

## STEPS TAKEN AFTER GRANTING THE MARKETING AUTHORIZATION

For procedures finalised after 1 September 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 <sup>1</sup>	Notification/Opinion issued on <sup>2</sup>	Commission Decision Issued/amended on
Changes to comply with supplements to pharmacopoeias	I/0001	I	30.03.01	-
Update of Summary of Product Characteristics (SPC) and Package Leaflet (PL): New interaction statements with <i>Hypericum perforatum</i> (St John's wort), methadone and combination oral contraceptive (OC).	II/0002	II	27.06.01	24.10.01
Annual Re-assessment	S/0003	S	21.02.02	17.05.02
_Change following modification(s) of the manufacturing authorisation(s)	I/0004	I	30.05.02	06.06.02
Change following modification(s) of the manufacturing authorisation(s)	I/0005	I	06.06.02	10.07.02
Change in the qualitative composition of immediate packaging material	I/006	I	12.05.03	22.05.03
Change in the batch size of finished product	I/0008	I	25.04.02	26.04.02
Minor changes in manufacture of the medicinal product	I/0009	I	25.04.02	26.04.02
The MAH applied to update the SPC, section 4.4 (special warnings and special precautions for use) and section 4.5 (Interactions with other medicinal products and other forms of interaction). The proposed changes include an interaction between amprenavir and delavirdine, an interaction between amprenavir and efavirenz and the class labelling relating to co-medication of amprenavir with HMG-CoA reductase inhibitors. Corresponding PL changes (and minor revisions including an update of the list of local representatives) are proposed as well.	II/0010	II	25.05.02	24.10.02
The MAH applied to update section 4.4 and section 4.8 of the SPC further to the CPMP request to implement the class labelling for "antiretroviral therapy (ART) and lipodystrophy" in the SPC. Corresponding amendments are proposed to the PL.	II/12	II	19.03.03	09.07.03
Change in specification of the medicinal product	I/0014	I	18.07.03	-
The variation concerns an update to sections 4.2 and 4.4 of the SPC as a class labelling on liver impairment and anti-HIV products adopted by the CPMP for all anti-retroviral medicinal products on 25 April 2003. Relevant changes are equally proposed for the PL section 2. Lipodystrophy wording is also implemented in the PL. Further proposed changes in SPC relate to contra-indication of co-administration with products with narrow therapeutic window that are substrates of CYP 3A4 and other forms of interaction in section 4.3, SPC interaction statement with Kaletra, and nevirapine in section 4.5 and re-arranged section 4.8, according to latest SPC guidelines.	II/0016	II	20.11.03	29.01.04

<sup>1</sup> 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); **III** 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.

<sup>2</sup> 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.

The variation concerns an update to sections 4.1 and 4.2, 4.3, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SPC with statements relating to the completion of specific obligation study PRO 300017 (a phase III randomised multicentre open-label study to evaluate the efficacy, safety and tolerance of Agenerase 600 mg BID in combination with ritonavir (100 mg BID) versus other PIs in HIV-infected PI-experienced adults over a 16 week period). Consequential changes are made to sections 1, 2 and 3 of the Package Leaflet (PL).	II/0017	II	20.11.03	29.01.04
Change in BR/QC testing - repl./add. of batch control/testing site	IA/0018	IA	16.10.03	-
All specific obligations stated in Annex IIC of the CPMP opinion dated 23 January 2003 have been fulfilled. There are no remaining grounds for the Marketing Authorisation to remain under exceptional circumstances.	S/0019	S	17.12.03	10.03.04
Change in shelf-life of finished product - as packaged for sale	IB/0020	IB	10.02.04	-
Change in the name and/or address of a manufacturer of the finished product	IA/0021	IA	24.05.04	-
To include the additional local representatives of the MAH for all 10 new European Member States and to present the list according to the latest EMEA/QRD Template.	N/0022	N	21.06.04	-

Medicinal product no longer authorised