STEPS TAKEN AFTER THE GRANTING MARKETING AUTHORIZATION

For procedures finalised after 30 November 2004 please refer to module 8B.

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
Change in or addition of manufacturing site(s) for part or all of the manufacturing process	I/0002	I	04.07.01	N/A
Extension of indication in locally advanced or metastatic breast cancer	II/001	II		21.03.02
Change in test procedure of active substance	I/003	I	26.02.03	11.03.03
Batch size of active substance	I/004	I	26.02.03	11.03.03
Minor changes in manufacture of the medicinal product	I/005	I	26.02.03	11.03.03
Change in the batch size of finished product	I/006	I	26.02.03	11.03.03
Minor change of manufacturing process of the active substance	I/007	I	26.02.03	11.03.03
Update of Summary of Product Characteristics and Package Leaflet	II/008	II	26.02.04	25.03.04

[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.