SAHPRA
SOUTH AFRICAN
HEALTH PRODUCTS
REGULATORY AUTHORITY

Progress of Regulatory work re **Access to medicines**

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SAAPI CONFERENCE 17 MAY 2019

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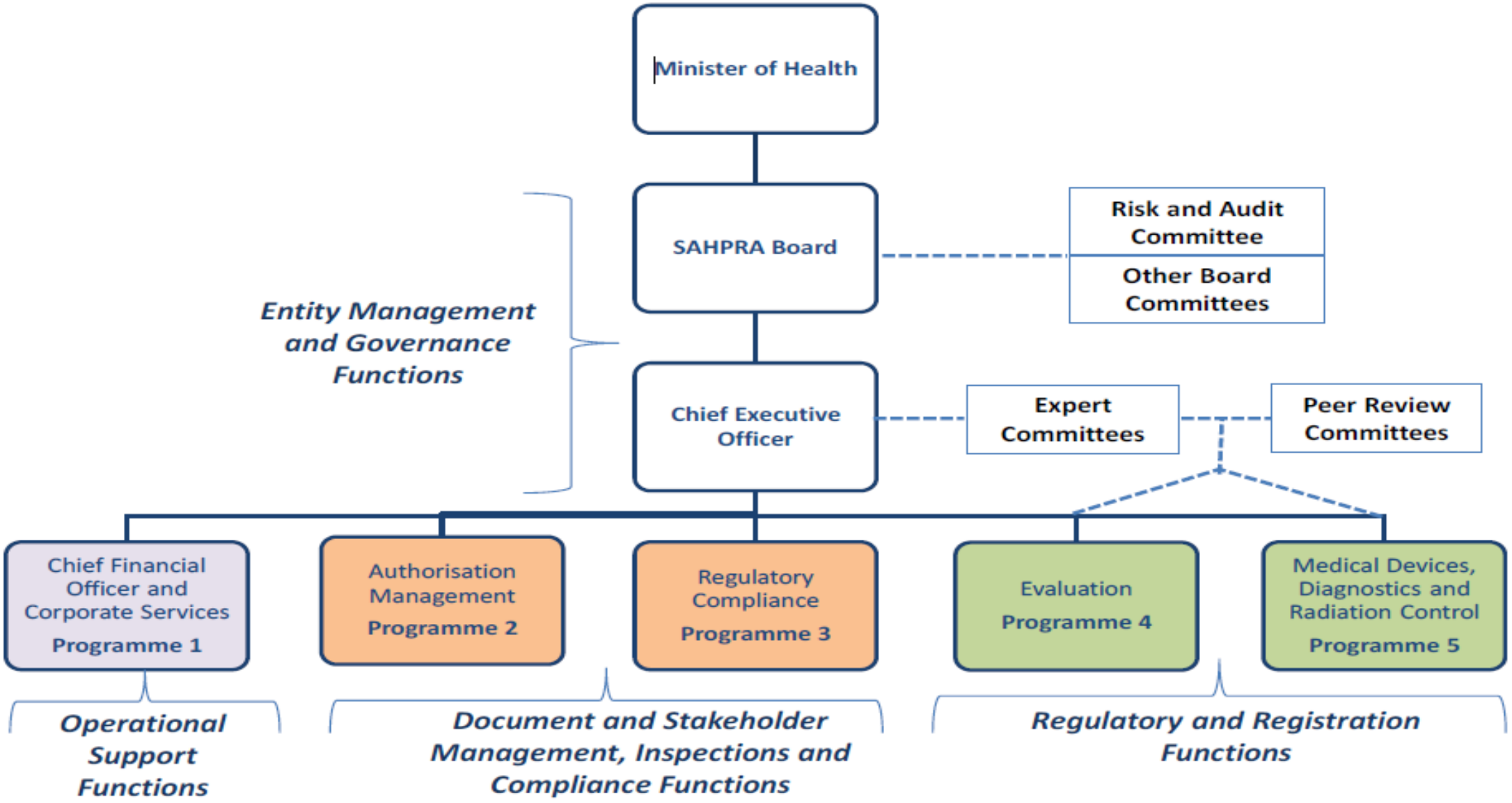
