South African Health Products
Regulatory Authority
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License Renewal_v2

QUESTIONS & ANSWERS:
License Renewal

Document History

[Final Guideline for implementation – Version 1]	04 02 2022
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Contents

List of abbreviations and definitions

Authorized Representative	natural person, resident in the Republic of South Africa, who a) has the written mandate to represent a manufacturer, importer, distributor, wholesaler, retailer or service provider in the Republic; b) acts on behalf of a manufacturer, importer, distributor, wholesaler, retailer or service provider for specified tasks with regard to the latter's obligations and in whose name the manufacturer License, distributor License, wholesaler License and or certificate of registration is issued; and c) is responsible for all aspects of the medical device or IVD, including performance, quality, safety and compliance with conditions of registration, clinical trials or clinical investigations;
Medical device	any instrument, appliance, material, machine, apparatus, implant or diagnostic reagent- (a) used or purporting to be suitable for use or manufactured or sold for use in- (i) the diagnosis, treatment, mitigation, modification, monitoring or prevention of disease, abnormal physical or mental states or the symptoms thereof; or (ii) restoring, correcting or modifying any somatic or psychic or organic function; or (iii) the diagnosis or prevention of pregnancy, and which does not achieve its purpose through chemical, pharmacological, immunological or metabolic means in or on the human body but which may be assisted in its function by such means; or (b) declared by the Minister by notice in the Gazette to be a medical device, and includes any part or an accessory of a medical device
IN VITRO Diagnostic Medical Devices (IVDs)	Means a medical device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.
"Manufacturer"	All operations that include the design, purchasing of material, specification development, production, fabrication, assembly, processing, reprocessing, releasing, packaging, repackaging, labelling and refurbishing of a medical device or IVD, as the case may be, and includes putting a collection of medical devices or IVDs, and possibly other products, together for a medical purpose in accordance with quality assurance and related controls

Distributor	Natural or legal person who a) imports or exports a medical device or IVD which is on the register for medical devices or on the register for IVDs in its final form, wrapping and packaging, with a view to the medical device or IVD being placed on the market under the natural or legal person's own name; and b) sells the medical device or IVD.
Wholesaler	A dealer who purchases medical devices or IVDs from a manufacturer or distributor and sells them to a retailer.
Classification	The medical devices regulatory framework has a classification system for medical devices and IVDs, as per the regulations of Act 101 of 1965South African risk classification as per classification guideline 8.05.
Quality Manual	A Quality Manual provides an overview of the documented quality management system which is in operation and must include information about the organization, the facilities, the key personnel, the quality assurance policies, procedures, work instructions, controls and activities which are undertaken by the organization to demonstrate its ability to provide medical devices and related services that consistently meet the South African regulatory requirements.

1. Introduction

The Medicines and Related Substances Act, 1965 (Act 101 of 1965) Amendment, No.14 of 2015, makes provision for the implementation of the regulatory oversight of medical devices in South Africa.

This document is a summary of questions that relate to the South African Health Products Regulatory Authority (SAHPRA) guidelines for licence renewal of medical device establishments:

a. MD031: Industry draft communication regarding requirements for the renewal of establishment license
b. 16.03 Guideline for a licence to manufacture, import, export or distribute medical devices and IVDs
c. 16.04 Licence to act as a wholesaler of medical devices and IVDs
d. Position paper for Amendments
e. 8.05: Classification guideline
f. 8.07: Medical device Quality Manual

Application forms:

a. 6.21 Licence Application to manufacture, import, distribute or export medical devices
b. 6.22 Licence Application to import, distribute or export medical devices
c. 6.26 Licence Application to Wholesale Medical Devices

And represents the South African Health Products Regulatory Authority current view.

2. Scope

The intention is to be a dynamic document that supplements and the above-mentioned documents.

Refer to the SAHPRA website (www.sahpra.org.za) for further information regarding the licensing renewal procedure.

3. Questions about submission requirements

3.1 When do I need to submit my license to the authority for renewal?

The license renewal application must be submitted at least 90 days prior to the license expiry date

Refer to your current license to confirm your organization's license expiry date.

