Quintanrix

Procedural steps taken and scientific information after the authorisation

MAJOR CHANGES[1]

No	Scope	Opinion issued on	Commission Decision Issued/ amended on	Product Information affected[2]	Summary
II/0008	Update of Summary of Product Characteristics and Package Leaflet Update of sections 4.4 and 4.8 of the SPC and PL 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 addition the MAH took the opportunity to update the list of local representatives in the PL.	15/11/2007	11/12/2007	SPC, PL	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 $\leq$ 28 weeks of gestation) and particularly for those with a previous history of respiratory immaturity. Nonetheless, preterm infants should not be withdrawn from the immunisation scheme because the benefit of vaccination outweighs the risk of apnoea.
II/0005	Change(s) to the test method(s) and/or specifications for the active substance Change(s) to the test method(s) and/or specifications for the finished product	15/09/2005	03/10/2005		
II/0004	Change(s) to the test method(s) and/or specifications for the finished product	23/06/2005	30/06/2005		
II/0003	Change(s) to the test method(s) and/or specifications for the finished product	23/06/2005	30/06/2005		
II/0002	Change(s) to the manufacturing process for the active substance	23/06/2005	30/06/2005		

[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)

MINOR CHANGES[3]

No	Scope	Product Information affected[2]	Date[4]
IB/0007	37_b_Change in the specification of the finished product - add. of new test parameter		28/09/2005
IA/0006	28_Change in any part of primary packaging material not in contact with finished product		27/06/2005
IB/0001	38_b_Change in test procedure of finished product - minor change, biol. active subst./excipient		13/05/2005

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