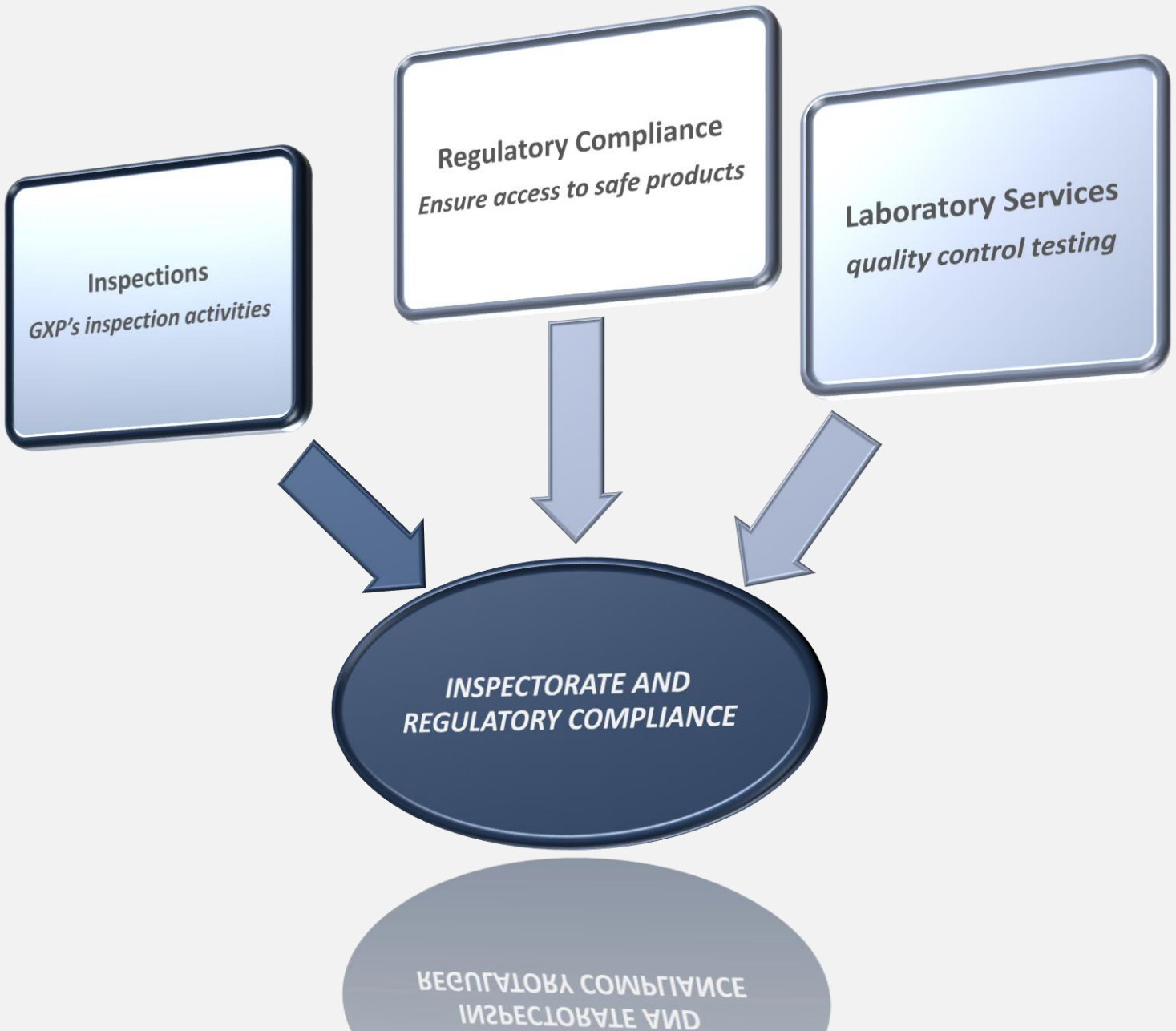
- Inspectorate & Regulatory Compliance
- Control of health products in terms of
  - Permits & Authorisations
  - Scheduling
  - Licensing
  - Exemptions
  - Advertising, Bonusing, Sampling & Marketing
  - Port of Entries
  - Counterfeits/ Substandard/ Falsified

