

Medicines Control Authority of Zimbabwe

106 Baines Avenue Tel: +263 242 736 981-7 708 255 / 792 165 / 0772 145 191/2/3

Email: mcaz@mcaz.co.zw Website: www.mcaz.co.zw

P.O. Box 10559 Harare Zimbabwe

REF: B/279/35/02/2024

CIRCULAR 2 of 2024

Date: 05/01/2024

To: MEDICINAL CANNABIS LICENCE HOLDERS

RE: RENEWAL OF LICENCES FOR THE PRODUCTION OF CANNABIS FOR

MEDICINAL AND SCIENTIFIC USE.

Reference is made to the above.

The Medicines Control Authority of Zimbabwe, "The Authority", would like to draw the attention of all producers of cannabis for medicinal and scientific use with licences issued in 2019 that the five (5) year validity period is lapsing this year. This applies to licence numbers: 001/2019 to 036/2019. In order to avoid inconveniences, all licences should be renewed before expiry. The Authority will not accept applications for renewal of expired licences.

Please find below, the requirements for renewal of licences as provided for in section 14 of the Dangerous Drugs (Production of Cannabis for medicinal and scientific use) Regulations, Statutory Instrument 62 of 2018 which states that:

- 14. (1) An application for the renewal of a producer's licence shall be made by a licensed producer and lodged with the Minister before the expiry of such licence and shall be accompanied by the following—(a) the appropriate fee; and
- (b) a copy of the original licence; and
- (c) a declaration signed and dated by the authorised person in charge stating that as of the date of the application—
- (i) to the best of that person's knowledge the information shown on the producer's licence as specified in section 6 (a) to (i) is correct and complete, and if applicable, the requirements of sections 12 and 13 have been met.
- (2) Subject to section 7, the Minister shall, after examining the information and documents required under subsection (1) and, if applicable, section 16, issue a renewed licence that contains the information set out in section 6 (a) to (j)
- (3) If a licensed producer submits an application in terms of section 11 or 12 together with an application in terms of subsection (1), the Minister may process them together.
- (4) Where an application for the renewal of a licence has been lodged with the Minister, the validity of the licence shall, where the applicant has not been given notice of the renewal or refusal of the application by the date of expiry of such licence, continue after the date of expiry until the decision of the Minister on the application is notified to the applicant by the Minister.

Please find attached, the proforma invoice for renewal of licence fees and application form.

Yours faithfully

MEDICINES CONTROL AUTHORITY OF ZIMBABWE





MCAZ Medicines Control Authority of Zimbabwe

106 Baines Avenue Tel +263 242 736 981-7 708 255 / 792 165 / 0772 145 191/2/3 Email mcaz@mcaz.co.zw Website: www.mcaz.co.zw

P.O Box 10559 Harare Zimbabwe

VAT Number 10068132 Business Partner Number 200023681

REF: B/279/21/13/2024

PROFORMA INVOICE

| All Medicinal Licence Holders | | | Date: 5 January 2024 |
|-------------------------------|------------|------------|-------------------------|
| VAT Number: | | | |
| Business Partner Number: | | | |
| RE: RENEWAL OF LICENCE FE | C E | | |
| NAME OF PRODUCT/SERVICE | QUANTITY | UNIT PRICE | AMOUNT PAYABLE (USD) |
| Renewal of licence fee | 1 | 20,000.00 | 20,000.00 |
| Total excluding VAT | | | 20,000.00 |
| 15% VAT | | | 3,000.00 |
| TOTAL AMOUNT PAYABLE (USD) | | | 23,000.00 |

Payment can be made by direct transfer only, to Medicines Control Authority of

Zimbabwe.

Bank:

Nedbank

Branch:

J Moyo Avenue

City:

Harare

Account Number:

11990276147

Swift Code:

MBCAZWHXXXX

Currency:

USD

Please note that direct transfers usually attract a commission charged by the banks leading to a shortfall in application fees. Provisions should be made to cover such shortfalls.

