Steps taken after granting the Marketing Authorisation

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

Scope	Application number	Type of modification[1]	Notification/ Opinion issued on[2]	Commission Decision Issued/amended on
Transfer of The Marketing Authorisation from Genetics Institute of Europe B.V to Wyeth Europe Ltd	T/01	T	19.12.02	31.01.03
Extension of shelf-life as foreseen at time of authorisation	I/02	I	25.04.03	10.06.03
Extension of shelf-life or retest period of the active substance	I/03	I	25.04.03	-
Address changes affecting the package leaflet (Annex IIIB), namely to update the addresses of the local representatives in all languages.	N/04	N	02.07.03	-
Address changes affecting the Package Leaflet (PL), namely to update the address of the local representatives in all languages. Furthermore minor changes are implemented in all language version of the Labelling and PL. Some specific changes have been implemented in the Greek Labelling and PL to correctly reflect the English version.	N/05	N	12.12.03	-

[1] In accordance with Commission Regulation (EC) No. 542/95 of 10 March 1995, as amended for procedures finalised before 1 October 2003. In accordance with Article 6 of Commission Regulation (EC) No 1085/2003 for procedures finalised after 1 October 2003 : : **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.