3.2 How do I apply for a Medical Device Establishment license renewal?

a. To get the application form

i. Visit the South African Health Products Regulatory Authority (SAHPRA) website at www.SAHPRA.org.za.

ii. Click on the tab "Health products" at the top of the page.

iii. Click on the tab "Medical devices", which is the fourth tab under the health products tab on the SAHPRA's home page.

iv. Select "Application Forms", which is the first link within on the medical devices tab (drop down).

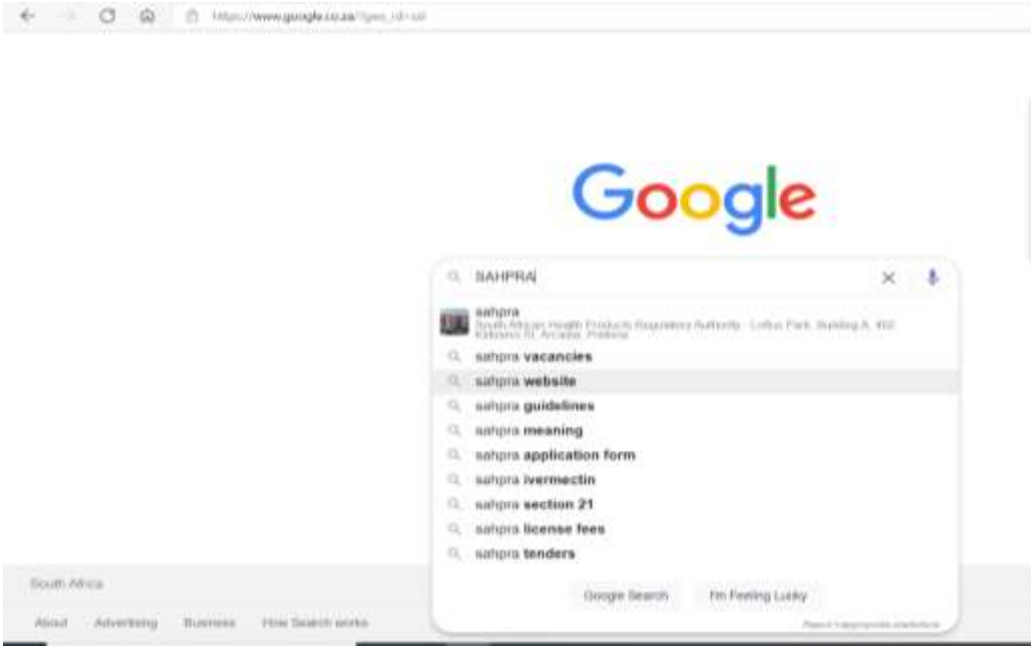
v. Select and download either licence application form:

o 6.21 – Manufacturer's Licence;

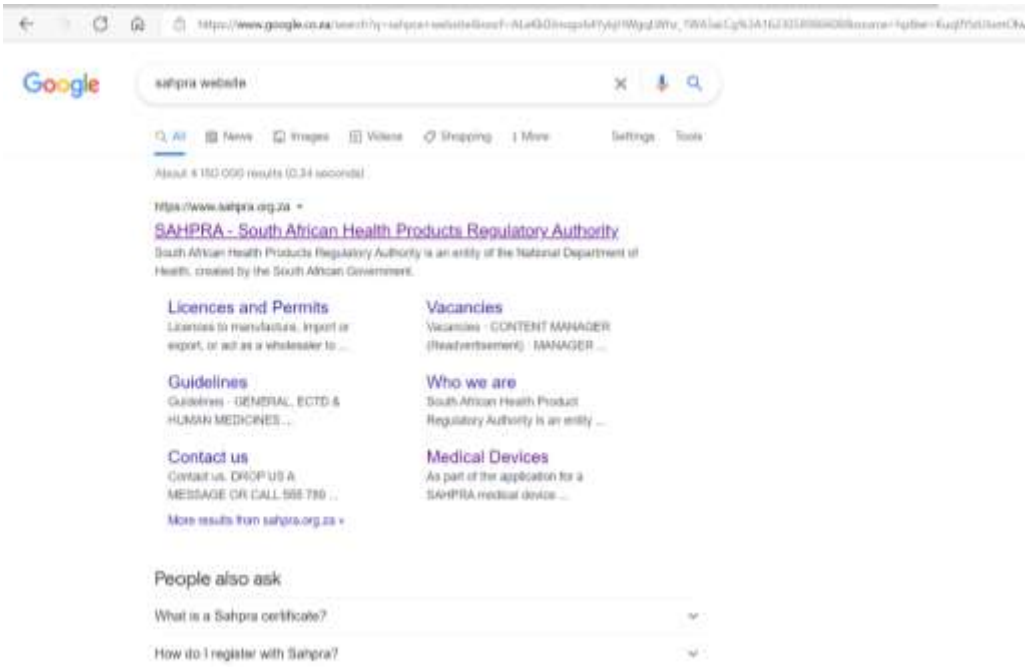
o 6.22 – Distributor's Licence;

