South African Health Products
Regulatory Authority
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Loftus Park
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GUIDE TO FEE DETERMINATION AND PAYMENTS OF PERMITS AND RELATED AUTHORIZATIONS IN REGULATORY COMPLIANCE UNIT June 2022

This guideline intends to assist applicants in differentiating between various types of permits, the requirements for each permit and the relevant fees applicable.
This guideline is applicable to Section 22A permits and related authorizations in Regulatory Compliance. The scope includes the application process, fee applicable and timeline for finalizing an application.

Document History

Version	Date	Reason for amendment
Version 1	20 June 2022	First Publication

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List of abbreviations and definitions

AWB	Air Waybill
Medicines Act	Medicines and Related Substances Act, 1965 (Act 101 of 1965) as amended;
Export	Includes deliver or supply within the Republic for dispatch to any destination outside the Republic;
Pharmacist	Means a person registered as such under the Pharmacy Act, 1974 (Act No. 53 of 1974),

1. Introduction

1.1. The South African Health Products Regulatory Authority (SAHPRA) (hereinafter referred to as the Authority) is a statutory body, established to provide for the monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, Scheduled substances, clinical trials and medical devices, IVDs and related matters in the public interest according to section 2A of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), as amended (Medicines Act).The Authority must ensure that health products and medicines registered or authorised by the Authority, during the entire life cycle, comply with the information that has been evaluated and approved by the Authority through section 2B(1)(c) of the Act.

1.2. The Regulatory Compliance Unit is responsible for issuance of permits for Schedule 5,6,7 and 8 in terms of Section 22A(9)(a)(i) and 22A(11) of the Medicines Act, these are also known as permits for narcotics and psychotropic substances. Therefore, these would include substances listed under other schedules when they contain a narcotic/psychotropic substance in combination doses, e.g. paracetamol with codeine

2. Scope

This guideline is applicable to Section 22A permits and related authorizations in Regulatory Compliance. The scope includes the application process, fee applicable and timeline for finalising an application.

3. Purpose

The guideline outlined the process for Section 22A permits application. It provides information about details requirements to be meet for successful application of permits and provide the details fee payable as part of the application.

4. Background

The Narcotics And Psychotropic substances are regulated to curb their illegally abuse. the permit are required to export narcotic and/or psychotropic substances in terms of the medicines and related substances act, 1965 (act 101 of 1965), the single convention on narcotic drugs, 1961, and the convention on psychotropic substances, 1971: regulation 20(4) and 20(7)(a)

5. PROCESS

The turnaround time for a decision to be provided on an application for a Section 22A(9) and 22A(11) permit is 20 working days form the date of receipt of a complete application. Applicants should follow-up directly with the unit if they have not received a response within this time.

Application requirements and process:

The following types of permits are issued in relation to Section 22A(9) and 22A(11).

a) Manufacturing or possession permits (*sec22a_permits@sahpra.org.za*.),

b) Import permits (sec22a_permits@sahpra.org.za); and

c) Export permits (sec22a_permits@sahpra.org.za.).

Applicants are expected to obtain a reference number (e.g. LEU, RCD and RCS) for the application prior to submission, the purpose of reference number is to link the application/s to the proof of payment. *Requests for reference number should be sent via email to sec22a_permits@sahpra.org.za . Applicant must ensure that application is fully completed, dated and signed by the pharmacist, with proof of payment. A complete application as outlined below would include:*

a) Manufacturing or possession permits must have

i. Application form, copy of Authorised person's ID, proof of SAPC registration, Company delegation letter with acceptance, expired permit if applicable, in case of research provide research proposal

b) Import permits

i. Application form (1 substance only), copy of Authorised person's ID, proof of SAPC registration, Company delegation letter with acceptance; and
ii. ITAC permit (applicable for precursor substances)

c) Export permits.

i. Application form (5 substances maximum), copy of Authorised person's ID, proof of SAPC registration, Company delegation letter with acceptance;
ii. ITAC permit (applicable for precursor substances); and
iii. Corresponding import permit from Regulatory Authority/government where applicable.

Complete applications should be submitted via email to sec22a_permits@sahpra.org.za. An acknowledgement will be sent to the client within 48 working hours.

6. REQUIREMENTS FOR ANY OTHER AUTHORISATIONS

a. Permit/Authorisations for import and export of samples

Application to import and export samples of registered medicines, must be on a company letterhead, with details of the required substances, batch numbers and expiry date and export /import details and address. The letter must be dated and signed letter by the Responsible pharmacist/ delegate pharmacist/authorised scientist and have ***the proof of payment of R350.*** Applications must be sent via email to samples@sahpra.org.za and copy Pebetsi.malope@sahpra.org.za and Educate.sebotsi@sahpra.org.za

b. Permit/Authorisations for import of health products for personal or any purpose without proper authorisation documentations via ports of entry will be reviewed (approval/rejection) at a fee

Request for authorisation/permit to release health products that were not accompanied by SAHPRA approval documents at Ports of entry. The applicant must provide supporting shipment documents e.g. official letter of request, invoice, AWB, any required supporting document, together with *the proof of payment of R350*. to the SAHPRA Border Technician at relevant port of entry. Applications must be sent via email to porthealth@sahpra.org.za copy Educate.sebotsi@sahpra.org.za and Mokgadi.fafudi@sahpra.org.za.

7. FEES PAYABLE PER PERMIT AND TYPE

Table 1 FEE STRUCTURE OF PERMITs

	Permit Type	Payment Ref Abbreviation	Request Payment Ref	Fees
1	Export Permit	LEUNo	*sec22a_permits@sahpra.org.za*.	R925
2	Export Authorizations	LEUNo	*sec22a_permits@sahpra.org.za*.	R925
3	Import Permit	LEUNo	*sec22a_permits@sahpra.org.za*.	R950
4	Import Authorizations	LEUNo	*sec22a_permits@sahpra.org.za*.	R950
5	Manufacturing Permit	LEUNo	*sec22a_permits@sahpra.org.za*.	R950
6	Possessions	LEUNo	*sec22a_permits@sahpra.org.za*.	R950
8	Samples for either registration/ analytical purposes	RCSNo	samples@sahpra.org.za	R350
9	Evaluation of unauthorised Imported medicine/health product at port of Entry for Releases/ Detainment	RCPENo	porthealth@sahpra.org.za	R350

BANK DETAILS

Account name: SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY
Special name: The Medicines Control Council
Account type: Cheque/Current Account
Account number: 40-5939-2080
Bank: ABSA
Bank Branch Code: 632005
Bank physical address: 240 VERMEULEN STREET, PRETORIA, 0001, SOUTH AFRICA
Swift Code: ABSAZAJJ

Reference

Medicines and Related Substances Act 101 of 1965 and the General Regulation