



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

Mrs TL Burger
MC Pharma (Pty) Ltd
62 Constantia Avenue
Mnandi
Centurion
0157
Tshwane

Dear Mrs Burger

Section 21 Authorization for PHENOBARBITONE 200MG INJECTION

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

- **Phenobarbitone 200mg 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.

Section 21 Authorisation re Phenobarbitone 200mg INJ 15092026-1

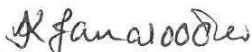
7. Participating Authorities (PAs) will provide a consolidated close out report of usage using the attached format on the date when an authorization lapses.
8. The full quantities imported in terms of this Section 21 authorisation must be accounted for.
9. Note that this authorization DOES NOT cover 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 **14 March 2027**.

Table 1: Provincial usage

Province	Six Months Estimate
Correctional Services	0
EC-MT	500
EC-PE	3 000
FS	1 100
GP	800
KZN	4 800
LP	3 000
MP	0
NC	600
NW	1 886
SAMHS	45
WC	2 000
Total	17 731

Yours sincerely



KHADIJA JAMALOODIEN

CHIEF DIRECTOR: HEALTH PRODUCTS PROCUREMENT

DATE: 16/9/2026

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

Section 21 Outcome Letter

2026-09-15

Ms Khadija Jamaloodien

Voortrekker Road, First, Dr AB Xuma, 112, Voortrekker Road, Pretoria, Gauteng, Tshwane,
Gauteng, South Africa, 0187

Tshwane

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 **2026-09-14** refers

- A. STATUS: Approved**
- B. APPLICANT: Ms Khadija Jamaloodien**
- C. IMPORTING COMPANY: MC PHARMA (PTY) LTD**
- D. NUMBER OF PATIENT/(S) INTENDED TO BE TREATED: 1**
- E. UNREGISTERED MEDICINES: GENERIC NAME (INN / ACTIVE INGREDIENT):
Phenobarbital Sodium Injection**
- F. TRADE NAME: Phenobarbitone 200 mg/mL**
- G. QUANTITY: 17730 Packs (10)**

H. LETTER NUMBER: S2100037599

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

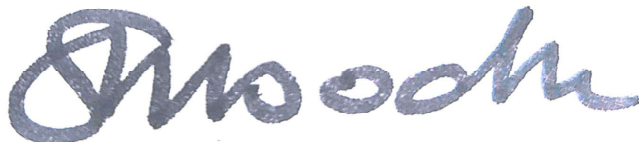
Comments:

No Data

Yours faithfully,

Shyamli Munbodh

Manager: Section 21 Category A Medicines

A handwritten signature in blue ink, appearing to read 'Shyamli Munbodh', enclosed within a thin black rectangular border.



health

Department:
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REPUBLIC OF SOUTH AFRICA



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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	S21RFQ185/2026
QUOTE ENQUIRY DATE	31/08/2026	QUOTE CLOSING DATE	07/09/2026	
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	Phenobarbitone 200mg Injection		
TRADE DESCRIPTION			
UNIT OF MEASURE	1 vial/ampoule	PACK or BOX (SIZE/ QUANTITY)	1
QUANTITY REQUIRED	15 800		

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	Not on tender
COMPANY NAME	MC Pharma (Pty) Ltd				
SUPPLIER NUMBER	MAAA0714828				
SECURITY CODE					
SUPPLIER CODE (NDoH)					
CONTACT PERSON 1	NAME	T Burger			
	PHONE		FAX		
	MOBILE	082 457 7894			
	E-MAIL	Tracy.Burger@mcpharma.co.za			
CONTACT PERSON 2	NAME	J Castle			
	PHONE				

