



European Medicines Agency
Press office

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PRESS RELEASE

European Medicines Agency recommends suspension of Hexavac

The European Medicines Agency (EMA) is recommending as a precautionary measure the suspension of the marketing authorisation for Hexavac due to concerns about the long-term protection against hepatitis B. Hexavac is a vaccine for infants and children against diphtheria, tetanus, whooping cough (pertussis), hepatitis B virus, polio virus and *Haemophilus influenzae* type b.

The recommendation was made by the Agency's Committee for Medicinal Products for Human Use (CHMP) at its meeting of 12-15 September 2005 following identification of a decreased immunogenicity (the ability of a vaccine to stimulate an immune response) of the hepatitis B component. This is supposed to be due to variability in the production process for the vaccine's hepatitis B component that could lead to a decreased long-term protection against hepatitis B.

This concern does not affect the protection against diphtheria, tetanus, whooping cough, polio and *Haemophilus influenzae* type b.

There is no immediate concern for children already vaccinated with Hexavac. However the Committee requested Sanofi Pasteur MSD, the marketing authorisation holder, to design a specific surveillance programme to investigate whether infants and children would need to be revaccinated at a later stage, for instance at adolescence, to ensure long-term protection against hepatitis B.

The Committee stresses the importance of vaccination and the benefits to the individual child and to the population in general. Alternative vaccines are available (hexavalent or equivalent combinations of vaccines) in the European Union to protect infants and children against these serious and potentially life-threatening diseases. Vaccination should be continued according to national recommendations and vaccination schedules.

Parents are advised to discuss any concerns with their child's healthcare professional. A question and answer document for parents and healthcare professionals is available on the EMA website (www.emea.eu.int).

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NOTES

1. The marketing authorisation holder for Hexavac is Sanofi Pasteur MSD. It was first authorised in the European Union in October 2000. Detailed information about the vaccine can be found in the European public assessment report (EPAR) on the EMA website [here](#).
2. The question and answer document is available [here](#).
3. The Committee has previously issued a number of statements concerning hexavalent vaccines, including Hexavac, the most recent of which can be found [here](#). The Committee confirmed its position on Hexavac in April 2005.
4. The suspension of a marketing authorisation is a precautionary measure, during which time a medicinal product is not available. The lifting of the suspension is conditional on the marketing authorisation holder resolving the issues identified by the Agency.
5. This press release, together with other information about the work of the EMA, may be found on the EMA web site at <http://www.emea.eu.int>

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