STEPS TAKEN AFTER GRANTING THE MARKETING AUTHORISATION

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

- On 7 May 2001, the European Commission approved a Type I variation for a change in the test procedure of the medicinal product.
- On 7 May 2001, the European Commission approved a Type I variation for a change in the test procedure of the active substance and the medicinal product.
- On 7 May 2001, the European Commission approved a Type I variation for a change in the test procedure of the active substance and the medicinal product.
- On 7 May 2001, the European Commission approved a Type I variation for a change to comply with supplements to pharmacopeias.
- On 16 October 2001, the European Commission approved a Type II variation (II/5) to update the SPC and package leaflet following the assessment of the 1st PSUR.
- On 8 October 2001, the European Commission approved a Type II variation for an increase in batch size and a change in specification.

Scope	Application number	Type of modification[1]	Notification/ Opinion issued on[2]	Commission Decision Issued/amended on
Minor change in package leaflet not connected to the SPC (Art. 61.3 Notification)	N/07	N	13.12.01	19.02.02
Change in the name of the marketing authorisation holder	I/08	I	07.12.01	19.02.02
Change in the specifications of the active substance	II/09	II	30.05.02	04.06.02
Change in test procedure of active substance and Change in in-process controls applied during the manufacture of the product	I/10	I	19.09.02	29.09.02
Extension of indication	II/11	II	19.03.03	26.06.03
Change in the manufacture of the active substance	II/12	II	22.05.03	02.06.03
Change in the test methods of the active substance and Change in the test methods of the finished product	II/13	II	25.09.03	30.09.03
Minor change in package leaflet not connected to the SPC (Art. 61.3 Notification)	N/14	N	18.07.03	28.08.03

[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 61(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.