Post Authorisation Assessments

Adequan 250mg/ml Solution for Injection

Vm 36483/4001

•	19 January 2015	Change to the MAH, from Novartis to Daiichi Sankyo Altkirch SARL.
•	09 June 2011	Variation to make minor changes to the SPC, labelling and package leaflet.
•	01 September 2010	Change in the name and/or address of a manufacturer of the active substance where no European Pharmacopoeia certificate of suitability is available.
•	01 September 2010	Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product.
•	01 September 2010	Change to batch release arrangements and quality control testing of the finished product.
•	01 September 2010	Deletion of any manufacturing site (including for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place).
•	28 July 2010	Variation to change the MAH and distributor.
•	09 January 2009	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.
•	30 July 2009	Variation to change in-process controls, primary packaging, the finished specifications for release, shelf life and analytical methods.
•	16 February 2009	Variation to change a name and/or an address of a manufacturer of the active substance where no European Pharmacopoeia certificate of suitability is available. Minor change to the approved test method for the active substance Replacement of a site for secondary packaging
•	27 February 2008	Variation to change the address of the MA
•	14 February 2008	Variation to bring the SPC and labels in line with the new legislation and to transfer the legal category from POM to POM-V
•	27 December 2007	Variation to increase the batch size for the finished product from 100 L to 200L and 460L
•	30 August 2006	Harmonise the drug substance PSGAG – changes to the tests, limits and analytical methods.
•	07 August 2006	Change to the batch release arrangements and quality control testing of the finished product.
•	06 December 2005	Renewal.
•	28 November 2002	Renewal.
•	12 November 2001	Deletion of an Indiciation.
•	13 August 2001	Addition of a secondary assembler of dosage form.

•	02 June 1998	Change in packaging material.
•	09 July 1997	Addition of a secondary assembler.
•	01 July 1997	Addition of an assembler of dosage form.
•	07 May 1997	Change to the withdrawal period.
•	17 January 1997	Change of source of a raw material.