Post Authorisation Assessments

Aqupharm No 11 Solution for Infusion

•	15 July 2015	Addition of an alternative site of quality control testing and batch release. Addition of alternative site of secondary packaging. Submission of a new Ph. Eur. Certificate of Suitability. Addition of an alternative site of manufacture for the finished product. Changes in the manufacturing process of the finished product. Change in the shelf-life of bags manufactured at the alternative site, to 36 months. Change to the immediate packaging used at the alternative manufacturing site.
•	09 June 2015	Submission of a new certificate of suitability.
•	26 February 2015	Change in distributor details.
•	04 June 2013	Change in name/address of MAH
•	05 June 2008	Addition of 250ml pack size
•	27 November 2007	Renewal
•	13 June 2007	Extension to add horses and cattle Addition of pack size (5000ml)
•	28 October 2004	Renewal
•	21 December 2000	Change to a manufacturing site of the dosage form Change to a manufacturer of an active substance
•	14 December 2000	Change to a manufacturer of an active substance
•	30 November 2000	Change to sterile container size
•	19 October 2000	Change of sterile container type
•	27 September 2000	Change to a manufacturer of an active substance
•	24 February 2000	Addition of a manufacturing site of dosage form Change of 3 manufacturers of an active substance
•	05 October 1999	Change of manufacturing site of dosage form
•	04 August 1998	Renewal
•	06 January 1998	Change of MAH