STEPS TAKEN AFTER GRANTING THE MARKETING AUTHORISATION

For procedures finalised after 01/09/2004, please refer to module 8B

- The MAH submitted in accordance with Commission Regulation (EC) No. 542/95 an application for a Type II variation relating to the extension of the storage time of the yeast cell paste intermediate product of the hepatitis B component of Procomvax, from 12 to 24 months. The EMEA adopted a positive opinion on 29 July 1999. Type II - Quality: Update of or change(s) to the pharmaceutical documentation
- The MAH submitted in accordance with Commission Regulation (EC) No. 542/95 an application for a Type II variation relating to the scale up of the hepatitis B component of Procomvax in a new fermentation facility. The EMEA adopted a positive opinion on 29 July 1999. Type II - Quality: Update of or change(s) to the pharmaceutical documentation
- The MAH submitted in accordance with Commission Regulation (EC) No. 542/95 an application for a Type I variation relating to an extension of shelf-life of the finished product from 24 months to 36 months, at 2 – 8 °C. The EMEA notified the European Commission and the MAH on 14 July 1999 that the variation is accepted. The Commission Decision amending the Community Marketing Authorisation was adopted on 30 September 1999. Quality change: Extension of shelf life as foreseen at time of authorisation.
- The MAH submitted in accordance with Commission Regulation (EC) No. 542/95 an application for a Type II variation relating to the addition of plastic bags as an alternative storage container for Hepatitis B yeast cell paste. The EMEA adopted a positive opinion on 19 January 2000. Quality change: Change to the pharmaceutical documentation
- The MAH submitted in accordance with Commission Regulation (EC) No. 542/95 an application for a Type I variation relating to an extension of shelf-life of the active substance (Haemophilus b Bulk) from 24 months to 36 months, at 2 – 8 °C The EMEA notified the European Commission and the MAH on 19 April 2000 that the variation is accepted. Quality change: Extension of the shelf life or retest period of the active substance.
- The MAH submitted in accordance with Article 10(3) of Council Directive No. 92/27/EE, a notification of a change of the local representatives for Greece and Germany in the Package Leaflet text (Annex IIIB) in all language versions The EMEA notified the European Commission and the MAH on 31 January 2000 that the change is accepted. The Commission Decision amending the Community Marketing Authorisation was adopted on 20 March 2000.
- The MAH submitted in accordance with Commission Regulation (EC) No. 542/95 an application for a Type I variation relating to a change in the name of the marketing authorisation holder from Pasteur Mérieux MSD S.N.C. to Aventis Pasteur MSD S.N.C. The EMEA notified the European Commission and the MAH on 16 May 2000 that the variation is accepted. The Commission Decision amending the Community Marketing Authorisation was adopted on 11 July 2000.

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
Quality changes: Update of or change(s) to the pharmaceutical documentation	II/0007	II	19.10.00	14.11.00
Quality changes: Change(s) to the test method(s) and/or specifications for the active substance. Quality: Change(s) to the test method(s) and/or specifications for the finished product	II/0009	II	19.10.00	14.11.00
Quality changes: Change(s) to the manufacturing process for the active substance	II/0010	II	31.05.01	21.06.01
Quality changes: Update of or change(s) to the pharmaceutical documentation	II/0011	II	23.08.01	07.09.01
Changes to the Patient Leaflet regarding some MAH local representative details	N/0012	N	13.07.01	13.08.01
Changes to the Patient Leaflet regarding the transfer of some MAH local representatives	N/0013	N	13.09.02	10.10.02
Quality changes: Change(s) to shelf-life or storage conditions.	II/14	II	25.09.03	02.10.03
Renewal of the Marketing Authorisation.	R/0015	R	24.03.04	02.08.04
Quality changes: Change(s) to the test method(s) and/or specifications for the active substance	II/0016	II	29.07.04	02.08.04

[1] In accordance with Commission Regulation (EC) No. 542/95 of 10 Mar 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.