Post Authorisation Assessments

Duvaxyn IE-T Plus

•	11 July 2013	Change of control tests performed during manufacture of the finished product
•	04 July 2013	Replacement of a supplier of starting material for the manufacture of the active substance. Submission of an updated Ph. Eur. Certificate of Suitability for a material used in the production of the active substance
•	05 October 2012	Addition of manufacturing site for testing and batch release
•	13 September 2012	Addition of an indication against new strains of Equine Influenza
•	28 June 2012	Removal of target animal batch safety test
•	24 November 2011	Addition of an manufacturing site for secondary packaging and labelling
•	23 March 2011	Change of shelf life from 12 months to 24 months
•	26 January 2011	Change of MAH
•	13 December 2010	Change in name of manufacturer of the active substance, manufacturing site for blending, filling and assembly, QC testing, labelling and batch release Change of name of manufacturing site for the active substance Change of name of manufacturing site for blending, filling and assembly
•	02 August 2010	Renewal
•	22 September 2009	Addition of manufacturing site for the active substance Addition of a manufacturing site for blending of the finished product
•	20 August 2008	Harmonisation of SPC
•	11 June 2008	Replacement of batch potency test
•	28 March 2008	Change of test performed on the active substance
•	27 June 2007	Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation
•	20 December 2006	Addition of an indication against South African influenza strain H3N8
•	14 September 2006	Change of supplier of a starting material for the active substance
•	07 September 2006	Addition of a new test site for safety test on finished product