

| Section | Products | Medical Devices | Pharma & Complementary |
|---------------------|--|--|--|
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2 April 2025

Dear Applicant,

PAYMENT OF RETENTION FEES FOR THE YEAR ENDING 31 DECEMBER 2025 IN RESPECT OF MEDICINES REGISTERED AND VARIOUS ESTABLISHMENT LICENCES ACTIVE UP UNTIL 31 DECEMBER 2024

1. Your attention is drawn to the provisions of the Medicines and Related Substances Act, 101 of 1965, as amended, making provision for the payment of retention fees to the South African Health Products Regulatory Authority (SAHPRA) in respect of medicines registered, medical devices including *in vitro* devices (IVDs) establishment licenses issued. These retention fees are payable on or before the last working day of 30 June that year, failing which the registration or licence may be cancelled.
2. Section 16(4) of the Medicines and Related Substances Act, 101 of 1965, as amended, states: If the person who is the holder of the certificate of registration issued in respect of any medicine, fails to pay the prescribed annual fee in respect of the retention of the registration of that medicine, before or on the prescribed date or such later date as the Chief Executive Officer may determine on application by that person, the Chief Executive Officer shall cancel the registration of that medicine, medical device or IVD.
3. Further to the above, the *Regulations relating to fees payable in terms of the Medicines and Related Substances Act*, GNR. 5856, published 12 February 2025, in conjunction with the Medicines and Related Substances Act, 101 of 1965, as amended, states: The following fees shall be paid to the Chief Executive Officer:

3.1 **Human medicines** - Schedule 3(h)(viii): “Annually, in respect of the retention of the registration of a medicine, the registration of which has been approved by the Authority in terms of Section 15(3): **R5 200**: Provided that this provision shall come into effect one year after the date on which the registration of said medicine was approved by the Authority in terms of Section 15(3); Provided further that the said fees payable during a particular **calendar year** shall be payable on or before the last working day of June of that year, failing which the registration may be cancelled in terms of Section 16(4).”

3.2 **Veterinary medicines** - Schedule 4(c)(viii): “Annually, in respect of the retention of the registration of a medicine, the registration of which has been approved by the Authority in terms of Section 15(3): **R2 400**: Provided that this provision shall come into effect one year after the date on which the Authority approved the registration of the said medicine in terms of Section 15(3); Provided further that the said fees payable during a particular calendar year shall be payable on or before the last working day of June that year, failing which the registration may be cancelled in terms of Section 16(4).”

3.3 “Schedule 8(e): Annually, in respect of the **retention of a licence** issued in terms of Section 22C(1)(b) of the Act: **R4 400**, and this fee is payable on or before the last working day of June that year, failing which the license may be cancelled.”

4. Payment process for Product Retention Fees

4.1 Payments can be made without an invoice as retention fees are a statutory requirement as per Section 3 above, but please note that the applicant will bear the risk if payment cannot be allocated due to the use of an incorrect reference.

4.2 SAHPRA will issue invoices from **12th- 30th May 2025** based on available information.

4.3 SAHPRA will communicate a product line listing and an invoice for retention fees for registered products to the applicant.

4.4 The applicant should verify the list. Queries must be sent to retentionfees@sahpra.org.za. (Refer to point 6 below.)

4.5 Payment should be made once the list has been verified as per the invoice issued or revised accordingly by SAHPRA.

4.6 Ensure that the appropriate reference number on the invoice is used when making payment to ensure the adequate/correct allocation of payment.

4.7 Once payment has been made, email the product list, copy of the invoice and proof of payment to retentionfees@sahpra.org.za.

4.8 In respect of an application for any changes or cancellation of the registration of products listed, that has not been finalised during this period, the current applicant/product holder is still responsible for the payment of the retention fees for the period as stipulated above.

5. Payment process for Establishment Licence Retention Fees

5.1 Payments can be made without an invoice as retention fees are a statutory requirement as per Section 3 above, but please note that the applicant will bear the risk if payment cannot be allocated due to the use of an incorrect reference.

