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Press Office

Press release

European Medicines Agency gives first opinion for a vaccine for use outside the EU

New vaccine offers protection against six WHO priority diseases

The European Medicines Agency has issued a scientific opinion recommending that the benefits of the vaccine Hexaxim outweigh its risks and that it can be used in regions outside the European Union (EU). This is the first such opinion on a vaccine.

The vaccine, developed by Sanofi Pasteur, offers protection against six World Health Organization (WHO) priority diseases: diphtheria, tetanus, pertussis (whooping cough), hepatitis B, polio and invasive disease caused by the bacterium *Haemophilus influenzae* type B, including meningitis. It is given to children between six weeks and two years of age.

The Agency's Committee for Medicinal Products for Human Use (CHMP) can give scientific opinions in cooperation with the WHO on human medicines that are intended for markets outside of the EU and that prevent or treat diseases of major public health interest. They may include vaccines used in the WHO's Expanded Programme on Immunization, as well as medicines for protection against public-health-priority, neglected or WHO target diseases such as HIV/AIDS, malaria and tuberculosis.

The CHMP bases its opinions on these medicines on the same standards of quality, safety and efficacy as for medicines for use within the EU.

Dr Tomas Salmonson, acting Chair of the CHMP said, "We are delighted to issue a positive opinion on this vaccine, which promises to relieve the burden of these six diseases. All of these diseases continue to cause unacceptable levels of illness and death across the globe.

"The Agency is looking forward to continuing its work with the WHO to speed up access to important medicines like this one in regions outside the EU."

The opinion was based on the results of clinical trials carried out in children in a range of countries outside the EU, which showed that there was an adequate immune response against all six diseases in all major ethnic groups. All of the active substances in the vaccine have already been used in other vaccines, except for the hepatitis B component.

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The evaluation team included experts from Brazil and Thailand nominated by the WHO and an expert from the WHO's vaccine prequalification programme.

Hexaxim can be used as primary or a booster vaccination. The primary vaccination is in accordance with the WHO's Expanded Programme on Immunization schedule. The vaccine is given as three doses at least four weeks apart. The most common side effects in clinical trials were pain and redness at the injection site, irritability and crying.

Sanofi Pasteur has committed to carrying out future studies looking at the long-term benefits of the vaccine, its use in combination with other vaccines and its effects in children with weakened immune systems. It will also monitor the side effects of the vaccine once it is being used.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. More information on Hexaxim is available in the summary of opinion on the Agency's website. The Agency will publish a European public assessment report (EPAR) reflecting the scientific conclusions reached at the end of the evaluation process within the next few weeks.
3. The main clinical trials of Hexaxim were carried out in Argentina, Mexico, Peru, Turkey, Thailand and South Africa.
4. Opinions on medicines for use outside the EU are not forwarded to the European Commission for the adoption of a decision.
5. Opinions for the use of medicines outside the EU are issued in accordance with Article 58 of Regulation (EC) No 726/2004. More information on this procedure is available on the Agency's website: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000157.jsp&mid=WC0b01ac05800240d1.
6. Information on the Expanded Program on Immunization is available on the WHO's website: http://www.who.int/immunization_delivery/en/.
7. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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