Veterinary Medicines Directorate

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Post Authorisation Assessments

Synulox Bolus 500 mg Film-Coated Tablets

Vm 42058/5177

14 January 2025	Change in legal entity of MA holder for Northern Ireland only 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.
15 December 2021	Submission of a new Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
27 August 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.
31 October 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. Introduction of a re-test period of the active substance.
07 September 2018	Deletion of Ph. Eur. certificates of suitability for an active substance. Deletion of Ph. Eur. certificates of suitability for an active substance. Submission of a new Ph. Eur. certificate of suitability for an active substance. Submission of a new Ph. Eur. certificate of suitability for an active substance. Submission of a new Ph. Eur. certificate of suitability for an active substance. Submission of a new Ph. Eur. certificate of suitability for an active substance. Introduction of a re-test period of the active substance. Introduction of a re-test period of the active substance.
12 September 2017	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.
26 June 2014	To change the Marketing Authorisation Holder and distributor.
22 July 2009	Variation to change the name of the finished product manufacturer.
06 February 2009	Variation to submit a new European Pharmacopoeia Certificate of Suitability for an active substance manufacturer.
06 February 2009	Variation to submit a new European Pharmacopoeia Certificate of Suitability for an active substance manufacturer.
22 January 2009	Variation to submit a new European Pharmacopoeia Certificate of Suitability for an active substance manufacturer.
20 July 2007	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from POM to POM-V.
15 January 2007	Renewal.
28 December 2006	Variation to increase the finished product withdrawal period.
28 July 2005	Variation to change the site of a manufacturing process for the active substance.
25 July 2005	Addition of a distributor.
27 February 2003	Change of the name of a dosage form assembler.
28 June 2001	Change in the active substance manufacturer.
09 May 2001	Renewal.
20 August 1998	Renewal.
30 June 1998	Change of shelf life of the finished product.
10 June 1998	Change of name and address of the Marketing Authorisation Holder.
10 December 1997	Change to the film coating composition.
10 December 1997	Variation concerning the manufacturer/assembler of dosage form.
10 December 1997	Change to the package quantities.