



Questions and Answers on the suspension of Hexavac

What is Hexavac and what is it used for?

Hexavac is a vaccine to protect infants and children against 6 diseases: diphtheria, tetanus, whooping cough (pertussis), hepatitis B virus, polio virus and *Haemophilus influenzae* type b.

Why has Hexavac been suspended?

Hexavac has been suspended as a precautionary measure due to concerns about the long-term protection against hepatitis B. This follows identification of decreased immunogenicity (body response to defend itself against a disease) 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.

My child has been vaccinated with Hexavac. Is my child protected against any of these six diseases?

Your child is protected against diphtheria, tetanus, whooping cough (pertussis), polio and *Haemophilus influenzae* type b. The concern relates only to hepatitis B, and in particular to the long-term protection (5-10 years). There is no immediate concern regarding short-term protection against hepatitis B.

My child has been vaccinated with Hexavac. Is there a need for an extra vaccination against hepatitis B?

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

My child has started a vaccination course with Hexavac. What shall I do?

There is no immediate concern. Please keep your next scheduled appointment with your health care professional. He or she will recommend how the course of vaccination should be completed in line with national recommendations.

The Agency's Committee for Medicinal Products for Human Use (CHMP) stress the importance of vaccination and the benefits to the individual child and to the population in general. Vaccination should be continued according to national recommendations and vaccination schedules. Parents are advised to discuss suitable alternatives and any concerns with their child's healthcare professional.

Are there any other vaccines that can be used instead of Hexavac?

Alternative vaccines (hexavalent or equivalent combinations of vaccines) are available in the European Union to protect infants and children against these serious and potentially life-threatening diseases.

What does the suspension of the marketing authorisation for Hexavac mean?

The suspension of a marketing authorisation is a precautionary measure, during which time a marketing authorisation holder may propose solutions to resolve issues identified by the Agency's scientific committees. During the time of suspension, Hexavac will not be available. However, once the issues are resolved, Hexavac may be reintroduced on the market.

Is there any link between the suspension and previous CHMP communication on sudden unexpected death (SUD)?

No, the two issues are not related. The CHMP previously reviewed the possible link between SUD and Hexavac and concluded that, on the basis of the available evidence, there was no risk to public health. Previous public statements can be found [here](#).

In which countries was Hexavac available?

Hexavac was available within the European Union in Austria, Cyprus, Czech Republic, France, Germany, Greece, Italy, Lithuania, Slovakia and Sweden. It was also available worldwide in another 19 countries.