



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

Mr T Mohan
UniPharmaceuticals (Pty) Ltd
Blue Valley Centre
Coatbridge Road
Kosmosdal
Centurion

Dear Mr Mohan

Section 21 Authorization for DIPHTHERIA ANTITOXIN 10 000IU INJ 10ML

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

- **Diphtheria Antitoxin 10 000IU Injection 10mL**

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.

Section 21 Authorisation re Diphtheria Antitoxin 10 000IU INJ 10mL 06112025-1

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 **06 May 2026**.

Table 1: Provincial estimates

Province	Six Months Estimate
Correctional Services	0
EC-MT	0
EC-PE	0
FS	0
GP	0
KZN	0
LP	30
MP	60
NC	0
NW	0
SAMHS	0
WC	800
Total	890

Yours sincerely



KHADIJA JAMALOODIEN
CHIEF DIRECTOR: SECTOR WIDE PROCUREMENT
DATE: 06-11-2025

Section 21 Outcome Letter

2025-11-06

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 **2025-11-05** refers

- A. STATUS: Approved**
- B. APPLICANT: Ms Buhle Mbongo**
- C. IMPORTING COMPANY: Unipharmaceuticals (Pty) Ltd**
- D. NUMBER OF PATIENT/(S) INTENDED TO BE TREATED: 89**
- E. UNREGISTERED MEDICINES: GENERIC NAME: No Data**
- F. TRADE NAME: Diphtheria Antitoxin BP 10000 IU**
- G. QUANTITY: 890 Packs (1)**

H. LETTER NUMBER: S2100015327

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

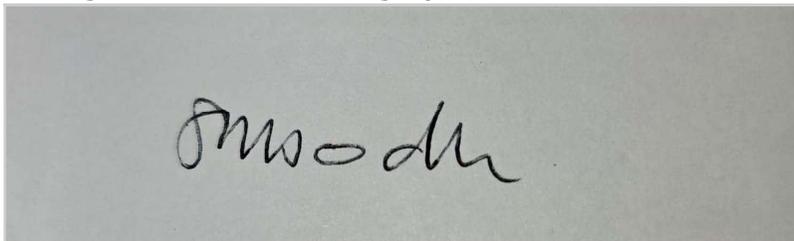
A progress report must be submitted once treatment is completed or on a reauthorization request

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.

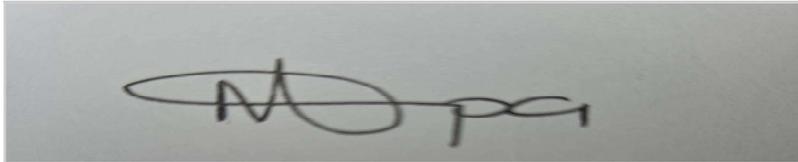
Ms Mahlodi Moropa

Final Approver

S2100015327



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





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	S21RFQ164
QUOTE ENQUIRY DATE	16/10/2025	QUOTE CLOSING DATE	27/10/2025		
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.	012 395 9539	FAX No.	N/A		

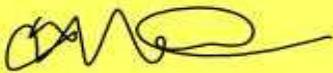
PRODUCT INFORMATION

DESCRIPTION PER MPC	DIPHTHERIA ANTITOXIN 10 000IU INJ 10ML				
TRADE DESCRIPTION	DIPHTHERIA ANTITOXIN B.P.				
UNIT OF MEASURE	1 vial	PACK or BOX (SIZE/ QUANTITY)	1 vial		
QUANTITY REQUIRED	890 vials				

TO BE COMPLETED BY THE SUPPLIER/ SERVICE PROVIDER

SUPPLIER CONTACT DETAILS (as per CSD)

COMPANY NAME	Unipharmaceuticals (PTY) Ltd				
SUPPLIER NUMBER	MAAA1624631				
SECURITY CODE	AE09309D-3649-4037-86D7-DF380CB5B171				
SUPPLIER CODE (NDoH)					
CONTACT PERSON 1	NAME	Mr Theren Mohan			
	PHONE	011 3182110	FAX		
	MOBILE	0724362055			
	E-MAIL	therenm@unipharmaceuticals.co.za			
CONTACT PERSON 2	NAME	Mrs Preeta Jekison			
	PHONE	011 318 2110			

