2015	Approval of revised mock-ups for 50 ml presentation.
•	09 January 2015	Increase to the shelf-life of the finished product, from 18 months to 3 years. Change in the specification limits of the finished product.
•	03 February 2014	Amendments to the SPC and product literature in line with Commission Decision regarding an Article 35 referral procedure.
•	16 December 2013	Submission of an updated Ph. Eur. Certificate of Suitability for an already approved manufacturer of the active substance.
•	11 July 2013	Change of distributor details.