	MOBILE	072 926 8778	
	E-MAIL	Junita.Castle@mcpharma.co.za	
<u>QUOTE DETAILS</u>			
PRICE PER UNIT (INCL. VAT)	R12.86	TOTAL PRICE (INCL. DELIVERY & VAT)	R203,188.00
VOLUMES AVAILABLE – 14DAYS			
VOLUMES AVAILABLE – 21DAYS			
VOLUMES AVAILABLE – 28DAYS			
VOLUMES AVAILABLE – 35DAYS	30 days after approval of permit		
VOLUMES AVAILABLE – 42DAYS			
VOLUMES AVAILABLE – 49DAYS			
VOLUMES AVAILABLE – 56DAYS			
VOLUMES AVAILABLE – 112DAYS			
QUOTE VALIDITY PERIOD	90 days		
NORMAL LEAD/DELIVERY TIME	3-7 days in country		
<u>DEVIATION TO SPECIFICATION</u>			
COMMENTS:			
<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	T Burger		
CAPACITY	Managing Director		
SIGNATURE (OF A DULY AUTHORISED REPRESENTATIVE OF THE SUPPLIER)	 pp		
DATE	7 September 2026		
<u>PROVINCIAL ESTIMATES</u>			
Province	Six Months Estimate		
DCS	0		
EC-MT	500		
EC-PE	3 000		
FS	1 100		
GP	800		
KZN	4 800		
LP	3 000		

MP	0
NC	600
NW	0
SAMHS	45
WC	2 000
<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**

MC Pharma (Pty) Ltd.
62 Constantia Avenue,
Mnandi, Centurion, 0157
Tel: +27 (0)12 668-3019
www.mcpharma.co.za



07 September 2026

QUOTATION # 20260907 P

TO: The National Department of Health

TEL: 012 395 0539

Email: Buhle.mbongo@health.gov.za

CONTACT PERSON / PATIENT: Buhle Mbongo

NB IMPORTED AND SUPPLIED UNDER SECTION 21 TERMS

PRODUCT CODE	DESCRIPTION	PACK SIZE	QUANTITY	PRICE EXCL	PRICE INCL
PHEN 001	Each vial contains 200 mg Phenobarbitone Sodium USP.	1's	15800	R11,18	R12,86
Brand		(packed in 10's)	1580	R176,644.00	R203,188.00
			Total	R176,644.00	R203,188.00

Valid for 90 days

Employee signature/s: _____

Date: 07 September 2026

Approved by: T Burger

07 September 2026

TO: The National Department of Health

Directorate: Affordable Medicines

TEL: 012 395 0539

Email: Buhle.mbongo@health.gov.za

Dear Ms Mbongo

Re: RFQ S21RFQ185 – Phenobarbital Sodium 200mg/ml Inj

- **Quantity:** 15800 ampoules
- **Delivery Time (weeks)** 30 days after approval of permit
- **Price (VAT inclusive) per vial** R12.86 per ampoule
- **Generic Name:** Phenobarbital Sodium 200mg/ml Inj
- **Trade/Brand Name:** Phenobarbital Sodium 200mg/ml Inj
- **Packaging:** 10 X 1ml ampoules
- **Specifications:** Phenobarbital Sodium 200mg/ml Inj_USP
- **Shelf-life:** 24 months
- **Package Insert:** Attached
- **Manufacturer:** Kwaliti Pharmaceuticals
- **Country of Origin:** India

Please note that the immediate availability of the product is on condition that the manufacturer receives the notice of our order as soon as possible.

We are looking forward to your positive response and please do not hesitate to make contact should you have any further requirements.

Regards

pp

T Burger
Managing Director

100 x 200 mm Maplitho Paper

Phenobarbital Sodium Injection USP

200 mg/ml

COMPOSITION:

Each ml contains:
Phenobarbital Sodium USP 200 mg
Alcohol USP 10% v/v
Propylene Glycol USP q.s. (as solvent)

Category:

Barbiturate.

General information:

Phenobarbital & Amylobarbitone belong to the group Barbiturates of CNS depressants. They are hypnotic drugs.

Moa:

Barbiturates are CNS depressants. They also augment inhibitory effects of GABA. Effects range from sedation and in high doses cause anaesthesia. Intramuscular, slow IV use injection

Indications:

Intractable insomnia. eclampsia, spastic excitatory states. Generalised tonic clonic seizures, febrile convulsion, temporal lobe epilepsy, cortical focal seizures, status epilepticus.

Pharmacodynamic Properties:

ATC Code: N03A A02 (antiepileptics, barbiturates and derivatives).

Phenobarbital is a long-acting barbiturate, which because of its depressant effect on the motor cortex, is used in the treatment of epilepsy. Phenobarbital has a widespread depressant action on cerebral function. It has selective anticonvulsant activity and, used in hypnotic doses, it alters the stages of sleep in a dose dependent manner.

It has sedative effects and has some protective action against all varieties of human partial and generalised epilepsy, with the exception of absence seizures. Phenobarbital is also effective in preventing seizures in the corresponding experimental animal models of epilepsy.