Please always fax or send us proof of payment after every deposit into our account with full details of payment (e.g. registration fees) or the invoice reference number.

Yours faithfully

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

R.Tugwete

for: DIRECTOR-GENERAL

DANGEROUS DRUGS ACT [CHAPTER 15:02]

APPLICATION FOR ISSUE OF A LICENCE FOR PRODUCTION OF CANNABIS

This form is submitted in terms of Section 5 (1) of the Dangerous Drugs (Production of Cannabis for Medicinal and Scientific Use) Regulations, 2017.

(To be submitted in duplicate) PART A (To be completed by individuals and sole traders) 1. Full name..... 2. Date and place of birth.... 3. Gender.... 4. Address (Home).... 5. Email address..... 6. Mobile phone number.... 7. Present place of employment..... 8. Position of applicant at place of employment (e.g. owner, manager, etc.) PART B (To be completed by companies) 9. If a company: Name of company (a) Physical address.... (b) Registered Office.... (c) Email Address.... (d) State shareholders or distribution of shares 10.PARTICULARS OF DIRECTORS: (a) Full names..... (b) Address....

(c) Citizenship....

| (d) Date of Birth |
|---|
| (e) Gender |
| PART C (To be completed by all applicants) |
| 11. Name under which business is conducted |
| 12. Physical address of premises to be licensed |
| |
| 13. Postal address of business |
| |
| 14. Telephone/Mobile number of proposedsite |
| 14A. Email address |
| 15.PARTICULARS OF AUTHORISED PERSON |
| (a) Full name |
| (b) Date and place of birth |
| (c) Gender |
| 16.PARTICULARS OF RESPONSIBLE PERSON |
| (a) Full name |
| (b) Date and place of birth |
| (c) Gender |
| 17. State the proposed activities |
| 18. The substances in respect of which each activity is to be conducted |
| 19. State the building/s within the site where the proposed activities are to be conducted (<i>if applicable</i>) |
| 20. Have you previously held a licence to produce cannabis? YES / |
| NO* |
| 21. Has any application made by you for a licence been refused or cancelled? YES/NO* |
| If YES, give details |
| 22. Name and address of nearest police station |
| 23. Name and approximate distance of nearest residence from premises to be licensed |
| 24. Particulars and date of any trading or other licence held by the applicant or business |
| 25. If an individual:- |
| |

| (a) are you a citizen of, or ordinarily resident in Zimbabwe? YES/NO*; |
|---|
| (b) if YES supply proof thereof; |
| (e) Have you within the preceding ten years of this application been convicted inside or outside Zimbabwe of an offence involving the wrongful dealing in or supply or possession of cannabis, or of an offence involving dishonesty? YES/NO* (Attach affidavit) |
| (f) If YES state details |
| 26. If a company:- |
| (a) Are the directors of the company or a majority thereof citizens or ordinarily resident in Zimbabwe? YES/NO* |
| (b) If YES supply proof thereof; |
| (c) If NO supply proof of exemption by the Minister; |
| (d) Has the company or any of the directors of the company within the preceding ten years of this application been convicted inside or outside Zimbabwe of an offence involving the wrongful dealing in or supply or possession of cannabis, or of an offence involving dishonesty? YES/NO*(Attach Affidavit) |
| (e) If YES state details |
| *Delete the inapplicable |
| NOTE: |
| Plans of the premises, the appropriate fee, proof of citizenship, residency or an exemption by the Minister, etc, are required to be attached to the application. Copies of original documents must be properly certified. If any plan document or fee required to be attached is not attached, the application cannot be accepted. If insufficient space is provided in the application, attach a sheet of paper with the additional information. |
| I enclose the proof of payment of the fee of |
| I do hereby declare that the facts herein are fully within my knowledge and to the best of my knowledge are true and correct. |
| Signature of applicant Date |
| Name and position of person in the company |