EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Public statement

Hexaxim

Withdrawal of the scientific opinion under Article 58

On 30 November 2020, Sanofi Pasteur informed the European Medicine Agency (EMA) of its decision to stop the manufacture of the Hexaxim (diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and haemophilus type B conjugate vaccine (adsorbed)) for commercial reasons.

Hexaxim 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 EU.

The CHMP gave a positive opinion on Hexaxim 21 June 2012.

Hexaxim is no longer used as the license of reference for international area. Hexaxim has since been replaced by Hexacima (the same vaccine registered via the EU centralised procedure) as the international license of reference, including for WHO prequalification purposes.

Patients and healthcare professionals who have questions should contact authorities in their country.

The European Public Assessment Report (EPAR) for Hexaxim will be updated to indicate that the medicine is no longer available.

[1] Regulation (EC) No 726/2004

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