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Public Statement

Tritanrix HepB

Cessation of validity of the marketing authorisation in the European Union

On 1 January 2014, the marketing authorisation of Tritanrix HepB (diphtheria, tetanus, pertussis (whole cell) and hepatitis-B (rDNA) vaccine (adsorbed)) ceased to be valid in the EU.

The cessation of validity is in accordance with provisions of the sunset clause[1], which stipulate that the marketing authorisation of a medicinal product lapses if the product has not been marketed in any EU Member States for three consecutive years.

The former marketing authorisation holder, GlaxoSmithKline Biologicals, permanently discontinued marketing of Tritanrix HepB in the EU in 2009. The European Commission had granted an exemption from the 'sunset clause' for Tritanrix HepB; however the exemption expired at the end of 2013.

GlaxoSmithKline Biologicals confirmed that it discontinued the marketing of the product due to the lack of demand in the EU.

Of note, the company has submitted an application under Article 58 of Regulation (EC) No 726/2004 for an identical product, Tritanrix HB, in order to ensure supply in some countries outside the EU where this vaccine is still used. A positive CHMP Opinion for this application was adopted on 19 December 2013.

Tritanrix HepB was granted marketing authorisation in the EU on 19 July 1996 and later obtained WHO pre-qualification. Tritanrix HepB was indicated for the active immunisation of infants from 6 weeks of age against diphtheria, tetanus, pertussis and hepatitis B.

The marketing authorisation was initially valid for a 5-year period. It was subsequently renewed for an additional 5-year period in 2001, and granted unlimited validity in 2006.

The European Public Assessment Report for Tritanrix HepB will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

[1] Article 14(5) of Regulation (EC) No 726/2004 ('sunset clause')

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