Procedural steps taken after granting the Marketing Authorisation

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

- On 7 August 2000, the Marketing Authorisation Holder submitted to the EMEA an application (II/1) for a Type II variation to add another presentation, i.e. a vial containing 5 ml solution in addition to the 2.5 ml vial, which was originally authorised on 27 July 2000. The opportunity was also taken to revise some of the preclinical safety margins defined in the original SPC. A positive CPMP opinion was given on 19 October 2000, and a Commission Decision with revised annexes was issued on 22 February 2001

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 or retest period of a precursor (from which the active substance is prepared *in situ*)	I/02	I	19.03.01	02.04.01
Update of the SPC (point 4.2, 4.8)	II/03	II	27.09.02	09.09.02
Change in name of MAH	I/004	I	25.03.02	07.05.02
Update of the SPC/PIL (point 4.2, 4.8)	II/05	II	25.07.02	28.10.02
Inclusion of alternative manufacturer of SnFP-CT	II/06	II	21.11.02	29.11.02
Minor change in Package Leaflet not connected with the SPC (Art. 61.3 Notification)	N/07	N	30.08.02	17.10.02
Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	N/08	N	16.12.03	20.01.04

[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.