Overview

Figure 1: MACRO ORGANISATIONAL STRUCTURE OF SAHPRA



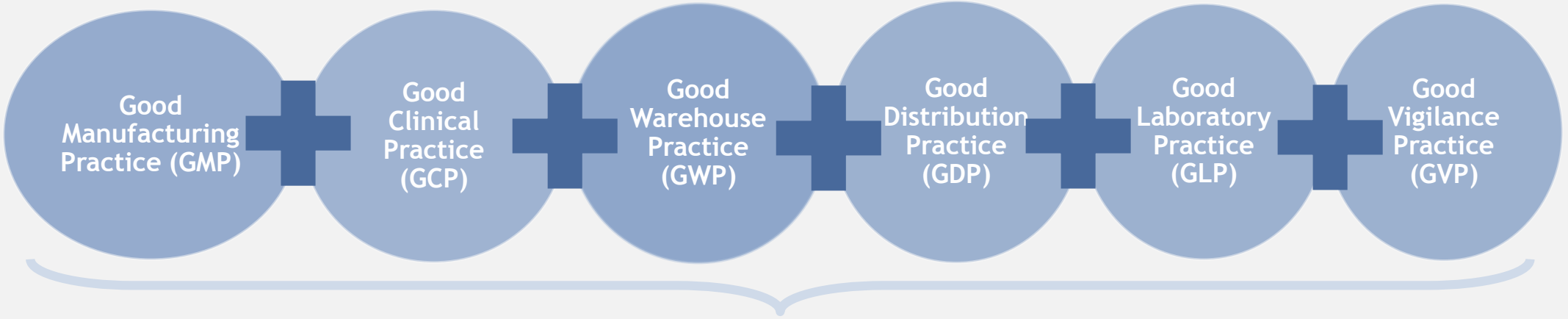
Programme 3 Unit



Inspectorate and regulatory compliance unit:

Main purpose:

- To ensure public **access to safe** health products through inspections and regulating compliance in accordance with applicable legislation. Our focus includes assessment of site compliance, with good regulatory and vigilance practices, including:



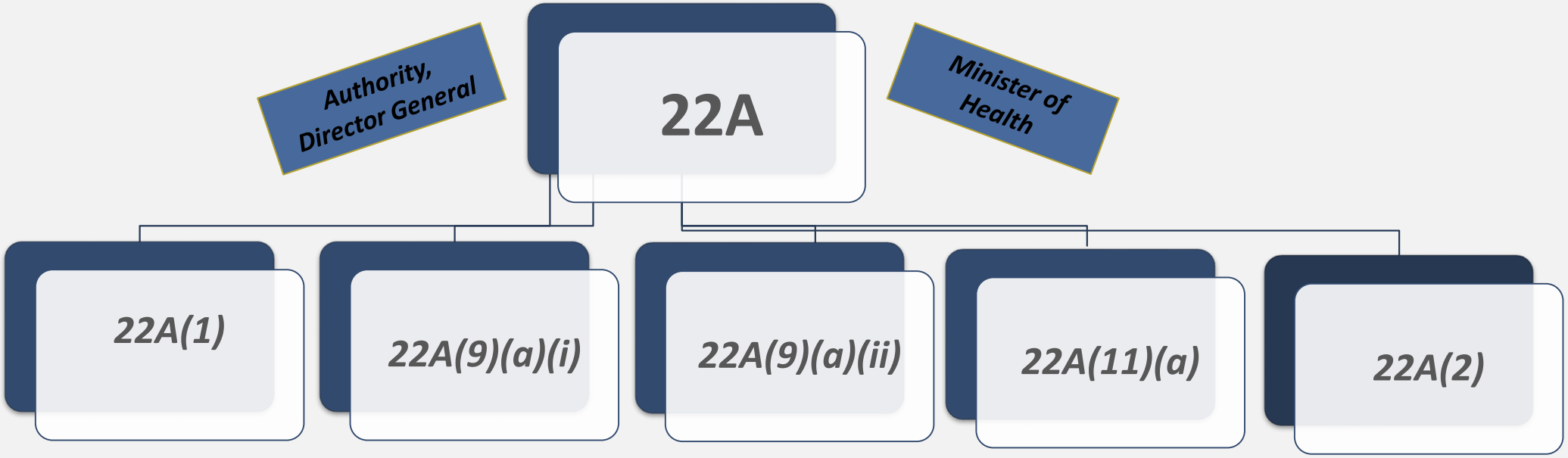
(locally and internationally)

