



health

Department:
Health
REPUBLIC OF SOUTH AFRICA

SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

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Enquiries: Mrs E Taute

Reference: Retention fees

20 June 2018

Dear Applicant,

PAYMENT OF RETENTION FEES FOR THE FINANCIAL YEAR ENDING 31 MARCH 2019 IN RESPECT OF MEDICINES REGISTERED UP AND UNTIL 31 DECEMBER 2017 AND/OR MANUFACTURE OR WHOLESALE LICENCES

- 1 Your attention is drawn to the provisions of the Medicines and Related Substances Act, 1965 (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 by no later than 30 June 2018, failing which the registration or licence may be cancelled.
- 2 According to Section 16(4) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) as amended: *“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 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, Government regulation GNR 784 as published in Government Gazette 39154 dated 1 September 2015 in conjunction with the Medicines and Related Substances Act, 1965 (Act 101 of 1965) as amended, states: *The following fees shall be paid to the Registrar:*
 - 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 Council in terms of section 15(3): **R1 100**: Provided that this provision shall come into effect one year after the date on which the registration of said medicine was approved by the Council 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 Council in terms of Section 15(3): **R850**: 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 Council 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: **R3 000**, and this fee is payable on or before the last working day of June that year, failing which registration may be cancelled”;
- 4 Please submit the following remittance advice:
- 4.1 A summary of registered medicines with proof of payment.
Note: Please indicate if any products were transferred to or from another applicant during 2017.
- 4.2 For licence payment, a copy of the invoice (if available) with proof of payment.
- 5 The remittance should be faxed to 012 395 8468 or e-mailed to Naazneen.Babamia@health.gov.za
In the event of failure to submit a remittance advice, your retention fees will be deemed to be unpaid and as such we refer you to paragraphs 2 and 3 above.
- 6 The preferred method of payment is by EFT:
- 6.1 Please note the bank details: Medicines Control Council, ABSA bank, cheque account number 40 5939 2080.
- 6.2 As reference state “**RET** Company Telephone number” e.g. “**RET** ABC Pharma 0123958034” or for licences state “**LIC**, invoice number (if available) or licence number (if invoice not available), company name, telephone number”, e.g. “**LIC** IN1014 ABC Pharma 0123958034”.
Note: RET refers to medicine registration and LIC refers to Licensing
- 7 In respect of changes in applicancy of registered products not yet finalised, or cancellation of registration during the current year you are still responsible for payment of the retention fees for the period as stipulated above.

Yours faithfully



pp ACTING CHIEF EXECUTIVE OFFICER