



health

Department:  
Health  
REPUBLIC OF SOUTH AFRICA



Private Bag X828, PRETORIA, 0001 Dr AB Xuma Building 1112 Voortrekker Road, Pretoria Townlands 351-JR,  
PRETORIA, 0187 Tel (012) 395 8000, Fax (012) 395 8918

Dr Johannes Willem  
Cipla Medpro Manufacturing (Pty) Ltd  
1474 South Coast Road  
Mobeni  
**DURBAN**  
4052

Dear Dr Willem

### **Section 21 Extension Authorization for Bivalent Oral Poliomyelitis Vaccine 20-Dose Vial 2mL**

Attached, please find the Authorization for exemption under Section 21 of the Medicines and Related Substances Act by SAHPRA granted for:

- **Bivalent Oral Poliomyelitis Vaccine 20-Dose Vial**

The quantities for which approval was granted are only estimates based on procurement by provinces over the last 6 months. Please note that the National Department of Health (NDOH) cannot guarantee the procurement of these quantities, as NDOH has no control over orders being placed by provincial depots, and current stock holding might influence estimated quantities.

The following process will be followed to ensure the quality of the product being brought in:

1. Manufacturer will submit an assay and identification of every batch imported.
2. An additional assay of every batch will be done by a quality control laboratory.
3. A random sample will be assayed during the authorized period by a quality control laboratory.
4. Aggregate statistics to be submitted to NDOH in the first week of each month of all orders received and quantities supplied per province.
5. The NDOH needs to be advised of the quantities and date of arrival of stocks in terms of this authorization within 7 days after arrival.
6. The supplier will provide monthly reports, by the 7<sup>th</sup> of each month, using the attached format of orders received and issues done.
7. Participating Authorities (PAs) will provide a consolidated close out report of usage using the attached format on the date when an authorization lapses.
8. The full quantities imported in terms of this Section 21 authorisation must be accounted for.

**Section 21 Extension Authorisation re Bivalent (Oral) Poliomyelitis Vaccine 2mL Vial 12032026-3**

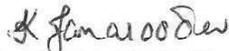
9. Note that this authorization DOES NOT cover supplies to the private sector.
10. Where this authorization is obtained to provide security of supply due to supply challenges from the contracted supplier, PAs are requested to buy out against contracted suppliers and ensure that related orders are cancelled accordingly to prevent over stocking once the contracted supplier gets back into stock.

It should be noted this authorization applies only for use of the product in the public sector with estimated usage quantities for a period of one month. The authorization is expected to expire on **07 September 2026**.

**Table 1: Provincial estimates**

Province	Six Months Estimate
DCS	0
EC-MT	10 800
EC-PE	12 000
FS	6 000
GP	30 000
KZN	26 000
LP	20 000
MP	14 000
NC	4 200
NW	9 650
SAMHS	300
WC	8 000
<b>Total</b>	<b>140 950</b>

Yours sincerely



**KHADIJA JAMALOODIEN**  
**CHIEF DIRECTOR: SECTOR WIDE PROCUREMENT**  
**DATE: 16/3/2026**

## Section 21 Outcome Letter

2026-03-07

Ms Buhle Mbongo

1112 Voortrekker Road

Pretoria

buhle.mbongo@health.gov.za

Dear Ms Buhle Mbongo

### **REQUEST TO USE UNREGISTERED MEDICINE IN TERMS OF SECTION 21 OF THE MEDICINES AND CONTROLLED SUBSTANCES ACT, 1965 (ACT 101 of 1965):**

Your application dated **2026-03-06** refers

- A. STATUS: Approved**
- B. APPLICANT: Ms Buhle Mbongo**
- C. IMPORTING COMPANY: Cipla Medpro Manufacturing (Pty) Ltd**
- D. NUMBER OF PATIENT/(S) INTENDED TO BE TREATED: 70500**
- E. UNREGISTERED MEDICINES: GENERIC NAME: No Data**
- F. TRADE NAME: Poliomyelitis Vaccine Oral 2 ml**
- G. QUANTITY: 141000 Packs (1 )**

S2100023712



SAHPRA Head Office  
Building A, Loftus Park  
2nd Floor  
Kirkness Str  
Arcadia  
0083

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**H. LETTER NUMBER: S2100023712**

Section 21 authorization letters are valid for a period of 6 months from the letter date, unless otherwise specified.

A progress report must be submitted once treatment is completed or on a reauthorization request

**Comments:**

Yours faithfully,

Dr Shyamli Munbodh

Manager: Section 21 Category A Medicines

A rectangular box containing a handwritten signature in black ink. The signature appears to be 'Ms Moropa' written in a cursive style.

