SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

SAHPRA
South African Health Products Regulatory Authority

LICENCE APPLICATION TO ACT AS WHOLESALER OF MEDICINE

- An application form for the purpose of **obtaining** a license **or renewing** an existing licence in terms of the provisions of the Medicines and Related Substances Act, 1965, Section 22C and 22D read together with Regulation 19 and 20 of the Act as the case may be.
- This form should be completed by or for each wholesaler or distributor of medicine who is not exempted from the requirement to hold a licence and who wishes to act as a wholesaler or distributor or wishes to renew their existing license.
- Incomplete forms may be returned to the applicant. Please type or print in black pen. Any alterations must be initialled and dated. Application forms with white out will be returned. All required copies of certificates should be certified.
- The prescribed application fee for a licence must accompany any of these licence application forms. For amount, refer to the summary of fees and charges available from the office of the Chief Executive Officer
- The completed form should be emailed to:
  gmplicensing@sahpra.org.za
- Licensing guidelines are available at the SAHPRA website: www.sahpra.org.za
- The licence is the property of South African Health Products Regulatory Authority and must be returned upon demand. The licence remains valid for the period of five years from the date of issue unless suspended or revoked by SAHPRA.
- After five years the Wholesaler or Distributor needs to renew the licence.

Guidance notes for General information

The Wholesaler's Business Name

Full, legal name of licence applicant or owner of the business who wishes to wholesale and distribute medicine (must be full, *legally identifiable name* e.g. 'ABC Pty Ltd', 'Newcorp Ltd' trading as XYZ', 'Gillian Linda Smith trading as MNR). Spaces are provided for the following options. Please insert as applicable.

a) The individual's full name if trading as an individual trader.

b) The name of the registered corporation or company under the Companies Act and **the registration number,** allocated by the Registrar of Companies.

c) The business name, or name under which you propose to trade for purposes of the Act [if different from (a) or (b)].

Declaration

This declaration seeks assurances that the requirements of Section 22C and 22D and Regulation 19 and 20 of the Act have been satisfied and that the information provided in the application is current and correct at the time it was signed by the wholesaler. The declaration in A (iii) is intended to establish whether a wholesaler has received a notice that its wholesaling operations do not comply with current acceptable quality assurance principles and good wholesaling practices as determined by South African Health Products Regulatory Authority. A penalty applies for false and misleading statements made in relation to this application.

Persons signing the declaration

Persons signing the declaration should be the wholesaler, or the wholesaler's duly appointed designee who is responsible to South African Health Products Regulatory Authority l for compliance with the Act – refer Regulation 19(1)(a)(iii).

Name	Full name
Position	The role in the organization e.g. Owner, Designee.

Site Master File

Part of the reporting aspects of the audit can be addressed by receiving information on related company details, e.g. details of the company's facilities, personnel structure and operating procedures including manufacturing activities, prior to audit.

It is expected that a Site Master File be prepared and submitted to the Inspectorate that should be in line with the guidelines on the preparation of a Site Master File, which can be obtained from the office of the Chief Executive Officer or the SAHPRA website: www.sahpra.org.za

Date of audit

Before a licence may be issued or renewed, the Inspectorate may have to conduct an audit of the company's wholesaling operations to assess conformity with the Good Wholesaling Principles as determined by South African Health Products Regulatory Authority. In order to schedule an audit, the applicant should indicate an approximate date by which they will be ready for an audit. If this date changes after the application is submitted the Inspectorate should be notified as soon as possible. The inspector assigned to undertake the audit will advise the manufacturer of the actual date of the audit approximately five working days beforehand.

Good Wholesaling Practices

Pursuant to the current GWP Guidelines, SAHPRA may determine written principles to be observed by a wholesaler of medicines or scheduled substances. These principles will primarily comprise the Guidelines on Good Wholesaling Practice (GWP). A copy of the current guidelines on GWP may be obtained by the wholesaler or distributor of medicines, biologicals or medical gas products from the office of the Chief Executive Officer or the website of the SAHPRA at www.sahpra.org.za

Note: If any of the details contained in this Application Form should change after this document has been signed, the Applicant will be obliged to submit an updated application form within 30 days, otherwise the Licence will automatically become null and void.

GENERAL INFORMATION

1.1 NAME OF PROPOSED LICENCE HOLDER

NOTE: Wholesaler Licences are granted to persons who, in the course of a business, act as a wholesaler or distributor of medicines. This can include:
(i) A legal person
(ii) A natural person

1.2 LICENCE NUMBER (if known)

1.3 IS YOUR BUSINESS REGISTERED WITH THE SOUTH AFRICAN PHARMACY COUNCIL AS A WHOLESALE PHARMACY?

YES	NO

Supply registration number and copy of certificate of recording

2.1 WHOLESALER'S BUSINESS DETAILS

Name of individual	
Registered company name if Corporation	
Name if trading under other business name	
Company or Corporation Registration number with the Registrar of Companies	

Has this site previously held any licence under the Medicines and Related Substances Act?

YES	NO

If YES, please attach details.

