SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

SAHPRA
South African
Health Products
Regulatory Authority

LICENCE APPLICATION FOR WHOLESALER TO EXPORT MEDICINAL PRODUCTS

- An application form for the purpose of **obtaining** a licence **by a licensed wholesaler to export medicinal products** (i.e. medicines, scheduled substances, medical devices and *in vitro* diagnostics) 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 each licensed wholesaler who wishes to export medicinal products or wishes to renew their existing export licence.
- 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 the licence application. See the summary of fees and charges available from the office of the Chief Executive Officer

  Note: Cheques should be made payable to **South African Health Products Regulatory Authority**
- The completed form should be sent to:

  The office of the Chief Executive Officer
  South African Health Products Regulatory Authority
  CSIR Campus, Building 10F, Meiring Naude Road,
  Brummeria, Pretoria, 0001
- 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 South African Health Products Regulatory Authority.
- After five years the Wholesaler needs to renew or reapply for a licence. The application for the renewal of the export licence should be submitted 90 days' prior the expiry of the existing licence.
- The licensed wholesaler - exporting medicinal products - must submit a list of the medicinal products intended for export on an annual basis.

Guidance notes for General information

The Business Name of the Wholesaler

Full, legal name of licence applicant or owner of the business who wishes to wholesale, distribute and export medicinal products (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 of the business, 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 and submitted 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 Responsible Pharmacist or Chief Executive Officer who is responsible to South African Health Products Regulatory Authority 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 an export 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 current 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 wholesaler of the actual date of the audit.

Good Wholesaling Practices

Pursuant to the current GWP Guidelines SAHPRA may determine written principles to be observed by a wholesaler of medicinal products. 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 invalid.

GENERAL INFORMATION

1.1 NAME OF THE LICENSED WHOLESALER

NOTE: Wholesaler Licences are granted to persons who, in the course of a business, act as a wholesaler of medicinal products. 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 administration 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 wholesaling of medicines	**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).		

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 PHARMACIST RESPONSIBLE FOR EXPORT ACTIVITIES AT THE WHOLESALER

Provide the following details of the pharmacist who is to control the wholesale or export of medicinal products 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 correct to the best of my knowledge and believed to be accurate and true.

I agree to be nominated as the pharmacist responsible for the export of medicinal products as detailed in this licence application.

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

6 CONTRACTS

6.1 A contractual agreement between the Holder of the Certificate of Registration (HCR) and the Wholesaler, stipulating that the appointed wholesaler is allowed to export their medicinal products outside the boarders of South Africa, is to be included in the application.

YES	**NO**

6.2 A contractual agreement between the Wholesaler and the foreign sites to where the exported medicinal products will be warehoused and stored is included in the application.

YES	**NO**

6.3 An authorization letter from the foreign Regulatory Authority, Government Agency or Department of Health approving the marketing of the exported medicinal products in their country, is included in the application.

YES	**NO**

6.4 The list of the medicinal products intended to be exported outside the boarders of South Africa is included in the application

YES	NO

6.5 Are all the countries, through which the medicinal products will pass before reaching their final destination, declared in the application?

YES	NO

The exportation of Schedule 5 and 6 controlled substances will not be approved or allowed, in terms of Regulation 15 of the Act (101 of 1965).

The Responsible Pharmacist of the wholesaler wanting to export must be aware of the fact that medicinal products for human use can only be obtained legally from the licensed manufacturers or licensed distributor of such products.

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.

		Tick (✔) one box only in each case	
A.	I declare that:	Yes	No
(i)	The wholesaler's licence has been 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 maintain good wholesaling principles pertaining to the wholesaling 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 Organisation	
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 authorised person above.