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Codeine Abuse

Presenter: Daphney Fafudi

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Control of codeine

- UN Treaties: Single Conventions on narcotic drugs (1961) and (1988 on prevention of illicit traffic)
  - Misuse, abuse, dependency, and addiction of these substances
- The Medicines Act, General regulations and Schedules: S6 or low dose combinations e.g. S2
- In prioritising public health and safety, we must minimise the risk of diversion of all controlled substances like codeine
- SAHPRA & NDOH reports on national estimates, consumption and assessments to the UN- INCB
  - Countries put in place regulations that ensures accurate data on consumption: manufacture, distribution, possession, use inc. waste management
- Member states are obliged to **establish efficient, accountable & transparent** systems for regulatory oversight of the supply chain (especially the Medicines Act & Pharmacy Act : for medical and scientific purpose)

The INCB is concerned about the rate of consumption of codeine in the country

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Supply chain levels of control

- SAHPRA issues permits for manufacturing (inc. API), import, export and possession of narcotics and psychotropic substance for medical and scientific use
- SAHPRA has officials at ports of entry
- Control of sales at wholesale level under discussion
- SAHPRA is acquiring an INCB electronic tool to manage the above
- There's growing concern over the availability and consumption of these substances in the illicit market
- This does not reflect well to the pharmacy profession, and
- This is observed throughout the supply chain (whether theft, hijacking, unprofessional conduct, relabelling of products for illegal export or other means)
- How does this happen with such a Complex pharmaceutical supply chain (require: import/export permits/prescription/pharmacist intervention)
- Hijackings, smuggling into other regions,
- e.g. Codeine containing syrup labelled: grape juice (for Canada/US markets)
- Current big gap is in demonstrating management and accountability re rational consumption at consumer/patient level (prevention dependency, abuse, addiction and illicit use)
  - Reality also shows upward trend re irrational use and illicit activities
  - Various substance abuse reports demonstrate this concern
  - Youth explains how easy it is to access these is alarming (youth are country's future)
  - SAHPRA inspectors uncover legit pharmacies without correct pharmacy personnel issuing these products –these are referred to SAPC

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Control of codeine and mandatory centralised data recording

- Pharmacy sector must work together support measures taken to ensure medicines are accessible, available and affordable. Sector must also embrace initiatives meant to prevent abuse, dependence, addiction and supply to illicit trade
- The consequences and impact of those directly affect negatively the country's health status and its future
- A combined effort is needed to combat this effect and this can be achieved if we start collecting data for information and better decision making
- SAHPRA and stakeholders are working towards implementing a Central data collection system - **mandatory** in seeking to address challenges currently faced
- The passion and commitment of pharma profession must strengthen to address concerns of irrational use, dependency, abuse and addition. Resulting in no need for rescheduling as it will prevent pharmacists from Pharmacists Initiated Therapy
- All have a responsibility in Ensuring rational access & use which Protects the public and provision of accurate reporting to INCB

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Overview & summary of some SAHPRA work into this matter

- SAHPRA conducted research on Codeine consumption
  - End April 2021 referred the matter for further investigation by Regulatory Compliance
- Strategic decision to focus on Cough syrups/mixture containing codeine
  - Highest consumption shown in the data
  - High incidents of misuse/abuse in the communities by youth
  - Easily accessible

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- Investigated the most consumed and concerning Codeine formulations
- Received annual consumption data
- Focused on to 20 consumers as that demonstrated over 90% consumption
- Top 10 are 80% consumers of the SA annual consumption by province all supply chain sectors
- Gauteng had over 90% consumption rate and hence unit started in GP
- Investigations are throughout supply chain sector Manufacturer, Wholesale, Community pharmacies, Clinics ,Dr prescribing
    - Hospitals had the least consumption

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- RC held meetings with the Manufacturer to understand production volumes and reconciliation of stock in the supply chain together with its oversight responsibility CSR
  - Meetings with Manufacturers and Wholesalers
  - Emphasis on concern with the irrational use of the product (misuse, abuse, dependency & addiction)
  - Top 50 consumer – breakdown by sector & province
  - Over 99% consumption Data given reconciled with manufactured/production
- Top 10 facilities were 80% consumers and are based in GP
- Data for Pharmacies: Wholesale, community & hospital, Clinics, Dispensing Doctors with volumes → SAHPRA could rank who purchased and this enabled prioritization of investigations

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- Progress of pharmacies Investigated in Gauteng selling highest quantities of Broncleer with Codeine and reasons thereof
  - Investigate whom these are sold to in the market
  - Ascertain that there are no leaks in the supply chain to illicit or unauthorised market
  - Use data to collate information to inform appropriate action needed
- Top 20 selling pharmacies were allocated to Inspectors in Gauteng
- Inspections began in September 2021
- Inspections were unannounced to facilities and reports are available
- All facilities were inspected

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Overview & summary of some SAHPRA work into this matter

- Several Meetings with Industry stakeholders on their various initiatives
  - Meetings with Statutory bodies, HOPS, Industry associations, education and awareness platforms including media and SAHPRA website
- Engaging and Cooperation with neighbouring countries and other regulators in the region/globally on the supply and use of these medicines

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FOR NOTING

- SAHPRA will keep visiting these 80% consumers
- Wholesales that do not put cap will be monitored
  - Regular meetings envisaged with RPs for establishing evidence of rational sales/capping
- Community pharmacies that operated without proper pharmacy human resources
  - Medicines sold by unauthorised personnel
  - stock being out but personnel taking bulk orders
- Increased incidence of Hijackings of codeine containing medicines

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Conclusion

- We all agree the nation is faced with scourge of substance abuse problem
- Lets collaborate in patient education and awaress
- The Centralised data collection will provides information on gaps, solutions needed and best possible interventions for narcotics drugs control
- There's indeed an urgent need for implementation to enforce a harmonized national patient care system for recording of, monitoring of and relevant intervention for these high-risk products.
- Such central database assist with the regulatory oversight of supply chain consumption.
- Work together in prevention, detection & response to substance abuse , leading to accurate reporting, in addition will help the country to assess the real needs for access and availability of codeine containing substances for medical purpose.
- The pharmacy profession needs to embrace and drive these required interventions in the best interest of rational medicine use and minimizing substance abuse with intention eradicate it

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Thank you