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Health Products
Regulatory Authority

SAHPRA's approach to prevention, detection and response to SF Medicines

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Prevent,
detect
& respond to
SF
•Comprehensive legal framework
•Education and awareness
•Multi-stakeholder engagement &enforcement
•Supply chain integrity

Overview of Regulatory Compliance functions

MARKET SURVEILLANCE AND CONTROL

- Prevention, detection and response to substandard and falsified medical products
  - Control of import activities (3-Frameworks)
  - market surveillance program for monitoring the quality of medical products throughout the supply chain, and
  - control of promotional, marketing and advertising activities
  - Stakeholder involvement throughout

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Legislation, Regulation & Mandate

- Provisions of the Medicines Act
  - 2A; 2B(1)(e), 14; 15, 22C(1b), 22A-(1),(7a),(9a), 22A-(11), 18, 18A, 19, 20, 22H, 23, 26, 28, 29, 30, 36 but not limited to
- Regulations
  - 5, 6, 7, 8, 10, 11, 12, 15, 23, 24 (1-5), 27, 28, 42, 29,44 (5 & 6), 50, 51, 52, 53
- Guidelines
  - **Guideline for Importation and Exportation of medicines**
  - **Guidelines for recall/ withdrawal of medicines**
  - **Guideline for Disposal of Unwanted Unwholesome Pharmaceutical Products**
  - **Guidelines for advertisement of medicines and health products**
  - **Guideline for release of import health products at port of entries**
  - **Port-of-Entry-guide-Importation-of-medicines_narcotics_psychotropics**
  - **Guide to fee determination and payments of permits and related authorizations in regulatory compliance unit**
  - **Guideline for Market Surveillance- Health Products**
  - **Guidelines for destruction of schedule 5,6,7, & 8 medicines/substances**
  - **Guideline -Donation of medicines medical devices and IVDs**
  - **Cultivation of Cannabis and manufacture for medicinal and research purposes**
- Enforcement aspects, e.g.
  - Sections 2B(1)(e)promote compliance to various sections of Medicines Act via investigations & inspection together with issuing of permits and authorisations, 30-Penalties lay Criminal charges in 29-Offences, 23 undesirable Regs Investigation 49,50,51,52
    - https://www.sahpra.org.za/wp-content/uploads/2021/10/5.09-Requirements_and_Guidelines-_
    - How-to-lodge-a-complaint-on-Medicines-and-Medical-devices_-Version_2.pdf
    - https://www.sahpra.org.za/rapid-alert-system/
    - https://www.sahpra.org.za/medicine-recalls/

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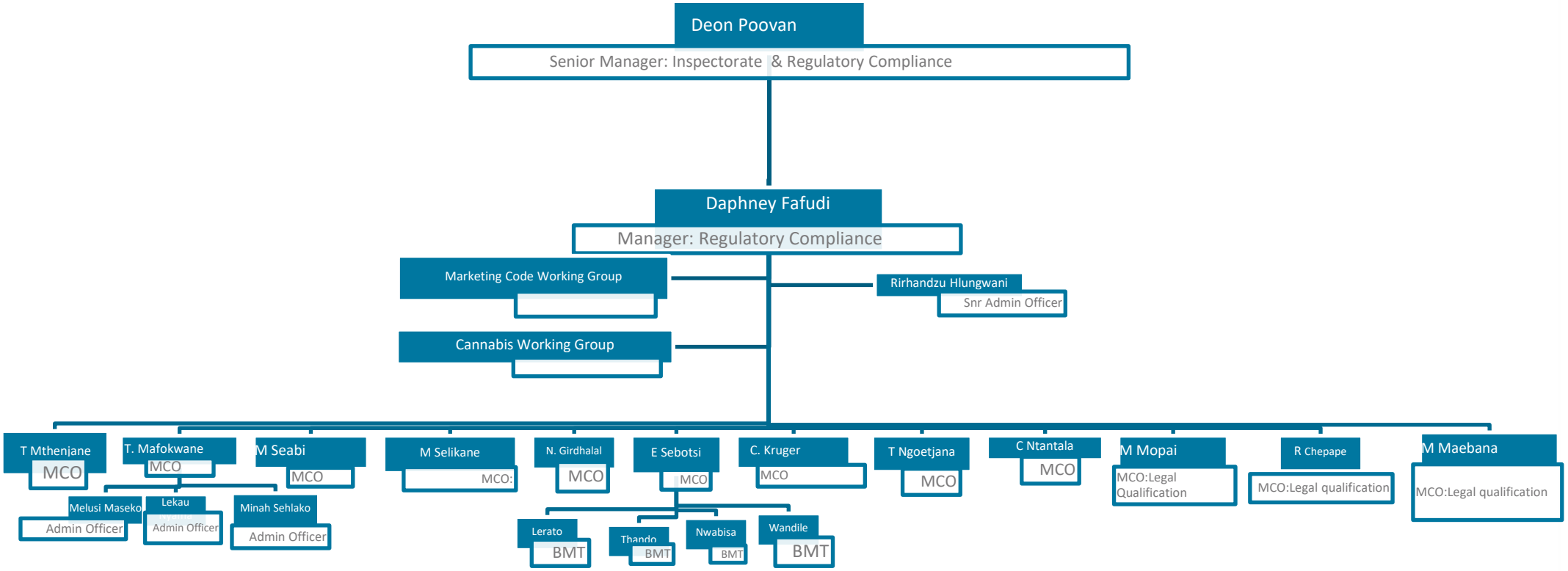
Regulatory Compliance Structure



