STEPS TAKEN AFTER GRANTING THE MARKETING AUTHORISATION

For procedures finalised after 30 July 2005 please refer to module 8B.

- On 21 July 1997 the CPMP issued a notification to the Commission relating to changes in the Package Leaflet not connected to the Summary of Product Characteristics. The European Commission amended the Decision on 18 March 1997.
- On 13 August 1997 the CPMP issued a notification to the Commission relating to changes in the labelling text of the immediate packaging in all 11 languages in order to have three combined languages on the Belgian label. The European Commission amended the Decision on 5 November 1997.
- The CPMP issued on 13 August 1997 a positive opinion for the transfer of the Marketing Authorisation for Vistide to Pharmacia & Upjohn SA, Luxembourg. The CPMP opinion with its revised Annexes was forwarded, in all official languages of the European Union, to the European Commission which adopted the Decision on 17 October 1997.
- On 4 March 1998 the Marketing Authorisation Holder notified the EMEA of its intention to introduce changes in the Package Leaflet not connected to the Summary of Product Characteristics. On 14 April 1998 the EMEA has notified the European Commission that the changes were accepted. The European Commission amended the Decision on 2 June 1998.
- On 27 May 1998 the Marketing Authorisation Holder submitted to the EMEA an application for a Type I variation relating to a change in the content of the manufacturing authorisation. On 1 July 1998 the EMEA notified the European Commission that the changes were accepted. This variation did not require any amendments to the Commission Decision.
- On 27 May 1998 the Marketing Authorisation Holder submitted to the EMEA another application for a Type I variation relating to an extension of the shelf-life. On 1 July 1998 the EMEA has notified the European Commission that the changes were accepted. The European Commission amended the Decision on 18 September 1998.
- On 25 August 1998 the Marketing Authorisation Holder submitted to the EMEA an application for a Type II variation relating to an update of the SPC and the Package Leaflet concerning the inclusion of a statement regarding the potential for iritis/uveitis associated with Vistide. On 19 November 1998 the CPMP issued a positive opinion. The European Commission amended the Decision on 26 February 1999.
- On 18 December 1998 the Marketing Authorisation Holder applied for an update of the Summary of Product Characteristics and the relevant sections of the Package Leaflet concerning the inclusion of new information regarding nephrotoxicity. On 25 March 1999 the CPMP issued a positive opinion. The European Commission amended the Decision on 17 June 1999.
- On 18 January 2000 the Marketing Authorisation Holder submitted to the EMEA an application for a Type II (09) variation relating to an update of section 4.8 of the SPC and the relevant section of the Package Leaflet following the CPMP Assessment of the 3rd and 4th Periodic Safety Update Reports. On 12 April 2000 the CPMP issued a positive opinion. The European Commission amended the Decision on 13 July 2000.

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
Change following modification(s) of the manufacturing authorisation(s)	I/0010	I	01.10.01	19.02.02
Change in the name and/or address of the marketing authorisation holder	I/0011	I	01.10.01	19.02.02
Change in or addition of manufacturer(s) of active substance	I/0012	I	09.11.01	19.11.01
5 year renewal of the Marketing Authorisation	R/0013	R	23.04.02	10.07.02
To update the Summary of Product Characteristics (SPC) section 4.8 ("Undesirable Effects") to reflect the frequencies of the adverse drug reactions in accordance with the SPC guideline. The frequencies of nephrotoxic effects are presented according to results in clinical trials. In section 6.6 ("Instructions for handling and disposal"), reference is made to contact the local representative for information in case of difficulty in obtaining probenecid. Relevant changes are also introduced in the Package Leaflet (PL). Moreover, the list of local representatives in the PL has been revised and some editorial changes have been made to the Danish, French and Portuguese translations.	II/0014	II	18.12.02	17.03.03
Change in the name and/or address of the marketing authorisation holder Change in the name and/or address of a manufacturer of the finished product	I/0015	I	27.09.04	24.06.05

[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.