

MAY 2022

COMMUNICATION TO STAKEHOLDERS ON PAYMENT OF ANNUAL RETENTION FEES FOR REGISTERED PRODUCTS

INTRODUCTION

The Medicines and Related Substances Act, 1965 (Act 101 of 1965) as amended, (“the Medicines Act”) makes provision for the payment of retention fees to the Regulatory Authority in respect of medicines, medical devices and IVDs registered and site licences issued.

Further to the above, Regulation GNR 784 as published in the Government Gazette 42474 dated 22 DECEMBER 2020 read in conjunction with the Medicines Act, states that : *The following fees shall be paid to the Chief Executive Officer:*

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).”*

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).”*

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”

In terms of the above Regulations the annual retention fees therefore become due in a particular calendar year (January – December) will be payable in June of the year it becomes due.

Furthermore, the above practice has been confirmed to be reasonable and it has been consistently applied.

NOTIFICATION OF ANNUAL RETENTION FEE PAYMENT

SAHPRA will issue the notification for payment of Annual retention fees in June 2022.

The notification will include guidance on the following information:

- Method of payment
- SAHPRA bank details
- References to be used
- Proof of payment
- Payment communication details

PROCESS FOR PAYMENT OF ANNUAL RETENTION FEE

- An applicant specific product line listing and the corresponding invoice will be communicated to the applicant before the 15th of June 2022.
- These retention fees are payable by no later than 30 June of the calendar year, failing which the registration cancellation process will commence.

A handwritten signature in black ink, appearing to be the initials 'B' followed by a stylized flourish.

CHIEF EXECUTIVE OFFICER