<Date>

Ixchiq (Chikungunya vaccine (live)): Use restricted to individuals at high risk of acquiring chikungunya infection

Dear Healthcare professional,

Valneva in agreement with the European Medicines Agency and the <National Competent Authority> would like to inform you of the following:

Summary

- **Ixchiq should only be given to individuals with a high risk of acquiring Chikungunya infection.**
- **This restriction of indication follows a routine EMA review of available safety data which evaluated the impact of serious adverse events reported with the vaccine (including aseptic meningitis), on the benefit-risk balance of Ixchiq. Some of these events resulted in hospitalisation and death.**
- **Healthcare professionals are reminded that:**
    - **Ixchiq is contraindicated in immunodeficient and immunosuppressed individuals due to disease or medical therapy, independent of age (e.g., from malignancies, chemotherapy, immunosuppressive therapy, congenital immunodeficiency, or HIV infection with severe immunosuppression).**
    - **Ixchiq is not recommended to be co-administered with other vaccines.**

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 18 years of age and older, which was later extended to adolescents 12 years and older. Ixchiq contains live-attenuated CHIKV of the Δ5nsP3 strain.

The restriction of indication for Ixchiq follows an EMA review of available safety data as part of a regular 6-monthly periodic safety update report (PSUR) for Ixchiq. The review also took into account findings from other recent reviews of the vaccine, including a review of a case of aseptic meningitis in a healthy young adult.

Known serious side effects linked to the vaccine particularly involved individuals aged 65 years and older and individuals with multiple underlying chronic medical conditions (e.g., cardiovascular disease, diabetes mellitus, chronic kidney disease, chronic obstructive pulmonary disease, neurodegenerative disease), but also young adults with no relevant comorbidities. In these individuals, serious or

prolonged chikungunya-like adverse reactions have been observed, sometimes leading to deterioration of general condition including malaise and decreased appetite, exacerbation of pre-existing diseases, brain disorders like encephalopathy and encephalitis, aseptic meningitis or confusional state.

These serious adverse reactions sometimes resulted in hospitalisation and, in a few cases, in death. Healthcare professionals are therefore reminded that the vaccine should only be given after careful consideration of the potential benefits and risks. It is contraindicated in immunodeficient or immunosuppressed individuals due to disease or medical therapy and should not be co-administered with other vaccines.

The product information of Ixchiq will be updated accordingly.

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	Use restricted to individuals at high risk of acquiring chikungunya infection
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 *Delete steps which are not applicable*	**Date**
DHPC and communication plan (in English) agreed by PRAC	11 June 2026
DHPC and communication plan (in English) agreed by CHMP/CMDh	25 June 2026
Submission of translated DHPCs to the national competent authorities for review	30 June 2026
Agreement of translations by national competent authorities	07 July 2026
Dissemination of DHPC	14 July 2026