Procedural steps taken and scientific information after the authorisation
Changes made after 01/11/2003

Zenapax

For procedures finalised before 01/11/2003, please refer to module 8A

MAJOR CHANGES[1]

No	Scope	Opinion issued on	Commission Decision Issued/ amended on	Product Information affected[2]	Summary
II/0024	Update of section 4.3, section 4.6 and section 5.3 of the SPC to delete the contraindication to pregnancy and to include the results of a non-clinical study in peri-and postnatal development in cynalmolgus monkeys, as requested by the CHMP following the assessment of a non-clinical follow up measure. The PL has been up dated accordingly. In addition the MAH takes the opportunity to make some minor editorial changes to the PL and updates the annexes with the QRD version 7.0 template including 4.8 with MedDRA frequencies**.**	28/06/2006	07/08/2006	SPC, Annex II, Labelling and PL	The contraindication to Zenapax has been in place since the initial marketing authorisation because at that time the reproductive toxicity was unknown. To date there is limited clinical data on exposure to Zenapax during pregnancy, however the results of a non-clinical study have not shown strong signal to hazardous effect with respect to the course of gestation and the health of the new born. Therefore the CHMP agreed to the deletion of the contraindication of the use of Zenapax during pregnancy from section 4.3 of the SPC. Rather a warning has been added to section 4.6 that Zenapax should not be used in pregnancy unless it is clearly necessary. Section 4.6 has been updated with the results of the non-clinical study with regards to recommendations on pregnancy and lactation. Section 5.3 has also been updated to reflect the results of this non-clinical study.
II/0023	Change(s) to the manufacturing process for the active substance	21/09/2006	27/09/2005		
II/0020	Update of or change(s) to the pharmaceutical documentation	23/02/2006	28/02/2006		

[1] Major changes e.g. Type II variations, Annex II applications, Renewals and Annual Reassessments
[2] SPC (Summary of Product Characteristics), Labelling, PL (Package Leaflet)

R/0018	Renewal of the marketing authorisation	21/01/2004	14/04/2004	SPC, Labelling, PL	Based on the CHMP review of the available information and on the basis of a re-evaluation of the benefit/risk balance, the CHMP is of the opinion that the quality, safety and efficacy of this medicinal product continues to be adequately and sufficiently demonstrated and therefore considered that the benefit/risk profile of Zenapax continues to be favourable.
II/0017	Change(s) to the manufacturing process for the active substance Quality changes Change(s) to shelf-life or storage conditions	17/12/2003	23/12/2003		

MINOR CHANGES[3]

No	Scope	Product Information affected[2]	Date[4]
IA/0026	05_Change in the name and/or address of a manufacturer of the finished product	PL	23/01/2007
IA/0025	16_b_Submission of new TSE certificate relating to active substance - other substances		31/05/2006
IA/0022	01_Change in the name and/or address of the marketing authorisation holder	SPC, Labelling, PL	12/01/2006
IB/0021	42_a_01_Change in shelf-life of finished product - as packaged for sale	SPC, Labelling, PL	07/11/2005
N/0019	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	Labelling, PL	28/06/2004

[3] Minor changes e.g. Type I variations and Notifications
[4] Date of entry into force of the change