Steps taken after granting the Marketing Authorisation

- On 4 November 2005 (date of notification), the EMEA approved a variation (Type IB No. 38b), optimising the antigenic mass ELISAs for measuring the antigenic content in Nobivac Piro.

- An Opinion on a Type II variation for changes to the product literature involving adaptation of adverse reactions warning and text reduction of vial and box labels was adopted by the CVMP on 17 January 2007. The corresponding Commission Decision was issued on 20 February 2007. Amendments have been incorporated into the relevant sections of the Commission Decision and of this EPAR.

- A Type IB variation to extend the shelf life of the lyophilisate of Nobivac Piro from 24 to 57 months was accepted by the EMEA on 12 February 2007.

- An Opinion on a Type II variation for the introduction of "dose equivalent" instead of "ml" as unit for the antigen content in the antigenic mass assay was adopted by the CVMP on 14 February 2007. The corresponding Commission Decision was issued on 20 February 2007. Amendments have been incorporated into the relevant sections of the Commission Decision and of this EPAR.

- An Opinion on a Type II variation for the introduction of Intervet International site Boxmeer (NL) as an additional site for production of active ingredients (*Babesia canis* and *Babesia rossi* Soluble Parasite Antigen) was adopted by the CVMP on 14 February 2007. The corresponding Commission Decision was issued on 20 February 2007. Amendments have been incorporated into the relevant sections of the Commission Decision and of this EPAR.

- On 16 July 2009, the European Commission renewed the marketing authorisation for Nobivac Piro. This decision was based on the favourable opinion and an assessment report adopted by the CVMP on 13 May 2009.

- On 18 May 2010, the Agency accepted a Type IB variation, classification B.1.b.1.z, for deletion of an in-process control test.