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 Summary of Product Characteristics (SPC) and Package Leaflet following changes requested by the CPMP following the adoption of a class labelling for nucleoside analogues in September 2000, changes requested by the CPMP in May 2001 following the assessment of safety follow-up measures and changes proposed by the Marketing Authorisation Holder following the availability of new safety data. The changes include contra-indications in patients with hepatic impairment, changes related to the hypersensitivity reaction, inclusion of cardiomyopathy under undesirable effects, the inclusion of an interaction between lamivudine and zalcitabine and a statement about the findings in preclinical carcinogenicity studies with abacavir in mice and rats.	II/0001	II	27.06.01	09.11.01
Minor change in the manufacturing process of the active substance and a consequential change in specification	I/0002	I	21.11.01	27.11.01
Change in test procedure for an intermediate used in the manufacture of the active substance	I/0003	I	12.10.01	-
Change in specification of starting material or intermediate used in the manufacture of the active substance.	I/0004	I	08.05.02	15.05.02
Update of the SPC further to the revised class labelling relating to lactic acidosis, safety related changes further to analyses of Periodic Safety Update Reports (PSURs) and other safety reports and harmonisation with Ziagen, Epivir and Combivir product information. The changes consist in the update of symptoms and signs of hypersensitivity reactions in section 4.4 ("Special warnings and special precautions for use") and 4.8 ("Undesirable effects"), inclusion of skin and subcutaneous tissue disorders as undesirable effects not associated with hypersensitivity reactions in section 4.8, and the inclusion of pure red cell aplasia, aplastic anemia and hepatitis in section 4.8. As a consequence, the Package Leaflet has been updated according to the above and according to the latest EMEA/QRD template. In addition, the list of local representatives has been revised.	II-0005	II	25.07.02	
Change in or addition of manufacturer(s) of active substance	I/0006	I	16.07.02	22.07.02
Minor change of manufacturing process of the active substance	I/0007	I	16.07.02	22.07.02
Change in batch size of active substance	I/0008	I	16.07.02	22.07.02
Change in test procedure for starting material/intermediate used in manuf. of active substance	I/0009	I	16.07.02	22.07.02
Update of the Summary of Product Characteristics to include the class labelling on Lipodystrophy in sections 4.4 (" Special warnings and special precautions for use") and 4.8 ("Undesirable Effects"). Relevant changes are equally proposed for the Package Leaflet. Additionally, the contact details of the local representatives for Finland, Greece, Ireland and Spain have been updated in Section 6 of the Package Leaflet.	II/0010	II	19.03.03	30.06.03
Withdrawal of the manufacturing authorisation for a site of manufacture	I-0013	I	18.07.03	22.07.03
Change in test procedure of active substance	I-0014	I	05/08/2003	Pending

For procedures finalised after 01/01/2001please refer to module 8B.

[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 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.