5.2 SAHPRA will issue invoices from **12th- 30th May 2025** based on available information.

5.3 Ensure that the appropriate reference number on the invoice is used when making payment to ensure the correct allocation of payment.

Who is eligible to pay the R4 400 annual retention fee?

- A licence holder who was in possession of a licence by 31 December 2024

Who is ineligible to pay the R4 400 annual retention fee?

- A licence holder whose new licence (Version 1) was issued in 2025.

5.4 Once payment has been made, email a copy of the invoice and proof of payment for **Medical Device Licences** to mdnotifications@sahpra.org.za.

5.5 Once payment is made, email a copy of the invoice proof of payment for **Pharma and Cannabis-related Licences** to smf@sahpra.org.za.

5.6 Once payment has been made, email a copy of the invoice and proof of payment for **Complementary Medicines Licences** (CAT D Licenses) to cmretentionfees@sahpra.org.za.

6. Query process

6.1 To query a product listing, the applicant should submit the following information:

- a) A product list on an MS Excel spreadsheet with the following headings:
 - i. Application number; date of registration; company name; product name.
- b) Copy of the registration certificate indicating transfer of Applicant or letter of cession.
- c) Applicant letter requesting cancellation or SAHPRA letter of cancellation until 31 December 2024.
- d) The lists will be reconciled, and where necessary a revised invoice will be issued.

To inquire about the current invoice regarding potential duplication, overpayment, or if the invoice is part of a renewal process:

- a) Proof of payments made during the licence period.

6.2 Product and licence holders who have not received an invoice by 30 June 2025 should inform SAHPRA through the dedicated email addresses as indicated in this notification (*Refer to points 5.4 - 5.6 above*).

6.3 If an official cancellation letter was not sent to SAHPRA, you will still be liable to pay the retention fee for June 2025.

6.4 All licence holders are required to pay the retention fee for products/pharma licence/medical device licence and complementary licence even in the year of renewal as required by the Medicines Act.

7. Banking details and references

7.1 Method of payment is via EFT within 30 days of receipt of a SAHPRA invoice.

7.2 Banking details: SAHPRA, **ABSA Bank, cheque account number 40 5939 2080**

7.3 Use the following payment reference for product retention fees: as referenced on the invoice such as "**HUMRET/Company name**" or "**VETRET/Company name**" and email the proof of payment to retentionfees@sahpra.org.za

- 7.4 Use the following payment reference for establishment licence retention fees relating to Pharma Licences and Cannabis licences: as referenced on the invoice such as “**INSRET/Licence No**” or “**CMRET/Licence No**” and email the proof of payment to smf@sahpra.org.za
- 7.5 Use the following payment reference for establishment licence retention fees relating to Medical Devices: as referenced on the invoice such as “**MDRET Licence No**” and email the proof of payment to mdnotifications@sahpra.org.za
- 7.6 Use the following payment reference for establishment licence retention fees relating to Complementary Medicines-specific licences: as referenced on the invoice such as “**CAT-DRET/Licence No**” and email the proof of payment to cmretentionfees@sahpra.org.za
- 7.7 The retention fees due will be deemed to be unpaid if proof of payment is not submitted within 30 days of receipt of a SAHPRA invoice. A process of cancellation of the relevant registration will then commence. This excludes non-payment due to outstanding queries.
- 7.8 Failure to submit proof of payment of any outstanding retention fees identified for prior periods will be deemed to be unpaid and a process of cancellation of the relevant registration will commence
- 7.9 Note that if no invoice is received, the process of cancellation will still be followed since retention fees are a statutory fee as explained in Section 3 above.
- 7.10 SAHPRA will levy interest on debts outstanding from 1 August 2025 for unpaid retention fees as per SAHPRA’s Debtors Management Policy. The interest rate will be calculated at the rate prescribed by the National Treasury.

Boitumelo Semete-Makokotlela

e-SignFlow

Dr Boitumelo Semete-Makokotlela
Chief Executive Officer
SAHPRA