Procomvax

Procedural steps taken and scientific information after the authorisation
Changes made after 01/09/2004

For procedures finalised before 01/09/2004, please refer to module 8A

MAJOR CHANGES[1]

No	Scope	Opinion issued on	Commission Decision Issued/ amended on	Product Information affected[2]	Summary
II/0030	Change(s) to shelf-life or storage conditions	24/07/2008	31/07/2008		
II/0029	Change(s) to the manufacturing process for the active substance Change(s) to the test method(s) and/or specifications for the active substance	24/04/2008	05/05/2008		
II/0027	Change(s) to shelf-life or storage conditions	24/01/2008	30/01/2008		
II/0028	Update of Summary of Product Characteristics Update of sections 4.4 and 4.8 of the SPC to implement the class labelling text on the risk of apnoea following vaccination of very prematurely born infants agreed by the CHMP in July 2007. In addiction the MAH took the opportunity to update the list of local representatives in the PL.	15/11/2007	11/12/2007	SPC	Following a review on the risk of apnoea in very premature infants after immunisation the CHMP recommended a class labelling on apnoea for all vaccines in very premature infants. The SPC was updated to include information about the potential risk of apnoea and the need for respiratory monitoring for 48-72h, when the primary immunisation series is administered to very premature infants (born ? 28 weeks of gestation) and particularly for those with a previous history of respiratory immaturity. As the benefit of the vaccination is high in this group of infants, vaccination should not be withheld or delayed.

[1] Major changes e.g. Type II variations, Annex II applications, Renewals and Annual Reassessments
[2] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet)

A20/0020	Article 20 Review On 13 February 2006, the European Commission triggered the procedure under Article 20 of Regulation (EC) No726/2004, after the CHMP expressed concerns on the low immunogenicity of the HepB vaccine component. The CHMP was requested to give an opinion as to whether the MA for Procomvax should be maintained, varied, suspended or withdrawn.	27/04/2006	28/07/2006	SPC, Annex II, Labelling, PL	Please refer to the Scientific Discussion: Procomvax-H-C-231-A20-20-SC
II/0019	Change(s) to the test method(s) and/or specifications for the active substance	15/09/2005	22/09/2005		
II/0017	Change(s) to shelf-life or storage conditions	17/02/2005	23/02/2005		

MINOR CHANGES[3]

No	**Scope**	**Product Information affected**[2]	**Date**[4]
N/0026	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	PL	11/09/2007
IA/0025	12_a_Change in spec. of active subst./agent used in manuf. of active subst. - tightening of spec. 37_a_Change in the specification of the finished product - tightening of specification limits		22/02/2007
IB/0023	38_b_Change in test procedure of finished product - minor change, biol. active subst./excipient		29/08/2006
IB/0022	12_a_Change in spec. of active subst./agent used in manuf. of active subst. - tightening		04/08/2006
IA/0021	12_a_Change in spec. of active subst./agent used in manuf. of active subst. - tightening of spec.		30/06/2006
IA/0018	01_Change in the name and/or address of the marketing authorisation holder	SPC, Labelling, PL	14/03/2005

[3] Minor changes e.g. Type I variations and Notifications
[4] Date of entry into force of the change