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Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021, please refer to the EMA website.

Mhyosphere PCV ID Emulsion for Injection for Pigs

Vm 17533/5007

•	24 July 2023	To remove the higher specification limit for the PCV2 CP potency on the finished product specifications for batch release. Update to section 4.6 SPC and to package leaflet section 7.
•	16 February 2023	To introduce a new quantification method by means of Mass Spectrometry combined with High Performance Liquid Chromatography to control the amount of PCV2 CP during the manufacturing process of the antigenic fraction of MYOSPHERE PCV ID.
•	30 November 2022	Change(s) in the SPC, labelling or package leaflet to sections 4.6 and 6 adverse reactions.
•	25 November 2022	Addition of an administration device which is not an integrated part of the primary packaging.
•	09 March 2022	Change in the specification limits of the finished product. Changes to a test procedure. Minor change in the manufacturing process of an immediate release solid oral dosage form. Minor change in the manufacturing process of an immediate release solid oral dosage form. Minor change in the manufacturing process of the active substance.