Veterinary Medicines Directorate

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Post Authorisation Assessments

Heptavac P Plus Suspension for Injection for Sheep

Vm 06376/5020

6 August 2026	Deletion of the backup test for endotoxin testing, since this test has never been used and will never be used for 3R reasons. Increase in maximum batch size to 5000 L for the finished product. Changes on the vaccine base preparation: add the possibility to use non-heated water for injections and shorten the sterilisation time. Continuous stirring to be performed till the end of the filling process to ensure homogeneity of the bulk vaccine. Add the possibility to use 10% w/v thiomersal solution to achieve the final thiomersal concentration in the vaccine bulk. Deletion of the sterility test on the vaccine base. Addition of Intervet International B.V., Boxmeer, NL as an alternative potency testing site for the Chauvoei blend. Addition of MSD AH Danube Biotech GmbH, Krems, Austria as blending and filling site for the finished product.
12 March 2026	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
30 October 2025	Change in shape and dimensions of the closure and container. Addition of a test procedure for active substances. Addition of a test procedure for active substances. Minor change to the in-process control test used in the manufacturing process of the active substances. Minor change to the in-process control test used in the manufacturing process of the active substances. Deletion of in-process test applied during the manufacture of the active substances Deletion of in-process test applied during the manufacture of the active substances. Changes in the manufacturing process of the active substances. Changes in the manufacturing process of the active substances Addition of a manufacturing site for manufacturing of active substances. Addition of a manufacturing site for manufacturing of active substances.
13 March 2025	Deletion of a manufacturing site for an active substance.
08 January 2025	Change in legal entity of MA holder from MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, MK7 7AJ to Intervet International B.V., Wim de Körverstraat 35, 5831 AN Boxmeer, Netherlands.
29 November 2024	Update of the acceptance criteria for the positive control used in

	the in vitro L+ and MLD test for C. perfringens type D toxin. Replacement of the coating antigen used in the potency ELISA of the C. perfringens type D toxin.
23 November 2024	To introduce standardisation (multiplication) factors (SFs) for the batch potency tests.
May 2024	To align the product information with the version 9.0 of the SPC/QRD templates.
24 October 2023	Change to comply with Ph. Eur.
30 June 2023	To update of the sterility test procedure performed on the finished product according to Ph.Eur. 2.6.1. Minor adjustments to the method suitability test to improve recovery of the A. brasiliensis reference strain.
17 April 2023	Addition of an in vitro potency ELISA for C. perfringens type C beta toxoid. Optimisation of the statistical analysis method for the Fab ELISA to confirm M. haemolytica identity and P. trehalosi identity/potency. Addition of Intervet International B.V., Boxmeer, NL, as finished product Quality Control test site for the C. perfringens type C beta toxoid potency test, M. haemolytica identity test and P. trehalosi identity/potency test.
05 April 2023	Addition of an in vitro toxicity test for C. chauvoei cells and toxoid. Addition of the use of bovine liver extract in Clostridia growth medium.
20 February 2023	Addition of an in vitro toxicity test for C. chauvoei cells and toxoid. Addition of the use of bovine liver extract in Clostridia growth medium.
24 June 2022	Change of a test procedure for the active substance. Change of a test procedure for the active substance. Change of a test procedure for the active substance.
16 June 2022	Changes to a test procedure for the finished product.
16 February 2022	Change to a test procedure (including replacement or addition) for the active substance. Change in the manufacturing process of the active substance. Change in the manufacturing process of the active substance. Change in the manufacturing process of the active substance. Change in the manufacturing process of the active substance. Change in the manufacturing process of the active substance. Change in the manufacturing process of the active substance.
05 October 2021	Update of the test procedure to comply with the updated general Ph. Eur monograph. Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product. Changes to a test procedure for the finished product. Changes to a test procedure for the finished product. Changes to a test procedure for the finished product. Changes to a test procedure for the finished product. Changes to a test procedure for the finished product. Addition of a site where batch control/testing takes place.
07 September 2021	Summary of Product Characteristics and product literature

	updated with regard to pharmacovigilance data.
15 June 2021	Change in the manufacturing process of the finished product.
11 January 2021	Changes to the labelling and/or package leaflet.
01 October 2020	Change in the name of a manufacturer of the finished product, also responsible for batch release.
11 September 2020	Change in the name of a manufacturer used in the manufacture of the active substance.
14 August 2020	Change in the name of the marketing authorisation holder from Intervet UK Limited to MSD Animal Health UK Limited.
26 April 2019	Addition of a manufacturer responsible for batch release of the finished product.
18 May 2018	Change in the manufacturing process of the active substance. Change in the manufacturing process of the active substance.
01 May 2018	Change in RMS from UK to IT.
01 November 2016	Change in name of manufacturer of the active substance.
02 December 2015	Change in the specification parameters and/or limits of the finished product
08 November 2012	Change to manufacturing process of an active substance Change to in-process test for an active substance
30 March 2012	Change of name of manufacturer of the finished product
14 July 2010	Update of detailed description of manufacturing process
01 September 2009	Change of address of MAH in Portugal only
02 April 2008	Renewal
13 October 2006	Change to manufacturing process of the active substance
20 May 2005	Change of distributor
17 January 2005	Change to test procedure performed on a starting material used in the manufacture of the active substance
12 July 2004	Repeat use
19 March 2004	Updates to the SPC
07 May 2003	Renewal
13 November 2002	Change to specification of the finished product
10 September 2002	Addition of 2 manufacturing sites for labelling and packaging Change to shape of packaging
31 January 2002	Change of supplier of a reagent used in the production of the finished product
07 November 2001	Change to the manufacturing process of the active substance
31 August 2001	Addition of a distributor
11 May 2001	Change of product name from ‘Heptavac P New’ to ‘Heptavac P Plus’
09 February 2001	QC Procedures
08 February 2001	Change to manufacturer of the active substance
01 August 2000	Change to specification of the active substance
31 March 2000	Change of name and address of the MAH
29 March 2000	Change to specification of the active substance
29 October 1999	Change of shelf life from 12 months to 24 months Change to manufacturing process of the active substance Change of product formulation Change to QC procedures
31 December 1998	Minor change in manufacturing procedure of the active substance