

## Post Authorisation Assessments

### Draxxin Plus 100 mg/ml + 120 mg/ml Solution for Injection for Cattle Vm 60021/3060

15 January 2025	Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible.
26 February 2025	Change in legal entity of MA holder in NI only to Zoetis Belgium S.A., 2nd Floor, Building 10, Cherrywood, Business Park, Loughlinstown, Dublin 18, D18 T3Y1, Ireland.
11 January 2025	Deletion of a non-significant specification parameter for an active substance.
09 October 2024	Updated version of an ASMF.
01 July 2024	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
10 April 2024	Addition of a secondary packaging site for the finished product. Addition of a secondary packaging site for the finished product.
13 October 2023	Minor change in the manufacturing process of the finished product, including editorial changes for increased clarity.
04 July 2023	Submission of an updated certificate of suitability.
31 March 2023	Change(s) in the SPC, labelling or package leaflet to sections 4.6 and 6. Alignment of the product information with version 9.0* of the QRD templates.
19 August 2022	Change in the batch size of the finished product.
08 February 2022	Changes to a test procedure for the active substance. Changes to a test procedure for the active substance. Addition of a new specification parameter with its corresponding test method of an active substance used in the manufacturing process of the active substance. Addition of a manufacturer of the active substance or addition of a site of manufacture
05 August 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
25 November 2020	Minor changes to an approved test procedure of the finished product.