European Medicines Agency

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PUBLIC STATEMENT ON
INFANRIX HepB

WITHDRAWAL OF THE MARKETING AUTHORISATION IN THE EUROPEAN UNION

On 25 April 2005 the European Commission adopted the decision withdrawing the Marketing Authorisation for the medicinal product for human use "INFANRIX HepB". It followed the notification by the Marketing Authorisation Holder (GlaxoSmithKline Biologicals) to voluntarily withdraw the Marketing Authorisation for INFANRIX HepB for marketing reasons. The MAH confirmed that this decision was based on commercial reasons and not due to any safety related concerns.

INFANRIX HepB [diphtheria toxoid, tetanus toxoid, acellular pertussis components (pertussis toxoid, filamentous haemagglutinin and pertactin), recombinant hepatitis B surface antigen (r-HBsAg)], was indicated for active immunization of all infants from the age of 2 months against diphtheria, tetanus, pertussis and hepatitis B.

It should be noted that there are other Community Marketing Authorisation valid throughout the European Union which contain the same antigens, i.e. diphtheria toxoid, tetanus toxoid, acellular pertussis, recombinant hepatitis B surface antigen (r-HBsAg).

As a consequence to this decision the European Public Assessment Report for INFANRIX HepB has been removed from the EMEA website.

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