STEPS TAKEN AFTER GRANTING THE MARKETING AUTHORISATION

For procedures finalised after 30 November 2004 please refer to module 8B.

- On 10 June 1996 the company Orion Corporation submitted to the EMEA an application for the modification of the package leaflet to include the list of contact points of the Marketing Authorisation Holder in the fifteen Member States. On 13 August 1996 the EMEA notified the European Commission, who amended the Commission Decision on 14 August 1996.
- On 21 March 1996 the company Orion Corporation (Finland) submitted to the EMEA an application for a transfer of the Marketing Authorisation from Ercopharm a/s (Denmark). The EMEA notified the European Commission, who amended the Commission Decision on 2 October 1996.
- Following review of the third Periodic Safety Update by the CPMP, the company Orion Corporation submitted an application for a Type II variation on 15 September 1997. The scope of the variation was to update the SPC; in particular with regard to thrombo-embolic events, elevation of transaminases and the addition of a sentence relating to effects on cholesterol and LDL. The CPMP, during its November 1997 plenary meeting, considered the changes acceptable and issued on 19 November 1997 a positive Opinion on the Type II variation. This Opinion was forwarded, in all official languages of the European Union, to the European Commission who adopted the corresponding Decision on 11 March 1998.

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 in the content of the manufacturing authorisation	I/004	I	19.04.99	25.05.99
Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	N/005	N	19.04.99	18.06.99
Change in specifications of active substance	I/006	I	18.05.99	N/A
Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	N/007	N	21.07.99	07.09.99
Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	N/008	N	09.11.99	20.01.00
Change in spedification of excipients in the medicinal product (excluding adjuvants for vaccines)	I/009	I	14.02.00	17.05.00
Update of Summary of Product Characteristics (section 4.8)	II/010	II	16.11.00	20.03.01
Renewal	R/011	R	25.01.01	18.05.01
TSE Compliance	II/012	II	29.03.01	06.04.01
Change in test procedure of active substance. Change in test procedures of the medicinal product.	I/013	I	16.07.01	16.07.01
Change in test procedure of active substance.	I/014	I	16.07.01	16.07.01
Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	N/015	N	17.06.02	18.07.02
Minor change of the manufacturing process of the active substance	I/016	I	20.05.03	28.05.03
Minor change in package leaflet not connected with the SPC (Art. 61.3 Notification)	N/017	N	20.11.03	22.12.03
Change in name and/or address of a manuf. of the active substance (no Ph. Eur. cert. avail.)	IA/018	IA	21.06.04	-
Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	N/019	N	16.07.04	-
Change in spec. of active subst./agent used in manuf. of active subst. - tightening of spec. and Change in test proc. for active substance - minor change	IA/020	IA	29.06.04	-

[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.