European Medicines Agency

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Public statement on Quintanrix

Withdrawal of the marketing authorisation in the European Union

On 1 August 2008, the marketing authorisation holder (MAH) responsible for Quintanrix, GlaxoSmithKline Biologicals, notified the European Commission of its decision to voluntarily withdraw the marketing authorisation for Quintanrix for commercial reasons. The MAH confirmed that this decision is not related to any safety concerns with Quintanrix.

Quintanrix was never marketed in the European Union.

Quintanrix (diphtheria, tetanus, pertussis [whole cell], hepatitis B [rDNA] and *Haemophilus* type b conjugate vaccine [adsorbed]) was indicated for primary immunisation of infants during the first year of life against diphtheria, tetanus, pertussis (whooping cough), hepatitis B and invasive diseases caused by *Haemophilus influenzae* type b ('Hib', a bacterium that causes meningitis), and for booster immunisation of young children during the second year of life.

Alternative vaccines are available throughout the European Union. These contain the same active substances as Quintanrix (diphtheria toxoid, tetanus toxoid, inactivated *Bordetella pertussis* [a bacterium that causes whooping cough], recombinant hepatitis B surface antigen [r-HBsAg, parts of the hepatitis B virus] and Hib polysaccharides [sugars from the bacterium Hib]).

On 28 August 2008, the European Commission issued a decision to withdraw the marketing authorisation for Quintanrix. Pursuant to this decision, the European public assessment report (EPAR) for Quintanrix will be updated to reflect that the marketing authorisation is no longer valid.

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