Steps taken after granting the Marketing Authorisation

- On 9 April 2008, the EMEA approved a variation (Type IB No.42) for a change of shelf life of the finished product from 1 year to 2 years for the PET vials.

- Following the first annual re-assessment the CVMP concluded on 16 April 2008 that, in relation to the specific obligations, the evidence continued to support a favourable benefit/risk profile for Nobilis Influenza H7N1. However, in view of the need for further data, full approval will remain conditional on the fulfilment of these outstanding specific obligations as outlined in Annex II of the Opinion. Amendments have been incorporated into the relevant sections of the Commission Decision and of this EPAR.

- Following the second annual re-assessment the CVMP concluded on 17 June 2009 that, in relation to the specific obligations, the evidence continued to support a favourable benefit/risk profile for Nobilis Influenza H7N1. However, in view of the need for further data, full approval will remain conditional on the fulfilment of these outstanding specific obligations as outlined in Annex II of the Opinion. Amendments have been incorporated into the relevant sections of the Commission Decision and of this EPAR.