



GlaxoSmithKline

To : Dr Eric Abadie
CHMP Chairman
EMEA,
7 Westferry Circus,
Canary Wharf,
London E14 HB,
United Kingdom

GlaxoSmithKline
Biologicals s.a.
Rue de l'Institut, 89
B-1330 Rixensart
Belgium

Tel. +32 (0) 2 656 81 11
Fax. +32 (0) 2 656 80 00
www.gsk-bio.com

Rixensart, October 11, 2007

Subject: *Withdrawal of application for the GlaxoSmithKline Biologicals S.A. Globorix vaccine (DTPw-HBV/Hib-MenAC, powder and suspension for suspension for injection) - EMEA/H/W/848 -*

Dear Dr. Abadie,

We would like to inform you that, at this point of time, GlaxoSmithKline Biologicals S.A. has taken the decision to withdraw the application for its DTPw-HBV/Hib-MenAC vaccine (Globorix, powder and suspension for suspension for injection), which was intended to be used for the primary immunisation of infants (during the first year of life) against diphtheria, tetanus, pertussis, hepatitis B, invasive disease caused by Haemophilus influenzae type b and Neisseria meningitidis serogroup A and C and for booster immunisation of young children during the second year of life.

This withdrawal is based on the following reasoning:

- GSK takes note of the WHO meningococcal disease strategy for the African meningitis belt to build upon the existing Expanded Program of Immunisation (EPI) vaccination schedule and, as an initial step, prioritise mass vaccination campaigns (catch up) in children older than one year of age with a monovalent meningitis A vaccine which will help to break the cycle of meningitis epidemics.
- Given that GSK's candidate multivalent DTPw-HBV/Hib-MenAC infant vaccine (GloborixTM) is intended for primary immunisation of infants (first year of life) and booster immunisation of young children (during the second year of life), the Company considers that GloborixTM does not fit in the current WHO vaccination strategy. The company has therefore decided to withdraw its application under Article 58 of Regulation (EC) No 726/2004 at this point in time.
- GSK continues to be committed to work with WHO to design an optimal EPI vaccination schedule as well as on how best to position routine infant immunisation against meningococcal disease in the context of such a calendar evolution in the future.

- GSK understands that the Expanded Programme for Immunisation (EPI) of the WHO for children in developing world countries is set to evolve over the coming years in order to accommodate the inclusion of additional and important vaccines for the African continent including pneumococcal, malaria, meningococcal etc.

The Company also wishes to highlight that there are no more clinical trials ongoing with the Globorix candidate vaccine.

The Company is revising its strategy and will reallocate its resources and commitment to vaccines for diseases of the developing world to other innovative vaccines which are urgently needed; examples are vaccines against malaria, pneumococcal, rotavirus and multivalent meningococcal diseases.

We reserve the right to make further submissions at a future date in this or other indication(s).

We agree for this letter to be published on the EMEA website.

Yours sincerely,