European Medicines Agency

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Public statement on Procomvax

Non-renewal of the marketing authorisation in the European Union

Sanofi Pasteur MSD S.N.C., the marketing authorisation holder (MAH) for Procomvax, has decided, for commercial reasons, not to apply for the second renewal of the marketing authorisation for this medicinal product. Consequently, the marketing authorisation for Procomvax expired on 14 May 2009.

The MAH has confirmed that this decision is not related to any safety concerns.

Procomvax (*Haemophilus influenzae* type b and hepatitis B vaccine) was indicated for vaccination against invasive disease caused by *Haemophilus influenzae* type b and against infection caused by all known subtypes of hepatitis B virus in infants six weeks to 15 months of age. It was authorised by the European Commission on 7 May 1999. The marketing authorisation was first renewed for five years on 14 May 2004.

Alternative vaccines containing the same active substances as Procomvax are available throughout the European Union.

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