European Medicines Agency

London, 4 December 2009
Doc. Ref. EMEA/780391/2009

Questions and answers on the risk of fever with Pandemrix in young children

The Committee for Medicinal Products for Human Use (CHMP) at the European Medicines Agency has reviewed data on the use of a second dose of the pandemic flu vaccine Pandemrix in children aged from 6 months to 3 years. The Committee noted that this second dose brings a further immune response, but that there is also an increased risk of fever. The CHMP recommended changes to the prescribing information to draw the doctors' attention to these findings, so that they can be taken into account when deciding whether to use a second dose of Pandemrix in young children.

What is Pandemrix?

Pandemrix is a vaccine to protect against infection with the virus that is causing the current pandemic (H1N1) 2009, also known as 'swine flu'.
Pandemrix contains small amounts of haemagglutinins (proteins from the surface) of the A(H1N1)v virus that has first been inactivated so that it does not cause any disease. The vaccine also contains an 'adjuvant' (a compound containing oil) to enhance the immune response.
The vaccine has been authorised since September 2009. The manufacturer is GlaxoSmithKline Biologicals S.A.

How is Pandemrix used?

Pandemrix is injected into the shoulder muscle. The dose given (0.5 ml or 0.25 ml) and the use of one or two doses depend on the age of the patient. Generally young children receive the lowest dose twice (at least three weeks apart).
The basis for these dose schedules is the results of clinical trials looking at the safety and immunogenicity of Pandemrix 'mock-up' vaccine (a vaccine prototype made using another strain), as well as early results of clinical trials with the currently authorised H1N1-containing vaccine in adults, including the elderly, and in children aged from 6 months to 3 years. Immunogenicity is the ability of the vaccines to trigger a response from the immune system, the body's natural defences, which will allow the vaccinated person to fight infection.

What has happened with Pandemrix?

In line with the manufacture's obligations following the approval of the vaccine, GlaxoSmithKline has continued to provide further results from its ongoing trials. They supplied further immunogenicity data on 27 November 2009 from 51 subjects in the clinical trial in children aged 6 months to 3 years who received a second dose of Pandemrix. The manufacturer also provided details of the number of children who experienced reactions after vaccination, such as fever, pain, redness and swelling at the site of injection, drowsiness, irritability and loss of appetite.

What are the recommendations of the Committee?

The CHMP looked at the latest data presented by the company. Because Pandemrix is currently being used throughout the European Union to vaccinate people against the pandemic, the Committee was also able to look at reports of side effects in children provided by the manufacturers and by some Member States.

The Committee acknowledged that the second dose triggered a further increase in the immune response. This increase can bring about further protection against pandemic flu.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 68
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

The Committee also noted that the data clearly indicate an increased ‘reactogenicity’ with the second dose of Pandemrix. This means that the children reacted more to the second dose than to the first dose. In particular, the proportion of children who had a fever after the second dose was higher. The CHMP noted that such findings were unexpected as they were not seen with the mock-up vaccine. The information coming from the Member States’ vaccination programmes confirmed these observations.

The CHMP recommended that these data should be included in the product information made available to doctors, parents and carers. The Committee also recommended that they are warned of the risk of reactions after vaccination with Pandemrix, especially of the risk of high fever after the second dose.

What is the advice to doctors and parents and carers?

- Doctors should continue vaccination of young children according to the recommendations given by the health authorities in each Member State.
- Parents and carers of young children (below 6 years of age) vaccinated with Pandemrix should be aware that fever may occur, and that this fever can be high (above 38ºC). They should monitor the child’s temperature after each vaccination, and give a medicine such as paracetamol to control the fever as necessary.

What will happen next?

The opinion of the CHMP is transmitted to the European Commission for the granting of a variation to the marketing authorisation.