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 28365/3000

05 February 2025	Change in the specification limits of the finished product.
28 April 2024	Submission of an updated certificate of suitability.
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.