STEPS TAKEN AFTER GRANTING THE MARKETING AUTHORIZATION

For procedures finalised after 01/04/2004 please refer to module 8B.

Scope	Application number	Type of modification[1]	Notification/ Opinion issued on[2]	Commission Decision Issued/amended on
Change(s) to the test method(s) and/or specifications for the active substance	II/0001	**II**	19/12/2002	09/01/2003
Change(s) to the manufacturing process for the active substance	II/0002	**II**	18/12/2002	09/01/2003
Change(s) to shelf-life or storage conditions	II/0003	**II**	19/12/2002	09/01/2003
Change(s) to the manufacturing process for the active substance	II/0004	**II**	20/02/2003	06/03/2003
Change(s) to the test method(s) and/or specifications for the finished product	II/0005	**II**	25/09/2003	02/10/2003
Change(s) to the manufacturing process for the active substance	II/0006	**II**	22/10/2003	30/10/2003
Change(s) to the manufacturing process for the active substance	II/0007	**II**	22/10/2003	30/10/2003
Amendment of sections 4.1, 4.2, 4.5, 4.8, 5.1 of the Summary of Product Characteristics (SPC) to extend the indication to include also children aged 1 to 5 years. As a consequence of the age extension, the MAH applied to include information on the concomitant administration of Ambirix with DTPa-IPV/Hib or MMR vaccines at separate injection sites in the second year of life.The Package Leaflet (PL) and labelling have been amended accordingly. In addition, the contacts of the German, Spanish, Irish, Portuguese and Finnish local representatives have been amended.	II/0010	**II**	21/01/04	31/03/04
Change in or addition of manufacturing site(s) for part or all of the manufacturing process	I/0009	**I**	18/07/2003	-
Change of the vaccine manufacturing facilities (filling and packaging) from "GlaxoSmithkline Biologicals Manufacturing SA" (GSK Bio Manufacturing) to "GlaxoSmithkline Biologicals SA" (GSK Bio).	IA/0011	**IA**	12/03/2004	-

[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.