STEPS TAKEN AFTER GRANTING THE MARKETING AUTHORISATION

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
Quality changes	II/001	II	26.04.01	23.05.01
Update of SPC and PL on pharmacokinetic parameters and risk of cardiotoxicity	II/002	II	21.03.02	22.05.02
Change in test procedures of the medicinal product	I/003	I	13.12.01	07.01.02
Change(s) to the manufacturing process for the active substance	II/004	II	19.09.02	14.01.03
Minor change of manufacturing process of the active substance	I/005	I	22.08.02	18.09.02
Minor changes in manufacture of the medicinal product	I/006	I	20.02.03	26.02.03
Change in test procedure of active substance	I/007	I	20.02.03	26.02.03
Change(s) to the test method(s) and/or specifications for the finished product	II/008	II	20.03.03	31.03.03
Change in or addition of manufacturing site(s) for part or all of the manufacturing process	I/009	I	03.10.03	14.10.03
Extension of Indication	II/011	II	22.04.04	10.06.04
Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	N/012	N	05.05.04	-
Update of Summary of Product Characteristics	II/013	II	16.09.04	22.10.04
Change in the specification of the finished product - tightening of specification limits	IB/014	IB	08.10.04	-
Quality changes	II/015	II	18.11.04	24.11.04

[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.