In different studies phenobarbital appears to have had inconsistent effects in suppressing experimental epileptic foci, and epileptic after-discharges, but it inhibits synaptic transmission, at least in the spinal cord. The drug's probable biochemical mechanism of action is through prolonging the opening time of Cl⁻ ion channels in postsynaptic neuronal membranes. This effect causes membrane hyperpolarisation and thus impairs nerve impulse propagation. Phenobarbital also decreases intraneuronal Na⁺ concentrations, and inhibits Ca²⁺ influx into depolarised synaptosomes. It raises brain serotonin levels, and inhibits noradrenaline (norepinephrine) reuptake into synaptosomes. These additional biochemical actions may contribute towards the anticonvulsant effects of the drug.

Pharmacokinetic properties

Metabolism:

The plasma half-life is about 75 to 120 hours in adults but is greatly prolonged in neonates, and shorter (about 21 to 75 hours) in children. The half-life is increased in the elderly and in neonates and is prolonged by renal and hepatic disorders. There is a considerable interindividual variation in Phenobarbital kinetics. Phenobarbital is only partly metabolised in the liver. It is about 40% plasma bound.

Elimination:

Excretion is mainly in the urine (and is increased in alkaline urine) with about 30% of the drug unchanged. The remainder is inactivated in the liver. Phenobarbital crosses the placenta and is secreted in the milk of nursing mothers

Therapeutic indications:

An anti-convulsant for the treatment all forms of epilepsy except absence seizures.

Posology:

Adults: 50 - 200mg as a single dose by intramuscular, subcutaneous or, after dilution 1 in 10 with Water for Injection, by intravenous injection, repeated, if necessary, after 6 hours.

Paediatric population:

3 - 5mg per kg body weight as a single dose by intramuscular injection.

Undesirable effects:

Antiepileptic hypersensitivity syndrome may occur. Symptoms include fever, rash, lymphadenopathy and hepatitis. Blood and the lymphatic system disorders: megaloblastic anaemia (due to folate

deficiency), agranulocytosis, thrombocytopenia.

Metabolism and nutritional disorders: osteomalacia, rickets.

Psychiatric disorders: paradoxical reaction (unusual excitement), hallucinations, restlessness and confusion in the elderly, mental depression, memory and cognitive impairment, drowsiness, lethargy.

Nervous system disorders: hyperactivity, behavioural disturbances in children, ataxia, nystagmus.

Cardiac disorders: hypotension.

Respiratory disorders: respiratory depression.

Hepato-biliary: hepatitis, cholestasis.

Skin and subcutaneous tissue disorders: allergic skin reactions (maculopapular morbilliform or scarlatiniform rashes), other skin reactions such as exfoliative dermatitis, erythema multiforme. Severe cutaneous adverse reactions (SCARs): Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) have been reported (see section 4.4) very rarely.

Musculoskeletal, connective tissue and bone disorders: There have been reports of decreased bone mineral density, osteopenia, osteoporosis and fractures in patients on long-term therapy with Phenobarbital. The mechanism by which Phenobarbital affects bone metabolism has not been identified.

Contraindications:

Hypersensitivity to phenobarbital, other barbiturates or to any of the excipients listed in section 6.1.

- Severe respiratory depression.
- Acute intermittent porphyria.
- Severe impairment of renal or hepatic function.

Adverse effects:

Main side effect is sedation (which disappears after a few weeks due to development of tolerance). In young and elderly it causes confusion and paradoxical excitement or agitation. Irritability and hyperactivity in children may be seen. Megaloblastic anaemia, osteomalacia and skin rashes may occur. Rarely hepatitis and agranulocytosis may occur. The toxicity is manifested by hypotension, ataxia, dizziness, respiratory depression, coma & death.

Special precautions:

Chronic use of barbiturates may result in intolerance and drug dependence. Barbiturates cause decreased efficacy of other drugs because of hepatic microsomal enzyme induction in liver and accelerated metabolism of oral anticoagulants, oral contraceptives and phenytoin. Respiratory insufficiency.

Interactions:

Alcohol & other CNS Depressants (other sedatives, hypnotics, anesthetics, antihistamines, tranquilizers, phenothiazines): Additive CNS depression.

Valproic acid: Increases efficacy of barbiturates. Half life of valproic acid may be decreased.

