health
Department:
Health
REPUBLIC OF SOUTH AFRICA

Private Bag X828, PRETORIA, 0001 Dr AB Xuma Building1112 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 Extension Authorization for ATROPINE 100MG INJECTION

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

- **Atropine 100mg Injection**

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 21authorisation 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 **06 February 2027**.

Table 1: Provincial uptake

Province	Six Months Estimate	Uptake
Correctional Services	0	0
EC-MT	6 000	0
EC-PE	300	
FS	2 500	100
GP	10 000	6 530
KZN	50	0
LP	0	0
MP	40	0
NC	0	0
NW	270	0
SAMHS	2 000	0
WC	0	0
Total	**21 160**	**6 630**

Yours sincerely

K Jamaloodien

KHADIJA JAMALOODIEN
CHIEF DIRECTOR: HEALTH PRODUCTS PROCUREMENT
DATE: 01/09/2026

S2100036347

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

Section 21 Outcome Letter

2026-09-01

Ms Khadija Jamaloodien

1112, Voortrekker Road, Pretoria Townlands 351-Jr, Pretoria, Gauteng, South Africa, 0187

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 **2026-08-26** refers

A. STATUS: Approved

B. APPLICANT: Ms Khadija Jamaloodien

C. IMPORTING COMPANY: EQUITY PHARMACEUTICAL (PTY) LTD

D. NUMBER OF PATIENT/(S) INTENDED TO BE TREATED: 1

E. UNREGISTERED MEDICINES: GENERIC NAME (INN / ACTIVE INGREDIENT): Atropine sulfate

F. TRADE NAME: Atropine 100 mg

G. QUANTITY: 13440 Packs (2)

SAHPRA
South African
Health Products
Regulatory Authority

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

H. LETTER NUMBER: S2100036347

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

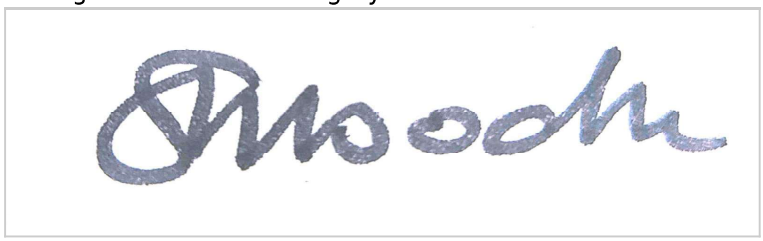
Comments:

No Data

Yours faithfully,

Shyamli Munbodh

Manager: Section 21 Category A Medicines



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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. 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	**ehrard@equitypharma.co.za**		
CONTACT PERSON 2	NAME	**Hannes Strydom**		
	PHONE	**0123451747**		
	MOBILE	*0826161954*		

	E-MAIL	**hannes@equitypharma.co.za**	
QUOTE DETAILS			
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		
DEVIATION TO SPECIFICATION			
COMMENTS: N/A			
DECLARATION BY SUPPLIER			
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**		

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

Please submit quotations to Section21Quotes@health.gov.za

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

EQUITY
PHARMACEUTICALS

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

National Department of Health

Directorate: Affordable Medicines

E-mail: Section21Quotes@health.gov.za

Attention: Ms Buhle Mbongo

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

Ehrard 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
Water for Injection BP q.s.
WARNING
Prescription Medicine
Use n fior medical supervsion
Discard unused portion
Do not use if solution is cloudy
Kwality Pharamteualicals Limited
Nag Giani, Majitha Road, Amristar - India
ATROPINE INJECTION BP
100 mg / 10 ml
Each ml contains / Atropine Sulfate BP 10 mg
For IV / IM Use
Sterile
Kwality Pharmmtecaittals 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