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DCGI grants market authorisation to Takedaâ??s dengue vaccine QDENGA

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QDENGA is now approved in 43 countries, with more than 32 million doses distributed globally

Takeda Biopharmaceuticals India has announced that the Drug Controller General of India (DCGI) has granted market authorisation (CT-20, New Drugs and Clinical Trials (NDCT) Rules, 2019) for QDENGA, Takeda's dengue vaccine for the prevention of dengue disease in individuals aged 4–60.

QDENGA is the first dengue vaccine approved in India and can be used in individuals regardless of previous dengue exposure, without the need for pre-vaccination testing.

The approval in India is based on results from Takeda's global clinical development programme, involving 19 Phase 1, 2 and 3 clinical trials with over 28,000 participants in both endemic and non-endemic regions. This included the pivotal Phase III TIDES (DEN-301) trial which evaluated the vaccine in over 20,000 participants across eight countries over an extended period to evaluate both the long-term safety and efficacy of QDENGA.

This approval is also supported by data from a Phase III clinical trial (DEN-302) conducted in Indian participants, which evaluated the safety and immunogenicity of the vaccine in individuals aged 4–60 years. The study demonstrated that QDENGA was found to be tolerated, safe and immunogenic in healthy adults, adolescents and children.

QDENGA is a tetravalent, live-attenuated vaccine designed to provide protection across all four dengue virus serotypes. The vaccine is administered subcutaneously 0.5 mL as a two-dose regimen, with doses given three months apart.

Following the approval by DCGI, Takeda will continue to collaborate with Indian regulatory authorities, public health stakeholders, and healthcare providers to support the planning, delivery, and availability of QDENGA in India.