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 Authorization for L-ASPARAGINASE 10 000IU INJ

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

- **L-Asparaginase 10 000IU 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 **22 March 2026**.

Table 1: Provincial estimates

Province	Six Months Estimate
Correctional Services	0
EC-MT	0
EC-PE	0
FS	150
GP	660
KZN	720
LP	0
MP	0
NC	50
NW	0
SAMHS	0
WC	350
Total	**1 930**

Yours sincerely

KHADIJA JAMALOODIEN
CHIEF DIRECTOR: SECTOR WIDE PROCUREMENT
DATE: 30/9/2025

S2100012744

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

Section 21 Outcome Letter

2025-10-01

Ms Buhle Mbongo

National Department Of Health

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 **2025-10-01** 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: 650

E. UNREGISTERED MEDICINES: GENERIC NAME: No Data

F. TRADE NAME: L-Asparaginase for Injection 10000 IU

G. QUANTITY: 1300 Packs (1)

SAHPRA
South African
Health Products
Regulatory Authority

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

H. LETTER NUMBER: S2100012744

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

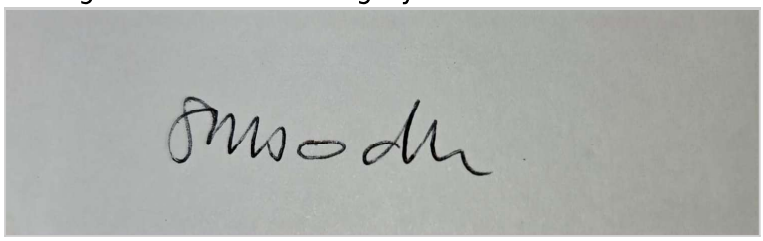
A progress report must be submitted once treatment is completed or on a reauthorization request

Comments:

Yours faithfully,

Dr Shyamli Munbodh

Manager: Section 21 Category A Medicines



Ms Mahlodi Moropa

Final Approver

S2100012744

SAHPRA
South African
Health Products
Regulatory Authority

SAHPRA Head Office
Building A, Loftus Park
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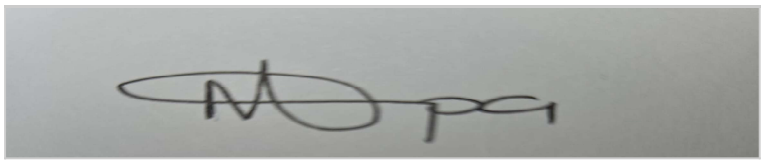

health
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REQUEST FOR QUOTATION FORM

- **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 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	**S21RFQ159**
QUOTE ENQUIRY DATE	**25/08/2025**	QUOTE CLOSING DATE			**02/09/2025**
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	**L-ASPARAGINASE 10 000 K.U INJECTION**		
TRADE DESCRIPTION	L-Asparaginase for Injection 10 000IU (Lyophilized)		
UNIT OF MEASURE	**1's**	PACK or BOX (*SIZE/ QUANTITY*)	**1 vial**
QUANTITY REQUIRED	**1300 vials/ampoules**		

TO BE COMPLETED BY THE SUPPLIER/ SERVICE PROVIDER

SUPPLIER CONTACT DETAILS (as per CSD)

COMPANY NAME	Equity Pharmaceuticals (Pty) Ltd			
SUPPLIER NUMBER	MAAA007480			
SECURITY CODE				
SUPPLIER CODE (NDoH)				
CONTACT PERSON 1	NAME	**Ehrard van Zyl**		
	PHONE	**012 345 1747**	FAX	**012 345 1412**
	MOBILE	*072 040 8511*		
	E-MAIL	**ehrard@equitypharma.co.za**		
CONTACT PERSON 2	NAME	**Jaco Schoeman**		
	PHONE	**012 345 1747**		

	MOBILE	*076 734 0080*
	E-MAIL	**jacos@equitypharma.co.za**

QUOTE DETAILS			
PRICE PER UNIT (INCL. VAT)	R 340.40	TOTAL PRICE (INCL. DELIVERY & VAT)	R 442 520.00
*STOCK'S EXPIRY DATE(SHELF-LIFE)			
VOLUMES AVAILABLE – 7DAYS			
VOLUMES AVAILABLE – 14DAYS			
VOLUMES AVAILABLE – 21DAYS			
VOLUMES AVAILABLE – 28DAYS			
VOLUMES AVAILABLE – 35DAYS	1 300		
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:

