Post Authorisation Assessments

Aqupharm 1 0.9% Solution for Infusion

•	15 July 2015	Addition of an alternative site of quality control testing and batch release. 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 the 250 ml, 500 ml and 1000 ml bags manufactured at the alternative site, to 36 months. Change to the immediate packaging used at the alternative manufacturing site. Addition of 100 ml and 500 ml pack sizes at the alternative manufacturing site.
•	26 February 2015	Change in distributor details.
•	04 June 2013	Change in name/address of MAH.
•	19 June 2008	Change in legal category from POM to POM-V. Changes to the SPC and Product Literature to bring in line with new legislation.
•	27 November 2007	Renewal.
•	28 October 2004	Renewal.
•	30 November 2000	Change of manufacturing site of dosage form.
•	19 October 2000	Change of sterile container type.
•	24 February 2000	Addition of a manufacturing site of dosage form. Change of manufacturer of the active substance.
•	05 October 1999	Change of manufacturing site of dosage form.
•	03 August 1998	Renewal.
•	06 January 1998	Change of MAH.