Chloramphenicol: Efficacy of barbiturates increased. Barbiturates may decrease efficacy of chloramphenicol.

MAOIs: Effects of barbiturates prolonged.

Efficacy of the following drugs decreased by barbiturates: Oral anticoagulants, digitoxin, TCAs, corticosteroids, doxycycline, oral contraceptives and estrogens, acetaminophen, beta-blockers, quinidine, rifampicin, theophylline and metronidazole.

Phenytoin: Effect on phenytoin metabolism is unpredictable.

Frusemide: May produce or aggravate orthostatic hypotension.

Griseofulvin: Interferes with absorption of oral griseofulvin leading to decreased blood levels.

Storage:

Store between temperature 8° to 25°C. Protect from light.
Keep out of the reach of children.

Presentation:

10 ampoules of 1 ml in a plastic tray and each tray packed in a printed box.

Manufactured by:

Kwality Pharmaceuticals Ltd.

Nag Kalan, Majitha Road, Amritsar - India



Pantone 300 C

Component : Label
Dimension : 60 x 16 mm
GSM : 60 gsm Chromo art sticker paper
Varnish / coating: U.V. coating
Colour : CMYK + Pantone

Phenobarbital

Sodium Injection USP

COMPOSITION: Each ml contains:

Phenobarbital Sodium USP .. 200 mg

Alcohol USP 10% v/v

Propylene Glycol USP q.s. (as solvent)

Dosage: As directed by the Physician.**Storage:** Store between temperature 8 to 25°C. Protect from light.

Batch No. :

Mfg. Date :

Exp. Date :

200 mg/ml**1 ml**

For I.M. / slow I.V. use

Keep out of the reach of children.

Warning:**Do not use if precipitate appears.**

Manufactured by:

Kwaliti Pharmaceuticals Ltd.

Nag Kalan, Majitha Road,

Amritsar - India

Mfg. Lic. No.: 1804-B

SHELF LIFE:- 36 MONTHS**CHECK LIST FOR LABELING**

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
11630/4	English													
Matching all parameters between Box and Label														
Previous specimen artwork : New				Designed by : Prabhjeet Singh				Order Quantity		Party Name		Packing		
Checked by :		Approved by :		Authorized by:		Party Approval		50000		Aziz Shafiz				
Production Incharge	QC Incharge	Q.A.		M.D.				Card Board used for carton :						
								☐ G/B ☐ W/B ☐ I.T.C. ☐ Pearl						
						SHELF LIFE 36 MONTHS								



Pantone 300 C

Component : Carton
Dimension : 149 x 13 x 65 mm
320 GSM Itc Cyber xl
Dripp off + Spot U.V.
Colour : CMYK + Pantone

200 mg/ml	
Phenobarbital Sodium Injection USP	
For I.M. / slow I.V. use	10 ampoules of 1 ml
COMPOSITION: Each ml contains: Phenobarbital Sodium USP 200 mg Alcohol USP 10% v/v Propylene Glycol USP q.s. (as solvent)	
Dosage: As directed by the Physician. Storage: Store between temperature 8 to 25°C. Protect from light. Warning: Do not use if precipitate appears.	
200 mg/ml	
Phenobarbital Sodium Injection USP	
For I.M. / slow I.V. use	10 ampoules of 1 ml
Manufactured by: Kwaliti Pharmaceuticals Ltd. Nag Kalan, Majitha Road, Amritsar - India	
Keep out of the reach of children. Read enclosed leaflet carefully before use. Mfg. Lic. No.: 1804-B	

Batch No. :
Mfg. Date :
Exp. Date :Narcotic Item required Mfg. Lic. No. and
Name and full address of Manufacturer**SHELF LIFE:- 36 MONTHS****CHECK LIST FOR LABELING**

CHECK LIST FOR LABELING														
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
11630/1	English													
Matching all parameters between Box and Label														
Previous specimen artwork : New				Designed by : Prabhjeet Singh				Order Quantity		Party Name		Packing		
Checked by :		Approved by :		Authorized by :		Party Approval		12500		Aziz Shafiz				
Production Incharge	QC Incharge	Q.A.		M.D.				Card Board used for carton :						
								☐ G/B ☐ W/B ☐ I.T.C. ☐ Pearl						
						SHELF LIFE 36 MONTHS								