SAHPRA
South African
Health Products
Regulatory Authority

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COMMUNICATION TO STAKEHOLDERS

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Medicines Certificate of Registration Renewal Implementation Framework

INTRODUCTION

This document outlines the approach that the South African Health Products Regulatory Authority (SAHPRA) has undertaken to implement the process of the renewal of the certificate of registration for medicinal products, ensuring a consistent approach to benefit all stakeholders, thereby guaranteeing that quality, efficacious, and safe products are available to the public.

To comply with the legal provisions, as set out in the Medicines and Related Substances Act (Act 101 of 1965), as amended, SAHPRA has implemented a process to renew the validity of human and veterinary medicine registrations. The framework covers the renewal of the certificate of registration for all registered medicines (human and veterinary).

Implementing this process will ensure that SAHPRA complies with the legal provisions, but it will also enable the Regulator to comply with the requirements as set out by the World Health Organization (WHO) in the Global Benchmarking Tool. SAHPRA intends to comply with the WHO Review Practice and the requirements contained in the WHO guidelines. This step is of particular importance to the Regulator and industry alike, as it may allow for regulators from other regions to rely on SAHPRA's regulatory decision for products registered, to facilitate shorter timelines for registrations in other markets.

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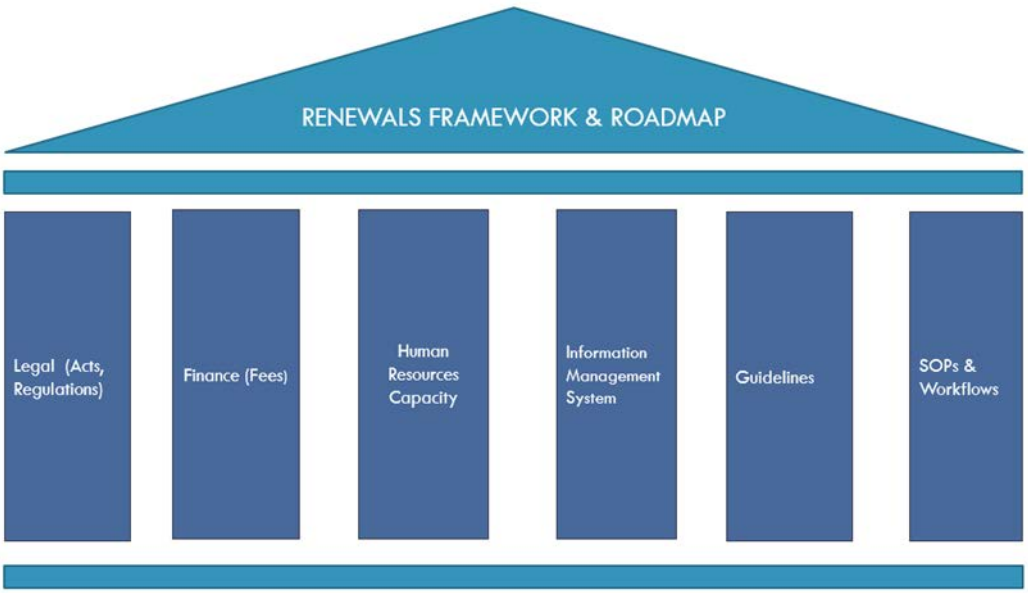
The process that has been implemented and detailed in the renewal of the certificate of registration guideline, is the product of research and consultations with the WHO, other regulatory authorities in the Southern African Development Community (SADC) region, other WHO Maturity Level 3 African Regulators, as well as the best practices adopted from regulators in the Middle East and North Africa (MENA) region.

The relevant legal provisions that may be referenced can be found in the Medicines and Related Substances Act No. 101 of 1965, as amended.

- Section 2B(1)(c) provides for the periodic re-evaluation or re-assessment and monitoring of medicines, medical devices and IVDs.

- Section 15(6)(a)(b) provides for the registration of medicines, medical devices, or IVDs. It further states that any registration under this section may be made subject to such conditions as may be determined by the Authority; and shall in the case of medicines be valid for five years.



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1 RENEWALS PROCESS IMPLEMENTATION

The registration renewal implementation process will follow the high-level 2023-2035 roadmap in **Annexure B**, accessible on the SAHPRA website [https://www.sahpra.org.za/]. Renewal applications must be submitted to SAHPRA six (6) months prior to the expiry of the medicinal product registration, and the required fees paid. The updated Regulations Regarding Fees Payable in Terms of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) have been gazetted on 12 February 2025 introducing a new fee dispensation, and the Fee Schedule, and explanatory notes for the fees payable for the renewal of the certificate of registration have been published on the SAHPRA website. All applications should be submitted with proof of payment in module 1.2.2.1.

Failure to submit a complete and compliant renewal application may result in registration expiration and the product registration no longer being valid. If the product registration has expired, the Applicant must submit a new product registration application, in line with the General Information Guideline No.: SAHPGL-HPA-07, accessible on the SAHPRA website.

