Procedural steps taken after granting the Marketing Authorisation

For procedures finalised after 1 February 2004 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
Replacement of an excipient with a comparable excipient	I/0001	I	08.06.01	-
Change to addresses of some local representatives	N/0002	N	19.12.01	
Addition of a manufacturing site for Starlix film-coated tablets and change in the batch release site	I/0003	I	12.06.02	11.07.02
Change in manufacturing batch size of finished product	I/0004	I	12.06.02	-
Addition of an alternative packaging site	I/0005	I	24.05.02	-
Addition of an alternative packaging site	I/0006	I	24.05.02	-
Extension of product shelf-life	I/0007	I	17.06.02	30.08.02
Change to the finished product specification	I/0008	I	10.10.02	-
Update of the Summary of Product Characteristics (SPC) to include new information regarding the interaction between nateglinide and sulfinpyrazone and to include information on the co-administration of nateglinide and gemfibrozil. The Package Leaflet has been updated accordingly. The paragraph on hepato-biliary disorders in section 4.8 of the SPC has been updated. In addition minor changes and an update of the local representatives have been done.	II/0009	II	25.09.03	14.01.04

[1] For variations before 1 October 2003 in accordance with Commission Regulation (EC) No. 542/95 of 10 March 1995, as amendedand and for variations after 1 October 2003 in accordance with Commission Regulation (EC) No. 1085/2003:
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 61(3) of Directive 2001/83/EC of the European Parliament and of the Council 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.