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Cooperation & collaborations with stakeholders local & International

- Organization
  - Unit relations cut across all divisions
- Cooperation and collaborations
  - Industry Applicants , Associations for 3-Frameworks , SAPC, HPCSA, DSD,
  - DOH, Port Health, SARS Customs, SAPS and its specialized units, Interpol, Pharma crime group, NCC, CIPC, NPA, Ports Agencies, Facebook, Google, SIU
  - Govt Dept & entities : DOH, DIRCO, DTIC, DSD,CDA, ITAC, DOJ, DSI, DHET,CSIR,MRC, DALRRD, UNODC, INCB narcotics and psychotropic substances annual estimates/quota, quarterly and annual reporting import, export, manufacture, possession, use and annual returns
  - WHO, ZAZIBONA, SADC, NRAs , PIC/s, UNODC, INCB

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SAHPRA interventions – Illegal/Noncompliant Supply Chain

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SAHPRA interventions – Illegal/Noncompliant Supply Chain

- Jurisdiction in the supply chain
  - Powers of inspectors which allows entry into any place that has medicine and health products
- Specific port of entries as per regulations
  - Developing capacity for presence at these ports
  - Working relationships with SARS and port health, who report on medicines entering other border posts
- SAHPRA initiated recalls and destructions
- Investigations triggered by internal and external triggers, not limited.

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Investigations

- SAHPRA Regulatory Compliance conducts investigations related to regulatory non compliances
- Over 50% of cases relates to substandard and/or falsified medicines
- Actions taken:
  - Recalls
  - Destructions
  - Arrests
  - Referrals to other authorities, SAPC, HPCSA, SAPS

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Investigations

- Majority of investigations have been reactive. SAHPRA leverages on current working relationships with SAPC, HPCSA, SAPS (Hawks), NPA.
- Due to the complex nature of these cases, monitoring is required to be conducted by SAHPRA.
- SAHPRA is also required to provide support in ensuring successful prosecution of charged persons:
  - Submission of Affidavits
  - Being witness for the prosecution
  - Testing of seized product

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Recalls / Withdrawals

- Majority of recalls are reactive and are applicant initiated.
- Recalls initiated for Medical Devices and Medicines
- SAHPRA is part of the rapid alert network, where substandard and falsified medicines are communicated across several countries, giving SAHPRA opportunity to proactively initiate recalls where SA is impacted.

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Contributors of SF

- A scourge of theft incidents for the past year
  - The lootings
  - Hijacking of medicines trucks
  - Ephedrine and pseudoephedrine APIs in kg: from 3 different manufacturers
  - Employees at Warehouse/distribution centers (dispatch)

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Imports

- 7 Official Ports of Entry
- We have officials at the busy ports: ORTIA, CPT, Durban
- Employment of Pharmacy Technicians

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Market surveilance

- Skin whitening/lightening/bleaching agents
  - Unregistered and registered corticosteroids
  - Via official ports with others smuggled at unauthorized ports
- APIs containing S4 and S5 substances: for unregistered/unauthorized pharmaceutical products “Compounding” of human and vet
  - These being advertised also on websites (unapproved products)