Progress operationally

- SAHPRA is:
  - Expanding technical and support staff complement to build much-needed regulatory capacity and expertise in South Africa
    - Over 100 key positions have been advertised and there will more at a later stage.
  - Re-engineering process to digitise and automate procedures amongst other things

Section 22A:Control of medicines, Scheduled substances, medical devices and IVDs

The sale, supply and use of a medicine or scheduled substance in South Africa is governed by section 22A of Medicines and Related Substances Act, 1965 (Act 101) of 1965), and the Regulations



Permits and Authorisations

22A(9) (a) No person shall-

(i) acquire, use, possess, manufacture, or supply any Schedule 7 or Schedule 8 substance, or manufacture any specified Schedule 5 or Schedule 6 substance unless he or she has been issued with a permit by the Director-General for such acquisition, use, possession, manufacture, or supply: Provided that the Director-General may, subject to such conditions as he or she may determine, acquire or authorise the use of any Schedule 7 or Schedule 8 substance in order to provide a medical practitioner, analyst, researcher or veterinarian therewith on the prescribed conditions for the treatment or prevention of a medical condition in a particular patient, or for the purposes of education, analysis or research;

(ii) **manufacture, use or supply** any Schedule 5 or Schedule 6 substance for other than medicinal purposes, unless he or she has been issued by the Director-General with a permit for such manufacture,

Import and Export

22A(11)(a) No person shall import or export any specified Schedule 5, Schedule 6, Schedule 7 or Schedule 8 substance or other substance or medicine prescribed for that purpose unless a permit has been issued to him or her by the Director-General in the prescribed manner and subject to such conditions as may be determined by the Director-General.

Legal Requirements on Import/Export

- Medicines and Related Substances Act, 1965;
- The Single Convention on Narcotic Drugs, 1961;
- The Convention on Psychotropic Substances, 1971;
- The UN Convention against Illicit Traffic in Narcotic Drugs & Psychotropic Substances, 1988

Permits & authorisations progress

- Import permits (S5-S8)
- Export permits (S5-S8)
- General Authorizations and those for Ephedra products Import and Export
- 22A(9)(ii) Permits (S5-S6) for research, possession, educational/training use of drugs/ Manufacturing
- Hemp production permits
- Medicinal Cannabis permit for research purpose

15 working days turnaround time Permits : up to date
Working on automating this function

Import Permits

Section 22A(11)

To comply with International treaties

Section 22A(7)

Importation of Schedule 1 to 6 substances for analytical purposes, manufacture of foods, cosmetics, educational or scientific purposes by any person other than a pharmacist, pharmacist intern or pharmacist's assistant acting under the personal supervision of a pharmacist

