Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Orbeseal Dry Cow 2.6 g Intramammary Suspension

Vm 60021/3063

20 March 2025	Change in legal entity from Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP to Zoetis Belgium S.A., 2nd Floor, Building 10, Cherrywood Business Park, Loughlinstown, Dublin 18, D18 T3Y1, Ireland.
12 March 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
19 January 2025	Substantial changes in the updated version of an ASMF.
02 December 2024	Submission of an updated CEP for the manufacture of an active substance.
01 December 2024	Addition of 144 syringes in plastic bucket.
04 April 2024	Replacement of a batch testing site for the finished product.
15 September 2023	One-off alignment of the product information with version 9.0* of the QRD templates.
12 September 2023	Change in description of the wipes used during administration.
23 April 2021	Changes to SPC following a PSUR. Addition of images to SPC.
15 January 2021	Addition of a manufacturing site for part or all of the manufacturing process of the finished product.
11 May 2020	Repeat use application to add 3 new member states
08 January 2020	Change in the address of the marketing authorisation holder from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London, EC4A 3AE to Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP.
15 October 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
01 October 2019	Change in the name and of the manufacturer of the finished product.
06 September 2019	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product for solid pharmaceutical forms.
29 August 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
19 December 2018	Renewal – UK as RMS

18 December 2018	Change in RMS from UK to FR.
25 September 2018	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
27 September 2017	Replacement of a supplier of packaging components or devices. Change in the name of a manufacturer of the active substance used in the manufacture of the active substance. Change in the name of a manufacturer of the active substance used in the manufacture of the active substance. Deletion of irradiation site for gamma irradiation. To harmonise the dossier across EU.
29 December 2016	Change in the address of the marketing authorisation holder in France, Czech Republic & Slovakia.
21 September 2015	Change to add an updated Certificate of Suitability
05 May 2015	Change to the QPPV contact details.
20 March 2014	Repeat use.
11 October 2013	Change of contact details of QPPV.
10 October 2013	Change in the name and/or address of the MAH in AT, BE, FR and LU only.
31 July 2013	Change of MAH.
31 July 2013	Change to distributor.
16 February 2012	Change in specification parameters and/or limits of an excipient.
10 February 2012	Change in name/address of manufacturer or supplier of the active substance, starting material, reagent, or intermediate used in the manufacture of the active substance.
03 February 2012	Change to name of MAH in Spain only.
09 December 2010	Changes to label/package leaflet not connected with the SPC.
28 July 2009	Change of name/address of site responsible for batch release.
02 September 2008	Renewal.
10 October 2007	Change to specification limits of the finished product.
02 August 2006	Change to contra-indications.
20 July 2006	Change to the shelf life of the finished product.
20 April 2006	Change of MAH in Portugal only.
17 June 2005	Addition of a distributor.
18 May 2005	Change to contra-indications.
03 February 2005	Change in the site of gamma irradiation.
11 February 2004	Change in the site of manufacture of the active substance.
11 December 2003	Addition of a site of batch release.
23 November 2003	Change in source of gamma irradiation and change in irradiation dose.
20 February 2003	MRP (UK as RMS).