South African Health Products
Regulatory Authority
Building A
Loftus Park
Arcadia
Pretoria

GUIDE ON HOW TO APPLY FOR LICENCE TO ACT AS A WHOLESALER OF MEDICINES AND /OR SCHEDULED SUBSTANCES

06 May 2022

This guideline is intended to provide recommendations to applicants wishing to submit an application for a licence to act as a wholesaler of medicine and/or scheduled substances. It is not intended as an exclusive approach leaflet and should not be taken as a complete or authoritative statement of the law. SAHPRA reserves the right to request any additional information to establish the safety, quality, and efficacy of a medicine and/or scheduled substances in keeping with the knowledge current at the time of evaluation. The SAHPRA is committed to ensure that all medicines and/or scheduled substances will be of the required quality, safety, and efficacy and that the wholesaler and/or distributor complies with acceptable quality assurance principles and good wholesaling / distributing practices as determined by SAHPRA. It is important that applicants adhere to the administrative requirements to avoid delays in the processing and evaluation of applications.

Document History

First publication released for implementation and comment --Version 0	November 2003
Date for finalisation/implementation---Version 1	January 2004
Version 2--Updated to amend various sections of the guideline	May 2022(for comments) Deadline for Comment 13 May 2022

BOITUMELO SEMETE-MAKOKOTLELA

CHIEF EXECUTIVE OFFICER

Contents

Table list

List of abbreviations and definitions

Table 1: List of Abbreviations

CEO	Chief Executive Officer
Act 101 of 1965/Medicines Act	Medicines and Related Substances Act 101 of 1965

GWP	Good Wholesaling Practices
SAHPRA	South African Health Products Regulatory Authority
SAPC	South African Pharmacy Council
RP	Responsible Pharmacist
Pharmacy Act	Pharmacy Act 53 of 1974
WL	Wholesaler Licence
CEO	Chief Executive Officer

Table 2: List of Definitions

Wholesaler	including a wholesale pharmacy means a person who holds, stores, delivers or purchases medicines or Scheduled substances from a manufacturer and sells them in terms of section 22H of the Act
Responsible pharmacist	means a responsible pharmacist as defined in Section 1 of the Pharmacy Act
Bonded warehouse	means a customs and excise warehouse licensed in terms of section 19 of the Customs and Excise Act, 1964 (Act No. 91 of 1964)

1. Introduction

The South African Health Products Regulatory Authority (SAHPRA or The Authority) regulates medicines for human and animal use, on behalf of the Department of Health and in accordance with the provisions of the Medicines and Related Substances Act; (Act 101 of 1965) as amended and the relevant Regulations made thereunder. (Hereafter referred to as the Act 101 of 1965 or the Medicines Act.) Amongst other things, it is unlawful for medicines or scheduled substances to be marketed, manufactured, distributed, and sold or supplied in the Republic of South Africa (RSA) except in accordance with the appropriate authorization, registration certificates, licences, clinical trial approvals or exemptions obtained from the Authority. The licensing system includes SAHPRA, the Chief Executive Officer of SAHPRA and the Program: Inspectorate and Regulatory Compliance, whose duties comprise the issue of licences to those engaged in the sale or supply of medicines and scheduled substances by way of wholesale dealing. Furthermore, the Good Wholesaling Practice (GWP) Inspectors and SAHPRA are responsible for ensuring that licence holders comply with the provisions and conditions of their licences. The wholesale or distribution of veterinary medicine or scheduled substances for animal use, registered with The Authority in terms of the provisions of the Medicines and Related Substances Act 101 of 1965 (Act 101 of 1965), is subject to the same legislation and the requirements are similar. The purpose of this Guidance Note is to provide guidance on the law covering the wholesale distribution of medicines and scheduled substances and wholesale dealing of medicines and scheduled substances for human and animal use and controlled in terms of the provisions of the Medicines Act.

2. Purpose

This guideline is intended to provide recommendations to applicants wishing to submit an application for a licence to act as a wholesaler of medicine and/or scheduled substances. It is not intended as an exclusive approach leaflet and should not be taken as a complete or authoritative statement of the law. SAHPRA reserves the right to request any additional information to establish the safety, quality, and efficacy of a medicine and/or scheduled substances in keeping with the knowledge current at the time of evaluation. The SAHPRA is committed to ensure that all medicines and/or scheduled substances will be of the required quality, safety, and efficacy and that the wholesaler and/or distributor complies with acceptable quality assurance principles and good wholesaling / distributing practices as determined by SAHPRA. It is important that applicants adhere to the administrative requirements to avoid delays in the processing and evaluation of applications.

