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Use of Varilrix (live attenuated varicella virus [OKA strain]) to be harmonised in the EU

On 25 February 2021, the European Medicines Agency (EMA) completed a review of Varilrix and recommended changes to the prescribing information in order to harmonise the way the medicine is used in the EU.

What is Varilrix?

Varilrix is a vaccine used for protecting individuals against chickenpox.

Varilrix contains a small amount of an attenuated (weakened) form of varicella virus, the virus that causes chickenpox. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend the body against a disease. When a person is given Varilrix, the immune system recognises the virus as foreign and makes antibodies against it. In the future, the immune system will be able to produce antibodies more quickly when the person comes into contact with this virus.

Why was Varilrix reviewed?

Varilrix has been authorised in the EU via national procedures. This has led to inconsistency across Member States in the way the medicine can be used, as seen in the differences in the prescribing information [summary of product characteristics (SmPC), labelling and package leaflet] in the countries where the medicine is marketed.

On 29 May 2020, GlaxoSmithKline Biologicals, the company that markets Varilrix, referred the matter to EMA in order to harmonise the marketing authorisations for Varilrix in the EU.

What is the outcome of the review?

After considering the available data on the use of Varilrix, the Agency concluded that the SmPC should be harmonised. The areas harmonised include:

4.1 Therapeutic indications

Varilrix can be given from the age of 12 months to protect against chickenpox (varicella). In some circumstances, it can also be used to vaccinate infants from 9 months of age.

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Varilrix can also be used within 3 days of exposure to a person with chickenpox; this may help prevent chickenpox or reduce the severity of disease.

Varilrix can be given to individuals at high risk of severe chickenpox.

4.2 Posology and method of administration

The vaccine can be given by injection under the skin or into the muscle in either the upper arm or outer thigh. People with bleeding disorders (such as thrombocytopenia or any blood clotting disorder) should be given Varilrix by injection under the skin.

Individuals from 12 months of age should receive 2 doses of Varilrix at least 6 weeks apart. The time between the first and second dose must not be less than 4 weeks.

In infants from 9 to 11 months of age, the time between the 2 doses should be at least 3 months.

4.3 Contraindications

Varilrix must not be used in people with a weakened immune system; whether they can receive the vaccine depends on the level of their immune defences.

People who have had an allergic reaction to any ingredients of Varilrix or any other vaccine against varicella should not receive Varilrix. Additionally, people allergic to the antibiotic neomycin should not receive the vaccine. However, people who have had a rash after direct skin contact with neomycin can be vaccinated, but should first discuss this with a doctor.

Varilrix must not be used during pregnancy; furthermore, pregnancy should be avoided for 1 month after vaccination.

Other changes

Other harmonised sections of the SmPC include sections 4.4 (special warnings and precautions for use), 4.5 (interaction with other medicinal products and other forms of interaction), 4.6 (fertility, pregnancy and lactation), 4.7 (effects on ability to drive and use machines), 4.8 (undesirable effects), and 5.1 (pharmacodynamic properties).

The package leaflet has been updated accordingly.

The amended information for doctors and patients is available here.

More about the procedure

The review of Varilrix was initiated on 25 June 2020 at the request of the marketing authorisation holder, GlaxoSmithKline Biologicals, under Article 30 of Directive 2001/83/EC.

The review was carried out by EMA's Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use.

A European Commission decision valid throughout the EU was issued on 21 April 2021.