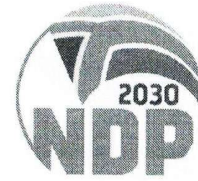




health

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 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 7th 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.

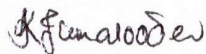
9. Note that this authorization DOES NOT cover supplies to the private sector.
10. Where this authorization is obtained to provide security of supply due to supply challenges from the contracted supplier, PAs are requested to buy out against contracted suppliers and ensure that related orders are cancelled accordingly to prevent overstocking 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 **11 January 2027**.

Table 1: Provincial estimates

Province	Six Months Estimate
DCS	0
EC-MT	13 020
EC-PE	
FS	6 900
GP	32 000
KZN	30 000
LP	16 000
MP	15 600
NC	5 000
NW	9 535
SAMHS	0
WC	16 000
Total	144 055

Yours sincerely



KHADIJA JAMALOODIEN

CHIEF DIRECTOR: HEALTH PRODUCTS PROCUREMENT

DATE: 13/7/2026

Section 21 Outcome Letter

2026-07-11

Ms Khadija Jamaloodien

National Department Of Health

Pretoria

buhle.mbongo@health.gov.za

Dear Ms Khadija Jamaloodien

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 **2026-07-03** refers

- A. STATUS: Approved**
- B. APPLICANT: Ms Khadija Jamaloodien**
- C. IMPORTING COMPANY: CIPLA LTD**
- D. NUMBER OF PATIENT/(S) INTENDED TO BE TREATED: 9**
- E. UNREGISTERED MEDICINES: GENERIC NAME: No Data**
- F. TRADE NAME: Poliomyelitis Vaccine (Oral) 0.2 ml**
- G. QUANTITY: 144000 Packs (9)**

H. LETTER NUMBER: S2100032872

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

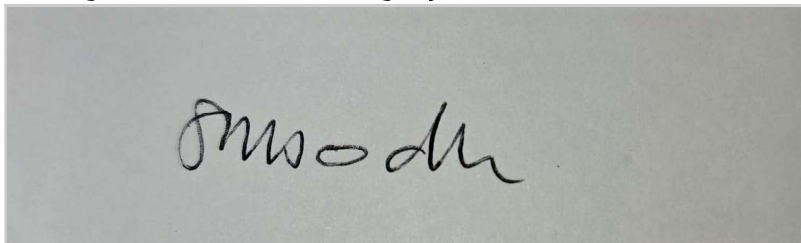
A progress report must be submitted once treatment is completed or on a reauthorization request

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

S2100032872



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

A rectangular box containing a handwritten signature in dark ink. The signature is stylized and appears to be a combination of letters, possibly 'M' and 'P'.



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

REQUEST FOR QUOTATION FORM

- Instruction to complete this Request for Quotation (RFQ)**
PLEASE PROVIDE A QUOTE FOR THE FOLLOWING PRODUCT(S).
PLEASE QUOTE ON THIS RFQ FORM AND ATTACH YOUR QUOTE WITH THE REQUESTED DETAILS.
THE SECTIONS HIGHLIGHTED IN YELLOW MUST BE COMPLETED BY THE SUPPLIER.
- THIS DOES NOT CONSTITUTE ANY OBLIGATION TO PROCURE THE ITEM AS THIS WILL BE SUBMITTED FOR CONSIDERATION TO PROVINCIAL PROCUREMENT UNITS TO SERVE AS A BUY OUT AGAINST CURRENT NON-COMPLIANT SUPPLIERS.**

ONLY RESPONSES FROM DULY REGISTERED SUPPLIERS WILL BE EVALUATED

REFERENCE NUMBER:	NORMAL		SECTION 21	X	S21RFQ178/2026
QUOTE ENQUIRY DATE	08/06/2026	QUOTE CLOSING DATE	15/06/2026		

FOR CRITICAL DELIVERY, DELIVERY REQUESTED ON/BEFORE
(SCM Practitioner to Specify if applicable)

REQUESTING INSTITUTION CONTACT DETAILS

NAME OF REQUESTOR	Buhle Mbongo				
EMAIL ADDRESS	Buhle.Mbongo@health.gov.za				
PHONE No.	066 261 4234	FAX No.	N/A		

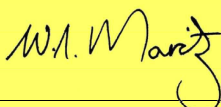
PRODUCT INFORMATION

DESCRIPTION PER MPC	Poliomyelitis Oral Bivalent Vaccine 20-Dose 2mL Vial		
TRADE DESCRIPTION	Poliomyelitis Vaccine (Oral) Bivalent type 1 and 3 – 20 Dose Vial (With VVM) with Droppers		
UNIT OF MEASURE	Vials	PACK or BOX (<u>SIZE/ QUANTITY</u>)	1 vial
QUANTITY REQUIRED	144 055		

