EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Media and Public Relations

Press release

First vaccine for prevention of dengue

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended granting a marketing authorisation for Dengvaxia (dengue tetravalent vaccine (live, attenuated)), for the prevention of dengue caused by dengue virus serotypes 1, 2, 3 and 4 in people who are between 9 and 45 years old, live in an endemic area and already had a prior dengue virus infection.

Dengue is caused by a virus which is transmitted by *Aedes* mosquitoes, a type of mosquito that is widely spread in tropical and subtropical regions. Most people who contract the disease experience mild, flu-like symptoms. However, around two percent of people affected will develop severe dengue, a potentially lethal complication that includes dengue haemorrhagic fever and/or dengue shock syndrome. Main risk factors for severe dengue include young age and chronic diseases. Secondary infection, in the form of two sequential infections by different serotypes, is also a risk factor for severe disease.

There are four types of dengue virus and people living in a dengue-endemic area can have several dengue infections in their lifetime. No specific treatments for dengue exist and prevention is mainly limited to the environmental management of mosquitoes. There is currently no vaccine available for dengue in the EU.

Dengue is by far the most common mosquito-borne viral disease affecting people worldwide (mainly in tropical areas); tens of millions of cases occur each year resulting in approximately 20,000-25,000 deaths, mainly in children[1].

The approved indication excludes the populations of the EU mainland and territories outside tropical areas since dengue is not endemic in these regions. However, a number of EU territories, mainly overseas, are situated in endemic areas, and these territories could benefit from this vaccine.

The benefits and safety of Dengvaxia have been evaluated in 31 clinical studies conducted mostly in dengue endemic areas (Latin America and Asia Pacific). Together, these trials included over 41,000 participants aged 9 months to 60 years receiving at least one dose of the vaccine. The overall available data demonstrate that for people between 9 and 45 years of age, the vaccine has positive effects in

[1] https://ecdc.europa.eu/en/dengue-fever/facts/factsheet

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preventing symptomatic and severe dengue disease in people who have had previous dengue infection and live in endemic areas. In people who have never had dengue, there is an increased risk of clinically severe dengue disease leading to hospitalisation when vaccinees are subsequently infected with dengue virus. The CHMP therefore recommends limiting the use of the vaccine to individuals with prior dengue virus infection, for whom laboratory confirmation of the previous infection is available before vaccination. In addition, because there are no safety, immunogenicity or efficacy data to support vaccination of individuals living in non-endemic areas and travelling to endemic areas, vaccination of these individuals is not recommended.

A number of additional risk minimisation measures will be put in place, such as educational material for physicians and a guide for healthcare professionals. Use of the vaccine should be according to official recommendation from Member States.

The opinion adopted by the CHMP is an intermediary step on Dengvaxia's path to patient access. The CHMP opinion will now be sent to the European Commission for the adoption of a decision on an EU-wide marketing authorisation. Once a marketing authorisation has been granted, decisions about price and reimbursement will take place at the level of each Member State, taking into account the potential role/use of this medicine in the context of the national health system of that country.

Notes

1. This press release, together with all related documents, is available on the Agency's website at:
2. The applicant for Dengvaxia is Sanofi Pasteur.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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