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Adverts

- Focal Medicines Control Officer/s
- Adverts of S2 and above on TV, radio, websites, social media platforms
  - Of registered products by reputable companies
  - During COVID-19 pandemic-MEC Edu
- Rise in Sale of medicines on platforms e.g. Takealot
  - Erectile dyfunction/sexual enhancers
  - Weigh loss

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Rise in Cyber Crime

- Fraudulent website are being setup to sell medicines
- Illegal medicines websites using open source channel
- Identifying the domain can be tricky
- Replication of the authentic website using a spoofed domains

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Challenges: fight substandard and falsified medicines of digital platforms

- Lack of sufficient legislative framework/outdated laws
- Weak enforcement - limited resources, shortage of manpower in enforcement agencies, competing priorities
- Limited awareness of hazards of counterfeits
- Porous borders and ports
- Lack of national policy & corruption
- Large informal economies

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Ongoing initiatives

- Legislated pharmaceutical supply chain
- Pharmaceutical Task Group & Industry Technical Group forum platforms
- Control of imports - seven medicines Ports of Entry
  - SAHPRA has officials at the 5 Ports of Entry (Increased inspection activities)
- Pharmaceutical Crime forum comprising of Brandholders / law enforcement agencies; Dept of Trade, Industry & Competition; Pharmaceutical Associations; Consumer protection; health statutory bodies; Interpol local & regional office; Customs; Mail centres; Port Health; Dept of Communications and Digital Technologies
- UNODC platforms & events on sharing information
- Recent networks includes US govt on fighting digital pharmaceutical crime on information sharing and training
- Collaborations and operations with other Law enforcement agencies and Regulatory Authorities locally, regionally and internationally
- Communication to public includes via accessible Media platforms and Webinars
- Harsh Penalties/fines on non-compliance & those whose products are implicated

Digital Health to fight SF medicines: To Battle Transnational Crime

- Gather and Share Information
- Transnational Crime Trends/Threats/Leads
- Transnational Crime Typologies/Characteristics
- Identifying Source, Destination, and Transit Countries
- GLEN/ICHIP Assist Link Up Law Enforcement from Source, Destination and Transit
- Countries to Address Transnational Crime
- Assessments
  - Threats/Vulnerabilities/Needs
- Highlighting Where There Could be Useful Collaboration Among ICHIP

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MARRIOTT

Benefits of collaborations & cooperationswith stakeholders locally & international

Learning on:

- investigative techniques,
- strengthening online enforcement and how to get prosecutors understanding from the onset of investigations etc.,
- the requirements for successful prosecution,
- Internet fraud and public health,
- Education and awareness,
- sharing lessons learnt

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KOMATSU
PC 210


CHEMICAL STORAGE AREA


DO NOT STORE
PALLETS NEAR
AGAINST THE FENCE

Cannabis: Licensing, permits & product authorisation

Cultivation

Extraction-intermediate /API

Manufacture

Export

R&D

SAHPRA is responsible for controlling and monitoring all MC related activities

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Transparency and outreach to the general public

- Information shared with the general public on the outputs or outcomes of the functions
  - The Annual Performance Plan and Report is tabled in parliament and is a public document.
  - They are published on SAHPRA website
  - Guidelines on our activities are on the website
  - Cultivation of medical cannabis Licences issued following our resolutions are published
  - Warnings, Alerts, notices, relating to recalls or updates on policy decisions
- Information sharing platforms/modalities
  - Via Website, Press release, interviews via various media platforms, collaboration, website annual report
    - https://www.sahpra.org.za/wp-content/uploads/2021/10/SAHPRA-202021-Annual-Report.pdf
    - https://www.sahpra.org.za/rapid-alert-system/
    - https://www.sahpra.org.za/safety-alerts/
- Process and frequency of information sharing
  - When need arises and as per Communications policy

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Performance evaluation and achievements

- Performance indicators and key performance indicators
  - Performance Management contracts are signed off at the beginning of the financial year.
  - Individual performance assessments aligned to the Annual Performance Plan are submitted to HR Department as the custodian of the process
  - Regulatory Compliance is included in the Annual Performance Plan, where 70% permits must be finalised within 20 working days. Also 70% of health product quality complaints reports must be produced within 30 working days
- Progress, improvement, main changes
  - Support from the QMS Unit, Risk Unit and the Performance monitoring unit
  - Improvement in terms of unit procedures
  - Recent Employment of new staff is encouraging
  - Team is motivated and eager to contribute and is working hard

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THANK YOU