

Enquiries: S Morar
Email: shethal.morar@sahpra.org.za
Reference: Retention Fees

06 May 2024

Dear Applicant,

**PAYMENT OF RETENTION FEES FOR THE YEAR ENDING 31 MARCH 2024
IN RESPECT OF MEDICINES AND/OR VARIOUS LICENCES REGISTERED
UNTIL 31 DECEMBER 2023:**

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 Regulatory Authority in respect of medicines, medical devices and IVDs registered, and site licences issued. These retention fees are payable no later than 30 June 2024, 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, medical device or IVD fails to pay the prescribed annual fee in respect of the retention of the registration of that medicine, medical device or IVD 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 *Fees payable in terms of the provisions of the Medicines and Related Substances Act, 1965* (GNR. 695, Government Gazette No. 42474, 24 May 2019) 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 1 (b) (iv): *“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 000**: 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 2 (b) (iv): “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 300**: Provided that this provision shall come into effect one year after the date on which the registration of the 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 that year, failing which the registration may be cancelled in terms of Section 16(4).”

3.3 Schedule 6(c): “Annually, in respect of the retention of a licence issued in terms of section 22C(1)(b) of the Act: **R4 200**, and this fee is payable on or before the last working day of June that year, failing which registration may be cancelled”.

Please note that the South African Health Products Regulatory Authority (SAHPRA) is in the process of publishing revised Fee Regulations which may impact the retention fee amount to be paid if gazetted before the end of June 2024. Further communication regarding the implementation date of the revised fee regulations will be communicated.

4. Payment process for Product Retention Fees:

4.1 Payments can be made without an invoice as retention fees are statutory fees as per Section 3 above.

4.2 SAHPRA will issue invoices 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, and queries must be sent to retentionfees@sahpra.org.za. See 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 utilised when making payment, to ensure 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 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 statutory fees as per Section 3 above.
- 5.2 SAHPRA will issue invoices based on available information.
- 5.3 An invoice will be sent to the licence holder for the payment of the Annual Retention fee.
- 5.4 Ensure that the appropriate reference number on the invoice is utilised when making payment, to ensure to ensure adequate/correct allocation of payment.

Who is eligible to pay the R4 200 annual retention fee?

- A licence holder who was in possession of a licence by 31 December 2023 and intends to retain and renew their licence.

Who is ineligible to pay the R4 200 annual retention fee?

- The licence holder whose new licence (Version 1) was issued in 2024.

- 5.5 Once payment has been made, email a copy of the invoice and proof of payment for **Medical Device-related Licences** to mdnotifications@sahpra.org.za.
- 5.6 Once payment is made, email a copy of the invoice and proof of payment for **Pharma and Cannabis-related Licences** to smf@sahpra.org.za.
- 5.7 Once payment has been made, email a copy of the invoice and proof of payment for **Complementary Medicines Licences** (CAT D LICENCES) 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 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 2023.
- d) The lists will be reconciled and, where necessary, a revised invoice will be issued.

6.2 To query the current invoice due to possible duplication, overpayment or if the invoice falls into a renewal process:

a) Proof of payments made during the licence period.

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

6.4 If an official cancellation letter was not sent to SAHPRA, you will still be liable for the retention fee as of 31 December 2023 for June 2024.

6.5 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 and Related Substances Act.

7 Bank details and references:

7.1 Method of payment is Electronic Funds Transfer (EFT) within 30 days of receipt of a SAHPRA invoice.

7.2 Bank 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 in the event that no invoice is received, the process of cancellation will still be followed and take place 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 2024 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.

Botumelo Semete-Makokotela

SIGNIFLOW

CHIEF EXECUTIVE OFFICER