	MOBILE	0822920021	
	E-MAIL	pharmacist@unipharmaceuticals.co.za	
<u>QUOTE DETAILS</u>			
PRICE PER VIAL (INCL. VAT)	R 644.00	TOTAL PRICE (INCL. DELIVERY & VAT)	R573,160.00
*STOCK'S EXPIRY DATE(SHELF-LIFE)	20 – 22 months		
VOLUMES AVAILABLE – 7DAYS			
VOLUMES AVAILABLE – 14DAYS			
VOLUMES AVAILABLE – 21DAYS			
VOLUMES AVAILABLE – 28DAYS			
VOLUMES AVAILABLE – 35DAYS			
VOLUMES AVAILABLE - 42DAYS			
VOLUMES AVAILABLE – 49DAYS			
VOLUMES AVAILABLE – 56DAYS	8 Weeks		
VOLUMES AVAILABLE – 112DAYS			
QUOTE VALIDITY PERIOD	30 Days		
NORMAL LEAD/DELIVERY TIME	8 Weeks		
<u>DEVIATION TO SPECIFICATION</u>			
<i>COMMENTS:</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	Mr Theren Mohan		
CAPACITY	Head of Pharma		
SIGNATURE (OF A DULY AUTHORISED REPRESENTATIVE OF THE SUPPLIER)			
DATE	27 th October 2025		
<i>Please submit quotations to Section21Quotes@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
- Central Supplier Database Summary Report (CSD), updated for the current month
- 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 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 with 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 form.
- The confirmation letter from manufacturer to supply South Africa with Bivalent Oral Poliomyelitis Vaccine (bOPV) must be provided (in cases of a bOPV RFQ).
- Kindly be advised that a picture format of an Artwork shall not be accepted. Artwork must be in a 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 required documentation shall not be considered.
- Any submission with blurry required 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.**

SUBMIT BOTH COMPLETED RFQ FORM AND QUOTATION (ON AN OFFICIAL COMPANY LETTERHEAD)

National Department of Health
Attention: Ms. Buhle Mbongo
Email: Section21Quotes@health.gov.za
Tel: 012 395 9539

24th October 2025

Re: Response to Diphtheria Antitoxin 10 000IU - S21RFQ164

Dear Buhle Mbongo

We trust this email finds you well. Please find below & attached Unipharmaceuticals offer, with a supplier code of **MAAA1624631**, response for **Diphtheria Antitoxin 10 000IU - S21RFQ164** to be supplied under section 21 terms to the National Department of Health, in South Africa (SA).

Product Details:

- Generic Name: **Diphtheria Antitoxin 10 000IU**
- Trade Name: **Diphtheria Antitoxin 10 000IU**
- Product Dosing: **10 000IU** (refer to package insert)
- Country of Origin: **India** (refer to PICS GMP)
- Manufacturer: **Vins Biologics** (refer to letter)
- **Total Quantity Offered:** 890 Vials in Total, with a **delivery time 8 Weeks landed in SA.**
- Packed in Box of 5 Vials per inner box.

Price per Amp delivered to Provincial Pharmaceutical Depots in SA:

Unit Price (1 Vial) Ex Vat	R560.00
Unit Price (1 Vial) Including Vat	R644.00
Total Vials	890
Total Price 890 Vials ex vat	R498,400.00
Vat	R74,760.00
Total Price 890 Vials Including Vat	R573,160.00

Please find attached the following documentation:

- Unipharmaceuticals Quote / Offer & Section 21 Completed form
- Artwork, Labelling & Package Insert
- Manufacturer Certificate

We look forward to your response and please feel free to reach out should you have any questions.

