Procedural steps taken after granting the Marketing Authorisation

For procedures finalised after 1 September 2004 please refer to module 8B

Scope	Application number	Type of modification[1]	Notification/ Opinion issued on[2]	Commission Decision Issued/amended on
Additional presentation (Flex Pen)	II/01	II	19.10.00	29.01.01
Change in test procedure of the active substance and the medicinal product	I/02	I	15.09.00	-
Withdrawal of 2 presentations (vials) with the EU numbers EU/1/00/142/001-002				29.01.01
Extension of shelf-life as foreseen at the time of authorisation	I/03	I	30.10.00	22.01.01
Quality changes, additional facility for purification of Insulin Aspart	II/0004	II	20.09.01	-
Optimisation of the manufacturing process	II/05	II	17.01.02	-
Change for the deletion of the bio identity test	II/06	II	21.02.02	-
Minor change of the manufacturing process of the active substance	I/07	I	21.02.02	-
Withdrawal of 2 presentations with the EU numbers EU/1/00/142/003 and EU/1/00/142/003/006				08.11.02
Additional site of manufacture and additional manufacturer/site responsible for batch release of the FlexPen finished product (Chartres, France).	I/08	I	16.07.2003	22.08.03
Increase of shelf life of NovoMix 30 FlexPen finished product from 18 to 24 months	I/09	I	08.08.2003	08.10.03
Minor changes in manufacture of the medicinal product	I/10	I/II	25.09.03	-
Qualitative change to the active substance(s)	X/11	X	03.06.04	24.08.04
Revision of the SPC and PL to standardise the product information text for all Novo Nordisk A/S insulin products, and to reflect in the PL the results of the readability tests	II/12	II	26.02.04	15.04.04
Update of sections 4.4 and 4.8 of SPC and PL	II/13	II	26.02.04	15.04.04

[1] In accordance with Commission Regulation (EC) No. 542/95 of 10 March 1995, as amended, and for variations after 1 October 2003 in accordance with Commission Regulation (EC) No 1085/2003: **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 Council Directive 2001/83/EC.

[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.

Update of or change(s) to the pharmaceutical documentation	II/14	II	24.03.04	
Update of section 4.2 and 5.1 of the SPC and PL to specify the use of NovoMix 30 in combination with metformin in patients with type 2 Diabetes mellitus that are insufficiently controlled on metformin alone.	II/15	II	22.04.04	07.07.04
Update of or change(s) to the pharmaceutical documentation	II/16	II	22.04.04	-
Change in the specification of immediate packaging - tightening of specification limits	I/17	Ib	22.06.04	-