CDSCO Approves India's First Dengue Vaccine, Strengthening National Dengue Prevention Efforts

CDSCO Clears Recombinant Live Attenuated Dengue Vaccine for Prevention of Dengue in Individuals Aged 4–60 Years

Dengue Vaccine Approved in 42 Countries with WHO Prequalification and Strong Global Safety Record

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In a Landmark step towards strengthening India's efforts for the prevention and control of dengue, the Central Drugs Standard Control Organisation (CDSCO), under the Ministry of Health and Family Welfare, has granted marketing authorisation for the Dengue Tetravalent Vaccine (Live, Attenuated) – Qdenga®, manufactured by Takeda GmbH, Germany and to be imported by M/s Takeda Biopharmaceuticals India Pvt. Ltd. This is the first dengue vaccine approved in the country for the prevention of dengue disease.

The approval has been granted after a comprehensive scientific evaluation of the vaccine's quality, safety and efficacy in accordance with the provisions of the Drugs and Cosmetics Act, 1940 and the Drugs Rules, 1945.

Qdenga® is a live, attenuated tetravalent dengue vaccine developed using recombinant DNA technology. The vaccine is produced in Vero cells, with genes encoding serotype-specific surface proteins engineered into a dengue virus type-2 backbone. The product contains genetically modified organisms (GMOs). It is supplied as a freeze-dried powder for reconstitution and is administered as a subcutaneous injection.

The vaccine is indicated for the prevention of dengue disease in individuals 4 to 60 years of age. The recommended immunisation schedule consists of two doses of 0.5 ml each, administered at an interval of three months (0 and 3 months).

The approval is supported by evidence generated through an extensive global clinical development programme evaluating the vaccine's safety, immunogenicity and efficacy across both dengue-endemic and non-endemic regions. Clinical studies were conducted in participants from more than eight countries, including Brazil, Thailand and Sri Lanka. The evaluation also included a pivotal Phase III safety and immunogenicity study conducted in the Indian population covering individuals aged 4 to 60 years.

The vaccine has already received regulatory approval in 42 countries, including the European Union, the United Kingdom, Switzerland, Indonesia, Malaysia and Thailand, and has also received World Health Organization (WHO) prequalification. Globally, more than 24 million doses of the vaccine have been distributed. Post-marketing surveillance data from countries where the vaccine is in use have demonstrated a favourable safety profile, with no significant safety concerns identified.

The approval of the country's first dengue vaccine marks an important milestone in India's public health response to dengue and is expected to complement the ongoing vector control, surveillance, early diagnosis and case management measures being implemented under the National Vector Borne Disease Control Programme.

The Ministry of Health and Family Welfare remains committed to ensuring timely access to safe, effective and quality-assured vaccines and medicines through a robust and science-based regulatory framework.

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