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EMA starts review of Ixchiq (live attenuated chikungunya vaccine)

Vaccine must not be used in people 65 years and above while review is underway

EMA's safety committee (PRAC) has started a review of Ixchiq (a live attenuated chikungunya vaccine) following reports of serious adverse events in elderly people.

Many of the people affected also had other illnesses and the exact cause of these adverse events and their relationship with the vaccine have not yet been determined.

So far 17 serious adverse events, including two cases resulting in death, have been reported worldwide in people aged between 62 and 89 years who received the vaccine.

Given that studies on Ixchiq mainly involved people below 65 years of age and the vast majority of serious cases concerned people 65 years of age and above, the Committee is temporarily recommending restricting the use of vaccine.

As a temporary measure while an in-depth review is ongoing, Ixchiq must not be used in adults aged 65 years and above. Ixchiq vaccination can continue in people under 65 years of age, in accordance with official recommendations.

In addition to the new restriction, the Committee is also reminding healthcare professionals that Ixchiq must not be given to people whose immune system is weakened because of disease or medical treatment. Persons with a weakened immune system are at greater risk of having complications from vaccines containing live attenuated viruses, regardless of age.

The PRAC will now review all available data to assess the benefits and risks of the vaccine and make a recommendation on whether to change the terms of its marketing authorisation.

Chikungunya is a mosquito-borne disease caused by the chikungunya virus. It is mostly present in tropical and subtropical regions. Symptoms include fever, painful joints, headache, muscle pain, joint swelling and rash. Most patients recover within a week, but some develop joint pain for several months or longer and a small proportion of patients may develop severe acute disease, which can lead to multiorgan failure.

Ixchiq was authorised as a single-dose vaccine for chikungunya on 28 June 2024. Around 43,400 doses have been used worldwide.

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In the EU/EEA, the vaccine is available in Austria, Belgium, Denmark, Finland, France, Germany, Luxembourg, the Netherlands, Norway and Sweden.

Information for the public

- Some people have experienced serious adverse events after having Ixchiq vaccination.
- As a precaution while EMA carries out a review, the vaccine must not be given to people 65 years of age and above.
- Ixchiq must also not be given to people who have a weakened immune system because of disease or a medical treatment, regardless of age.

Information for healthcare professionals

- EMA's safety committee (PRAC) is reviewing Ixchiq following reports of serious adverse events in elderly people.
- So far 17 serious cases have been reported in people from 62 to 89 years of age, two of which resulted in death. One of the fatal cases concerned an 84-year-old man who developed encephalitis. The second concerned a 77-year-old man with Parkinson's disease whose difficulty with swallowing worsened and may have caused aspiration pneumonia.
- The two fatal cases occurred in the French overseas department of La Réunion, where a vaccination campaign is underway following a recent chikungunya outbreak.
- Given that studies on Ixchiq mainly involved people below 65 years of age and the vast majority of the serious cases concerned persons 65 years of age and above, the Committee is temporarily recommending restricting the use of vaccine. While an in-depth review is ongoing, Ixchiq will be contraindicated in adults aged 65 years and above.
- In addition, EMA is reminding healthcare professionals that Ixchiq is contraindicated in people who are immunodeficient or immunosuppressed because of disease or medical treatment. These include patients with congenital immunodeficiency, haematological cancers and solid tumours, patients with HIV infection who are severely immunocompromised and patients receiving chemotherapy or long-term immunosuppressive therapy.
- A direct healthcare professional communication (DHPC) will be sent to relevant healthcare professionals. The DHPC will also be published on a dedicated page on EMA's website.
- The product information for Ixchiq will be updated with the latest recommendation for adults 65 years of age and above.

More about the vaccine

Ixchiq is a vaccine used to help protect people from 12 to 64 years of age against chikungunya disease. It contains a strain of the chikungunya virus that has been attenuated (weakened) so that it does not cause disease.

When a person is given Ixchiq, the immune system recognises the weakened virus as 'foreign' and makes antibodies against it. If the person later comes into contact with the chikungunya virus, the

immune system will be able to fight off the virus more effectively and so help to protect the person against chikungunya.

More about the procedure

The review of Ixchiq has been initiated at the request of the European Commission, under Article 20 of Regulation (EC) No 726/2004.

The review is being carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which has made temporary recommendations at the start of the review. The PRAC's temporary recommendations will be sent to the European Commission which will issue a legally binding decision applicable in all EU Member States.

Once the full review is concluded, the PRAC's final recommendations will be forwarded to the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt an opinion. The final stage of the review procedure is the adoption by the European Commission of a legally binding decision applicable in all EU Member States.