TO BE COMPLETED BY THE SUPPLIER/ SERVICE PROVIDER

SUPPLIER CONTACT DETAILS (as per CSD)

DID YOU BID ITEM FOR TENDER	YES		NO	X	IF NO, WHY	<u>Not on tender</u>	
COMPANY NAME	Cipla Medpro Manufacturing (Pty) Ltd						
SUPPLIER NUMBER	MAAA1168386						
SECURITY CODE	2DED438B-80A9-457F-89CA-E570DF24BCD6						
SUPPLIER CODE (NDoH)	VS2P5						
CONTACT PERSON 1	NAME	Willem Maritz					
	PHONE	0113159150				FAX	
	MOBILE	0828874926					
	E-MAIL	Willem.maritz@cipla.com					
CONTACT PERSON 2	NAME						

	PHONE	
	MOBILE	
	E-MAIL	
<u>QUOTE DETAILS</u>		
PRICE PER UNIT (INCL. VAT)	R82.27	TOTAL PRICE (INCL. DELIVERY & VAT) R11851404.85
VOLUMES AVAILABLE – 14DAYS		
VOLUMES AVAILABLE – 21DAYS		
VOLUMES AVAILABLE – 28DAYS		
VOLUMES AVAILABLE – 35DAYS		
VOLUMES AVAILABLE – 42DAYS	144 055 from date of order, provided DCGI, Government of India permit issued in time.	
VOLUMES AVAILABLE – 49DAYS		
VOLUMES AVAILABLE – 56DAYS		
VOLUMES AVAILABLE – 112DAYS		
QUOTE VALIDITY PERIOD		
NORMAL LEAD/DELIVERY TIME		
<u>DEVIATION TO SPECIFICATION</u>		
<i>COMMENTS: Shipper of 50 vials with Droppers packed separately in shipper carton. Please order in multiples of 50 (one shipper carton) Additionally please note stock arrival in SA subject to NCL testing and SAHPRA approval, can take 4 to 8 weeks to complete.</i>		
<u>DECLARATION BY SUPPLIER</u>		
I hereby declare that in submitting this bid, there has been no consultation, communication, agreement or arrangement with any competitor/supplier regarding the price, quality, quantity, specifications and conditions or delivery particulars of the products or services to which this bid invitation relates.		
NAME	Willem Maritz	
CAPACITY	Director – State Business	
SIGNATURE (OF A DULY AUTHORISED REPRESENTATIVE OF THE SUPPLIER)	 Cipla Medpro Manufacturing (PTY) LTD Co Reg no: 2000/001167/07 VAT No: 4550264545 1474 South Coast Road Mobeni, 4052, KZN CSD supplier No: MAAA1168386 Supplier code: VS2P5 Unique registration reference number: 20EDM438B-80A9-457F-89CA-E570DF248CD6	
DATE	17 June 2026	
<u>PROVINCIAL ESTIMATES</u>		
Province	Six Months Estimate	
DCS	0	
EC-MT	13 020	
EC-PE		
FS	6 900	
GP	32 000	

KZN	30 000
LP	16 000
MP	15 600
NC	5 000
NW	9 535
SAMHS	0
WC	16 000
<i>Please submit quotations to Buhle.Mbongo@health.gov.za</i>	

Please ensure that you include the following as part of the Quotation:

- Delivery Time (Weeks)
- Price (Vat Inclusive)
- Generic Name
- Trade Name
- Quotation on Official Company Letterhead
- Central Supplier Database Summary Report (CSD)
- Medicine Registration Certificate (Only for Locally Registered Products)
- *Artwork/Labelling
- *Package Insert: (Please attach)
- *Manufacturer Certificate: (Please attach)
- *Country of Origin: (Please indicate)

*Additional items required when submitting a quote for a Section 21 Item (Unregistered Medicine)

All of the above is required to expedite the process in considering the quotation.

Please **SUBMIT COMPLETED RFQ FORM AND QUOTATIONS ON AN OFFICIAL COMPANY LETTERHEAD**

NB:

- The supplier submitting the quotation must be the same entity which the provinces will place their orders
- The size of each individual attachment must not be more than 2MB (you may attach multiple files in one email but collectively they should not be more than 2MB in size).
- Please ensure that you provide all prescribed documentation that is outlined on page two of this RFQ.
- The confirmation letter from manufacturer to Supply South Africa with Bivalent oral Poliomyelitis Vaccine (bOPV) must be provided (only in cases of Bivalent oral Poliomyelitis Vaccine RFQ)
- Kindly be advised that a picture format of an Artwork shall not be accepted. Artwork must be in pdf or word format only.
- All prices must please be submitted in two decimals and in ZAR.
- If submitting more than one quotation, please make sure that your subject line includes e.g., 1 of 2 or 1 of 3 etc.
- Any submission with missing documentation shall not be considered.
- Any submission with blurry relevant documents shall not be considered.
- The only electronic GMP Certificate considered is that from EUDRA
- CSD must be updated for the current month of the RFQ date.
- **Email subject line for responses with quotes must be kept unchanged from the originally sent RFQ email.**

Please **SUBMIT COMPLETED RFQ FORM AND QUOTATIONS ON AN OFFICIAL COMPANY LETTERHEAD**



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 June 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 – R82.27 including VAT at 15%, per vial.

