EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EMADOC-1700519818-3141937
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): Dengue Tetravalent Vaccine (Live, Attenuated)

Procedure No. PSUV dengue tetravalent vaccine

Period covered by the PSUR:
19 August 2024 to 18 August 2025

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Scientific conclusions

Based on the PRAC Rapporteur review of data on safety and efficacy, the PRAC considers that the risk-benefit balance of medicinal products containing dengue tetravalent vaccine (live, attenuated) remains unchanged but recommends that the terms of the Article 58 CHMP Scientific Opinion should be varied as follows:

In view of available data on anaphylaxis from spontaneous reports including 72 cases with a known time to onset, the PRAC concluded that the product information of products containing Dengue tetravalent vaccine (live, attenuated) 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 Article 58 CHMP Scientific Opinion

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

The CHMP recommends that the terms of the Article 58 CHMP Scientific Opinion should be varied.