Veterinary Medicines Directorate

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Post Authorisation Assessments

Genestran 75 micrograms/ml Solution for Injection for Cattle, Horses and Pigs

Vm 24745/5002

12 February 2025	Addition of a manufacturing site for part of the manufacturing process of the finished product.
12 February 2025	Addition of a sterility testing site.
12 February 2025	Other changes to the active substance: - Substantial changes in the updated version of the ASMF or the active substance part of the dossier.
17 January 2025	One-off alignment of the product information with version 3 of the GB QRD templates.
19 March 2024	Addition of a secondary packaging site for the finished product. (NI)
08 June 2023	Addition of a secondary packaging site of a finished product. (GB)
21 July 2021	Updated ASMF.
09 December 2020	Tightening of specification limits of an active substance.
01 May 2019	Addition of a supplier of packaging components or devices. Addition of a manufacturer responsible for batch release including batch control. Addition of a site where batch control/testing takes place. Addition of secondary packaging site of the finished product. Increase in batch size (including batch size range) of the finished product. Addition of a manufacturing site of the finished product. Addition of a manufacturing site of the finished product.
10 January 2018	Replacement of a site where batch control/testing takes place.
23 February 2017	Change in the SPC, labelling or package leaflet due to new data.
06 July 2016	To submit updated ASMF for currently authorised active substance manufacturer
22 June 2016	Addition of a manufacturer of the active substance.
09 September 2013	Extension of shelf life of the finished product as packaged for sale from 2 years to 3 years.
07 May 2013	Addition of a 50ml glass vial presentation, with cartons of 1 vial available.
02 April 2013	Addition of a batch size.
07 December 2012	To change the QPPV.
26 October 2011	Repeat Use Comm.
07 April 2011	Changes to the primary packaging material not in contact with the finished product.
07 April 2011	Changes to an existing pharmacovigilance system.
11 March 2011	Renewal – UK as CMS

30 September 2010	To add a pack size of the finished product – Cardboard box with 5 vials of 20 ml
28 April 2010	Repeat Use Comm
06 October 2009	To change the Marketing Authorisation Holder.
24 August 2009	To make a minor change in the test procedure of the finished product.
24 August 2009	To change the address of the manufacturer of the finished product.
08 July 2009	To replace the batch release site.