2.2 ADDRESS FOR COMMUNICATIONS

Town / City	**Postal Code**

3.1 LICENCE HOLDER CONTACT

Surname		**Initials**		**Title**	

Telephone number	
Fax number	
E-mail address	

3.2 SUPPLY REGISTRATION NUMBER AND COPY OF CERTIFICATE OF RECORDING OF PHARMACY OWNER WITH PHARMACY COUNCIL

SITE INFORMATION

Please complete separate forms for each site (including admin offices) from which storage, distribution or related activities take place

4.1 SITE NAME

4.2 SITE ADDRESS

Town	**Postal Code**

4.3 SUPPLY LICENCE NUMBER AND COPY OF LICENCE FOR THE PREMISES OBTAINED FROM THE DEPARTMENT OF HEALTH

	In operation prior to 2 May 2003	

4.4 SITE TYPE

Is this site used for distribution (the onward dispatch of ready packed orders) only?	**YES**	**NO**
Is this site used for other purposes?	**YES**	**NO**
Please specify these other purposes below (e.g. order receipt, invoicing, assembly/picking of orders, handling of goods returned from customers).		

Does the proposed licence holder also hold a Manufacturer's Licence naming this site?

YES	**NO**

Is this site named on any other wholesaler or manufacturer's licence?
If so please give the name of the company and their licence number.

4.5 SITE MASTER FILE (Tick the appropriate block)

Enclosed ☐ **Submitted before** ☐

Note: Before a licence audit is conducted wholesalers are required to submit a Site Master File. SMF previously submitted must not be older than **2 years**.

4.6 SITE MASTER FILE NUMBER (if known)

4.7 CATEGORIES OF PRODUCTS HANDLED AT THIS SITE

Please indicate by ticking the appropriate box

General Sale List	
Scheduled Medicines; S1-S4	
Controlled Medicines; S5 -S6	
Biological Products	

4.8 SPECIFIC ACTIVITIES

Please indicate by ticking the appropriate box

Imported unregistered medicines are handled at this site	
Medicines are exported from this site on behalf of Applicants	

4.9 METHOD OF DISTRIBUTION

Please indicate by ticking the appropriate box

Post	
Courier/Van service	
Own courier/Van service	
Customer collection	
Other, please specify below	

4.10 FACILITIES ON SITE

Is the description of the facilities available for the storage and distribution of medicinal products detailed in the Site Master File?	**YES**	**NO**

If not, please provide a brief description (approximately 500 words) of the facilities available for the storage and distribution of medicinal products on a separate sheet of paper.

4.11 EQUIPMENT ON SITE

Is a description of the major items of equipment other than transport available for the storage and distribution of medicinal products detailed in the Site Master File?	**YES**	**NO**

If not, please provide a brief description (approximately 500 words) of the equipment available for the storage and distribution of medicinal products on a separate sheet of paper. In particular please provide details of any refrigeration equipment available.

5 THE RESPONSIBLE PHARMACIST

Please give the following details of the person who is to carry out the functions of the Responsible Pharmacist.

5.1 Surname | **Initials** | **Title**

5.2 Business Address

Town	**Postal Code**

Business telephone number

5.3 The Responsible Pharmacist

Please give the following details of the pharmacist who is to control the wholesale or export of medicine or scheduled substance in terms of the provisions of Regulation 19 of the Act.

Surname	
First Names	
Position In Company	
SAPC Registration Number	

Relevant qualifications

Degree/Diploma	Field of Study	Institution	Year Graduated

Relevant experience (last job first)

Number of Years	Employer	Position Held

Please submit a certified copy of the candidate's Registration Certificate from the SA Pharmacy Council with this application.

I confirm that the above particulars are to the best of my knowledge and belief accurate and true.

I agree to be nominated as the Pharmacist responsible for the manufacture, import or export of medicines or scheduled substances as detailed in this license application.

Signed (designee):	Date:
Signed (responsible pharmacist):	Date:

DECLARATION

Applicants should note that in terms of the provisions of the Medicines and Related Substance Act, 1965 it is an offence to make false and misleading statements in connection with an application for a licence to act as Wholesaler or Distributor.

		Tick (✔) one box only in each case	
A.	I declare that:	Yes	No
(i)	The wholesaler had a licence revoked after being granted such a licence.		
(ii)	The wholesaler has been convicted of an offence against the Medicines and Related Substance Act, 1965 or a law of a state or territory relating to medicines or scheduled substances.		
(iii)	The wholesaler failed on more than one occasion to observe the wholesale principles in connection with the wholesale of medicines or medical devices.		
(iv)	The information provided in this application is current and correct.		

If parts (i), (ii) or (iii) of the declaration were answered in the affirmative, details should be provided on additional pages.

B. I / We apply for the **granting / renewal** (*indicate by crossing out the non applicable section*) of a Wholesaler Licence to the proposed holder named in this application form in respect of the activities to which the application refers.

1. The licence is subject to all the Standard Provisions applicable to Wholesaler Licences under regulations for the time being in force under Section 22C of the Medicines and Related Substance Act, 1965 (Act 101 of 1965).
2. The activities are conducted only in accordance with the information set out in the application or furnished in connection with it.
3. To the best of my / our knowledge and belief the particulars I / we have given in this form are correct and complete.

The above declaration must be signed:

- in the case of a corporation or company, by the designee / natural person who shall be responsible to SAHPRA for compliance with the Act.
- in the case of other enterprises, by the owner.

Name	
Signature	
Position within Organization	
Date	

Note: This is a legal document. Any changes to the application once submitted must be made in writing detailing the requested variation and be signed by the authorized person above.