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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): chikungunya vaccine (live)

Procedure No. PSUSA/00011058/202511

Period covered by the PSUR:
6 months to 08 November 2025

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for chikungunya vaccine (live), the scientific conclusions of PRAC are as follows:

In view of available data on serious adverse reactions from spontaneous reports and in view of a plausible mechanism of action, the PRAC considers a restriction of the indication is warranted. The PRAC concluded that the product information of products containing chikungunya vaccine (live) should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for chikungunya vaccine (live) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing chikungunya vaccine (live) is unchanged subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.