3. Background

The distribution of medicines in South Africa is governed strictly by the Medicines and Related Substances Act No.101 of 1965, as amended (Medicines Act). The most recent amendments were brought into effect on 1 June 2017.

Other pieces of legislation govern the movement of medicines in the supply chain and persons authorised to distribute medicines within the supply chain including the:

- Pharmacy Act No. 53 of 1974, as amended.
- Health Professions Act No.56 of 1974, as amended (HPA).
- National Health Act No 61 of 2003, on human tissue.
- Animal Diseases Act No 35 of 1984, on medicines with animal content

The wholesaling and distribution of medicine and scheduled substances requires a licence that must be obtained from the South African Health Products Regulatory Authority (SAHPRA).

4. Scope

This document lays down guidelines on how to apply for a licence to wholesale and distribute Medicines and Scheduled Substances and applies equally to products for human and for veterinary use as per Act 101 of 1965. In this Guideline, the word "should" indicates requirements that are expected to apply unless shown to be inapplicable or replaced by an alternative demonstrated to provide at least an equivalent level of quality assurance. The scope also includes the following:

4.1 All activities consisting of procuring, holding, supplying, or exporting medicines and medicinal substances, apart from supplying medicines and scheduled substances to the public, are wholesale distribution. Transport companies are seen as third-party service providers to licensed wholesalers and are not licensed separately by SAHPRA.

4.2 Wholesaling of unregistered medicines and scheduled substances e.g., investigational medicinal products, or medicines and scheduled substances solely for export purposes are also controlled in accordance with the relevant provisions of the Act 101 of 1965 and its relevant regulations.

4.3 Wholesale dealing is the sale of medicines and scheduled substances in the course of a business, to a person who buys it for selling or supply, or for administration to a human being or animal. Therefore, the wholesale licence entails any sale or supply except to the end-user (patient) and to another wholesaler. A wholesaler should not engage in retail activities.

4.4 Section 22C of the Medicines Act read together with Regulation 1 provides that: "wholesaler", including a wholesale pharmacy, means a dealer or trader who acquires any medicine or scheduled substances from an approved manufacturer or primary importer and sells or distributes it to the retail sector.

4.5 Section 22H of the Medicines Act prohibits any wholesaler from buying any medicine from any other source except from the original manufacturer or from the primary importer of the finished product, except when specifically exempted by the Director-General of Health from such provisions.

4.6 The scope also includes the licencing of Government's Provincial Depots

5. Guiding Principles

5.1. All parties involved in the supply chain of medicines and scheduled substances are responsible for the effective, efficient, and safe handling, storage, and distribution of such products in a manner that does not risk exposure to storage(temperature, humidity, light) outside of their recommended storage conditions. This would prevent any excursions from the recommended storage conditions that could potentially affect the quality, safety, and effectiveness of the products.

5.2. The principles of Good Wholesaling Practices are equally applicable to medicines and scheduled substances moving through the supply chain from the manufacturer to the end user, as well as medicines and scheduled substances which are moving backwards in the supply chain because of the return or recall thereof.

5.3. All parties involved in the wholesaling process should apply due diligence with adherence to the principles of Good Wholesaling Practices, for example, procedures relating to traceability, recognition of security risks, purchasing suspect products, poor storage, or failure to establish the bona fides of purchasers.

6. Persons Requiring a Wholesale Licence

Persons who in the course of a business are engaged in:

a) Wholesale distribution of medicines and scheduled substances.

b) Wholesale dealing of medicines and scheduled substances for human and animal use

c) Requires a wholesale dealer's (WL) licence unless exemption was obtained.

7. Persons who do not require a Wholesale Licence

7.1. The Holder of a certificate of Registration if the product has not left the premises of the licensed manufacturer or assembler before it is sold or supplied.

7.2. A person who holds a manufacturer's licence does not also need a wholesale licence in order to distribute those products to which the manufacturer's licence relates, but if any other products are distributed a wholesale licence is required.

7.3. Activities that are not wholesale distribution are therefore not licensed as such.

7.4. A pharmacist in a registered pharmacy, hospital or health centre, or someone acting under his supervision, who sells or supplies a medicines or scheduled substances in accordance with a practitioner's prescription.

