

Biovac, IVI to develop & manufacture oral cholera vaccine for African and global markets

24 November 2022 | News

For increasing production volumes in order to reduce the critical shortage of vaccines needed to prevent cholera globally

South African based biopharmaceutical company Biovac has concluded a ground-breaking licensing and technology transfer agreement with the International Vaccine Institute (IVI), a non-profit international organisation headquartered in South Korea, for the manufacture of an oral cholera vaccine (OCV).

The project is significant for Biovac as it enables drug substance manufacturing capability to be built, that is, production of the antigen/raw material needed to manufacture actual vaccines. This is one of the remaining steps in the vaccine manufacturing value chain that is currently missing not only at Biovac but across the African vaccine manufacturing landscape.

The partnership with IVI aims to license and transfer technology with the ultimate aim of increasing production volumes in order to reduce the critical shortage of vaccines needed to prevent cholera globally. This transfer of technology will also establish and demonstrate capacity for Good Manufacturing Process (GMP) scale-up, local manufacture of clinical trial product, and end-to-end production of vaccines in Africa for African and worldwide usage. After many decades, this will be a critical step forward for vaccine production on the continent.

The agreement is underpinned by collective support of R120 million (\$6.9 million) from Wellcome and the Bill & Melinda Gates Foundation for the first phase of the project. It will allow Biovac to expand its capabilities from filling and packaging of vaccine vials to end-to-end vaccine product development and drug substance manufacture.

The technology transfer process will commence in January 2023, with the first clinical trial batches expected to be produced in 2024 and licensing of the product by the South African National Regulatory Authority (SAHPRA) to be concluded in 2026 alongside WHO Prequalification certification which will follow shortly thereafter.