



health

Department:
Health
REPUBLIC OF SOUTH AFRICA



MEDIA STATEMENT

To: Editors & Health Journalists
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South Africa prepares for potential new adult TB vaccine

Pretoria: The Department of Health welcomes progress made towards a new tuberculosis (TB) vaccine and confirms preparatory work to ensure timely access for South Africans as part of ongoing efforts to eliminate this epidemic as a public health threat by the year 2030.

A vaccine that prevents TB disease in adolescents and adults will be a game-changer for TB control and elimination, both globally and here in South Africa. The M72/ASOIE vaccine showed promise in phase 1 and phase 2 trials and is now in phase 3 trials in South Africa, Kenya, Zambia, Malawi and Indonesia.

Once approved, it will be the first TB vaccine introduced in over a century, because currently we have only the Bacille Calmette-Guérin (BCG) vaccine, which is given to newborn infants and children under 5 years old and offers limited protection later in life.

Therefore, to ensure we can offer protection to South Africans at the earliest opportunity if the trial is successful, the Department of Health is proactively preparing for registration and introduction of the new vaccine.

The Department has been informed by officials from the Gates Medical Research Institute and the Bill & Melinda Gates Foundation that an agreement has been reached with the world's largest vaccine manufacturer - the Serum Institute of India - about the number of doses produced and sold globally of the TB vaccine.

This agreement also provides for progressive production by pharmaceutical partners in South Africa and Indonesia over time, and this will consequently boost the economic growth of our country. This is

arguably a major step toward a new TB vaccine — the first significant advance since BCG more than 100 years ago.

The Department of Health welcomes this important agreement and stands ready to support the production and introduction of the M72/ASO1E vaccine in South Africa once the trial results are known and the vaccine has been registered by the South African Health Products Regulatory Authority (SAHPRA).

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