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EMA starts review of Varilrix (live attenuated varicella virus, OKA strain)

EMA has started a review of the vaccine Varilrix, used for protecting individuals against varicella (chickenpox). The active substance in Varilrix is live attenuated varicella virus (OKA strain).

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

EMA will consider the available data on Varilrix and will amend the prescribing information to harmonise the way Varilrix is used in the EU.

The amended information for doctors and patients will be available on the EMA website once the review is concluded.

More about the medicine

Varilrix, which contains a weakened strain of the varicella virus, is for use in healthy people to protect them against chickenpox. It is authorised in Austria, Belgium, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Italy, Latvia, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Spain and Sweden as well as the United Kingdom[1].

More about the procedure

The review of Varilrix has been initiated at the request of the marketing authorisation holder, GlaxoSmithKline Biologicals, under Article 30 of Directive 2001/83/EC.

The review is being carried out by EMA's Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt the Agency's opinion.

[1] As of 1 February 2020, the UK is no longer an EU Member State. However, EU law still applies to the UK during the transition period.

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The CHMP opinion will then be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.