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10 May 2023

Ministry of Health, Republic of South Africa

Office of the Director General

Dear Dr Buthelezi

**Re: Recommendation for registration and use of novel oral poliovirus vaccine (nOPV2) to support preparedness and response planning in the event of vaccine-derived poliovirus-2 (VDPV-2) outbreak in South Africa**

Risk of vaccine-derived poliovirus-2 (VDPV-2) in South Africa: VDPV-2 is a neurovirulent poliovirus that has been identified<sup>1</sup> in southern Africa including Botswana (4 environmental detections over December 2022-February 2023). We are at high risk of introduction of VDPV-2 because of the mobility of persons between affected countries and South Africa.

Consequences of VDPV-2 introduction in South Africa: Infection with a neurovirulent strain of poliovirus such as VDPV-2 will lead to lifelong paralysis unless a person is fully vaccinated against poliovirus. Vaccination against poliovirus type 2 may be achieved using inactivated poliovirus vaccine (IPV) against strains 1,2 & 3 (part of routine immunisation) or monovalent oral polio vaccine type 2 (OPV-2) (only used in outbreak settings). Our current OPV for routine immunisation does not contain poliovirus type 2, as this was withdrawn from global vaccination schedules in 2016. In South Africa, vaccination coverage with IPV which is included in the hexavalent vaccine is estimated to be 91% and 86% respectively. This suggests that up to 14% of children in each birth cohort amounting to 14,000 children are vulnerable to polio.

WHO preparedness and response to VDPV-2 detections: To support VDPV-2 outbreak response the WHO developed a monovalent oral polio vaccine serotype 2 (mOPV2), and later a novel OPV-2 (nOPV) stockpile (the latter to make risk of reversion to neurovirulence less likely). The nOPV2 vaccine is not registered in South Africa, however it is currently

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<sup>1</sup> (data from WHO on 8 May 2023 <https://polioeradication.org/polio-today/polio-now/>)



available under an Emergency Use Listing (EUL) of the World Health Organization (WHO). Under the EUL, nOPV2 has been approved for targeted use during a Public Health Emergency of International Concern, which polio has been since 2014. Given the increasing threat of cVDPV2 outbreaks to vulnerable, under-immunised and high-risk populations, the EUL allows for expedited deployment of nOPV2.

Actions required by South Africa to access nOPV2: South Africa must register nOPV2 with the South African Health Products Regulatory Authority. Thereafter, South Africa should meet additional requirements of the WHO in order to use nOPV2 as part of a VDPV2 outbreak response. These are detailed in documents provided<sup>2</sup> including in “Preparing for nOPV2 Use: An overview on requirements for countries”.

**Recommendation: NAGI recommends that nOPV2 be licenced and be available for use in the event of a VDPV2 outbreak.**



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DATE: 10 May 2023

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<sup>2</sup> <https://polioeradication.org/polio-today/polio-now/outbreak-preparedness-response/>