



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## IXCHIQ

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification <sup>1</sup> issued on	Commission Decision Issued <sup>2</sup> / amended on	Product Information affected <sup>3</sup>	Summary
II/0001	Extension of indication to include active immunisation for the prevention of disease caused by chikungunya virus (CHIKV) in adolescents 12 years and older for IxchIQ, based on interim 6 months results from study VLA1553-321; this is a randomised, double-blinded, multicentre study to	27/02/2025	28/03/2025	SmPC, Annex II and PL	Please refer to Scientific Discussion 'IxchIQ- Procedure No. EMEA/H/C/005797/II/0001

<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).



	<p>evaluate the immunogenicity and safety of the adult dose of VLA1553 6 months following vaccination in adolescents from 12 years to less than 18 years of age after a single immunisation. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Annex II and the Package Leaflet are updated in accordance. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI. The RMP version 2.1 has been agreed.</p> <p>C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one</p>				
IB/0002	<p>B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data</p>	28/01/2025	n/a		