

Korea-based EuBiologics' cholera vaccine achieves WHO prequalification

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Production and supply of Euvichol-S expected to help address cholera vaccine shortages



EuBiologics and the International Vaccine Institute (IVI), based in South Korea, have announced that Euvichol-S, an improved oral cholera vaccine (OCV) developed jointly by EuBiologics and IVI, has achieved World Health Organization prequalification (PQ).

Euvichol-S is a new OCV that has improved productivity by about 40 percent over the existing Euvichol-Plus by modifying the formulation and manufacturing method of the original vaccine material.

In May last year, EuBiologics submitted a PQ application to WHO with technical support from IVI after a field inspection of its GMP facilities by the Korean Ministry of Food and Drug Safety on behalf of WHO. The new vaccine received an export license from KMFDS in December before winning the WHO seal of approval in about 10 months after application.

EuBiologics will now be able to produce and supply three oral cholera vaccines, including Euvichol (in glass vials) and Euvichol-Plus. There is a significant global shortage of vaccine for cholera prevention as reported recently by The New York Times, and the expected supply of Euvichol-S to UN agencies is expected to ease this supply shortage.

Euvichol-S was developed through technological collaboration between EuBiologics and Dr Julia Lynch's team at IVI, and its efficacy was demonstrated in a Phase 3 comparative clinical trial in Nepal last year. The development of the vaccine was funded by the Bill & Melinda Gates Foundation, and the vaccine will be produced and distributed by EuBiologics. After the scale-up process, Euvichol-S will be mass produced in GMP facilities at the company's Chuncheon Plant 1 and Plant 2 in the Republic of Korea beginning in the second quarter.