7.5. A group of persons who order goods jointly for subsequent retail sale by an individual.

8. How to obtain a Licence

8.1. Standard application form for wholesale dealer's licence (WL) to act as a wholesaler of or distributor of medicines and/or scheduled substances is available from the Office of the Chief Executive Officer of SAHPRA or from the SAHPRA website www.sahpra.org.za

8.2. An application for WL should be accompanied by the prescribed application fee (see the gazetted published fees in the SAHPRA website) and in the case of a new Wholesaler an additional inspection fee will be required.

The application form shall provide acceptable documentation proof obtained from the following institutions:

8.2.1 The SA Pharmacy Council, of:

- The particulars of the owner of the business, which includes the Certificate of recording of a Pharmacy Owner
- The registration of the responsible pharmacist
- Certificate of recording of a Pharmacy.

8.2.2 The Director-General of Health:

- A licence for the premises wherein or from which such business shall be carried on.

NOTE: All wholesalers in operation prior to 2 May 2003 are deemed to have a premises licence

8.2.3 Additional documents required:

- Cover Letter -Which explains the reason for the application and type, i.e., whether it is a NEW/RENEWAL/AMENDMENT application.
- CIPC/CIPRO/DTI CERTIFICATES OR DOCUMENTS proving ownership of the business

8.3 The application for WL should include the qualification of staff to store, distribute and sell medicines or scheduled substances and should be able to comply with good wholesale / distribution practices as determined by SAHPRA.

8.4 The application for the WL should have a Site Master File document (guideline found in the SAHPRA website www.sahpra.org.za) attached to it. This Site Master File document should include:

- A copy of the local area plan of the location of the business premises indicating all adjacent properties and the nature of the business being carried out, on such premises.
- A floor plan of the building in which the business premises are situated

- A plan of the actual layout of the business premises
- An inventory of equipment to be used in conducting the business
- A manual of procedures and practices to be implemented to ensure the safety, efficacy and quality of medicines, or scheduled substances or medical devices to be distributed and sold.

8.5 The application for the WL should specify the medicines or scheduled substances to be distributed and sold.

8.6 The Authority (SAHPRA) will only issue a WL when it is satisfied, usually following an inspection of a site by the designated Inspectors, that the information contained in the application is accurate and in compliance with requirements of the legislation and good wholesale practices.

8.7 Where appropriate, SAHPRA may refuse to grant a licence. In such cases the CEO of SAHPRA will notify the applicant to furnish The Authority with such additional documentation or information as The Authority may require. The notification will set out the reason for the proposal and give the applicant a reasonable period to respond. The applicant may make written representations. Before making a final decision on its proposal The Authority will take the applicant's written representation into consideration.

8.8 The legislative basis for the information required when applying for a WL may be found in the Medicines Act.

8.8.1 Section 22C(1)(b) of the Act 101 of 1965

8.8.2 Regulation 23 of the regulations to the Act 101 of 1965

9. Wholesale Licence Holder's-Obligations

9.1. The standard provisions for wholesale licence (WL) require a licence holder to:

a. Provide and maintain suitable staff, premises, equipment, and facilities;

b. Provide information as requested by The Authority regarding the type and quantity of any Medicines or scheduled substances which he/she currently handles, stores, or distributes;

c. Inform the Authority of any proposed structural alterations to or discontinuance of use of premises to which the licence relates or which have been approved from time to time by SAHPRA;

d. Retain such transaction documents as are necessary to facilitate the withdrawal or recall of any medicines or scheduled substances;

e. Permit SAHPRA to carry out inspections, take samples or copies of documents;

f. To have in place an emergency plan for the recall of medicines or scheduled substances;

g. To keep specified records and legal documents as required by the Medicines Act that are available for inspection by SAHPRA for a period of five years after the date of receipt or dispatch;

h. To appoint and designate a Responsible Pharmacist under whose personal supervision all activities take place;

i. Appoint and designate a natural person who resides in the Republic who shall be responsible to SAHPRA for compliance with the Act 101 of 1965;

j. To obtain medicines or scheduled substances only from licensed manufacturers and/or approved importers whose licences relate to those medicines or scheduled substances or from persons who are exempt from holding such licenses;

k. Apply for the renewal of the license every 5 years at least 180 days before the expiry of the existing licence.

