STEPS TAKEN AFTER GRANTING THE MARKETING AUTHORISATION

For procedures finalised after 01 February 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[1]	Notification/ Opinion issued on[2]	Commission Decision Issued/amended on
Extension of shelf-life as foreseen at time of authorisation	I/0001	I	18.05.01	04.07.01
Change in specification of medicinal product	I/0002	I	31.05.01	
This notification relates to a change affecting the Package Leaflet (Annex IIIB). Linguistic changes that improve the linguistic quality and readability of the Package Leaflet have also been included.	N/0003	N	23.05.01	02.07.01
Minor change of manufacturing process of the active substance	I/0004	I	18.05.01	
This notification relates to address changes affecting the Labelling and Package Leaflet (Annex IIIB).	N/0005	N	12.09.01	29.10.01
Change in the batch size of finished product	I/0006	I	15.02.02	18.02.02
Minor changes in manufacture of the medicinal product	I/0007	I	08.03.02	18.03.02
First Annual Reassessment of the benefit/risk. The Community marketing Authorisation remains under exceptional circumstances for the medicinal product.	S/0008	S	24.04.02	
Change to sections 4.8 "Undesirable effects" and 4.9 "Overdose" of the SPC further to evaluation of PSUR2 covering the period from 1 July 2001 to 31 December 2001. The PL has been updated accordingly.	II/0009	II	18.12.02	07.03.03
Change(s) to the test method(s) and/or specifications for the finished product	II/0010	II	21.11.02	26.11.02
Change in or addition of manufacturing site(s) for part or all of the manufacturing process	I/0011	I	08.11.02	
Minor change of manufacturing process of the active substance	I/0012	I	18.12.02	19.12.02
Second Annual Reassessment of benefit/risk. The Community Marketing Authorisation remains under exceptional circumstances.	S/0013	S	25.04.03	15.07.03
Changes to the sections 4.6 "Pregnancy and lactation" and 5.3 "Preclinical Safety Data" of the SPC further to the evaluation of PSUR3 covering the period from 1 January 2002 to 30 June 2002.	II/0014	II	22.05.03	16.09.03
Change to the botulinum toxin type B reference standard, which is used as a control in the size exclusion chromatography and the SDS-PAGE assay	I/0015	I	29.08.03	
Changes to the sections 4.8 "Undesirable effects" and 5.2 "Pharmacokinetics properties" of the SPC further to the evaluation of PSUR number 4 covering the period from 1 July 2002 to 31 December 2002. In addition, an amendment to section 5.3 "Preclinical Safety Data" is proposed to correctly reflect the conclusions on reproductive toxicity studies already made through variation EMEA/H/C/301/II/14. The Package Leaflet has been updated accordingly.	II/0016	II	20.11.03	29.01.04
The Marketing Authorisation Holder (MAH) applied for the addition of an appearance test of the sodium succinate to the raw material specifications for this excipient.	IB/17	IB	11.12.03	
The MAH applied for the addition of an appearance of solution test to the raw material specifications for sodium succinate. The MAH also took the opportunity to add Sigma-Aldrich as an additional supplier of this excipient.	IB/18	IB	11.12.03	

Medicinal product no longer authorised

[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.

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