



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 E van Zyl
Equity Pharmaceuticals (Pty) Ltd
100 Sovereign Road
Route 21 Corporate Park
Nellmapius Drive
Irene
Pretoria

Dear Mr van Zyl

Section 21 Authorization for ATROPINE 100MG/10ML INJECTION 10ML

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

- **Atropine 100mg/10mL 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.

Department of Health • Lefapha la Pholo • Lefapha la Bophelo • uMnyango wezeMpilo • Muhasho wa Mutakalo • Departement van Gesondheid • Kgoro ya Maphelo • Ndzawulo ya Rihanyo • LiTiko le Thempilo • ISebe lezeMpilo • UmNyango WezamaPhilo

Batho Pele - putting people first

Section 21 Authorisation re Atropine 100mg/10mL INJ 12032026-1

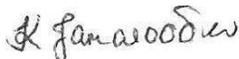
8. The full quantities imported in terms of this Section 21 authorisation must be accounted for.
9. Note that this authorization DOES NOT cover supplies to the private sector.
10. Where this authorization is obtained to provide security of supply due to supply challenges from the contracted supplier, 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 **05 September 2026**.

Table 1: Provincial estimates

Province	Six Months Estimate
DCS	0
EC-MT	6 000
EC-PE	300
FS	2 500
GP	10 000
KZN	50
LP	0
MP	40
NC	0
NW	270
SAMHS	2 000
WC	0
Total	21 160

Yours sincerely



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

Section 21 Outcome Letter

2026-03-05

Ms Buhle Mbongo

100 Sovereign Drive

Centurion

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 **2026-03-03** refers

- A. STATUS: Approved**
- B. APPLICANT: Ms Buhle Mbongo**
- C. IMPORTING COMPANY: EQUITY PHARMACEUTICAL (PTY) LTD**
- D. NUMBER OF PATIENT/(S) INTENDED TO BE TREATED: 5000**
- E. UNREGISTERED MEDICINES: GENERIC NAME: No Data**
- F. TRADE NAME: Atropine Injection BP 10 mg/mL**
- G. QUANTITY: 20000 Packs (1)**

H. LETTER NUMBER: S2100023366

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

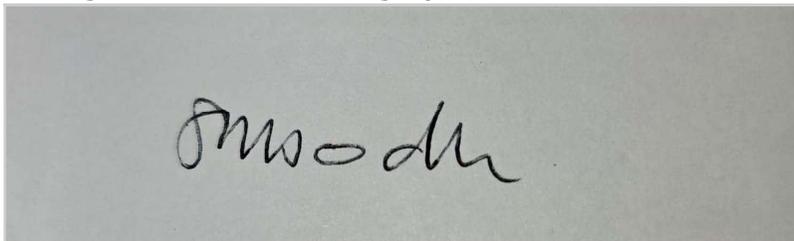
A progress report must be submitted once treatment is completed or on a reauthorization request

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.

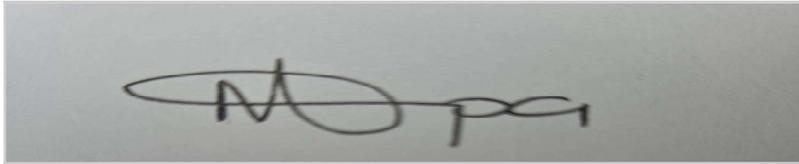
Ms Mahlodi Moropa

Final Approver

S2100023366



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				
<ul style="list-style-type: none"> 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. IT MAY ALSO 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	S21RFQ167
QUOTE ENQUIRY DATE	03/02/2026	QUOTE CLOSING DATE	12/02/2026	
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.	012 395 9539	FAX No.	N/A	
PRODUCT INFORMATION				
DESCRIPTION PER MPC	ATROPINE 100MG/10ML INJ 10ML			
TRADE DESCRIPTION	Atropine 100mg/10ML INJ 10ML			
UNIT OF MEASURE	1	PACK or BOX (SIZE/ QUANTITY)	1	
QUANTITY REQUIRED	20 000 vials/ampoules			
TO BE COMPLETED BY THE SUPPLIER/ SERVICE PROVIDER				
SUPPLIER CONTACT DETAILS (as per CSD)				
COMPANY NAME	Equity Pharmaceuticals (Pty) Ltd			
SUPPLIER NUMBER	MAAA0007480			
SUPPLIER CODE (NDoH)				
CONTACT PERSON 1	NAME	Ehrard van Zyl		
	PHONE	0123451747	FAX	0123451412
	MOBILE	0720408511		
	E-MAIL	ehrd@equitypharma.co.za		
CONTACT PERSON 2	NAME	Hannes Strydom		
	PHONE	0123451747		
	MOBILE	0826161954		

	E-MAIL	hannes@equitypharma.co.za	
<u>QUOTE DETAILS</u>			
PRICE PER VIAL (INCL. VAT)	R 21.62	TOTAL PRICE (INCL. DELIVERY & VAT)	R 432 400.00
*STOCK'S EXPIRY DATE(SHELF-LIFE)	24 months		
VOLUMES AVAILABLE – 7DAYS			
VOLUMES AVAILABLE – 14DAYS			
VOLUMES AVAILABLE – 21DAYS			
VOLUMES AVAILABLE – 28DAYS	20 000		
VOLUMES AVAILABLE – 35DAYS			
VOLUMES AVAILABLE - 42DAYS			
VOLUMES AVAILABLE – 49DAYS			
VOLUMES AVAILABLE – 56DAYS			
VOLUMES AVAILABLE – 112DAYS			
QUOTE VALIDITY PERIOD	180 days		
NORMAL LEAD/DELIVERY TIME	3 days		
<u>DEVIATION TO SPECIFICATION</u>			
COMMENTS: N/A			
<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	Ehrard van Zyl		
CAPACITY	Business Unit Manager: Specialist Medicine		
SIGNATURE (OF A DULY AUTHORISED REPRESENTATIVE OF THE SUPPLIER)			
DATE	12/02/2026		
<u>PROVINCIAL ESTIMATES</u>			
Province	Six Months Estimate		
DCS	0		
EC-MT	6 000		
EC-PE	300		
FS	2 500		
GP	10 000		
KZN	50		
LP	0		
MP	40		
NC	0		
NW	270		
SAMHS	2 000		
WC	0		

