Veterinary Medicines Directorate

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# Post Authorisation Assessments

## Actionis 50 mg/ml, Suspension for Injection for Pigs and Cattle

Vm 31592/5004

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| • | 10 November 2023 | Change in immediate packaging of the finished product.<br>One-off alignment of the product information with version 9.0* of the QRD templates. |
| • | 10 October 2023 | Change in any part of the primary packaging material not in contact with the finished product formulation.<br>Change in the name or address or contact details of a manufacturer responsible for batch release.<br>Change in the name or address or contact details of the manufacturer of the finished product.<br>Change in the name or address or contact details of the marketing authorisation holder.<br>Changes to the labelling or the SPC package leaflet which shall not be connected with the SPC: administrative information concerning the holder´s representative.<br>Deletion of a finished product manufacturer.<br>Changes to the quality part of the dossier: Deletion of - one of the authorised finishes product containers. |
| • | 10 August 2023 | Substantial changes in an updated version of an ASMF. |
| • | 25 August 2021 | Variation to update the ASMF for the active substance manufacturer. |
| • | 04 March 2021 | Replacement to a test procedure for the finished product. |
| • | 29 June 2020 | Replacement to a test procedure for the finished product. |
| • | 28 April 2020 | Addition of a supplier of packaging components or devices. |
| • | 24 July 2018 | Addition of a manufacturing site of the finished product.<br>Change in the batch size range of the finished product. |
| • | 05 April 2018 | Deletion of a manufacturing site for an active substance. |
| • | 27 September 2017 | Changes to a test procedure for the finished product. |
| • | 26 July 2017 | Submission of updated ASMF |
| • | 05 July 2017 | Change to part of the (primary) packaging material not in contact with the finished product formulation. |
| • | 12 April 2017 | Changes in the qualitative and quantitative composition of the immediate packaging of the finished product. |
| • | 06 April 2016 | Renewal - UK as CMS |
| • | 01 September 2015 | Changes to the product labelling. |
| • | 22 June 2015 | Addition of a local UK representative |
| • | 25 March 2015 | Addition of a new manufacturer of the active substance.<br>Addition of new specification parameters and the corresponding test methods. |

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| • | 29 March 2012 | Changes in Summary of Product Characteristics (SPC), labelling or package leaflet following a referral procedure |