Kind regards



Mr. Theren Mohan
Head of Unipharmaceuticals (Pty) Ltd

Unipharmaceuticals (Pty) Ltd



Registration No:2020/566329/07 | Vat: 4470295637
Office A4, 1st Floor, Blue Valley Centre, Coatbridge Road, Kosmosdal, Centurion, 0157, South Africa
Tel: +27 (0) 11 318 2110 | Fax: +27 (0) 11 318 2965 | E: pharmacist@unipharmaceuticals.co.za
Directors: Z Hansa & T Mohan

Into Africa- for Africa- by Africans -who understand the African landscape

For the Medical Profession

DIPHTHERIA ANTITOXIN 10000 I.U. I.P./B.P. 10 mL

Composition:

Each mL contains:
Enzyme refined, Equine Diphtheria antitoxic immunoglobulin fragments not less than 1000 I.U.
Preservative : Cresol I.P./B.P. ≤ 0.25% v/v
Excipients : Sodium Chloride I.P./B.P.
Stabilizer : Glycine I.P./B.P.

Description:

Diphtheria antitoxin is prepared by hyperimmunising Equines with diphtheria toxin/toxoid. Plasma obtained from hyperimmunised Equines which is rich in antibodies to diphtheria toxin is enzyme refined, purified and concentrated. The antitoxin has specific capacity of neutralizing toxin secreted by *Corynebacterium diphtheriae*, the causative organism of diphtheria.

Pharmacodynamic/Pharmacokinetics

Not applicable.

Use in prophylaxis:

The use of diphtheria antitoxin is not recommended for prophylaxis as its protective effect is of short duration (1 to 2 weeks only) and furthermore, it may cause sensitization to horse sera. Instead, the contacts of diphtheria patients should receive a dose (0.5 mL) of adsorbed diphtheria vaccine (Diphtheria vaccine, adsorbed PTAP), or adsorbed diphtheria - tetanus vaccine, (D-T vaccine adsorbed PTAP, which protects against both diphtheria and tetanus) and followed after 1 to 2 months with the second dose. Prophylaxis with diphtheria vaccine gives protection for many years and is practically free from reaction.

Use in treatment:

A dose of 10,000 to 30,000 I.U. of diphtheria antitoxin may be injected intramuscularly in mild to moderately severe cases of diphtheria and upto a maximum of 100,000 I.U. in severe cases after testing serum sensitivity (see below for reactions to horse serum). I.V. route is the preferred route of administration in severe cases. In that case Diphtheria Antitoxin is mixed in 250 to 500 mL of normal saline and administered over 2-4 hours. In addition, antibiotics & corticosteroids may be administered. It is advised that after recovery from diphtheria, patients should be actively immunised for long term protection by the use of two doses at an interval of 1 to 2 months with adsorbed diphtheria vaccine or with adsorbed diphtheria - tetanus vaccine.

Reactions to Equine serum:

Injection of diphtheria antitoxin in horse-serum-sensitive individuals can produce immediate reaction of acute anaphylaxis which could sometimes be fatal unless immediately countered by

injecting 1 mL of 1:1000 adrenaline intramuscularly. Every care should be taken to prevent this reaction. Before injection of diphtheria antitoxin, it is necessary to enquire from the patient (1) whether he/she has had injections of any serum before, (2) whether there is personal or family history of allergy i.e. asthma, eczema or drug allergy. The sensitivity of the patient to serum is tested by injecting subcutaneously 0.1 mL of diphtheria antitoxin diluted 1:10 and the patient is observed for 30 minutes for local and general reactions. If the test dose shows either local reaction such as wheal and flare or general anaphylactic reaction such as pallor, sweating, nausea, vomiting, urticaria or fall of blood pressure these should be treated with 1 mL of 1:1000 adrenaline (which should always be kept handy) before injecting the main dose of diphtheria antitoxin. Half the dose of adrenaline may be repeated 15 minutes later if necessary.

Dosage and Administration:

In allergic individuals Diphtheria antitoxin is to be injected 15 to 30 min. after administration of antihistamines such as injectable pheniramine maleate and injectable hydrocortisone intramuscularly. One mL of adrenaline (1:1000) may be injected intramuscularly at the same time as the antiserum. Administration of hydrocortisone or adrenaline may be repeated if necessary.

