

PROCEDURAL STEPS TAKEN AFTER GRANTING THE MARKETING AUTHORISATION

For procedures finalised after 1 September 2004 please refer to module 8B.

Luveris

MAJOR CHANGES

No	Scope	Opinion issued on	Commission Decision Issued/amended on	Summary
II/0006	Change in formulation	21/02/2002	15/05/2002	
II/0020	Change of the test procedure of active substance	26/06/2003	02/07/2003	
II/0024	Extension of the shelf-life of active substance	22/04/2004	27/04/2004	
II/0025	Increase of the batch size of the finished product	23/06/2004	01/07/2004	

MINOR CHANGES

No	Scope	Notification issued on ¹
I/0001	Extension of shelf-life as foreseen at time of authorisation	11/02/2001
I/0003	Changes to comply with supplements to pharmacopoeias	16/02/2001
I/0004	Change in test procedures of the medicinal product	19/10/2001
I/0005	Change in the name and/or address of the marketing authorisation holder	20/07/2001
I/0007	Change in test procedure of active substance	20/08/2001
I/0008	Change in test procedures of the medicinal product	19/10/2001
I/0009	Change in test procedure of active substance	19/10/2001
I/0011	Change in specification of starting material/intermediate used in manufacturer of the active substance	12/09/2001
I/0012	Extension of shelf-life as foreseen at time of authorisation	10/11/2001
I/0014	Change in specification of the medicinal product	14/01/2002
I/0015	Change in supplier of an intermediate compound used in manufacture of the active substance	21/08/2002
I/0016	Change in or addition of manufacturing site(s) for part or all of the manufacturing process	28/11/2002
I/0017	Change in in-process controls applied during the manufacture of the product	16/01/2003
N/0018	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	10/02/2003
I/0019	Extension of the shelf-life of the active substance	08/05/2003
I/0021	Change of the manufacturing site for part of manufacturing process	08/10/2003
I/0022	Change in container shape	15/08/2003
I/0023	Extension of shelf-life of finished product	15/01/2004
N/0027	Inclusion of additional local representatives of the MAH for all new Member States	21/07/2004

¹ Date of entry into force of the change