IXCHIQ

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, please also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
A20	Since January 2025, a large chikungunya	07/05/2025	16/05/2025	Annex I, III	Please refer to the assessment report on temporary

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

	outbreak has been affecting the French islands of La Réunion and Mayotte prompting a vaccination campaign targeting initially individuals over 65 years of age with comorbidities, at risk of severe disease. The campaign was later extended to individuals aged 18 years and older. The French Haute Autorité de Santé (HAS) has temporarily suspended the use of Ixchiq in adults aged 65 and older after two serious adverse events (SAEs) resulting in hospitalisation, including one death, were reported. On 05 May 2025, the European Commission (EC) triggered an Article 20 procedure resulting from pharmacovigilance data, and requested the Pharmacovigilance Risk Assessment Committee (PRAC) to assess the impact of the above concerns on the benefit-risk balance of Ixchiq. PRAC has started a safety assessment and will review all available data. While the review is ongoing, PRAC recommends, as a temporary measures, that Ixchiq should be contraindicated in individuals aged 65 years and older while the review is ongoing.		(temporary measures)		measures:IXCHIQ EMEA/H/A-20/1540
Variation type IA / EMA/VR/0000258143	A.5 Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - A.5.b The activities for which the manufacturer/importer is	21/03/2025	N/A		

	responsible do not include batch release - Accepted				