

Post Authorisation Assessments

Deccox 6% w/w Premix for Medicated Feeding Stuff for Sheep and Cattle Vm 42058/5190

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| 01 July 2024 | Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI) |
| 08 April 2021 | Deletion of manufacturing site for a manufacturer responsible for batch release. Deletion of manufacturing site for a site where batch control takes place. |
| 24 November 2020 | Increase in batch size from 1020 kg to 1520 kg of the finished product. |
| 13 August 2020 | Replacement of a site where batch control/testing takes place. |
| 10 June 2020 | Change in testing frequency of specification parameters for an intermediate in the manufacturing process of the active substance. |
| 09 March 2020 | Addition of a test procedure for the finished product. |
| 12 November 2019 | 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, 1 st Floor, Birchwood Building Springfield Drive Leatherhead Surrey, KT22 7LP. |
| 11 July 2019 | Change in the SPC, labelling or package leaflet due to new data. |
| 08 May 2019 | Addition of a manufacturer responsible for batch release of the finished product. |
| 25 September 2018 | Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS. |
| 23 April 2018 | Change in RMS from UK to ES. |
| 05 April 2018 | Update to the SPC following the implementation of the new template. |
| January 2018 | To update section 6.2 of the SPC to V 8.1 of QRD template. |
| 06 July 2016 | Changes in the manufacturing process of the active substance |
| 01 April 2015 | Change in test procedure for the finished product. |
| 03 December 2014 | Minor changes to the manufacturing process of the active substance. Increase to the batch sizes used in the manufacturing process of the active substance. |
| 13 November 2013 | Renewal. |
| 16 August 2013 | Change of distributor and MAH from Pfizer Limited to Zoetis UK Limited. |
| 28 November 2011 | Batch control. |
| 21 November 2011 | Batch control |
| 10 August 2011 | Change of MAH from Alpharma Animal Health BVBA to Pfizer Ltd. |
| 10 June 2009 | To change the batch size of the active ingredient including |

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| | changes to the in-process controls and specification. |
| 14 August 2008 | Mutual recognition procedure. |
| 28 December 2006 | Changes to bring the SPC and product literature in line with new regulations. |
| 10 May 2006 | Change of address of the MAH. |
| 09 September 2005 | Change in a test procedure for the active substance. |
| 07 September 2005 | Change to the specification for the active substance. |
| 03 December 2004 | Change of product name from Decoquinat to Deccox. |
| 22 October 2004 | Change of marketing authorisation holder (MAH) name and address from Alpharma As to Alpharma Animal Health BVBA. |