* An application form for the purpose of **obtaining** a licence **by a licensed wholesaler to export medicinal products** (i.e. medicines and scheduled substances) in terms of the provisions of the Medicines and Related Substances Act, 101 of 1965, Section 22C and 22D read together with the General Regulations 23 and 24 of the Medicine 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.
* Licensing guidelines are available at the SAHPRA website: [www.sahpra.org.za](file:///C%3A%5CUsers%5Cmolokwanej%5CAppData%5CLocal%5CMicrosoft%5CWindows%5CINetCache%5CContent.Outlook%5CQXH1OGTD%5Cwww.sahpra.org.za)
* 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 application will only be recognised if accompanied by the prescribed application fee for a licence. For the amount, refer to the summary of fees and charges available on the SAHPRA website: <https://www.sahpra.org.za/wp-content/uploads/2021/01/Published-SAHPRA-Fees.pdf>
* The completed form and supporting documents should be emailed to:

 gmplicensing@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 otherwise suspended or revoked by South African Health Products Regulatory Authority.
* Licensing guidelines are available at the SAHPRA website: <https://www.sahpra.org.za/inspectorate-and-regulatory-compliance/>
* **An application for renewal of the licence must be submitted at least 180 days before 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.](file:///C%3A%5CUsers%5Cmolokwanej%5CAppData%5CLocal%5CMicrosoft%5CWindows%5CINetCache%5CContent.Outlook%5CQXH1OGTD%5Cwww.sahpra.org.za)

**Date of audit**

Before an exportlicence 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](file:///C%3A%5CUsers%5Cmolokwanej%5CAppData%5CLocal%5CMicrosoft%5CWindows%5CINetCache%5CContent.Outlook%5CQXH1OGTD%5Cwww.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 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 WHOLESALER’S BUSINESS DETAILS**

|  |  |
| --- | --- |
| Name of business owner |  |
| Registered company name if Corporation  |  |
| Name if trading under other business name |  |
| Company or Corporation Registration number issued by the registrar of Companies |  |

**1.3 SITE/PHYSICAL ADDRESS**

|  |
| --- |
|  |
|  |
|  |
| **Town/City** | **Postal Code** |
| **Province** |

**1.4 ADDRESS FOR COMMUNICATIONS (IF DIFFERENT FROM PHYSICAL ADDRESS)**

|  |
| --- |
|  |
|  |
|  |
| **Town/City** | **Postal Code** |
| **Province** |

**1.5 LICENCE HOLDER CONTACT**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Surname** |  | **Initials**  |  | **Title**  |  |

|  |  |
| --- | --- |
| **Telephone number** |  |
| **Fax number** |  |
| **E-mail address** |  |

**1.6 HAS THE SITE previously held A SAHPRA licence? If YES, PROVIDE THE LICENCE NUMBER**

|  |
| --- |
|  |

**1.7 IS YOUR BUSINESS REGISTERED WITH THE SOUTH AFRICAN PHARMACY COUNCIL AS A MANUFACTURING PHARMACY?**

|  |  |
| --- | --- |
| **YES** | **NO** |

**If yes, supply the Y registration number and copy of certificate of recording**

|  |
| --- |
| **Y** |

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

|  |
| --- |
|  |

|  |
| --- |
| **SITE INFORMATION** |

**2.1 SITE MASTER FILE (Tick the appropriate block)**

**Enclosed Submitted before 20**

**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**.

**2.2 SITE MASTER FILE NUMBER**

|  |
| --- |
|  |

 **Note:** If not known, request a Site Master File Number from smf@sahpra.org.za

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

|  |
| --- |
|  |

**2.4 SITE CONTACT (RESPONSIBLE PHARMACIST)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Surname** |  | **Initials** |  | **Title** |  |

|  |  |
| --- | --- |
| **Telephone number** |  |
| **Fax number** |  |
| **E-mail address** |  |

**2.5 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). |
|  |

**2.6 CATEGORIES OF PRODUCTS HANDLED AT THIS SITE**

 **Please indicate by ticking the appropriate box**

|  |  |
| --- | --- |
| General Sale List; S0  |  |
| Scheduled Medicines; S1-S4 |  |
| Controlled Medicines; S5 -S6 |  |
| Time & Temperature Sensitive Pharmaceutical Product e.g. Fridge items such as vaccines and biological medicines  |  |

**2.7 SPECIFIC ACTIVITIES**

 **Please indicate by ticking the appropriate box**

|  |  |
| --- | --- |
| SAHPRA authorised Section 21 Medicines are handled at this site  |  |
| Unregistered Investigational Products are handled at this site |  |
| Medicines are exported from this site on behalf of Applicants |  |

**2.8 METHOD OF DISTRIBUTION**

Please indicate by ticking the appropriate box

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

**2.9 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. |

**2.10 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. |

**3. 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: |

**4. CONTRACTS**

4.1 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** |

4.2 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** |

4.3 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** |

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

|  |  |
| --- | --- |
| **YES** | **NO** |

4.5 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 unless Section 22A read together with Regulations 26 and 27 of the Medicine Act (101 of 1965) are adhered too.**

**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 Holders of the Registration Certificate of such products.**

**5. PROPOSED DATE OF AUDIT**

 Approximate date when ready for audit

|  |
| --- |
|  |

**6. list of supporting documents to be submitted**

|  |  |  |
| --- | --- | --- |
|  | **Yes** | **No** |
| Proof Of Payment |  |  |
| Existing SAHPRA Licence for Renewal and Amendment Applications |  |  |
| Cover Letter |  |  |
| Site Master File |  |  |
| Signed Declaration |  |  |
| Sahpra Inspection Resolution |  |  |
| CIPC/CIPRO/DTI Certificate (Docs) |  |  |
| NDOH Premises Licence |  |  |
| Registration of Responsible Pharmacist |  |  |
| SAPC Record of a Pharmacy |  |  |
| SAPC Record of a Pharmacy Owner |  |  |
| Municipal Approval/Zoning Certificate |  |  |

|  |
| --- |
| **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 of a Wholesaler to Export Medicinal Products.*

|  |  |
| --- | --- |
|  | *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 of the new/ renewed/ amended** (*indicate by crossing out the non-applicable section*) 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.**