

STEPS AFTER GRANTING THE MARKETING AUTHORISATION

For procedures finalised after 1 September 2003 please refer to module 8B.

Scope	Application number	Type of modification ¹	Notification/ Opinion issued on ²	Commission Decision Issued/amended on
Demonstration of TSE compliance	II/0001	II	26/04/2001	-
Change in the insulin glargine production process	II/0002	II	27/06/2001	-
Change to the manufacturing process for the active substance	II/0003	II	27/06/2001	-
New presentation(s) Addition of a new volume vial of 10 ml	II/0004	II	25/04/2002	09/08/2002
Change in the batch size of finished product	I/0005	I/II	25/04/2003	-
Change in supplier of an intermediate compound used in manufacture of the active substance	I/007	I	19/07/2003	

¹ In accordance with Commission Regulation (EC) No. 542/95 of 10 March 1995, as amended: **I** refers to a minor variation (Type I variation); **II** refers to a major variation (Type II variation); **I/II** refers to a minor variation following the procedure set out in Article 6, 7 and 8 of the Regulation; **X** refers to an Annex II application.

T refers to a transfer of a Marketing Authorisation in accordance with Commission Regulation (EC) No 2141/96 of 7 November 1996.

N refers to a notification in accordance with Article 61(3) of Directive 2001/83/EC of 6 November 2001.

² For Notifications and Type I variations, the date of entry into force of the change is the EMEA Notification date. The Commission Decision will be amended accordingly.