

NeoSpect

Procedural steps taken and scientific information after the authorisation Changes made after 01/06/2003

For procedures finalised before 01/06/2003, please refer to module 8A

MAJOR CHANGES¹

No	Scope	Opinion issued on	Commission Decision Issued/ amended on	Product Information affected ²	Summary
T/0009	Transfer of Marketing Authorisation Holder	03/03/2006	22/03/2006	SPC, Labelling, PL	Amersham Health AS submitted an application for the transfer of the Marketing Authorisation to CIS bio international.
R/0006	Renewal of the marketing authorisation	15/09/2005	31/01/2006	SPC, Annex II, Labelling, PL	

MINOR CHANGES³

No	Scope	Product Information affected ²	Date ⁴
N/0015	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	PL	11/04/2008
N/0014	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	Labelling, PL	17/08/2007
N/0013	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	PL	22/09/2006
IB/0012	37_a_Change in the specification of the finished product - tightening of specification limits		01/08/2006
IB/0011	37_a_Change in the specification of the finished product - tightening of specification limits		01/08/2006
IA/0010	08_b_01_Change in BR/QC testing - repl./add. manuf. responsible for BR - not incl. BC/testing	SPC, Annex II, PL	29/05/2006
IB/0008	13_b_Change in test proc. for active substance - other changes (replacement/addition)		10/11/2005
IB/0007	13_b_Change in test proc. for active substance - other changes (replacement/addition)		10/11/2005
N/0005	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	Labelling, PL	22/07/2005

¹ Major changes e.g. Type II variations, Annex II applications, Renewals and Annual Reassessments

² SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet)

³ Minor changes e.g. Type I variations and Notifications

⁴ Date of entry into force of the change

No	Scope	Product Information affected ²	Date ⁴
IB/0004	13_b_Change in test proc. for active substance - other changes (replacement/addition)		26/03/2004

Medicinal product no longer authorised