Base line exchange rate used is calculated as R16.56 vs 1 USD. As per reserve bank published official rates for period 17 May 2026 until 17 June 2026 (3 month average)

QUOTE VALID UNTIL 30/10/2026.

Price is firm for validity period.

Stock can be delivered in bulk to South Africa upon placing of order with supplier within 6 Weeks. Shelf life is normally 24 months, stock offered will have at least 50% or better shelf life remaining at time of delivery.

Please note upon arrival of stock in South Africa stock is still subject to testing and approval of NCL and SAHPRA that can take additional 4 to 8 weeks.

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

The delivery of bOPV stocks is also subject to DCGI, Govt. of India approval which can add to the lead time to ship stock to SA if permit is delayed.

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

E&OE

Cipla Medpro Manufacturing (Pty) Ltd

Cipla Medpro Manufacturing (PTY) LTD
Co Reg no: 2000/001167/07
VAT No: 4550264545
1474 South Coast Road
Mobeni, 4052, KZN
CSD supplier No: MAAA1168386
Supplier code: VS2P5
Unique registration reference number:
2DED438B-80A9-457F-89CA-E570DF24BCD6

Cipla Medpro Distribution Centre (Pty) Ltd, 6 Rivergate Road, Rivergate Industrial Park, Parklands, 7441, RSA T +27 21 556 6997 F +27 21 556 1872 Ltd. Co. Reg. No. 1995/004005/07.
Cipla Medpro South Africa (Pty) Ltd, 1474 South Coast Road, Mobeni, 4052, RSA T +27 31 451 3800 F +27 31 451 3889 Co. Reg. No. 2002/018027/07.
Cipla Medpro Manufacturing (Pty) Ltd, 1474 South Coast Road, Mobeni, 4052, RSA T +27 31 451 3800 F +27 31 451 3889 Co. Reg. No. 2000/001167/07.
Mirren (Pty) Ltd, 18 Golden Drive, Morehill, Benoni, 1511, RSA T +27 11 425 4026 F +27 11 425 4009 Reg. No. 1983/001128/07.

SII **Poliomyelitis Vaccine (oral)**
2 ml - 20 doses

2 ml - 20 doses

Bivalent Type 1 and 3

Each dose of 2 drops (0.1 ml) contains Polio virus (Sabin), grown on vero cells

Type - I $\geq 10^{6.0}$ CCID₅₀

Type - III $\geq 10^{5.8}$ CCID₅₀

1 dose = 2 drops, oral route

Store at - 20°C. Not for injection.

Bulk source: Bilthoven Biologicals, The Netherlands.

Manufactured by:

SERUM INSTITUTE OF INDIA PVT. LTD.

Hadapsar, Pune 411 028, INDIA

20

20 doses



Meets W.H.O. requirements.

20021324/01

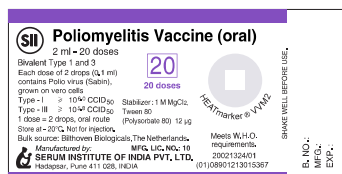
(01)08901213015367

SHAKE WELL BEFORE USE.

B. NO.:

MFG.:

EXP.:



File Name: E:\Artworks NL\Hadapsar\Export\Polio\BBIO\BBIO - Bivalent 10 & 20 dose-NL.cdr

Date: 19.01.2026



Corporate Plant
Format

Title	Artwork Format		
Format No.	2002-0001-F0003-002		
Effective Date	30/07/2024	Page No.	1 of 1

SII

Poliomyelitis Vaccine (oral) Bivalent Type 1 and 3
Vacuna Antipoliomielítica (oral) Bivalente Tipo 1 y 3
Vaccin Poliomyélique (oral) Bivalent Type 1 et 3

50 x 20 Dose / Dosis Vials / Frascos / Flacons
2 drops/gotas/gouttes (0.1 ml / 0.1 ml) / Dose / Dosis Oral
Not for injection / No es para inyección / Pas destiné à l'injection
Store / Conservar / Conserve at / a / à -20°C
Bulk source: Bilthoven Biologicals, The Netherlands.
Fuente a granel: Bilthoven Biológicos B.V., Bilthoven, Los Países Bajos.
Source du vrac: Bilthoven Biologicals B.V., Bilthoven, Les Pays-Bas.
Meets W.H.O. requirements / Cumple con los requisitos de la O.M.S.
Conforme aux exigences de l'O.M.S.

