STEPS TAKEN AFTER GRANTING THE MARKETING AUTHORISATION

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

Scope	Application number	Type of modification[1]	Notification/ Opinion issued on[2]	Commission Decision Issued/amended on
Quality changes	II-0001	II	26/04/01	06/08/01
Quality: Change(s) to container Update of Summary of Product Characteristics (SPC) and Package Leaflet (PL)	II-0002	II	26/07/01	29/01/02
Quality: Change(s) to container Update of SPC and PL	II-0003	II	26/07/01	29/01/02
Update of the SPC (section 4.8) and PL to incorporate new safety information	II-0004	II	23/08/01	28/01/02
Update of the SPC (section 4.5) to reflect available data on concomitant administration with meningococcal C conjugate vaccine.	II-0005	II	20/09/01	19/02/02
Minor changes in the PL (contact detail of a MAH local representative).	N-0006	N	07/11/01	28/02/02
Change in the specifications of the active substance	I-0007	I	25/06/02	28/06/02
Update of the SPC (sections 4.8 and 4.9) and PL to incorporate new safety information.	II-0009	II	19/09/02	6.12.02
Extension of the shelf life of the finished product.	I-0011	I	23/09/02	17/10/02
Extension of the shelf life of the active substance	I-0010	I	26/09/02	08/10/02
The MAH wishes to update the SPC section 4.4/ 4.5 to include results from two studies assessing co-administration of Prevenar with multicomponent vaccines (hexavalent vaccines).	II-0008	II	22/05/03	16/09/03
Change(s) to the test method(s) and/or specifications for the active substance	II-0012	II	22/05/03	28/05/03
Change in specification of the medicinal product	I-0013	I	06/06/03	10/06/03
Extension of shelf-life as foreseen at time of authorisation	I-0016	I	11/07/03	11/08/03
Change in test procedure for starting material/intermediate used in manuf. of active substance	I-0014	I	30/07/03	5/08/03
Change in specification of active substance or agent used in manufacturing of active substance - tightening of specification limits	IB/0025	IB	18/02/04	
Change in specification of active substance or agent used in manufacturing of active substance- tightening of specification limits	IB/0024	IB	18/02/04	
Change in specification of active substance or agent used in manufacturing of active substance- tightening of specification limits	IB/0022	IB	18/02/04	
Change in specification of active substance or agent used in manufacturing of active substance- tightening of specification limits	IB/0021	IB	18/02/04	
Change in specification of active substance or agent used in manufacturing of active substance- tightening of specification limits	IB/0020	IB	18/02/04	
Addition or replacement of measuring or administration device	IA/0030	IB	15/04/04	
Change(s) to the test method(s) and/or specifications for the active substance	II-0019	II	22/04/04	27/04/04
Change in the name and/or address of a manufacturer of the finished product	IA/0035	IB	24/05/04	
Change in name and/or address of a manufacturer of the active substance	IA/0034	IB	24/05/04	

[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.

Change in test procedure of finished product - minor change to approved test procedure	IA/0040	IB	08/06/04	
Change(s) to the manufacturing process for the active substance	II-0029	II	23/06/04	01/07/04
Change(s) to the test method(s) and/or specifications for the finished product	II-0026	II	23/06/04	01/07/04
The MAH applied for amendments of sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SPC to extend the therapeutic indications to the age range from 2 to 5 years. The PL has been amended accordingly. In addition, the list of local representatives of the PL was completed with the contacts of the ten new European Member States.	II-0018	II	23/06/04	02/08/04
Change in any part of primary packaging material not in contact with finished product	IA/0045	IB	09/07/04	
Addition or replacement of measuring or administration device	IA/0044	IB	09/07/04	
Addition or replacement of measuring or administration device	IA/0043	IB	09/07/04	
Change in any part of primary packaging material not in contact with finished product	IA/0049	IB	21/07/04	
Quality changes	II/0038	II	29/07/04	02/08/04
Change(s) to the manufacturing process for the active substance	II/0037	II	29/07/04	02/08/04
Change(s) to the manufacturing process for the active substance	II/0033	II	29/07/04	02/08/04
Change(s) to the test method(s) and/or specifications for the active substance	II/0032	II	29/07/04	02/08/04
Quality changes	II/0031	II	29/07/04	02/08/04
Change in specification of active substance or agent used in manufacturing of active substance- tightening of specification limits	IB/0046	IB	30/07/04	