Veterinary Medicines Directorate

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Post Authorisation Assessments

Surolan Ear Drops and Cutaneous Suspension

Vm 00879/4171

•	26 July 2023	One-off alignment of the product information with version 9.0* of the QRD template.
•	09 March 2023	Change to comply with Ph. Eur. Deletion of a manufacturing site for an active substance. Deletion of a non-significant specification parameter. Deletion of a non-significant specification parameter. Deletion of a non-significant specification parameter. Editorial changes to part 2 of the dossier. Submission of an updated Ph. Eur. CEP for a non-sterile active substance.
•	04 August 2022	Update to SPC and QRD following PSUR assessment.
•	14 July 2022	Change to comply with the current Ph. Eur. Monograph for Polymyxin B sulfate. Changes to register existing stability testing site details for prednisolone acetate which has not previously been registered in error. Editorial updates to revised dossier sections included in this grouped variation submission. Updated certificate of suitability from an already approved manufacturer. Updated certificate of suitability from an already approved manufacturer. Updated certificate of suitability from an already approved manufacturer.
•	29 July 2021	Change in the address of a manufacturer used in the manufacture of the active substance. Change in the address of a manufacturer of the finished product, also responsible for batch release.
•	24 September 2020	Change of MAH from Eli Lilly and Company Limited, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL to Elanco Europe Ltd. Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom.
•	27 April 2020	Deletion of manufacturing site of the finished product.
•	27 November 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	28 June 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer

•	23 February 2017	Changes to the labelling.
•	26 January 2017	Addition of a manufacturer responsible for batch release including batch control/testing. Addition of a manufacturing site of the finished product. Addition of a manufacturing site of the finished product. Submission of a new or updated Ph. Eur. Certificate of Suitability. Changes to the quality control testing arrangements for the active substance – addition of a site where testing takes place. Change in the manufacturing process of the finished product. Addition of a manufacturing site of the finished product.
•	08 August 2016	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer
•	10 September 2015	Change in test procedure for the finished product.
•	25 October 2013	Grouped variation to change in-process test procedure used in the manufacture of the finished product. Change in the specification parameters and limits of the finished product.
•	23 October 2012	Submission of an updated Certificate of Suitability for an existing active substance manufacturer.
•	13 June 2012	Variation to change the Marketing Authorisation Holder.
•	14 March 2012	Grouped variation to change the distributor.
•	17 January 2012	Variation to change the immediate packaging of the finished product.
•	05 July 2011	Submission of an updated Certificate of Suitability for an existing manufacturer of the active substance.
•	22 March 2011	Variation to decrease the shelf life of the finished product.
•	16 February 2011	Variation to seek approval for mock-ups prior to marketing.
•	13 October 2010	Variation to change the packaging specifications.
•	05 August 2009	Variation to update a Certificate of Suitability for an active substance manufacturer; encompassing a name change of the manufacturer.
•	05 August 2009	Grouped variation to submit a new Certificate of Suitability for an active substance. Change the name and address of an active substance manufacturer.
•	05 August 2009	Variation to increase the maximum batch size.
•	12 November 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from POM to POM-V.
•	27 February 2008	Variation to change the address of the Marketing Authorisation Holder.
•	25 May 2007	Variation to change Part I and Part II of the dossier.
•	18 September 2006	Variation to submit a new European Pharmacopoeia Certificate of Suitability.
•	24 August 2006	Renewal.
•	28 January 2005	Variation to change the manufacturing process of the active substance; concerning the usage of materials of animal origin.

•	04 November 2004	Variation to change the name of an active substance manufacturer.
•	29 September 2004	Addition of an active substance manufacturer.
•	17 February 2004	Harmonisation of the SPC between the UK and IE.
•	31 July 2003	Variation to amend the active substance specification.
•	12 July 2002	Extension of the finished product shelf life.
•	31 May 2002	Renewal.
•	10 April 2002	Change in the manufacturing process of the finished product.
•	10 April 2002	Change in the test method for the finished product.
•	10 April 2002	Change in the test method for the finished product.
•	07 March 2002	Addition of a pack size.
•	13 August 2001	Addition of a site of secondary assembly only.
•	03 November 1999	Change to the 'Indications' on the SPC/PL.
•	03 November 1999	Change to the 'Therapeutic Indications' on the SPC/PL.
•	18 November 1997	Variation concerning the shelf life of the finished product.
•	01 August 1996	Change to the name and address of the Marketing Authorisation Holder.
•	21 August 1995	Variation concerning the 'Importer'.