Steps taken after granting the Marketing Authorisation

- On 14 October 2003, the EMEA notified the European Commission about changes in the list of local representatives. Amendments have been incorporated in Annex IIIB of the Commission Decision and the relevant sections of this EPAR.

- On 12 February 2004, the EMEA notified the European Commission about changes in the list of local representatives. Amendments have been incorporated in Annex IIIB of the Commission Decision and the relevant sections of this EPAR.

- On 30 June 2004, the EMEA notified the European Commission of changes to the aspects of the labelling not connected to the SPC. Amendments have been incorporated in Annex IIIA of the Commission Decision and the relevant sections of this EPAR.

- On 19 May 2005, the European Commission approved a Type II variation regarding a change in the maximum size of production batches. The European Commission decision was based on a positive opinion by CVMP as adopted on 18 May 2005.

- On 10 January 2008, the European Commission renewed the marketing authorisation for Nobilis OR Inac. This decision was based on the favourable opinion and an assessment report adopted by the CVMP on 7 November 2007.