11 November 2021
EMA/CHMP/618604/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Dengvaxia

dengue tetravalent vaccine (live, attenuated)

On 11 November 2021, the Committee for Medicinal Products for Human Use (CHMP) recommended changes to the terms of the marketing authorisation for the medicinal product Dengvaxia. The marketing authorisation holder for this medicinal product is Sanofi Pasteur.

The CHMP adopted a new indication as follows:[2]

> *Dengvaxia is indicated for the prevention of dengue disease caused by dengue virus serotypes 1, 2, 3 and 4 in individuals ~~9~~* ***6*** *to 45 years of age with* ***test-confirmed previous dengue infection*** *~~prior dengue virus infection and living in endemic areas~~.*

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after the respective decisions on these changes to the marketing authorisation have been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] New text in bold, removed text as strikethrough

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