Product submission roadmaps per Applicant have been shared with Applicants in July 2022, listing the products to be submitted for registration renewal during a specific quarter for the specified year. For example, during Phase 1 there were only 46 Applicants with 185 product lines requiring renewal of registration, all registered in 2018. The first renewal submissions were expected during June 2023, in line with the high-level 2023-2035 roadmap (**Annexure B**, accessible on the SAHPRA website). Thereafter, Applicants will be required to complete submissions monthly, as detailed in their schedule. **Please note** that renewal applications may only be submitted during the timeframe indicated for that product in the Applicant-specific roadmap, not earlier or later, unless it is a duplicate or clone/replica to be submitted together with a master application that was registered in 2018 or before. This will be done on a case-by-case basis. For duplicates or clones/replicas registered in 2019 and onwards, they will be renewed as per the roadmap schedule and not with the master.

2 GUIDELINES AND FORMS

After deliberation with Industry stakeholders, an updated registration renewal guideline has been

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published on the SAHPRA website, namely SAHPGL-HPA-04 Renewal of Registration of Human and Veterinary Medicines.

ASSESSMENT PROCESS

Please refer to the latest guideline (SAHPGL-HPA-04, Renewal of the Certificate of Registration of Human and Veterinary Medicines), for details about the renewal of the certificate of registration process.

3 FEES FOR RENEWALS PROCESS

SAHPRA charges a fee for applications to be renewed. The fees are derived from a cost-to-serve analysis. The new fee structure was published for implementation on 12 February 2025, accessible on the SAHPRA website.

4 RENEWAL SUBMISSION SCHEDULES AND OTHER INFORMATION

By means of providing further clarity and guidance, SAHPRA would like to confirm the following with regard to the communicated schedules – refer to **Annexure B**, for the high-level 2023-2035 roadmap accessible on the SAHPRA website:

a) The current list of active products, according to the SAHPRA medicines register, has been plotted over 13 years to spread the planning period and administrative burden across a reasonable timeframe.

b) For the submissions of products currently registered – and on this schedule – the Health Products Authorisation (HPA) Unit has divided these into different years and quarters per year, so SAHPRA can receive the renewal submissions for the relevant products in the **first month** of each of those identified quarters, i.e., if a product appears in PHASE 2 Q3, SAHPRA requires receipt of the submission(s) in July 2024; if it was PHASE 1 Q2, it would equate to August 2023.

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c) For products registered from October 2022, an expiry date is indicated on the registration certificate, and for these products, the expiry date, minus six (6) months, will be the product's renewal submission window in five (5) years.

d) Please note that the SIAMED column is an internal vlookup reference marker and may be ignored by industry colleagues.

e) Old Medicines not registered do not form part of the renewals process.

f) No variations will be allowed during a renewal application review, as variations must follow their normal submission processes.

g) No applications with pending TOAs will be allowed during the renewal application process.

h) Completed SAHPRA-specific QIS to be submitted in Module 3.2.R.8 – Other (refer to the SAHPRA QOS Template (GLF-PEM-02D) and QIS Template (GLF-PEM-02C).

i) All applications for the renewal of the certificate of registration of Human medicines refer to the latest version of the 2.21 ZA-SAHPRA eCTD Specification and document matrix available on the SAHPRA website.

j) All applications for the renewal of the certificate of registration for Veterinary medicines refer to the latest version of 2.58 ZA- SAHPRA CTD e-Submission Specification available on the SAHPRA website.

For all applications for the renewal of the certificate of registration, a full Electronic Common Technical Document (eCTD) baseline submission, in line with the General Information Guideline for registration, should be submitted *(only if the dossier has not yet been converted to eCTD*).

k) Dormant products cannot be exempted from the legislated requirement for renewal of a registration. The dossiers for these products are to be maintained, and variations should be submitted in line with the lifecycle management requirement. The expectation is that the information on the safety, quality, and efficacy for any product submitted for a registration renewal review will be up-to-date and will meet the requirements, as set out in the relevant SAHPRA guidelines.

Applicants will be given a "grace" period to December 2025, following the implementation of renewals after which they must submit renewal applications of dormant products.

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5 PILOT UPDATE

The review of the pilot applications has been completed. The learnings from the pilot have been incorporated into the guideline and templates to streamline the process.

6 RENEWALS CERTIFICATION

Standard documentation required for an updated certificate:

6.1 Application form (M1.2.1)

The application form must include the up-to-date variation history.

6.2 Medicine register details (M1.5.2.2.1)

The information that has been applied for through the DVP and approved through the variation's summary must be added to module 1.5.2.2.1 medicine register details under the "proposed column" and NOT the "current column". Only information appearing on the current registration certificate must be included under the "current column".

6.3 Copy of current approved registration certificate (M1.5.2.2.2)

6.4 If applicable, variations summary (appended to the registration certificate in M1.5.2.2.2) as well as any other approvals received from Pharmaceutical Evaluations Management (PEM) for the FPP manufacturer/ Primary Packer.

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7 ANNEXURES

Annexure B: High-Level 2023-2035 Renewals Roadmap, accessible on SAHPRA website.