o 6.23 – Wholesaler's Licence

b. Step 1: type 'SAHPRA Website' on your search engine.

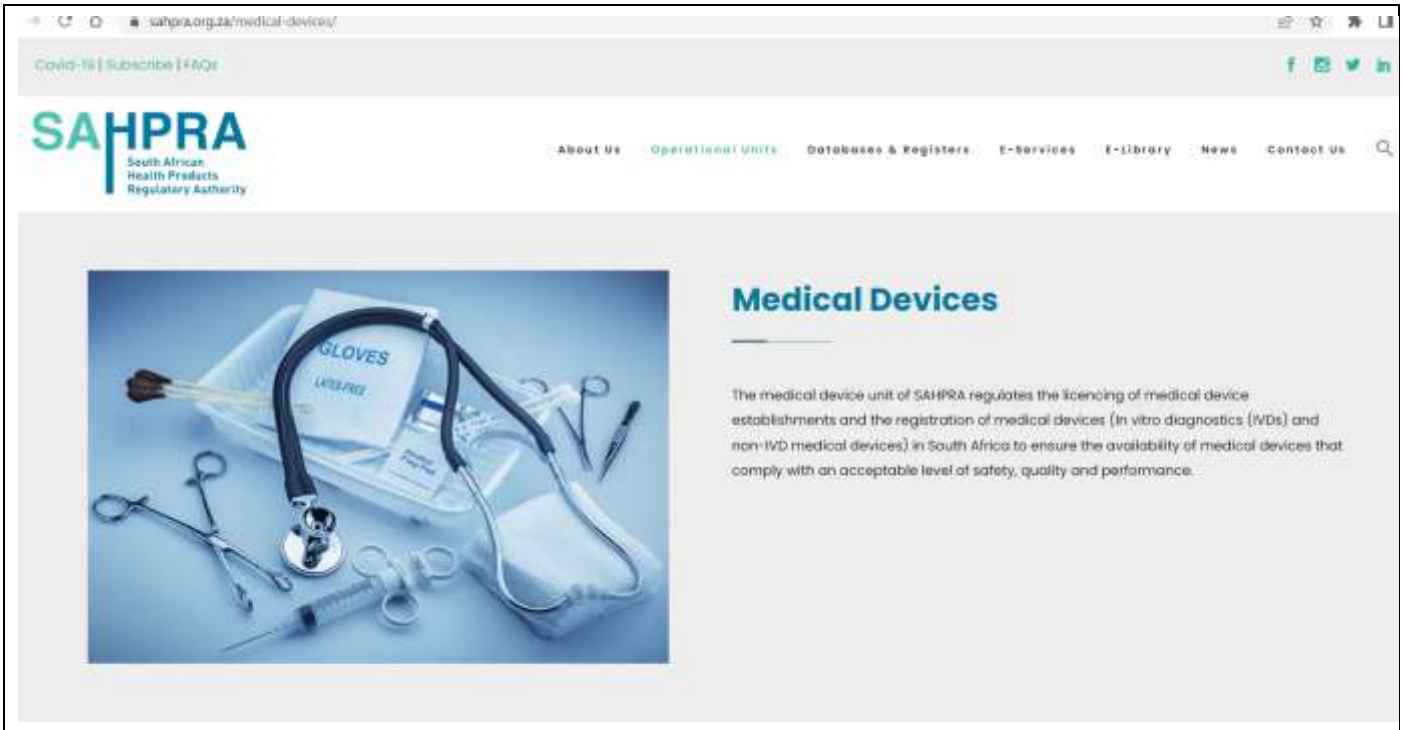


c. Step 2: Select the SAHPRA link

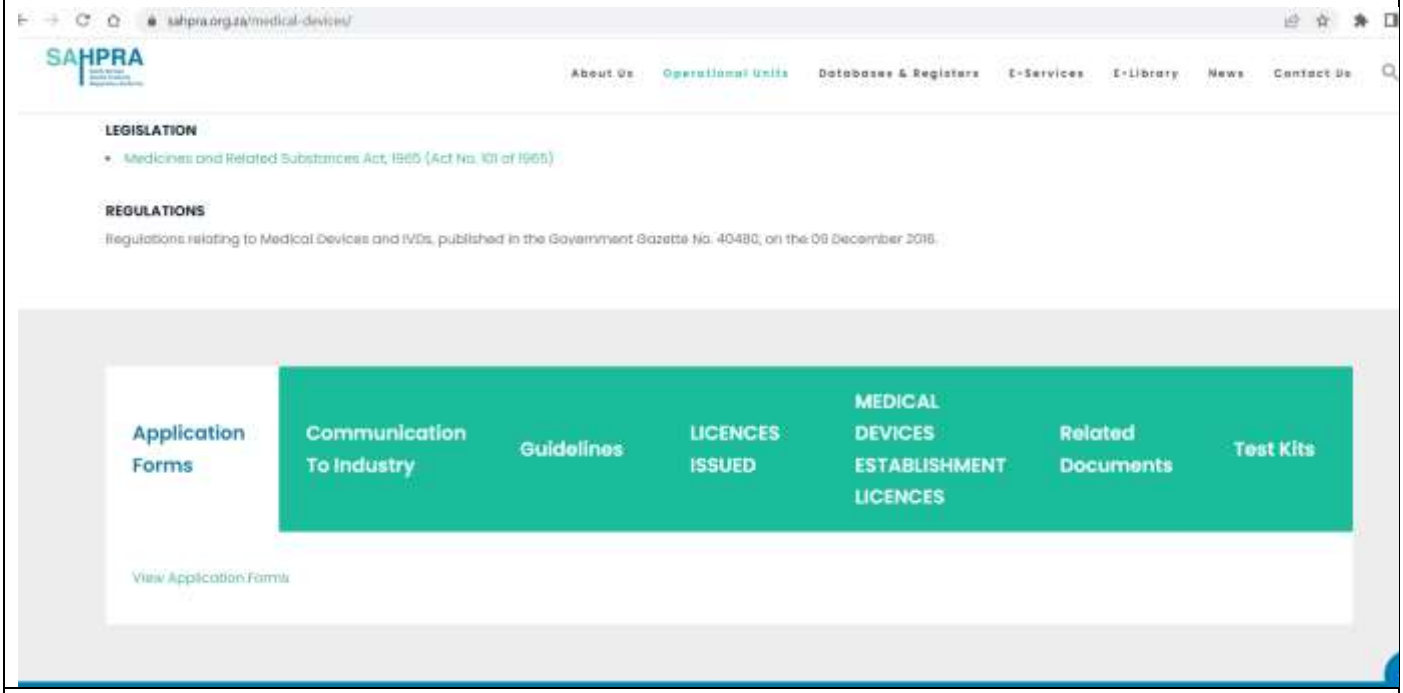


D. Step 3: On the SAHPRA website, select Operational units tab.

e. Step 4: Select Medical devices tab



f. Step 5: Scroll down to application forms and Select the appropriate application form. Download and complete the application form.



