

## 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 <sup>1</sup>	Notification/Opinion issued on <sup>2</sup>	Commission Decision Issued/amended on
Additional indication (treatment for adult patients with GIST)	II/001	II	21.02.02	24.05.02
Extension of indication (CML)	II/002	II	19.09.02	19.12.02
Extension of indication (children)	II/003	II	19.09.02	19.12.02
Update of the SPC (point 4.5)	II/004	II	19.09.02	19.12.02
Change in or addition of manufacturing site(s) for part or all of the manufacturing process	I/005	I	13.12.02	07.01.03
Change or addition of a new pharmaceutical form and addition of new strength	X/006	X	24.07.03	11.11.03
Change or addition of a new pharmaceutical form and addition of new strength	X/007	X	24.07.03	11.11.03
Update of Summary of Product Characteristics and Package Leaflet	II/008	II	25.04.03	14.07.03
Annual reassessment	S/010	S	19.03.03	30.06.03
Annual reassessment	S/011	S	21.01.04	31.03.04
Change in pack size - change in no. of units outside range of appr. pack size	IB/012	IB	25.05.04	-
Change in pack size - change in no. of units outside range of appr. pack size	IB/013	IB	25.05.04	-
Change in pack size - change in no. of units outside range of appr. pack size	IB/014	IB	25.05.04	-
Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	N/015	N	14.05.04	-
Change in batch size of active substance or intermediate - up to 10-fold	IA/016	IA	18.06.04	-

<sup>1</sup> 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.

<sup>2</sup> 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.