

Takeda secures India approval for first dengue vaccine

July 22, 2026 | News

TAK-003 has been authorised for dengue prevention in individuals aged four to 60 years without the need for pre-vaccination testing.



Takeda has received marketing authorisation from India's Drug Controller General of India for TAK-003, its dengue vaccine for individuals aged four to 60 years.

The approval makes TAK-003 India's first approved dengue vaccine. It can be used regardless of previous dengue exposure and does not require pre-vaccination testing.

The approval comes as dengue becomes a more persistent public health challenge in India. Takeda noted that reported dengue cases in the country have increased more than 11-fold in the past two decades, with transmission no longer limited to the monsoon season.

TAK-003 is based on a live-attenuated dengue serotype 2 virus, which provides the genetic backbone for all four dengue virus serotypes. The vaccine is designed to help protect against dengue disease caused by any of the four serotypes.

The approval is supported by Takeda's global clinical development programme, including a local Phase 3 study and data from the pivotal Phase 3 Tetravalent Immunization against Dengue Efficacy Study. The company described TIDES as the largest and longest efficacy trial conducted for a dengue vaccine.

Takeda said the TIDES trial showed sustained protection against dengue and dengue-related hospitalisation, with a favourable safety profile. The company also cited seven-year data showing continued protection across all four serotypes.

Since its 2022 launch, TAK-003 has been approved in 43 countries, with more than 32 million doses distributed globally. The vaccine has also received WHO prequalification, supporting eligibility for procurement through agencies such as UNICEF and PAHO.

The vaccine is already approved in Indonesia, Thailand, Malaysia and Vietnam, alongside India. It has also been distributed through public and private programmes across Asia, Latin America and Europe, including Brazil's National Immunization Program and public programmes in Argentina, Colombia and Indonesia.

Takeda said it will continue working with Indian regulatory authorities, public health stakeholders and healthcare providers to support planning, delivery and availability of TAK-003 in India.