European Medicines Agency
Press office

London, 16 October 2007
Doc. Ref. EMEA/475583/2007

PRESS RELEASE
GlaxoSmithKline Biologicals withdraws its application for a scientific opinion for Globorix

The European Medicines Agency (EMEA) has been formally notified by GlaxoSmithKline Biologicals s.a. of its decision to withdraw the application for a scientific opinion for the medicinal product Globorix vaccine (DTPw-HBV/Hib-MenAC, powder and suspension for suspension for injection). Globorix was intended to be used exclusively for markets outside of the European Union (EU).

The application for Globorix was submitted under Article 58 of Regulation (EC) No 726/2004, which allows the Agency's Committee for Medicinal Products for Human Use (CHMP) to give opinions, in cooperation with the World Health Organization (WHO), on products that are intended for use outside the EU. Medicines eligible for this procedure are used to prevent or treat diseases of major public health interest. This includes vaccines used in the WHO Expanded Programme on Immunization or for protection against a public health priority disease, as well as medicines for WHO target diseases such as HIV/AIDS, malaria or tuberculosis.

Globorix was expected to be used for primary immunisation of infants (during the first year of life) and for booster immunisation (during the second year of life) against diphtheria, tetanus, pertussis, hepatitis B, invasive disease caused by *Haemophilus influenzae* type b and *Neisseria meningitidis* serogroups A and C.

The application for a scientific opinion for Globorix was submitted to the EMEA on 2 March 2007. At the time of the withdrawal, it was under review by the Agency's Committee for Medicinal Products for Human Use (CHMP).

In its official letter, the company stated that the withdrawal of Globorix was based on its consideration that Globorix does not fit in the current WHO vaccination strategy in relation to meningococcal disease in the African meningitis belt.

More information about Globorix and the state of the scientific assessment at the time of withdrawal will be made available in a question-and-answer document that will be published on the EMEA website after the next meeting of the CHMP on 15-18 October 2007.

--ENDS--

NOTES

1. The withdrawal letter from the company is available here.
2. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
3. The legal basis for a CHMP scientific opinion in the context of cooperation with the WHO is Article 58 of Regulation (EC) No 726/2004. The text of the Regulation can be found here. An EMEA guideline is available here.
4. The highest burden of meningococcal disease occurs in sub-Saharan Africa, which is known as the "Meningitis Belt", an area that stretches from Senegal in the west to Ethiopia in the east, with an estimated total population of 300 million people. For more information, please go to the WHO website: http://www.who.int/en/.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 09
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

5. This press release, together with other information about the work of the EMEA, can be found on the EMEA website: http://www.emea.europa.eu

Media enquiries only to:
Martin Harvey Allchurch or Monika Benstetter
Tel: (44-20) 74 18 84 27, E-mail: press@emea.europa.eu