Steps taken after granting the Marketing Authorisation

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
Update of section 4.8 of the Summary of Product Characteristics (SPC) and Package Leaflet to include Congestive Heart Failure and pulmonary oedema. In addition, further to the review of the 2nd PSUR hepatic events and elevated liver enzymes were added to section 4.8 of the SPC.	II/0001	II	14.12.00	20.03.01
Change in batch size of active substance	I/0002	I	22.11.00	-
Minor change of manufacturing process of the active substance	I/0003	I	22.11.00	-
Minor change of manufacturing process of the active substance	I/0004	I	22.11.00	-
Quality changes: scientific information and PhEur certificate of suitability related to TSE	II/0005	II	29.03.01	-
Update of section 4.8 of the Summary of Product Characteristics (SPC) and section 4 of the Package Leaflet (PL) regarding the presentation of information on adverse events. In addition a minor amendment of section 2 of the PL has been made to better reflect the corresponding wording in the SPC.	II/0006	II	27.06.01	31.10.01
Change in specification of starting material/intermediate used in the manufacture of the active substance	I/0007	I	23.11.01	-
Minor change of manufacturing process of the active substance	I/0008	I	14.01.02	-
Change in the name of a manufacturer of the medicinal product	I/0009	I	22.03.02	02.05.02
Change in test procedures of the medicinal product	I/0011	I	28.05.02	-
Change of legal status with the consequent change in section 4.2 of the Summary of Product Characteristics	II/0012	II	25.07.02	18.10.02
Update of section 4.8 of the Summary of Product Characteristics to include angioedema and urticaria. The Package Leaflet has been amended accordingly.	II/0013	II	25.07.02	18.10.02
Change in the name and/or address of the Marketing Authorisation Holder	I/0014	I	24.07.02	18.09.02
Minor change in the Package Leaflet not connected with the SPC	N/0015	N	15.11.02	11.12.03
Update of sections 4.4 and 4.8 of the Summary of Product Characteristics to include information on rapid and excessive weight gain. The Package Leaflet has been amended accordingly.	II/0016	II	23.01.03	23.04.03
Replacement of an excipient with a comparable excipient	I/0017	I	19.12.02	-
Extension of indication to the use of rosiglitazone as second line monotherapy in type 2 diabetes mellitus patients. Summary of Product Characteristics and Package Leaflet have been updated.	II/0018	II	22.05.03	28.08.03

[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.