Changes: to enable Effectiveness and efficiency

- MCC: 8 weekly Committee meetings then additional 8 weeks for Council, the resolution
- Authority: capacitating and empowering technical level to decision making and only escalating to senior levels on a need basis
- We have lost 6 inspectors within a the last year
- Number of Acting positions
- To become transparent to stakeholders
- The Authority is revamping the Licensing task and process to align itself with the goals and targets set

- Aligning with other regulators

- Decentralising certain tasks and removing red-tapes

Scheduling and Control of medicines

- All medicines are subject to a scheduling process on the basis of the substances they contain (active pharmaceutical ingredients - APIs)
- Section 22A(2) – Schedules approved by the Minister, on the recommendation of the Authority
- Section 37A – provides for amendments to the Schedules
- Schedules are published in the Gazette or amended by subsequent notice in the Gazette

Scheduling and Control of Medicines

- the Authority
  - ensures that there is appropriate levels of control consistent with international drug control conventions
  - ensures timely implementation of policies and resolutions of the International Narcotics Control Board (INCB) particularly for substances with potential for addiction, abuse and misuse

Section 22A:Control of medicines, Scheduled substances, medical devices and IVDs

Other applicable sections of the Act are(but not limited to..)

Sec 14: Prohibition on the sale of medicines, medical devices or IVDs which are subject to registration and are not registered

Sec 15: Registration of medicines, Medical device & IVDs

Sec 21: Authorization of sale of unregistered medicine

Sec 22C: Provides for the registration of facilities whereby medicines can be manufactured and stored

Sec 36: Exclusion of any medicine, Medical device & IVDs

Sec 29: Offenses

Sec 30: Penalties

Sec 18: Advertising, Bonusing, Sampling, Marketing

Section 21 of the Act enables access to unregistered medicine or investigational product under specified conditions

- **Specified conditions include:**
  - Patient/s with an illness where a clinical need can be demonstrated & **evidence exists to support use**
  - the medicine is available in **other countries**, but not yet registered in South Africa
  - continued access to medicines provided to patients following completion of a **clinical trial**.

Approval letter valid for 6 months

Section 36:

Exclusion of any medicine, Scheduled substance, medical device or IVD from operation of Act:

- **Can be for Registered products:**
  - amendment applications
  - post-registration quality amendment applications still under evaluation
  - products on state tender,
  - changes relating to manufacturing sites,
  - packaging materials
  - additional/alternate sources of API's as priority public health products required e.g. ARVs and TB medications.
  - out of stock in SA,
  - Transfer of Applicancy etc.; or
- **Any request for exemption other than registered product**
  - Act of compassion (Cyclone Idai)
    - Request to Export medicines by wholesaler

Section 18

Medical Devices

&

Complementary medicines

22G Pricing committee

SAHPRA consults with them whenever required (within DOH)

Port of Entries

- Provides for dedicated port of entries for medicines

  Regulation 6(1)

  - **Port of Entries for Medicines**
    - Cape Town International Airport or harbour;
    - Port Elizabeth International Airport or harbour
    - Durban International Airport or harbour
    - OR Tambo International Airport

  - **Port of Exit – any border post**

  - **Transmission of medicines through republic** Reg 7
    - stored in a licenced bonded warehouse

Documents required: Importation of medicines

- Copy of certificate of Registration of the Medicine/s
- Copy of certificate of registration of the Company
- Import permit for S5 or S6/ narcotic and/ psychotropic substances

Roles of Different Stakeholders

- **SARS**
  - Check documents
  - Prohibited and Restricted List
- **Port Health**
  - Inspection of documents
  - Cargo inspection
  - Liaise with DOH Law Enforcement
- **SAPS**
  - Investigate transgression
  - Detention of cargo or offender

Counterfeits/Substandard/ Falsified health products

There is an established forum attending to this challenge & those who are not yet involved can contact SMASA

Regulatory Compliance programme is looking forward to participating better once relevant positions that were advertised are filled

"Stop being afraid of what could go wrong and start being excited of what could go right"

by Toni Robbins

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Thank you!