3.3 . What process must I follow as an applicant to do renewal my establishment license once I have downloaded the forms?

Prepare the following (not in any particular order) and submit

A cover letter

- All applications should be submitted with a Cover letter that has been prepared on a company letterhead, signed by the authorised representative and it should be dated.

• The Cover letter must be addressed to the CEO and marked for the attention of the Medical Device Unit. Complete application form Pay application Fees Supporting documents
3.4 Which documents must be submitted ?
a. Step 1: Prepare the cover letter on the company's letter head. The cover letter must indicate a. The intention of the application on the subject matter b. Mention any update made that do not affect the information details of the current License List non-exhaustive i. Addition and or subtraction of product listing in relevant tables as per organization's Activities c. Mention any update made that may affect the information details of the current license (If any) d. List of attachments i. Proof of payment (relevant to the established as published in latest gazette Fees) https://www.sahpra.org.za/wp-content/uploads/2021/01/Published-SAHPRA-Fees.pdf ii. Completed application form and signed declaration Form Signed and initialled PDF Excel sheet Application Form for Manufacturers/ Distributor ; Signed and initialled PDF for wholesaler iii. Quality Manual for Manufacturer /Distributor or Site Master File in case of the Wholesaler iv. In case the organization already has a Copy of the ISO 13485:2016 – A certified copy v. Copy of current License vi. Proof of evidence for payment of retention Fees for FY 2020 & 2021 (as applicable) vii. QMS declaration document viii. CV of Authorized Representative ix. Other relevant supporting documents as applicable e. Confirmation that there are no changes made to the current activities carried by the organization
B . Step 2: Complete the application Form as per the company activities (business operations) i. Ensure the form is the same as the latest application form submitted to the Authority ii. Ensure the form in a PDF format is initialled in each page and Declaration is signed iii. Share both the PDF and Excel spreadsheet (complete all relevant areas)
c. Step 3: Ensure the following documents are also attached and submitted with the renewal of your establishment license application i. Quality Manual (For Manufacturer, Distributor (importer and Export))

ii. Site Master File (For Wholesaler) or Quality Manual

iii. ISO 13485:2016 QMS certificate in the name of the South African licensed medical device establishment and at the same address .(as applicable)

iv. In case, the organization does not have an ISO 13485:2016 Certificate, a declaration by the Authorised Representative that the organization has implemented a quality management system aligned to the ISO143485:2016 standard and that a certified copy of certification to ISO13485:2016 standard will be submitted to the Authority once acquired and no later than 01 April 2025.

v. CV of Authorized Representative

vi. Proof of payment for retention fees for Year of 2020, 2021 and 2022

vii. Proof of Payment of the Establishment application renewal fee.

viii. Other Supporting document deemed relevant to the application as applicable

d. Step 4: Submission of the application to the authority

a. The license renewal application must be submitted at least 90 days prior to the license expiry date.

b. Submit the application to the authority (SAHPRA) using the following contact details

Mdadmin@sahpra.org.za

c. Large submissions can be submitted via secure electronic document transfer

Important to Note: For your email communication please use the following information as email subject: Establishment License Renewal- XXXXX (i.e., Company name)

3.5 How long does it take to process the application?

The processing of the establishment license renewal application by the Authority may be for a period of at least 6 to 8 weeks.

Important Notification: The applicant must ensure that all documents are submitted all at once to minimize the unforeseeable delays on the review of the application

The applicant is required to respond to the deficiencies noted in the observation letter within 2 working days of receiving the communication letter. Only 2 review opportunities are allowed .

3.6 With Whom do I follow-up on the progress of my application?

The follow-up on the progress of the application can be done using the following contact:

i. Mdadmin@sahpra.org.za

ii. Mdenquiry@sahpra.org.za

iii. June.searela@sahpra.org.za

3.7 Can I include amendment to my Establishment License renewal application?

a. The following changes are allowed during the application :

Licensees are not required to make application for amendment of a medical device establishment licence in the event of a change in the product listings provided in section 4.1, 4.2, 4.3, 4.4 and 17.3 of the manufacturers and distributors licence application form and section 3 of the wholesaler's application form:

Provided that the class of medical device/s for which the licensee has been licensed is not affected and does not change.