Adverse Effects:

In some cases symptoms such as itching, urticaria rash, pains in joints and muscles, fever, enlargement of lymph glands appear 7-12 days after the injection of diphtheria antitoxin. These should be treated with antihistamines and corticosteroids. Usually these symptoms of serum sickness last a few days and the patients recover without any complications.

Storage: Store at a temperature between 2°C to 8°C in a refrigerator. Do not freeze.

Presentation: Vials containing 10000 I.U. (10 mL).

Shelf Life: Two years from the date of manufacturing.

Disposal: Left over Diphtheria Antitoxin 10000 I.U. and used empty vials should be discarded as biomedical waste.

Manufactured by:



VINS BIOPRODUCTS LIMITED

Survey No: 117, Thimmapur (V), Kothur (Mandal),
Rangareddy (Dist.), Telangana, India - 509325

Code: 130202061 A.W.No: 14/AAW/PI/01.01 DT: 13.10.2017

Size = 110 x 140 mm

Label

DIPHTHERIA ANTITOXIN B.P. Mfg. Lic. No.: 01/MN/AP/03/Sera/G

10 mL (Therapeutic - 10,000 I.U.) Single Dose

Each mL contains:
 Enzyme refined, Equine Diphtheria antitoxic immunoglobulin fragments not less than 1000 I.U.
 Preservative : Cresol B.P. ≤ 0.25% w/v
 Excipients : Sodium Chloride B.P.
 Stabilizer : Glycine B.P.
 For Intramuscular Use Only. Refer package insert for dosage.
 Store between 2°C to 8°C. Do not freeze.

Manufactured by:
 **VINS BIOPRODUCTS LIMITED**
 Survey No. 117, Thimmapur (V), Kothur (Mandal),
 Rangareddy (Dist.), Telangana, India - 508325

Warning: To be sold/used on the prescription of a Registered Medical Practitioner only.

CANC 13021903
A/1/Net 1/18/10/0101

Size: 70x30mm

- Pantone 2607 C
- Pantone 803 C
- Cyan
- Black

Mono Carton

Size: 85(L)x(30)x55(H)mm

DIPHTHERIA ANTITOXIN B.P.

(Therapeutic - 10,000 I.U.)

Single Dose

10 mL

Each mL contains:
 Enzyme refined, Equine Diphtheria antitoxic immunoglobulin fragments not less than 1000 I.U.
 Preservative: Cresol B.P. ≤ 0.25% w/v
 Excipients : Sodium Chloride B.P.
 Stabilizer : Glycine B.P.
 For Intramuscular Use Only. Refer package insert for dosage.
 Store between 2°C to 8°C. Do not freeze.

Warning: To be sold/used on the prescription of a Registered Medical Practitioner only.

DIPHTHERIA ANTITOXIN B.P.
 (Therapeutic - 10,000 I.U.)

Single Dose

10 mL

Manufactured by:
 **VINS BIOPRODUCTS LIMITED**
 Survey No. 117, Thimmapur (V), Kothur (Mandal),
 Rangareddy (Dist.), Telangana, India - 508325

Mfg. Lic. No.: 01/MN/AP/03/Sera/G
 Batch No.:
 Mfg. Date:
 Exp. Date:

CANC 13021903
A/1/Net 1/18/10/0101

CANC 13021903
A/1/Net 1/18/10/0101

- Pantone 2607 C
- Pantone 485 C
- Gold Foil
- Cyan
- Black



DIPHTHERIA ANTITOXIN B.P.

(Therapeutic - 10,000 I.U.)

Single Dose

10 mL

10 UFL



Manufactured by
VINS BIOPRODUCTS LIMITED
Survey No. 117, Tempapur (V), Kothur (Mandali),
Rangireddy (Dist.), Telangana, India - 508325

Manufactured under license under approval
issued by the Government of India
VINS BIOPRODUCTS LIMITED