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Human Medicines Development and Evaluation

Public statement on

Hexavac [diphtheria, tetanus, acellular pertussis, inactivated poliomyelitis, hepatitis b (recombinant) and haemophilus influenzae type b conjugate vaccine, adjuvanted]

Withdrawal of marketing authorisation in the European Union

On 23 October 2000, the European Commission issued a marketing authorisation valid throughout the European Union for the medicinal product Hexavac (diphtheria, tetanus, acellular pertussis, inactivated poliomyelitis, hepatitis b (recombinant) and haemophilus influenzae type b conjugate vaccine, adjuvanted), which had been approved for diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and *Haemophilus influenzae* type b immunisation.

On 17 November 2005, the European Commission suspended the marketing authorisation on the recommendation of the Agency's Committee for Medicinal Products for Human Use (CHMP) further to the CHMP's review of the short and long-term protection afforded by recombinant hepatitis B vaccines.

The marketing authorisation holder (MAH) for Hexavac was Sanofi Pasteur MSD, SNC.

The European Commission was notified by a letter dated 11 April 2012 of the MAH's decision to voluntarily withdraw the marketing authorisation for Hexavac for commercial reasons. Hexavac has not been marketed in any EU country since the suspension in 2005.

On 28 June 2012, the European Commission issued a decision withdrawing the marketing authorisation for Hexavac.

Pursuant to this decision the European Public Assessment Report for Hexavac will be updated to reflect the fact that the marketing authorisation is no longer valid.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