Steps taken after granting the Marketing Authorisation

For procedures finalised after 1 December 2003 please refer to module 8B

Scope	Application number	Type of modification[1]	Notification/ Opinion issued on[2]	Commission Decision Issued/amended on
Extension of shelf life as foreseen at time of authorisation.	I-0001	I	07.06.02	11.07.02
Extension of shelf life or retest period of the active substance.	I-0002	I	08.07.02	-
Changes to the prefilled syringe plunger stopper (change in the sterilisation dose range and removal of bioburden alert and limit levels) and to analytical methods.	II-0003	II	23.01.03	-
Changes to amend the Package Leaflet to include three changes of address of the local representatives.	N-0004	N	11.10.02	23.10.02
To amend sections 4.4, 4.5 and 4.8 of the SPC to introduce information on the concurrent use of anakinra with etanercept, ie clinical study results showing increased rate of serious infections and neutropenia with no increase in clinical benefit	II-0006	II	23.01.03	23.04.03
Change(s) to the manufacturing process for the active substance 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 Quality changes	II-0007	II	22.05.03	-
Change(s) to the test method(s) and/or specifications for the finished product Change(s) to shelf-life or storage conditions	II-0008	II	20.11.03	-

[1] In accordance with Commission Regulation (EC) No. 542/95 of 10 March 1995, as amended for procedures finalised before 01 October 2003. In accordance with Article 6 of Commission Regulation (EC) No 1085/2003 for procedures finalised after 01 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.
S refers to an annual reassessment.

[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.