

# PHARMA CONNECT AFRICA CONFERENCE 2019

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IS SOUTH AFRICA FALLING BEHIND ?

# INTRODUCTION

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- OUR LEGISLATIVE FRAMEWORK
- S 22C(1)(b) of Act 101 provides that upon application, the authority may issue a licence to some one acting as a distributor, wholesaler or manufacturer of *inter alia* a medicine or scheduled substance to import, export, manufacture, do wholesaling or distribute.
- S 22C (6) of Act 101 prohibits sale of any medicine or scheduled substance unless issued with a licence.
- S 29 (k) of Act 101 provides *inter alia* that any person who contravenes S 22 C (5) and (6) commits an offence.

# SCHEDULING STATUS

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- I.t.o the Schedules to Act 101 of 1965, Cannabidiol (cbd) is S4 when intended for therapeutic purposes
- Dronabinol – transdelta – 9 – tetrahydrocannabinol (thc) is S6 when intended for therapeutic purposes
- Cbd is S7 except when intended for therapeutic purposes
- Cannabis (Dagga) is schedule 7

# COMPLIANCE WITH INTERNATIONAL TREATIES - THE 1961 CONVENTION

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**IS IT ALLOWED TO POSSES CANNABIS??**

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# THE GUIDELINE DOCUMENT

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- Site Master File
- Security
- Personnel
- Documentation
- Quality Control Measures
- Off take agreements
- The filling up of the application form should be preceded by the reading of the Guideline document.

# WHAT HAPPENS DURING INSPECTION?

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- Site inspection
- Round table discussions
- Written report sent to the applicant
- Response from the applicant

## 2<sup>ND</sup> ROUND OF INSPECTION

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The cycle repeats and if site is not ok by the 3<sup>rd</sup> round, the file gets closed. If the applicant is still interested, a new application should be submitted.



# THE STATUS QUO AT SAHPRA

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- We have applied to the International Narcotics Control Board (INCB) for quota allocation
- 16 sites were inspected in the past year.
- The 3 resolution letters advising applicants that they met the minimum requirements.
- Inspections ongoing

# THANK YOU

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RAMARUMO R CHEPAPE

MOBILE: 082 492 4955

MEDICINES CONTROL OFFICER (LAW ENFORCEMENT UNIT) – SOUTH AFRICAN HEALTH PRODUCT REGULATORY AUTHORITY