STEPS TAKEN AFTER GRANTING THE MARKETING AUTHORISATION

For procedures finalised after 1 October 2002 please refer to module 8B.

- The MAH submitted to the EMEA on 27 December 1996 an application for a Type I variation in order to include labelling and packaging responsibility of the finished product for the following manufacturing site: Mallinckrodt Medical, B.V., Westerduinweg 3, 1755 ZG Petten, The Netherlands. The procedure started on 3 January 1997. The EMEA accepted the Variation and issued the relevant notification on 20 January 1997. This variation did not require any amendment to the Community Marketing Authorisation.
- The MAH submitted to the EMEA on 14 January 1997 an application for a Type I variation following a 60 days procedure to revise the isoelectric focusing specifications in the finished product specifications. The procedure started on 24 January 1997. The CPMP adopted a positive opinion on 19 March 1997. This variation did not require any amendment to the Community Marketing Authorisation.
- The MAH submitted to the EMEA on 3 April 1997 an application for a Type I variation related to the extension of the shelf life of the product from 24 to 36 months at 2-8°C. The procedure started on 20 June 1997. The EMEA accepted the Variation and issued the relevant notification on 14 July 1997. Annexes I and IIIB to the Community Marketing Authorisation were amended accordingly.
- The MAH submitted to the EMEA on 17 December application for a Type I variation related to the change of the name and address of Immunomedics B.V., Westerduinweg 3, 1755 ZG Petten, The Netherlands to: Immunomedics Europe, Haarlmmerstraat 30, 2181 HC Hillegom The Netherlands. The procedure started on 7 January 1998. The EMEA accepted the Variation and issued the relevant notifications on 15 January 1998. Annexes I, IIIA and IIIB to the Community Marketing Authorisation were amended accordingly.
- The MAH submitted to the EMEA on 24 November 1997 an application for a Type II variation to introduce a change of the manufacturing site from Newark, NJ to Morris Plains, NJ and two significant changes in the manufacturing process. The procedure started on 19 December 1997. The CPMP adopted a positive opinion on 27 May 1998. This variation did not require any amendment to the Community Marketing Authorisation.
- The MAH submitted to the EMEA on 22 December an application for a Type I variation in order to change the manufacturer responsible for import into EU and batch release of the finished product from: Mallinckrodt Medical, B.V., Westerduinweg 3, 1755 ZG Petten, The Netherland to: Eli Lilly Deutschland GmbH, Teichweg 3 D-35396 Geissen, Germany. The procedure started on 5 January 1998. The EMEA accepted the Variation and issued the relevant notification on 15 January 1998. Annexes I, II and III to the Community Marketing Authorisation were amended accordingly.
- The MAH submitted to the EMEA on 19 March 1999 an application for a Type I variation related to the extension of the shelf life of the product from 36 to 48 months at 2-8ºC. The procedure started on 26 March 1999. The EMEA accepted the Variation and issued the relevant notification on 26 April 1999. Annexes I and IIIB to the Community Marketing Authorisation were amended accordingly.
- The MAH submitted to the EMEA on 19 March 1999 an application for a Type I variation in order to change the name of manufacturer responsible for import into EU and batch release in the European Economic Area from: Eli Lilly Deutschland GmbH, to: Eli Lilly Pharma Fertigung und Distribution GmbH & Co. KG. The procedure started on 26 March 1999. The EMEA accepted the Variation and issued the relevant notification on 26 April 1999. Annexes I, II and III to the Community Marketing Authorisation were amended accordingly.

Subsequent post Marketing Authorisation applications agreed upon are summarised in the table below:

Scope	Application number	Type of modification[1]	Notification/ Opinion issued on[2]	Commission Decision Issued/amended on
Extension of shelf-life as foreseen at time of authorisation	I/0006	I	22.07.98	15.04.99
Extension of shelf life from 36 to 48 months	I/0007	I	26.04.99	18.06.99
Change in the name of the manufacturer responsible for importation and batch release	I/0008	I	26.04.99	18.06.99
Change in or addition of manufacturing site(s) for part or all of the manufacturing process	I/0009	I	06.08.99	17.08.99
Change in or addition of manufacturing site(s) for part or all of the manufacturing process	I/001I	I	06.09.00	
Changes to comply with supplements to pharmacopoeias	I/0012	I	15.02.01	20.03.01
Renewal	R/0013	R	21.02.02	30.09.02
Change in manufacturing authorisation	I/0015	I	08.05.02	17.06.02
Transfer of Marketing Authorisation Holder	T/0016	T	23.08.02	18.09.02

[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 10(3) of Council Directive 92/27/EEC of 31 March 1992.

[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.