Update of the GMDN codes and GMDN descriptors

b. The following changes are regarded as amendment and the amendment fee

i. Change in the organization address (Location)

ii. Change of the company name

iii. Change of company's activities

iv. Addition the product list: Class D products

v. Addition to the product list of another class of product which were not part of the latest issued establishment license

vi. Change in Particulars of personnel responsible for operation on the premises on behalf of the licence holder including: Authorized Representative / Manufacture /Import / Distribution / Export Control Person / Quality Control Person

vii. Update of the authorized representative information (new and update of their information)

viii. Update of the License Holders information (new and update of their information)

Please note: The amendment can only be done only once the renewal establishment application is completed. That is the applicant has been issued their latest Establishment license so to ensure that the license does not expire while awaiting the amendment process finalisation

3.8 How much does it cost to apply for a renewal of the Medical Device Establishment License?

a. Fees payable are determined in consultation with National Treasury and are published in the Government Gazette.

Please note: Ensure that to use the latest Fees as Gazette .

c. To find the latest Fees gazette:

- Visit the Sahpra website as www.sahpra.org.za
- Once on the site: select publication
- On a drop down select Fees
- Download the fees (PDF document)

d. The following fees, as published in Government Gazette No. 1379 on 22 December 2020, Section 4b) are currently applicable for licence renewal:

- Manufacturer's Licence Fee – R22 000
- Distributor's Licence Fee – R12 600

• Wholesaler's Licence Fee – R12 600 Application for the amendment to an existing license to manufacture, distribute, wholesale, import, export -R5300
e. Very important: The fee for a medical device establishment licence application renewal is payable upon application and proof of payment should be submitted together with the completed licence application.
f. Note: Fees are updated from time to time. The onus is on the applicant to ensure that payment is made in line with the current fees' structures, as published in the Government Gazette.
3.9 How do I make a payment to SAHPRA?
a. Payments to the SAHPRA must be made through electronic funds transfer (EFT).
b. The SAHPRA banking details are: • Account name: SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY • Account type: CHEQUE ACCOUNT • Account number: 40-5939-2080 • Bank: ABSA • Bank branch code: 632005 • Bank physical address: 240 Madiba Street, Pretoria, 0001, South Africa
c. Swift Code for application fee for a Renewal of the license application: MD RLIC *company name*
d. Swift Code for application fee for an amendment application: MD AMD * company name*
e. Swift code for license collection fee: MD *company name*
f. Swift code for retention fee: MD RET *company name*
g. Very important: Refer to the latest fees published in the government gazette on: Published-SAHPRA-Fees.pdf: https://www.sahpra.org.za/wp-content/uploads/2021/01/Published-SAHPRA-Fees.pdf
3.10 How much does the retention Fees cost?
Note: Refer to previously and current gazette Fees for correct retention fees a. For the year 2020: R4000 b. For the year 2021: R4200
3.11 Submitting an application in less than 90 days of expiry
Renewal applications submitted less than 6 weeks prior to expiry will not be accepted , Applicant are required to submit new licence application as the licence will expire while the application is being processed
3.12 Submitting an application when the licence has expired

Submissions of applications which have superseded the licence expiry date will not be accepted , Applicant will be required to submit new licence application as the licence has superseded the expiry date.

We wish to draw to you attention that in terms of section 22C(6) of the Medicines and Related Substance Act, No medical device or IVD establishment, manufacturer, wholesaler or distributor referred to in subsection (1) (b) shall manufacture, act as a wholesaler of or distribute, as the case may be, any medicine, Scheduled substance, medical device or IVD unless he or she is the holder of a licence contemplated in the said subsection.

Amendment History

Version	Date	Reason for amendment
V1 Feb 2022	February 2022	First publication
V2 Sep 2022	September 2022	Technical Update