Steps taken after granting the Marketing Authorisation

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

Scope	Application number	Type of modification[1]	Notification/ Opinion issued on[2]	Commission Decision Issued/amended on
This notification relates to address changes affecting the labelling (Annex IIIA) and the package leaflet (Annex IIIB), namely to update the address of local representatives in all languages and to correct spelling mistakes in the labelling (IIIA).	N/0001	N	17.01.03	24.02.03
The Marketing Authorisation Holder applied for a change in the rhAPC drug substance method of manufacture to introduce a maximum number of three consecutive freeze-thaw cycles of the rhAPC drug substance prior to compounding the drug product.	II/0002	II	22.05.03	-
Update of the SPC for Xigris 5 mg and 20 mg to include the results from a follow up study (EVBI) of the pivotal PROWESS trial. In addition, the MAH has taken this opportunity to add the MAH number in the SPC and the labelling as well as the date of first authorisation in the SPC. Finally, minor linguistic corrections have been implemented to the SPC and PL of the Finnish, French, German, Portuguese, Spanish and Swedish translations of the Commission Decision.	II/0003	II	22.05.03	11.08.03
First annual reassessment	S/0005	S	20.11.03	23.02.04
Change in test procedure of active substance Change in test procedures of the medicinal product	I/0006	I	20.11.03	-
Change(s) to shelf-life or storage conditions	II/0007	II	03.06.04	09.06.04
Update of sections 4.9 of the SPC in order to include post marketing information concerning overdose. In addition section 6.6 has been updated to strength cautious during administration in order to avoid overdose. Corresponding changes have been included PL. The List of local representatives of the Marketing Authorisation Holder has been updated.	II/0008	II	24.03.04	15.06.04
Change in shelf-life of finished product - as packaged for sale	IB/0009	IB	06.05.04	-
Change(s) to the test method(s) and/or specifications for the active substance Change(s) to the test method(s) and/or specifications for the finished product Changes in specifications & test methods to determine excipient concentration for Xigris drug product and revision of these methods in active substance.	II/0010	II	16.09.04	-

[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.