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Public statement

Tritanrix HB

Withdrawal of the scientific opinion under Article 58

GlaxoSmithKline Biologicals S.A has requested the European Medicines Agency (EMA) to withdraw its scientific opinion for Tritanrix HB.

Tritanrix HB was evaluated by EMA under the Article 58 provision[1], whereby EMA's Committee for Medicinal Products for Human Use (CHMP), in cooperation with the World Health organization (WHO), gives scientific opinions on medicines intended for use outside the European Union (EU).

The CHMP gave a positive opinion on Tritanrix HB in December 2013.

The decision to request the withdrawal was based on commercial considerations. GlaxoSmithKline Biologicals S.A had already informed EMA in March 2014 of its intention to discontinue production of Tritanrix HB (and Tritanrix HB + *Hib*).

Following the decision of GlaxoSmithKline Biologicals S.A, the scientific opinion for Tritanrix HB will no longer be updated and the CHMP will make no further recommendations on its conditions of use.

[1] Regulation (EC) No 726/2004

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