STEPS TAKEN AFTER GRANTING THE MARKETING AUTHORISATION

For procedures finalised after 7 May 2002 please refer to module 8B.

- **EMEA/H/C/280/II/01** The Marketing Authorisation Holder submitted on 28th July 2000 an application for a Type II variation (Use in combination with ribavirin for the treatment of chronic Hepatitis C), pursuant to Article 4 of Commission Regulation (EC) No. 542/95 of 10 March 1995, as amended. A positive opinion was given on 14th December 2000 and a Decision by the European Commission on 26 March 2001.
- **EMEA/H/C/280/II/02** A type II variation was started on 30th June 2000 (Improvement of the manufacturing process), pursuant to Article 6 of Commission Regulation (EC) No. 542/95 of 10 March 1995, as amended. A positive opinion was adopted by the CPMP on 28 August 2000 with a European Commission Decision on 14th September 2000.
- **EMEA/H/C/280/I/03** A Type I following Type II variation (Minor change of manufacturing process of the active substance), pursuant to Article 4 of Commission Regulation (EC) No. 542/95 of 10 March 1995, as amended was started on 30th June 2000. The Head of the Human Medicines Evaluation Unit signed a positive notification on 28 August 2000.
- **EMEA/H/C/280/I/04** A Type I (point 20) variation (Extension of shelf life from 24 to 36 months), pursuant to Article 4 of Commission Regulation (EC) No. 542/95 of 10 March 1995, as amended was started on 17th July 2000. The Head of Sector Quality of Medicines signed a positive notification on 11 August 2000 and the European Commission granted a Commission Decision on 16 November 2000.
- **EMEA/H/C/280/I/05 A** Type I (point 30) variation (Additional pack sizes), pursuant to Article 4 of Commission Regulation (EC) No. 542/95 of 10 March 1995, as amended was started on 17th July 2000. The Head of Sector Quality of Medicines signed a positive notification on 10 August 2000 and the European Commission granted a Commission Decision on 16 November 2000.
- **EMEA/H/C/280/I/06 -10 Five** Type I (point 14) variations (Change in the specifications of the active substance), pursuant to Article 4 of Commission Regulation (EC) No. 542/95 of 10 March 1995, as amended were started on 19th September 2000. The Head of the Human Medicines Evaluation Unit signed a positive notification on 19 October 2000.
- **EMEA/H/C/280/I/11 A** Type I (point 24) variation (Change in the test procedure of the active substance), pursuant to Article 4 of Commission Regulation (EC) No. 542/95 of 10 March 1995, as amended was started on 19th September 2000. The Head of the Human Medicines Evaluation Unit signed a positive notification on 19 December 2000.
- **EMEA/H/C/280/I/12 A** Type I (point 24) variation (Change in the test procedure of the active substance), pursuant to Article 4 of Commission Regulation (EC) No. 542/95 of 10 March 1995, as amended was started on 29th November 2000. The Head of the Human Medicines Evaluation Unit signed a positive notification on 4 January 2001.

EMEA/H/C/280/I/16 A Type I variation, No. 20a (Extension of shelf life), pursuant to Article 4 of Commission Regulation (EC) No. 542/95 of 10 March 1995, as amended was started on3rd May 2001. The Head of Sector Quality of Medicines signed a positive notification on 1st June 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
Quality changes (TSE compliance)	II/0013	II	20.09.01	15.10.01
Extension of shelf-life or retest period of the active substance	I/0017	I	28.01.02	04.03.02
Change in specifications of active substance	I/0018	I	26.03.02	
Line Extension: Powder and solvent for solution for injection in pre-filled pen	X/0014	X	20.09.01	06.02.02
Update of SPC and PL	II/0015	II	15.11.01	07.05.02

[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.