health
MPUMALANGA PROVINCE
REPUBLIC OF SOUTH AFRICA

Indwe Building, Government Boulevard, Riverside Park, Ext. 2, Mbombela, 1200, Mpumalanga Province
Private Bag X11285, Mbombela, 1200, Mpumalanga Province
Tel l: +27 (13) 766 3429, Fax: +27 (13) 766 3458

Litiko Letemphilo | Departement van Gesondheid | UmNyango WezeMaphilo

MPUMALANGA PHARMACEUTICAL DEPOT DATABASE REGISTRATION FORM

The purpose of this form is to obtain details of suppliers which will be captured on the database at the Mpumalanga Pharmaceutical Depot and to evaluate the potential supplier's quality system suitability for the supply of the product/s being considered. The Mpumalanga Pharmaceutical Depot reserves the right to request evidence for some responses as required. The checklist will identify when evidence is required.

COMPANY INFORMATION

Company Name:	
Central Supplier Database (CSD) number	
Company Address: (Offices)	
Company Address: (Warehouse or factory)	
Primary contact e-mail address:	
Contact Number/s #:	
Primary Contact name:	
Contact Person that will receive the electronic requests for quotations	
Contact e-mail address:	
Contact Number/s:	
Contact name:	

COMPANY CLASSIFICATION

Company/Supplier **SAHPRA** license Classification: (Please tick the relevant boxes)

Distributor	Manufacturer	Importer

Trading commodities/goods

Pharmaceutical Items:

Please provide a brief description of goods supplied: _____

_____

_____

_____

(Note: a full product list should be attached to this form)

Surgical Items:

Please provide a brief description of goods supplied: _____

_____

_____

_____

(Note: a full product list should be attached to this form)

Indicate the individuals in your business that has/have ownership interests in other entities

Name	**Name of other Firm/Company**	**Title in other Firm**	**% of Ownership**	**Type of Business of other Firm**

Are you associated with other company(s) / enterprise(s)? If “yes” list below.

Name of Company	Nature of Association	Contact Person	Contact Number

Warehousing and Distribution Information	Yes	No
Is there any service/activity subcontracted? E.g. third-party logistics		
If yes, what services/activities are subcontracted		

General Quality System Questions

Quality System Certification	Yes	No
Does your company hold any recognized Quality System Certification? (e.g., ISO 9001, ISO 13485, Good Distribution Practice certification….)		
Provide details of certification and attach a valid copy of certification:		

Regulatory Inspections	Yes	No
Has your facility been inspected by a Regulatory Authority e.g. SAHPRA and/or ISO Body		
If yes, when was the last inspection conducted at your facility		

Mpumalanga Pharmaceutical Depot Audit/Evaluation	Yes	No
Are you willing to allow an audit by Mpumalanga Pharmaceutical Depot or its representative, if necessary?		
If no, provide reason		

Section A – Supplier Quality Management System

Attention: Please provide Explanation for "No" or "N/A" responses.

Mpumalanga Pharmaceutical Depot Requested Product Suppliers			
Questions	**Yes**	**No**	**N/A**
1. Do all regulated medicines, medical devices and IVDs have a valid regulatory certificate, where applicable (e.g. SAHPRA; US 510k/EU; CE Mark/CFDA etc.)			
2. Are certificates available on request?			
Comments:			
3. Are products in compliance with all the SAHPRA regulatory requirements for distribution in South Africa (Classification, Labelling, Packaging, Local Authority Notification, Product Recall etc.)?			
Comments			
4. Are Instructions For Use (IFUs) available in the local official language i.e. English where required and can be provided upon request?			
Comments			
5. Are Safety data sheets available in the local official language i.e. English and can be provided upon request? If Applicable			
Comments:			
6. Does the product offered conform with all relevant safety standards?			
Comments:			

Documentation			
Questions	**Yes**	**No**	**N/A**
1. Is there an employee training program (or comparable program) to document training requirements for each job function?			
Comments:			

Section A – Supplier Quality Management System

Attention: Please provide an Explanation for "No" or "N/A" responses

Questions	**Yes**	**No**	**N/A**
2. Are all documents retained for sufficient periods past material release, and according to a controlled retention schedule?			
Comments:			
Management Responsibility			
Questions	**Yes**	**No**	**N/A**
1. Does senior management oversee the integrity of the Quality Management System when changes are planned and implemented?			
Comments:			
2. Is there a formal internal audit program or comparable assessment program?			
Comments			
3. Are the results of the audits documented, and are nonconformities tracked for correction?			
Comments:			
4. Does management perform regular reviews of the quality system results, including:			
a) Results of audits or comparable assessment program?			
b) Customer feedback (Satisfaction, characteristics)			
c) Process performances/product conformity			
d) Status of corrective actions and preventative actions?			
e) Follow-up actions from previous reviews?			
f) Changes that could affect the Quality System and new or revised regulatory requirements			
g) Recommendations for improvements?			
Comments:			

5. Do the reviews result in documented plans for:			
a) Improvements of effectiveness of the Quality System and processes?			
b) Resource needs being addressed.			
Comments:			

Questions	Yes	No	N/A
6. Is the Quality System Supported through maintenance of adequate facilities and resources?			
Comments:			

Compulsory documents to be included:

- CSD Registration Report
- Company Registration Documents (CIPC)
- Valid South African Health Products Regulatory Authority (SAHPRA) License as a Manufacturer or Distributor or Importer of Pharmaceuticals and Medical Devices
- Valid South African Pharmacy Council (SAPC) Registration Certificates for Manufacturers, importers and distributors of medicines
- Proof of banking details
- Product list/ Catalogue (pharmaceuticals and surgical items)

DECLARATION

I declare that the above information furnished is true and correct and this includes the Equity Ownership claimed. Any conflict of the interest must be declared in the comment space below.

Owner/duly authorized representative

Names in full: _____

Designation: _____

Signature: _____

Date: _____

Witness:

Names in full: _____

Signature: _____

Supplier notes and comments:

Section B

Supplier Change Notification

The Supplier agrees to notify the Mpumalanga Pharmaceutical Depot in writing if they plan to make any changes in their management, key contacts, company ownership or processes which may have impact upon the product or services they provide.

Supplier Representative

I certify that the information in this questionnaire is correct and verifiable.

Name	**Designation**	**Signature**	**Date**

MPUMALANGA PHARMACEUTICAL DEPOT APPROVAL (FOR OFFICE USE ONLY)

I confirm that all services provided to the Mpumalanga Pharmaceutical Depot were addressed by the supplier. I confirm that the results of this questionnaire have been reviewed and any required actions will be taken.

☐ Initial Evaluation ☐ Re-evaluation

I confirm that any Supplier questions marked as “No” or “N/A” have been addressed and substantiated as to why it is acceptable.

Comment

Supplier status: ☐ Approved ☐ Restricted ☐ Not Approved

Name	**Designation**	**Signature**	**Date**

NB: The completed database form must be submitted with all the supporting documents on or before the 06th of December 2024 at the following address:

E-mail

Depotdatabase@mpuhealth.gov.za

or

Physical

Att: Ms B. Thela / Ms D. Komane
14 Cnr Jaspis and Dr Mandela Drive,
Middelburg Industrial Area,
Mpumalanga Province
1050

For any technical queries regarding this notice must be in writing, addressed to this email: BabalwaT@mpuhealth.gov.za Ms Babalwa C. Thela on **013 283 4000** and for administration enquiries email: SimphiweN@mpuhealth.gov.za or contact Mr Simphiwe Nkosi on **013 766 3083.**