Manufactured by / Fabricada por / Fabriqué par :
SERUM INSTITUTE OF INDIA PVT. LTD.
S, Nos, 203-205, 212, 223, 268-270 (H) & 104-110,
113-114, 168-170 (M), Hadapsar, Pune 411 028, INDIA

MFG. LIC. NO. : 10 /
NUM DE MATRICULA DE FABR : 10 /
NOM DE FABR : 10

20021318/01

B. NO./LOTE/LOT:
MFG./FABR.:
EXP.:

Unvarnished area for
batch details overprinting
100 x 29 mm

Reason for issue: SII address updated		Specification: Self adhesive label (Auto - Clavable) Printed on 45 gsm bi-axially oriented, glossy clear polypropylene film with a print - receptive coating and release paper of 62 gsm supplied in roll form. White background required on complete label.		
Customer: Export 50 x 2 ml -20 doses				
Product: Poliomyelitis Vaccine (oral) - Bivalent Name (Bulk source: Bilthoven Biologicals, The Netherlands)		Colour: Pantone 2665 C and Black		
Item Code number: 20021318/01		Specification No.:		Artwork made to: 100%
Supersedes Item Code:20021318/0			Dimensions: 100 x 90 mm	
Prepared By	Reviewed By	Approved By		Authorized By
PACKAGING DEVELOPMENT	QUALITY CONTROL	REGULATORY AFFAIRS	CLINICAL RESEARCH & PHARMACOVIGILANCE	QUALITY ASSURANCE



SERUM INSTITUTE OF INDIA PVT. LTD.

Cyrus Poonawalla Group

**Corporate Plant
Format**

Title	Artwork Format		
Format No.	2002-0001-F0003-002		
Effective Date	30/07/2024	Page No.	1 of 1

Poliomyelitis Vaccine (oral) Bivalent Type 1 and 3
Vacuna Antipoliomielítica (oral) Bivalente Tipo 1 y 3
Vaccin Poliomyélique (oral) Bivalent Type 1 et 3

6 x 50 x 20 Dose / Dosis Vials / Frascos / Flacons
2 drops/gotas/gouttes (0,1 ml / 0,1 ml) / Dose / Dosis Oral
Not for injection / No es para inyección / Pas destiné à l'injection
Store / Conservar / Conserve at / a / à -20°C
Bulk source: Bilthoven Biologicals, The Netherlands.
Fuente a granel: Bilthoven Biológicos B.V., Bilthoven, Los Países Bajos.
Source du vrac: Bilthoven Biologicals B.V., Bilthoven, Les Pays-Bas.
Meets W.H.O. requirements / Cumple con los requisitos de la O.M.S.
Conforme aux exigences de l'O.M.S.

Manufactured by / Fabricada por / Fabriqué par :
SERUM INSTITUTE OF INDIA PVT. LTD.
S. Nos. 203-205, 212, 223, 268-270 (H) & 104-110,
113-114, 168-170 (M), Hadapsar, Pune 411 028, INDIA

MFG. LIC. NO. : 10 /
NUM DE MATRICULA DE FABR : 10 /
NOM DE FABR : 10

20

20021317/01

B. NO./LOTE/LOT:
MFG./FABR.:
EXP.:

Unvarnished area for
batch details overprinting
140 x 27 mm

Reason for issue: SII address updated		Specification: Self adhesive label (Auto - Clavable) Printed on 45 gsm bi-axially oriented, glossy clear polypropylene film with a print - receptive coating and release paper of 62 gsm supplied in roll form. White background required on complete label.		
Customer: Export 6 x 50 x 2 ml -20 doses				
Product: Poliomyelitis Vaccine (oral) - Bivalent Name (Bulk source: Bilthoven Biologicals, The Netherlands)		Colour: Pantone 2665 C and Black		
Item Code number: 20021317/01		Specification No.:		Artwork made to: 100%
Supersedes Item Code:20021317/0			Dimensions: 140 x 90 mm	
Prepared By	Reviewed By	Approved By		Authorized By
PACKAGING DEVELOPMENT	QUALITY CONTROL	REGULATORY AFFAIRS	CLINICAL RESEARCH & PHARMACOVIGILANCE	QUALITY ASSURANCE

File Name: E:\Artworks NL\Hadapsar\Export\Polio\BBIO\BBIO - Bivalent 10 & 20 dose-NL.cdr

Date: 19.01.2026

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