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Press Office

Public statement

Infanrix Penta (diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rdna), poliomyelitis (inactivated) vaccine (adsorbed))

Cessation of validity of the marketing authorisation in the European Union

On 23 October 2000, the European Commission granted a marketing authorisation valid throughout the European Union (EU) for the medicinal product Infanrix Penta (diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) vaccine (adsorbed)), indicated for primary and booster vaccination of infants against diphtheria, tetanus, pertussis, hepatitis B and poliomyelitis.

On 30 May 2013, the Marketing Authorisation Holder of Infanrix Penta, GlaxoSmithKline Biologicals, informed the European Medicines Agency that marketing of Infanrix Penta had been permanently ceased on 21 December 2008. In accordance with article 14(5) of Regulation (EC) No 726/2004 ('sunset clause'), the marketing authorisation of a medicinal product lapses if the product has not been marketed in any of the Member States for three consecutive years.

Because of this, the marketing authorisation for Infanrix Penta is no longer valid.

The Marketing Authorisation Holder of Infanrix Penta has confirmed that cessation of marketing was due to lack of demand for this vaccine.

Pursuant to the expiry of the marketing authorisation, the European Assessment Report (EPAR) for Infanrix Penta is updated to reflect that the marketing authorisation is no longer valid.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8613
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

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