<Date>

Ixchiq (Chikungunya vaccine (live)): new contraindication in patients aged 65 years and older while EU-wide review is ongoing

Dear Healthcare Professional,

Valneva in agreement with the European Medicines Agency and the <National Competent Authority> would like to inform you of the following while an EU review is carried out:

Summary

- **As of 02 May 2025, 17 serious adverse events have been reported worldwide in people aged between 62 to 89 years following vaccination with Ixchiq.**
- **As a temporary measure, while a thorough assessment of all available data is performed, Ixchiq must not be used in adults aged 65 years and above. Ixchiq can continue to be used in people aged 12-64 years, in accordance with official recommendations.**
- **Healthcare professionals are reminded that Ixchiq is contraindicated in immunodeficient or immunosuppressed individuals due to disease or medical therapy, independent of age.**

Background on the safety concern

Ixchiq has been authorised in the European Union (EU) since 28 June 2024 for the active immunisation for the prevention of disease caused by chikungunya virus (CHIKV) in individuals 12 years and older. Ixchiq contains live-attenuated CHIKV of the Δ5nsP3 strain.

According to the most recent estimated data, a total of 43,400 doses of Ixchiq have been administered across La Réunion, mainland France (including overseas departments), the United States, other EU countries, and Canada. Among these, it is estimated that 43 percent (16,236 doses) were administered to individuals aged 65 years and older, those at highest risk for severe outcomes from CHIKV infection.

As of 02 May 2025, 19 cases of serious adverse events following vaccination with Ixchiq have been reported worldwide, thereof 11 from France including La Réunion, 7 from the United States and 1 from Austria. Many of the patients 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 cases involved vaccinated individuals aged between 62 and 89 years, two of which resulted in death.

In the light of these findings and given that studies on Ixchiq mainly involved people below 65 years of age, as a temporary measure while an in-depth review is ongoing, Ixchiq must not be used in adults aged 65 years and above. Ixchiq can continue to be used in people aged 12-64 years, in accordance with official recommendations.

In addition, the healthcare professionals are reminded that Ixchiq is contraindicated in patients 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.

The product information of Ixchiq is being updated accordingly. Further advice will be communicated as appropriate at the end of the review.

Call for reporting

Healthcare professionals are asked to report any suspected adverse drug reactions in accordance with the national spontaneous reporting system and include batch/lot number if available.

<include the details (e.g. name, postal address, fax number, website address) on how to access the national spontaneous reporting system>.

Company contact point

<Contact point details for access to further information, including relevant website address(es), telephone numbers and a postal address>

DHPC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	IXCHIQ/Chikungunya vaccine (live)
Marketing authorisation holder(s)	Valneva Austria GmbH
Safety concern and purpose of the communication	New contraindication in patients aged 65 years and older while EU-wide review is ongoing
DHPC recipients	Travel medicine specialists, travel medicine clinics, general practitioners, infectious diseases practitioners and, in endemic areas, healthcare professionals involved in vaccination. Target groups will be further defined at national level, in agreement with the respective national competent authority.
Member States where the DHPC will be distributed	All EU/EEA Member states where the medicinal product is marketed.

Timetable	Date
DHPC and communication plan (in English) agreed by PRAC	07 May 2025
Submission of translated DHPCs to the national competent authorities for review	12 May 2025
Agreement of translations by national competent authorities	15 May 2025
Dissemination of DHPC	22 May 2025