

COMMUNICATION TO STAKEHOLDERS

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Fee Schedule and Explanatory Notes – Renewal of the Certificate of Registration

INTRODUCTION

This document is intended to provide clarification on the fees payable in terms of the Medicines and Related Substances Act, 101 of 1965, that have been gazetted on 12 February 2025, for applications for the renewal of the certificate of registration.

Reference is made to FN04-2024/25 Newly Gazetted *Regulation Regarding Fees Payable in Terms of the Medicines and Related Substances Act*, 101 of 1965, SAHPRA Payment Guideline (SAHPGL-FIN-01) and Renewal of the Certificate of Registration of Human and Veterinary Medicine requirements and process (SAHPGL-HPA-04) accessible on SAHPRA's website.

The fees are self-explanatory, however, in the case of the fees payable for applications for the renewal of the certificate of registration, there are several options listed which require clarity and hence the focus of this explanatory note is for clarification as defined in 3(h)(ix), (x), section 4(c)(ii) and (iii) of the fee regulations.

This explanatory note provides clarity on the capping of fees in the case of line extensions as well as, provide information on payments for, product type and multiple submissions. These clarifications are applicable to applications for the renewal of the certificate of registration of registered medicines.

1 FEES PAYABLE

1.1 Category A (Human Medicines)**

1.1.1 NCE

South African Rand (ZAR) basic fee of R34 000 for the master and/or R13 500 per line extension, a maximum of two-line extensions per application is payable.

1.1.2 Generic Medicines

South African Rand (ZAR) basic fee of R31 600 for the master and/or R9 600 per line extension, a maximum of two-line extensions per application is payable.

1.2 Category C (Veterinary Medicines)**

1.2.1 NCE

South African Rand (ZAR) basic fee of R34 000 for the master and/ or R13 500 per line extension, a maximum of two-line extensions per application is payable.

1.2.2 Generic Medicines

South African Rand (ZAR) basic fee of R31 600 for the master and/ or R9 600 per line extension, a maximum of two-line extensions per application is payable.

Legend:

(*) refers to masters, duplicates, replicas and clones will be charged separately and according to the application type, i.e. NCE/generic.

(†) refers to products where there is a master and more than 2-line extensions registered, only a fee for the Master and 2-line extensions is expected.

Explanatory notes:

- All applications for the renewal of the certificate of registration submitted before 13 February 2025 and after the gazette date will have to adhere to the new Fee Regulation and revised SAHPRA Payment Guideline (SAHPGL-FIN-01) accessible on SAHPRA's website.

- All applications should be submitted with the proof of payment included in Module 1.2.2.1.
- For applications that have already been submitted and where an approval letter has been sent to the Holder of the Certificate of Registration (HCR), a closing sequence with the proof of payment included in Module 1.2.2.1 should be submitted.
 - The submission type “Renewal” and the sequence type “closing information” should be used.
 - Following receipt of the appropriate payment, Renewals will issue a revised registration certificate.
 - For applications where there have been amendments that may affect the certificate of registration since the submission of the renewal application, e.g. the deletion of FPRC or proprietary name changes, etc., the closing sequence submitted should also contain the amended, application form in Module 1.2.1 and medicine register details in Module 1.5.2.2. The proof of approvals/variation summary for these amendments should also be included in Module 1.0.3 and 1.5.2.2.1 respectively.
 - For applications received after 13 February 2025, the certificate of registration will be revised with information as contained in the application submitted.
- For applications that have already been submitted and a query letter has been sent to the HCR, the payment should be included in Module 1.2.2.1 of the response to queries application.
- All payments should use the respective Renewals payment reference **BI RNW/ or HU RNW/ or VT RNW/**, as indicated in the SAHPRA Payment Guideline (SAHPGL-FIN-01) guiding on payment fees <https://www.sahpra.org.za/guidelines/>

For any further clarification contact the Renewals team, renewals@sahpra.org.za

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SIGNIFLOW

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