

## India finally realizes its indigenous JE vaccine dream

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The first indigenous vaccine against Japanese encephalitis, using strain, identified, characterized, manufactured and tested in India, has finally been commercialized. The Vero cell-derived purified inactivated Japanese encephalitis vaccine-JENVAC from Hyderabad based Bharat Biotech, is being termed as a great alternative to the existing cheap vaccines being imported so far from China. The vaccine approved by the Drug Controller General of India, pioneers as the first vaccine ever to be manufactured in a public-private collaboration. The vaccine aims to provide better immunogenicity and long term protection owing to unique manufacturing technologies.

Japanese encephalitis is the most common cause of viral encephalitis in Asia-Pacific. It causes inflammation of the brain, symptoms include high fever, headache, sensitivity to light, stiff neck and back, vomiting, confusion and, in severe cases, seizures, paralysis and coma. The disease which is transmitted via mosquitoes, with pigs and water birds acting as amplifying hosts for the virus, is the leading cause of viral encephalitis in Asia with ~ 50,000 clinical cases reported annually. In India, the disease affects close to 171 districts and claims hundreds of lives each year, especially in Goarkhpur district of Uttar Pradesh.

The biggest advantage of JENVAC over live attenuated vaccines is that this vaccine could be administered even during an epidemic as it is an extremely purified and inactivated vaccine. In the clinical trials JENVAC showed superior safety and immunogenicity, in head to head comparison with the live SA14-14-2 vaccine. The vaccine met all its primary and secondary endpoints, in the age group of 1 to 50 years, after 1 or 2 doses of vaccination. Phase III trials showed 98.7% sero-protection 28 days after the 1st dose and 99.8% sero-protection 28 days after dose the 2nd dose. The results proved that JENVAC can be administered as a single dose during epidemics for mass vaccination campaigns and also as a 2 dose schedule during routine immunization as part of the National Immunization program in endemic regions.

Bharat Biotech is looking at a dual pricing strategy for JENVAC, so as to cater to both public and private agencies. While the anticipated price is said to be between Rs 140 to Rs 160/- per dose in private market, the government price is still in

negotiation.

Speaking on the occasion, Dr Krishna Ella, chairman and managing director, Bharat Biotech expressed his satisfaction over success of the project which he termed a political as well as social commitment. "I am overwhelmed at the successful culmination of an idea and its execution over the period of time. Equally satisfying has been the role played by the government agencies and regulators in ensuring that this vaccine becomes a reality," mentioned Dr Ella. "JENVAC has the potential to reduce disease burden and reduce India's import of JE vaccines. Bharat Biotech has a long history of developing novel health care solutions through public private partnerships, we hope to continue the same in years to come," he added further.

Describing the vaccine as an "Indian solution for an Indian problem", Union Health and Family Welfare Minister Ghulam Nabi Azad said this completely indigenous vaccine was an outstanding example of public-private partnership and a remarkable milestone in the emergence of India as an innovative and self-sufficient technology hub.

Dr V M Katoch, secretary, Department of Health Research, Govt of India, said " JENVAC not only represents as a successful example of developing a totally Indian product of immense public health importance by public -private partnership but also will prove to be a good stimulus to ICMR institutes and other institutions to move fast with their leads to fully developed products by following this route"