STEPS TAKEN AFTER GRANTING THE MARKETING AUTHORISATION

For procedures finalised after 1 September 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
Change in pack size for a medicinal product.	I/0001	I	30.08.01	
Change in the name of a manufacturer of the medicinal product.	I/0003	I	22.11.01	15.11.01
Change of manufacturing site for part or all of the manufacturing process of the medicinal product.	I/0002	I	30.11.01	-
The change relates to the transfer of local representatives for Nordic countries (Finland, Sweden, Denmark, Norway and Island) to Belgium (Bruxelles) mentioned in the Package Leaflet text (Annex IIIB) in all language version.	N/0004	N	23.10.02	-
The marketing authorisation holder applied to introduce a new 1-vial pack of the HBVAXPRO 5µg/0.5ml, which includes an empty syringe with needle. The marketing authorisation holder took the opportunity of this variation to update the list of local representatives in the package leaflet and to introduce the product information for the new EU member states.	IA/006	IA	05/07/04	-
Change(s) to the test method(s) and/or specifications for the active substanceChange(s) to the test method(s) and/or specifications for the finished product	II/0005	II	29/07/04	03/08/04

[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.

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