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# Post Authorisation Assessments

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

## BTVPUR Suspension for Injection for Sheep and Cattle

Vm 04491/5007

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|---|---|---|
| • | 20 February 2024 | Minor changes to process related equipment. |
| • | 31 October 2023 | Update to the description of starting materials of biological origin. |
| • | 21 July 2023 | Alignment of the product information with version 9.0* of the QRD templates.<br>Change(s) in the SPC, labelling or package leaflet to section Adverse events. |
| • | 11 April 2023 | Change in the name or address or contact details of a qualified person for pharmacovigilance. |
| • | 20 December 2022 | To add use of recombinant trypsin as a substitute to porcine trypsin for the manufacture of the active substance. |
| • | 26 May 2022 | Addition of a new specification parameter to the specification with its corresponding test method of an excipient. |
| • | 23 March 2022 | Deletion of manufacturing site for an active substance.<br>Change in the manufacturer of the active. |
| • | 09 February 2022 | Changes in the composition (excipients) of the finished product.<br>Change in the manufacturing process of the finished product. |
| • | 15 December 2021 | Changes to the labelling and package leaflet. |
| • | 02 July 2021 | Change in the specification parameters and/or limits of the immediate packaging of the finished product. |
| • | 25 March 2021 | Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. |