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	**02/09/2025**

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
- 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.
- The confirmation letter from manufacturer to supply South Africa with bOPV must be provided
- 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.
- **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)

EQUITY
PHARMACEUTICALS

02/09/2025

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 # 20250902

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
	L-Asparaginase for Injection 10 000IU	1's	1	R 296.00	R 340.40
			1 300	**R 384 800.00**	**R 442 520.00**
			1 300	**R 384 800.00**	**R 442 520.00**

Valid for 180 days

Employee Signature: _____

Date: 02/09/2025

Approved by: Ehrard van Zyl

EQUITY
PHARMACEUTICALS

02/09/2025

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 – L-Asparaginase – Section 21 Supply

Trust you are well. Please find below our quotation for *L-Asparaginase* supplied under section 21 terms.

• Quantity:	**1 300 vials**
• Delivery Time (Weeks):	**5 Weeks**
• Price (Vat Inclusive):	**R 340.40 per vial**
• Generic Name:	**L-Asparaginase**
• Trade Name:	**L-Asparaginase for Injection 10 000IU**
• Packaging:	**1's**
• Specifications:	**10 000IU**
• Shelf Life:	**36 months**
• Package Insert:	**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

Component : Carton
Dimension : 50 x 30 x 75 mm
Colour : CMYK
GSM : 320 gsm ITC CYBER XL
UV COATING

L-ASPARAGINASE
For Injection

Batch :
Mfg. :
Exp. :

10000 I.U. / Vial

L-ASPARAGINASE
For Injection

Contains the enzyme L-asparagine amidohydrolase, type EC-2, derived from *Escherichia Coli*

Lyophilized
For IM / IV use

Single Use Vial
Discard Unused Portion

Composition:
Each vial contains:
L-Asparaginase .... 10000 I.U.

Inactive ingredient:
Mannitol ..... 80 mg

No preservative

Directions for Reconstitution:
See accompanying package insert.

Dosage and administration:
As directed by the Oncologist.

Must reconstitute prior to administration. See accompanying package insert for complete dosage recommendations.

Storage:
Store between 2°C to 8°C.
Protect from light.
Do not freeze.
Keep out of the reach of children.

10000 I.U. / Vial

L-ASPARAGINASE
For Injection

Contains the enzyme L-asparagine amidohydrolase, type EC-2, derived from *Escherichia Coli*

Lyophilized
For IM / IV use

Single Use Vial
Discard Unused Portion

If any foreign Particle is visible after dissolving the contents, Please do not use the solution.

Caution: May be a contact irritant. Avoid contact with skin, mucous membranes, or eyes. Do not inhale the dust or vapor. In case of contact, wash with copious amount of water for at least 15 minutes.

WARNING:
Cytotoxic Agent. May cause severe reactions including sudden death.

Mfg. Lic. No.: BNZ/08/41

Manufactured by :
Kwality Pharmaceuticals Ltd.
1-A, Industrial Area, Raja Ka Bagh, Tehsil Nurpur, Distt. Kangra, (H.P.) - 176201. INDIA

Expiry Date is 36 months from the Mfg. Date. For eg. Feb/2019 to Jan/2022

Check List for Labeling — Formulation No.:

Work Order No. :	Version	Pharmacop.	Spell.	Compo.	Batch, Mfg. Exp.	Expiry as per Schedule 'P'	M.R.P.	Mfg. Lic.No./ Nutral Code	Packing	Category	Mfg. Name	Reg. No.	Check Order for strength, Volume & Packing	STORAGE
13682/1	ENGLISH													
Matching all parameters between Box and Label														

Matching the parameter with label of leader brand

Previous specimen artwork : NEW	Ramesh Kumar	Order Quantity	Party Name	Packing
		2500 Vial	SD Pharma	

Checked by :		Approved by :	Authorized by:	Party Approval
Production Incharge	QC Incharge	Q.A.	M.D.	

Card Board used for carton :
□ G/B □ W/B □ I.T.C. □ Pearl

100 X 170 mm

L-ASPARAGINASE FOR INJECTION

Contains the enzyme L-asparagine amidohydrolase, type EC-2,
derived from Escherichia Coli

10000 I.U. / Vial

COMPOSITION:
Each vial contains:
L-Asparaginase ..... 10000 I.U.
Inactive ingredient:
Mannitol ..... 80 mg

No preservative

PHARMACOLOGICAL CLASSIFICATION:
Cytostatic agents

PHARMACOLOGICAL ACTION:
The tumour cells of acute leukaemia require exogenous Asparagine as an essential nutrient for their growth. Asparaginase is an enzyme which catalyses the hydrolysis of L-Asparagine to aspartic acid and ammonia, thus interfering with the metabolism of the malignant cells.

