



## Post Authorisation Assessments

### Aurizon Ear Drops, Suspension

Vm 08007/4085

•	March 2024	Submission of an updated certificate of suitability. (NI)
•	21 December 2023	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. (NI)
•	26 April 2023	Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: – active substance.
•	07 November 2022	Change in test procedure of finished product – other change. Change in test procedure of finished product - other change. Change in test procedure of finished product - other change.
•	13 April 2022	Deletion of manufacturing site for an active substance. Changes to a test procedure for the active substance. Changes to a test procedure for the active substance. Change of a re-test period of the active substance.
•	09 March 2022	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	27 May 2021	Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product. Minor change in the manufacturing process of the finished product. Deletion of a non-significant in-process test applied during the manufacture of the finished product.
•	11 September 2018	Change in the address of the marketing authorisation holder from Vétoquinol UK Limited, Vetoquinol House, Great Slade, Buckingham Industrial Park, Buckingham, MK18 1PA to Vetoquinol UK Limited, Steadings Barn, Pury Hill Business Park, Nr Alderton, Towcester, Northamptonshire, NN12 7LS.
•	25 April 2017	Deletion of manufacturing site for an active substance. Submission of an updated Ph. Eur. certificate of suitability for an active substance manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance manufacturer. Extension of a re-test period of the active substance.

•	10 November 2016	Addition of a new active substance manufacturing site. Change in the manufacturer of a starting material.
•	11 September 2010	Submission of an updated Ph. Eur. Certificate of Suitability
•	18 December 2009	Change in the manufacturing process of an active substance
•	14 April 2009	Addition of a new manufacturer of the active substance
•	17 October 2008	Changes in the specification of the active substance
•	04 June 2008	Deletion of a manufacturing site
•	16 March 2006	Addition of a manufacturer of the active substance
•	29 December 2005	Renewal
•	13 May 2005	Minor change in test procedure on the finished product
•	22 December 2004	Repeat use procedure – France as RMS
•	28 October 2004	Change of MAH
•	13 August 2004	Change in specification of the finished product