

SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

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Enquiries: M Wondo

Reference: CA00023

5th March 2019

The Chief Executive Officer,
Elpasso Farms (Pty) Ltd
567 (54) LA Quinta Street,
Silver Lakes Golf Estate,
Pretoria,
0081

Tel: +27 79 038 8786

Dear Dr Chitsunge,

SAHPRA RESOLUTION: INSPECTIONS IN TERMS OF SECTION 2B(E) OF THE MEDICINES ACT AND REGULATION 45; ELPASSO FARMS (PTY) LTD, CULLINAN, PRETORIA

The inspection reports and your subsequent responses relating to the application for cultivation of medicinal cannabis from Elpasso referenced CA00023 conducted by the Inspectors of the Regulatory Authority, Mr. M Wondo and Ms. MD Fafudi. The inspectors conducted the first inspection at Elpasso on 10 August 2018 and a verification inspection on 19 December 2018 with Mr. G Molewa.

The Authority resolved that:

GACP Status: Based on the areas inspected, people met, documents reviewed and the findings of the inspection performed on the above-mentioned dates as well as the responses provided, the Authority is **satisfied** that Elpasso is operating at an acceptable level of compliance with regards to the principles and guidelines of Cultivation of medicinal cannabis.

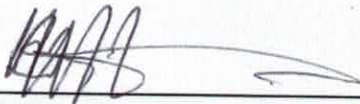
Conditions;

- The licence be issued to Elpasso for the cultivation of medicinal cannabis only
- Elpasso to provide the latest off-take agreements for the product recipients
- Elpasso production quantity to be limited to 146 000 kg / annum of medical cannabis, subject to approval by INCB (International Narcotics Control Board)
- No extraction processes of cannabis products to be conducted at Elpasso
- No finished product manufacturing processes at Elpasso
- Elpasso to provide production reconciliation reports every three months
- Elpasso to provide annual reconciliation reports for CBD and THC yields
- Elpasso to comply with SAHPRA Cultivation Guidelines for control and security at the facility
- No cannabis product should be sold directly to the public

- The Authority must be informed of any changes in senior management at the company

The resolution reflects the status of compliance at Elpasso at the time of the inspection and should not be relied upon to reflect the GACP compliance status if more than three years have elapsed since the date of this letter.

Yours faithfully



ACTING CHIEF EXECUTIVE OFFICER

DATE: 2019/03/13