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), 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 of reviewing 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 (*only in cases of a Bivalent Oral Poliomyelitis Vaccine 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



12/02/2026

National Department of Health
Directorate: Affordable Medicines
E-mail: Section21Quotes@health.gov.za
Attention: Ms Buhle Mbongo

Equity Pharmaceuticals (Pty) Ltd.
1997/009942/07

+27 12 345 1747
+27 12 345 1412
equity@equitypharma.co.za

www.clinigengroup.com
www.equitypharma.co.za

Dear Ms Mbongo

Re: Request for quotation – Atropine 100mg/10ml INJ 10ML – Section 21 Supply

Trust you are well. Please find below our quotation for Atropine sulphate 10mg/ml supplied under section 21 terms.

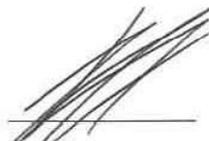
- Quantity: **20 000 vials**
- Delivery Time (Weeks): **5 weeks**
- Price (Vat Inclusive): **R 21.62 incl. vat per vial**
- Generic Name: **Atropine sulphate 10mg/ml**
- Trade Name: **Atropine 100MG/10ML INJ 10ML**
- Packaging: **1 x 10ml**
- Specifications: **10mg/ml (10ml)**
- Shelf Life: **24 months**
- Package Insert: **Please find attached**
- Manufacturer: **Kwality Pharmaceuticals Ltd.**
- Country of Origin: **India**

Please note that the immediate availability of the product is conditioned on the manufacturer receiving notice of our order as soon as possible. Unfortunately, the stock cannot be reserved for our purposes for too long.

We look forward to your response.

Please contact me if you require any additional information.

Kind Regards



Ehrhard van Zyl

12/02/2026



Equity Pharmaceuticals (Pty) Ltd.
1997/009942/07

+27 12 345 1747
+27 12 345 1412
equity@equitypharma.co.za

www.clinigengroup.com
www.equitypharma.co.za

QUOTATION # 20260212

TO: National Department of Health

TEL : 012 395 9539

FAX :

Email : Section21Quotes@health.gov.za

CONTACT PERSON / PATIENT : Buhle Mbongo

NB IMPORTED AND SUPPLIED UNDER SECTION 21 TERMS

PRODUCT CODE	DESCRIPTION	PACK SIZE	QUANTITY	PRICE EXCL	TOTAL INCL
	Atropine 100mg/10ml	1 x 10ml	1	R 18.80	R 21.62
			20 000	R 376 000.00	R 432 400.00
			20 000	R 376 000.00	R 432 400.00

Valid for 180 days

Employee Signature: _____

Date: 12/02/2026

Approved by: Ehrard van Zyl / Jaco Schoeman

ATROPINE INJECTION BP

100 mg / 10 ml

Each ml contains:
Atropine Sulfate BP 10 mg

For Intravenous / Intramuscular Use
Sterile Solution

COMPOSITION ...

Each ml Sulfate BP 10 mg
10mg; Water for Injection BP q.s.



WARNING

- Prescription Medicine
- Use n for medical supervision
- Discard unused portion
- Do not use if solution is cloudy



Kwality Pharmaceuticals Limited
Nag Glam, Majitha Road, Amritsar - India



100 ml

ATROPINE INJECTION BP,

100 mg / 10 ml

Each ml contains / Atropine Sulfate BP 10 mg

For IV / IM Use

Sterile

Each 10 ml 10 ml
10 ml 10 ml

Kwality Pharmaceuticals Ltd. - India

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Atropine Injection BP 10 mg/ml (100 mg/10 ml)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains Atropine Sulfate BP 10 mg. Each 10 ml vial contains 100 mg Atropine Sulfate BP. Excipients: Water for Injection BP.

3. PHARMACEUTICAL FORM

Sterile, clear, colourless solution for injection.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Pre-anaesthetic medication, symptomatic bradycardia, antidote in organophosphate poisoning, muscarinic mushroom poisoning.

4.2 Posology and method of administration

Dose individualised. Adults: 0.5 mg IV every 3–5 minutes (max 3 mg). Routes: IV, IM, SC.

4.3 Contraindications

Hypersensitivity, narrow-angle glaucoma, urinary retention, severe ulcerative colitis.

4.4 Special warnings and precautions

Use with caution in elderly and cardiac patients. Monitor closely.

4.8 Undesirable effects

Dry mouth, blurred vision, tachycardia, constipation, urinary retention.

4.9 Overdose

Hyperthermia, delirium, severe tachycardia. Supportive treatment.

5. PHARMACOLOGICAL PROPERTIES

Anticholinergic agent blocking muscarinic receptors.

6. PHARMACEUTICAL PARTICULARS

Excipients: Water for Injection BP. Shelf life: 36 months. Store below 30°C. Protect from light. 10 ml glass vial, single use.

7. MANUFACTURER

Kwality Pharmaceuticals Limited, Nag Kalan, Majitha Road, Amritsar, Punjab – India. Manufacturing Licence No.: 1800-OSP.

8. DATE OF REVISION

12 February 2026