INDICATIONS:
Lymphoblastic leukaemia (acute lymphatic leukaemia).
The different mechanism of action of L-Asparaginase and the fact that no cross resistance with other anti-leukaemic agents exists always justify a therapeutic trial when resistance against conventional cytostatiscs has developed.

CONTRA-INDICATIONS:
Pregnancy.
Safety during lactation has not been established.
Patients with a history of hypersensitivity to Asparaginase.

DOSAGE AND DIRECTIONS FOR USE:
The dry powder in the vial is dissolved, agitating slightly, with the added solvent i.e. 5% glucose or xylitol or sterile physiological saline solution. The product is usually administered at doses of 200 to 800 IU/kg daily or on every other day. The dose should be adjusted according to the age and general condition of the patient.
According to clinical data the maximum tolerable dose is 2 000 IU/kg daily. Some authors recommend that the continuous dose after remission is 50 IU/kg daily. The duration of administration is usually 2 weeks. Treatment should be carried out as in-patient therapy.
L-Asparaginase is administered by slow intravenous injection or a rapid intravenous infusion (20 to 30 minutes) with physiological sodium chloride solution.
L-Asparaginase can be combined with differently acting cytostatics and/or corticosteroids. The stated dosage for Asparaginase can be maintained. In order to exclude the possibility of hypersensitivity the following tests should, as a rule, be performed prior to administration or before resuming treatment after an interruption. The detailed procedures of the tests should follow the routine ones in each laboratory.
a. Intracutaneous injection: 1 to 10 IU of Asparaginase in a volume of 0.1 mL is to be injected intracutaneously on the palmar side of the forearm. The absence of abnormal signs should be confirmed 30 minutes to several hours after the injection.
b. Intravenous injection: Asparaginase, dissolved in a maximum of 250 mL of glucose solution, is administered by drop-infusion at doses of 50 - 100 IU/kg depending on the age of the patient. The condition of the patient should be observed for one day and absence of any abnormal reaction confirmed.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:
Shock symptoms may occur infrequently. If any symptoms such as clouding of consciousness, convulsions, blood pressure decrease, chills, fever or vomiting are observed, discontinue administration immediately and adequate measures should be taken.
Hypersensitivity
Hypersensitivity reactions such as rash may occur.
Haematology
Since severe abnormality of coagulation (decrease of fibrinogen, prothrombin, plasminogen AT III and protein C etc) such as cerebral haemorrhage, cerebral infarction and pulmonary haemorrhage may occur, monitor the patient carefully by frequent laboratory examinations. *
Furthermore thrombocytopenia and anaemia may occur.
Hepatic
Since hyperammonemia with disturbance of consciousness may occur, monitor the patient carefully by periodical examinations.
Furthermore, hepatic disorder and fatty liver may occur.
Renal
Proteinurea, diuretic failure, azotemia and oedema may occur.
Pancreatic
Since acute pancreatitis may occur and secretion dysfunction of pancreas (necrosis of Langerhans' islets) may induce diabetes, monitor the patients carefully. *
Brain
Death has been reported due to the wide range organic dysfunction of the brain.
Gastrointestinal
Anorexia, nausea, vomiting and diarrhoea may occur.
Pshychoneurologic
Malaise, headache, and infrequently somnolence, anxiety, disturbance of consciousness and coma may occur.
Other
Fever and glucose tolerance abnormality may occur.

- If any abnormal findings are observed, discontinue administration or adequate measures should be taken. Great care should be taken at the beginning of the administration. In view of the risk of sensitization once treatment has begun it should not be interrupted. If, however, an interruption should become unavoidable then treatment must be resumed with small doses (beginning with 10 IU/kg of body mass). If tolerance remains good the dose may be increased to the full daily dose in the course of 5 days.

It should be given cautiously to patients with impaired liver function. In patients with pancreatitis or a history of pancreatitis, acute haemorrhagic-pancreatitis has been reported following L-Asparaginase administration.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Treatment is symptomatic and supportive.

PRESENTATION:
Each vial containing 10000 IU packed in a printed carton.

STORAGE:
Store between 2°C to 8°C.Protect from light. Do not freeze.
KEEP OUT OF THE REACH OF CHILDREN.

Manufactured by :
Kwality Pharmaceuticals Ltd.
1-A, Industrial Area, Raja Ka Bagh, Tehsil Nurpur,
Distt. Kangra, (H.P.) - 176201. INDIA