18 October 2018
EMA/CHMP/666423/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Dengvaxia

Dengue tetravalent vaccine (live, attenuated)

On 18 October 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Dengvaxia, intended for prophylaxis against dengue disease. The applicant for this medicinal product is Sanofi Pasteur.

Dengvaxia will be available as a powder and solvent to be made into a suspension for injection. The active substance of Dengvaxia is made of chimeric yellow fever-based live attenuated viruses, which contain 2 surface dengue proteins from each of serotypes 1 to 4 of dengue virus. Following administration, the viruses replicate locally and induce neutralizing antibodies and cell-mediated immune responses against the four dengue virus serotypes.

The benefits with Dengvaxia are its ability to protect against symptomatic dengue infection, including severe forms of the disease, in individuals who have had dengue infection before. The most common side effects are headache, injection site pain, malaise, myalgia, asthenia and fever.

The full indication is: "Dengvaxia is indicated for the prevention of dengue disease caused by dengue virus serotypes 1, 2, 3 and 4 in individuals 9 to 45 years of age with prior dengue virus infection and living in endemic areas. The use of Dengvaxia should be in accordance with official recommendations".

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has 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

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