

WHO prequalifies Biological E's oral polio vaccine

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The World Health Organization (WHO) has prequalified an additional novel oral polio vaccine type 2 (nOPV2), further strengthening the global supply of a vaccine at the heart of efforts to stop poliovirus type 2 outbreaks more sustainably and accelerate progress towards polio eradication.

The newly prequalified product is manufactured by Biological E. Limited (BioE), India, using in-house bulk vaccine following a technology transfer from PT Bio Farma (Persero), Indonesia. This prequalification builds on earlier WHO listings of nOPV2 manufactured by PT Bio Farma, as well as the vaccine formulated and filled by BioE using bulk supplies from PT Bio Farma.

With this latest addition, WHO continues to diversify and strengthen the manufacturing base for quality-assured nOPV2, helping to ensure a more resilient, reliable and sustainable vaccine supply for countries responding to outbreaks.

The nOPV2 was developed to address outbreaks of circulating vaccine-derived poliovirus type 2 (cVDPV2), which can emerge in under-immunised populations. Compared with the traditional monovalent oral polio vaccine type 2, nOPV2 is designed to be more genetically stable, reducing the risk of seeding new outbreaks while retaining its effectiveness in rapidly interrupting virus transmission.

nOPV2 is indicated for active immunisation in all age groups and is authorized for emergency use in response to outbreaks caused by poliovirus type 2, when and where required by the Global Polio Eradication Initiative (GPEI) or WHO. Since its first deployment, the vaccine has been used in numerous outbreak responses, reaching hundreds of millions of children and contributing to reductions in cVDPV2 transmission in several affected countries.