10. Inspections [as stipulated by Section 28 of Act 101 of 1965 read together with Regulation 23(3)].

10.1. The Inspectorate Unit's GWP Inspectors carry out regular and repeated inspection of wholesale distribution sites. Inspections enable SAHPRA to confirm that licence holders are complying with the conditions of their licences, with the provisions of the Medicines Act and with Good Wholesaling Practice (GWP) / Good Distribution Practice (GDP).

10.2. Amongst other things, Inspectors are empowered to:

a) Enter any place or premises from which the owner is the holder of a licence to act as wholesaler or distributor of medicines or scheduled substances;

b) Inspect the premises used in the storage and distribution of medicines or scheduled substances and inspect any documentation or records relating to the storage and distribution of medicines or scheduled substances;

c) Take samples;

d) Seize any book, record, documentation or medicine, scheduled substances.

It is required by legislation that licence holders shall make their premises available for inspection by the

Inspectorate at any reasonable time.

10.3 Following an inspection, the Inspector prepares a report of his findings. A letter is sent to the licence applicant or holder noting any deficiencies found and asking for proposals to remedy them. In the event of serious non-compliance with GWP/GDP, the report is referred to The Authority for formal action, which can include the refusal, suspension or revoking of a licence.

11. Powers to Suspend or Revoke a Wholesale/Distributor Licence (as per the provisions of Section 22E of Act 101 of 1965)

11.1. The Authority may revoke or suspend a licence when a statutory condition of that licence is no longer being met, or the licence holder does not comply with the Act 101 of 1965 or if the RP fails to control the distribution of medicines and/or scheduled substances.

11.2. The Authority will give the licence holder notice of its removal. The licence holder will be given a notice of not less than 20 days form the day of the notice to respond and give reasons why such licence should not be removed.

11.3. A licence holder or applicant may at any time within the period of 30 days from the date on which the decision is served on him appeal to the Minister to question the validity of SAHPRA's decision as per Section 24A of Act 101 of 1965.

12. Process to follow when a SAHPRA licenced site ceases to exist

If a SAHPRA licenced site ceases to exist due to any business conditions, the process outlined below shall be followed;

12.1. The Company's CEO/MD together with the RP must write a letter in their company's letter head addressed to the CEO of SAHPRA in not less than 30 days to the closure of the site as per Regulation 23(9) of Act 101 of 1965. The letter must confirm to SAHPRA the proposed date closure.

12.2. The Company must confirm to SAHPRA that the intended closure has been communicated to NDOH and to the SAPC.

12.3. The Company to return to SAHPRA the original licence with all its Annexures within 10days of closure of the business.

13. Fees Payable

13.1. The Medicines and Related Substances Act 101 of 1965 introduced provisions in terms of Section 35 (1) (xxxi) and (xxxii) read together with Section 35 (4) for the payment of fees for

licences, certificates, and inspections. The current fees legislation for medicines and scheduled substances is contained in the Medicines Regulations as amended.

13.2. Fees are currently payable for the following:

a. Licence applications (new and amendment applications)

b. Licence renewal

c. Licence issue

d. Performance of inspections

An annual retention fee is also payable during the currency of a licence.

13.3 A schedule of the current fees is available from the Office of the Chief Executive Officer of SAHPRA or on the SAHPRA website at www.sahpra.org.za

13.4 When SAHPRA plans to make changes to the amount or frequency of fees, licence holders are consulted and given the opportunity to comment on the new fee proposals. Details of the new fees are published in the government gazette and on the South African Health Products Regulatory Authority's website at www.sahpra.org.za

14. Contact Details

SAHPRA and Program 3(Inspectorate and Regulatory Compliance) can be contacted at:

The Office of the Chief Executive Officer

South African Health Products Regulatory Authority

Private Bag X828

Pretoria

0001

Tel: 012 501 0300

Email: enquiries@sahpra.org.za

15. References

15.1. Related Regulations

- Medicines and Related Substances Act 101 of 1965
- Pharmacy Act No. 53 of 1974
- Health Professions Act No.56 of 1974, as amended (HPA).
- National Health Act No 61 of 2003, on human tissue.
- Animal Diseases Act No 35 of 1984, on medicines with animal content

16. Amendment History

Table 3: Update History

Version	Date	Reason for amendment
Version 1	January 2004	Date of Finalisation and Implementation
Version 2…	March 2022	Amendment to various sections of the Guideline and due for comments