STEPS TAKEN 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
Change to the manufacturing process of the active substance	II/0001	II	19/10/2000	-
Additional presentations: Lantus OptiSet, solution for injection in 3 ml pre-filled pens: packs of 3, 4, 5 and 10 pens	II/0002	II	19/10/2000	06/02/2001
Change to the manufacturing process of the active substance	II/0003	II	01/03/2001	-
Demonstration of TSE compliance	II/0004	II	26/04/2001	-
Change in the insulin glargine production process	II/0005	II	27/06/2001	-
Addition of a new volume vial of 10 ml	II/0006	II	26/07/2001	28/01/2002
The indication has been extended for the use of Lantus in children of 6 years or above. In addition a class wording regarding hypoglycaemic reactions after transfer from animal source insulin to human insulin has been included in section 4.4 of the SPC. The Package Leaflet has been updated accordingly.	II/0007	II	21/11/2002	04/03/2003
Change in the dosing scheme for Lantus with the consequent change in section 4.2 of the SPC. In addition a warning concerning "hypoglycaemia" has been included in section 4.4 of the SPC. The Package Leaflet has been updated accordingly.	II/0008	II	19/09/2002	05/12/2002
Additional presentations: packs of 1, 3, 6, 8, 9 cartridges and packs of 1, 6, 8, 9 pre-filled pens (OptiSet).	I/0009	I	19/03/2003	22/04/2003
Change in the batch size of finished product	I/0010	I/II	25/04/2003	-
Change in supplier of an intermediate compound used in manufacture of the active substance	I/0011	I	19/06/2003	-
Minor change in the labelling	N/0013	N	29/08/2003	-

[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.