Steps taken after granting the Marketing Authorisation

Subsequent post Marketing Authorisation applications agreed upon are summarised in the table below:

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
Change in container shape	I/0001	I	02.08.01	-
Change in test procedure of active substance	I/0002	I/II	26.07.01	-
Change in specification of excipients in the medicinal product	I/0003	I	17.07.01	-
Change in specification of medicinal product	I/0005	I	02.08.01	-
Change in specification of excipients in the medicinal product	I/0006	I	17.07.01	-
Change in specification of excipients in the medicinal product	I/0007	I	02.08.01	-
Change in test procedure of active substance	I/0008	I(II)	17.01.02	-
Change to the test method(s) and/or specifications of the finished product. Update of the Summary of Characeteristics (update of the ATC code in the SPC as follows: Bone Morphogenetic Proteins, ATC code: M05BC02).	II/0009	II	23.01.03	08.04.03
Change in the name of the medicinal product (either invented name of common name) into Osigraft.	I/0010	I	09.07.02	03.10.02
Change in test procedure of active substance	I/0011	I(II)	25.07.02	-
Synthesis or recovery of non-pharmacopoeial excipients in the medicinal products	I/0012	I	02.08.02	-
Change in test procedure of active substance	I/0013	I(II)	02.08.02	-
Extension of shelf-life as foreseen at time of authorisation	I/0014	I	17.10.02	12.11.02
Update of or change(s) to the pharmaceutical documentation	II/0015	II	20.11.03	-
Change in test procedures of the medicinal product Change in test procedures of non-pharmacopoeial excipients	I/0016	I	17.11.03	-
Change(s) to the test method(s) and/or specifications for the finished product	II/0017	II	24.03.04	-
Change(s) to the manufacturing process for the finished product	II/0018	II	03.06.04	-
Change(s) to the manufacturing process for the finished product	II/0019	II	29.07.04	-
Change(s) to the test method(s) and/or specifications for the active substance	II/0020	II	29.07.04	-
Update of or change(s) to the pharmaceutical documentation Change(s) to the manufacturing process for the active substance	II/0021	II	16.09.04	-

[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.

[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.