



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 Extension Authorization for PROTAMINE 10MG/ML INJECTION 5ML

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

- **Protamine 10mg/mL injection 5mL**

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 Extension re Protamine 10mg/mL INJ 5mL 27052026-1

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 **26 November 2026**.

Table 1: Provincial usage

Province	Six Months Estimate	Actual Uptake
DSC	0	0
EC-MT	0	200
EC-PE	400	
FS	600	520
GP	3000	0
KZN	1200	0
LP	240	0
MP	250	0
NC	30	0
NW	340	0
SAMHS	20	0
WC	2500	2200
Total	8 580	2920

Yours sincerely


KHADIJA JAMALOODIEN
CHIEF DIRECTOR: SECTOR WIDE PROCUREMENT
DATE: 27/5/2026

Section 21 Outcome Letter

2026-05-26

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 **2026-05-22** refers

- A. STATUS: Approved**
 - B. APPLICANT: Ms Buhle Mbongo**
 - C. IMPORTING COMPANY: MC PHARMA (PTY) LTD**
 - D. NUMBER OF PATIENT/(S) INTENDED TO BE TREATED: 9**
 - E. UNREGISTERED MEDICINES: GENERIC NAME: No Data**
 - F. TRADE NAME: Protamine Sulphate INJ 10 mg/mL**
 - G. QUANTITY: 7560 Packs (1)**
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