

MVC's ENVACGEN® receives first enterovirus A71 vaccine marketing authorisation in Vietnam

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Joins forces with Substipharm Biologics to expand Southeast Asian market



Taiwan-based Medigen Vaccine Biologics Corp. (MVC) and Substipharm Biologics, based in Paris, have achieved a milestone with Vietnam's approval of ENVACGEN®, the first Enterovirus 71 (EV-A71) vaccine in the country.

This builds on MVC's dominance in Taiwan, where the vaccine holds over 97% market share. The collaboration aims to address a critical unmet need in pediatric health across Southeast Asia.

EV-A71 is a major cause of severe neurological complications and deaths among young children in Asia, particularly in Vietnam, which reported 180,000 cases and 31 deaths in 2023. The vaccine offers 100% efficacy, protects infants as young as two months old, and provides immunogenicity lasting over five years. With Vietnam's 1.36 million annual births, MVC's production expertise and Substipharm's marketing capabilities are poised to meet regional demand.

Leaders from both companies emphasized the significance of this development. Leo Lee, MVC's CEO, highlighted the vaccine's role in MVC's global mission, while Fabrice Baschiera, CEO of Substipharm Biologics, noted the rising EV-A71 threat, citing a 28.9% increase in hand, foot, and mouth disease (HFMD) cases in 2025.

ENVACGEN® demonstrated 100% efficacy in trials, with all confirmed cases in the placebo group and a statistical efficacy of 96.8% (CI: 85.5%, 100%). MVC, established in 2012, is a leader in vaccine innovation with PIC/S GMP-certified facilities and a portfolio including enterovirus and influenza vaccines. During COVID-19, MVC was Taiwan's sole domestic manufacturer with Emergency Use Authorization.

Substipharma, a French pharmaceutical company distributing over 90 products in 100+ countries, expanded into biologics with IMOJEV®, a Japanese encephalitis vaccine now available in 14 Asia-Pacific markets. Substipharma Biologics operates in Switzerland, Thailand, and Vietnam, reinforcing its regional presence.