Steps taken after granting the Marketing Authorisation

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

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 or addition of manufacturing site(s) for part or all of the manufacturing process	I/0001	I	15.11.00	-
Change in supplier of an intermediate compound used in the manufacture of the active substance Minor change of manufacturing process of the active substance Change in specification of starting material or intermediate used in the manufacture of the active substance	I/0002	I	04.12.00	-
Change in pack size for a medicinal product	I/0003	I	12.12.00	16.02.01
Change in or addition of manufacturer(s) of active substance. Change in supplier of an intermediate compound used in manufacture of the active substance. Minor change of manufacturing process of the active substance. Change in test procedure of active substance.	I/0004	I	06.04.01	-
Update of section 5.1 of the Summary of Product Characteristics	II/0005	II	13.12.01	12.04.02
Change of legal status with the consequent change in section 4.2 of the Summary of Product Characteristics	II/0006	II	21.11.02	17.03.03
Change in or addition of manufacturer(s) of active substance Minor change of manufacturing process of the active substance Change in test procedure of active substance	I/0007	I	11.12.02	-
Increase of the maximum daily dose of pioglitazone to 45 mg	II/008	II	22.05.03	28.08.03
Extension of indication for the use of pioglitazone as second line monotherapy	II/009	II	22.05.03	28.08.03
Additional strength: tablets of 45 mg	X/0010	X	26.06.03	16.09.03

[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 61(3) of Directive 2001/83/EC of 6 November 2001.

[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.