Ms Mahlodi Moropa

Final Approver

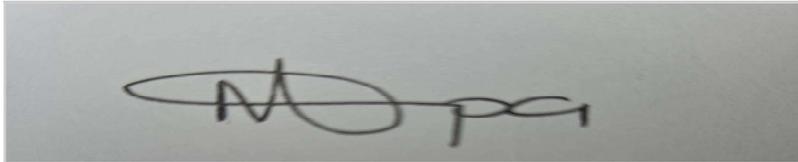
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S2100023712



SAHPRA Head Office  
Building A, Loftus Park  
2nd Floor  
Kirkness Str  
Arcadia  
0083





To: National Department of Health

CC: Head of Pharmaceutical Services  
Depot Managers  
District Managers  
Drug Controllers

From: Cipla Medpro South Africa (Pty) Ltd

Tel: 021 914 0520

Date: 17 March 2025

Re: RFQ for Section 21 Quotation: S21RFQ131 Bivalent Oral Polio Vaccine 3mL 20 Dropper Vial

Please find a Quote for:

Poliomyelitis Vaccine (Oral) Bivalent type 1 and 3 – 20 Dose Vial (With VVM) with Droppers – R87.10 including VAT at 15%, per vial.

QUOTE VALID UNTIL 30/11/2026.

Price is firm for validity period.

Stock can be delivered in bulk to South Africa upon placing of order within 13 Weeks. Shelf life is normally 24 months, stock offered will have at least 50% or better shelf life remaining at time of delivery.

Packaging is Serum Institute of India Pvt Ltd, standard UNICEF packaging.

The delivery of bOPV stocks is also subject to DCGL, Govt. of India approval.

Company Name: Cipla Medpro Manufacturing (Pty) Ltd  
Supplier number: MAAA1168386  
Security code: 2DED438B-80A9-457F-89CA-E570DF24BCD6  
Supplier Code (NDoH): VS2P5

Cipla Medpro Manufacturing (Pty) Ltd reserves the right to recall the validity of this quote if there are any errors and/or omissions in this quote as well as to decline additional orders if it is beyond the company's manufacturing capabilities or will cause unrealistic lead times upon consultation with the procuring authorities and manufacturer.

Regards

For and on behalf of

Willem Maritz  
Director - State Business.

Cell: 082 887 4926

e-mail: [willem.maritz@cipla.com](mailto:willem.maritz@cipla.com)

E&OE

Cipla Medpro Manufacturing (Pty) Ltd



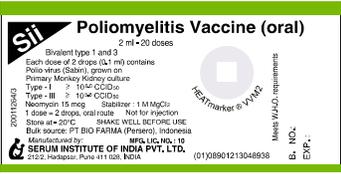
**Sii** **Poliomyelitis Vaccine (oral)**  
 2 ml - 20 doses  
 Bivalent type 1 and 3  
 Each dose of 2 drops (0.1 ml) contains  
 Polio virus (Sabin), grown on  
 Primary Monkey Kidney culture  
 Type - I  $\geq 10^{6.0}$  CCID<sub>50</sub>  
 Type - III  $\geq 10^{5.8}$  CCID<sub>50</sub>  
 Neomycin 15 mcg Stabilizer : 1 M MgCl<sub>2</sub>  
 1 dose = 2 drops, oral route Not for injection  
 Store at - 20°C SHAKE WELL BEFORE USE  
 Bulk source: PT BIO FARMA (Persero), Indonesia  
 Manufactured by: **SERUM INSTITUTE OF INDIA PVT. LTD.**  
 212/2, Hadapsar, Pune 411 028, INDIA  
 MFG. LIC. NO. : 10  
 (01)08901213048938

20011264/3

HEATmarker® VVM2

Meets W.H.O. requirements

B. NO. :  
 EXP. :



Reason for issue: Addition of "PVT." in Co. Name		Specification: Happa nylon block		
Customer: Exports - WHO		To be printed on chromo art paper 80 gsm with release paper of 62 gsm supplied in roll form.		
Product: <b>ORAL POLIO VACCINE - Bivalent</b> 2 ml -20 doses		Colour: Pantone 376 C and Black		
Item Code number: 20011264/3	Specification No.:	Artwork made to: 100%		
Supercedes Item Code: 20011264/2		Dimensions: 48 x 24 mm		
PACKAGING DEVELOPMENT	QUALITY CONTROL	REGULATORY AFFAIRS	MEDICAL DEPARTMENT	QUALITY ASSURANCE



