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Malaysia calls for phase 4 Dengvaxia study

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Sanofi Pasteur's dengue vaccine Dengvaxia will have to undergo phase 4 testing in Malaysia



Sanofi Pasteur's dengue vaccine Dengvaxia will have to undergo phase 4 testing in Malaysia before the endemic country agrees to sign off on a full approval.

Malaysia’s National Pharmaceutical Regulatory Agency’s Drug Control Authority, which conditionally approved the vaccine, pointed out that if the study fails to verify the clinical benefit or are not conducted with due diligence, DCA may withdraw.

The French vaccinemaker will conduct the two-year trial jointly with the country’s Ministry of Health, aiming to further assess the vaccine’s effectiveness and safety. Before the readout, the vaccine will only be available to eligible trial volunteers 9 to 45 years old. It won't be covered by Malaysia’s National Immunisation Programme, meaning that participants will need to pay to get vaccinated.

The company expected €200 million in sales for last year, but the shot brought in just €55 million. Dengvaxia is now approved in 14 counties, mainly Asian and Latin American countries where dengue poses a noticeable threat, and boasts a World Health Organization endorsement. But its sales still haven't picked up to the levels Sanofi would like for a shot it spent $1.5 billion and 20 years to develop.