Mr. Mlungisi Wondo
Medicines Control Officer
Law Enforcement Unit
National Department of Health
PURPOSE

- Governance Matters
- Documents for Importation
- Processes to be followed
- Roles of different Stakeholders
  - SARS
  - Port Health
  - MCC/NDoH
Governance Matters

- Section 27 of the Constitution (Act 108 of 1998)
  - Every citizen of the Republic of South Africa has the right to access to healthcare facilities

- Medicines and Related Substances Act, 1965 (Act 101 of 1965)
  - Makes provision for the control and access to medicines
  - Provides for medicines registration.
  - Provides for the registration of facilities whereby medicines can be manufactured and stored
  - Provides for procedures to be adopted when selling medicines
  - Provides for dedicated port of entries for medicines
  - Provides for the appointment of Inspectors
Governance Matters

- Promotion of Administration Justice Act, 2000 (Act 3 of 2000)
- Promotion of Access to Information Act, 2000 (Act 2 of 2000)
Control of Access to Medicines

Medicine means any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in-

(a) the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in man; or

(b) restoring, correcting or modifying any somatic or psychic or organic function in man, and includes any veterinary medicine;
Control of Access to Medicines

- Section 22A:
  - Only pharmacist, doctors, veterinarians, those registered under SA Allied Health Professional
  - Nurses under certain conditions
  - Prescription presentation
REGULATION 12: IMPORTATION OF MEDICINES INTO THE REPUBLIC

(1) No person shall import any medicine or scheduled substance, including medicines imported in terms of section 15C of the Act, read together with regulation 7, into the Republic except through one of the following ports of entry:

- Cape Town Airport or harbour;
- Port Elizabeth Airport or harbour;
- Durban Airport or harbour; and
- OR Tambo International Airport (JHB)
(2) A person can only import a medicine or scheduled substance if such person:

(a) is licensed in terms of the Act to import medicines; and

(b) in the case of unregistered medicines, is authorised by the Council to import such unregistered medicines.
Controls on Importation of Medicines

- Port of Exit – any border post
- Goods in Transit – facilitated through designated port of entries
REGULATION 13:

(1) Medicines, scheduled substances and mixtures containing scheduled substances that are transmitted through the Republic shall:

a) while in the Republic be stored in a bonded warehouse which is registered with the Council; and

b) not be manipulated while in the bonded warehouse unless authorised by the Council.

(2) A bonded warehouse referred to in subregulation (1) must comply with good storage conditions as determined by the Council.
Documents Required for Importation of Medicines

- Registered Medicines
  - Copy of Registration Certificate
  - Import permit – narcotic drugs and psychotropic substances
  - Copy of company’s registration certificate

- Unregistered Medicines and experimental drugs
  - Section 21 Approval
  - Section 15 Approval
  - Regulation 16 – Personal use
Process to be Followed

- **Customs:**
  - Receives documents from clearing agent of importer
  - If product imported is medicine or raw materials – detained for Port Health
  - If documents are acceptable – passed over to Port Health

- **Port Health**
  - Documents from Customs, satisfactory – approve cargo
  - Narcotics or psychotropic substances – accompanied by Import Permits issued by DG of DoH
  - If Port Health Officials are not satisfied with the information - referred to Law Enforcement for ruling or inspection
Process to be Followed

- Law Enforcement Referrals:
  - No import permits for narcotics or psychotropics
  - Product registration certificates not attached
  - Importation of medicines by Wholesalers and Importers not registered in terms of section 22C of Act 101
  - Port Health may refer imported products when in doubt
Process to be Followed

Importation of Unregistered Medicines:

- Section 21 – Council authorisation – Port Health only releases the unregistered medicine – Council approval
- Samples Required for Product Registration in Terms of Section 15 – Importer will be issued with a letter of authorisation
- Medicines for Personal use by Persons Visiting the Republic of South Africa – persons visiting RSA – apply for permission to bring their personal medicine – letter of authorisation – Port Health / Port of Entry
Roles of different stakeholders

- **SARS**
  - Guardians
  - Assessment of Documents
  - Referrals to relevant bodies (for medicines based on Restricted and Prohibited list)

- **Port Health**
  - In case of doubt, refer to MCC
## ORGANIC CHEMICALS

### HEADING | DESIGNATION OF GOODS | RESTRICTION | AUTHORITY | ACTION
--- | --- | --- | --- | ---
29.1 Habit-forming drugs as listed in chapter 30
29.4 Products of subheading 2937.00 may only be imported through the following ports:
   a. Cape Town (Airport and Harbor)
   b. Port Elizabeth
   c. Durban (Airport and Harbor)
   d. ORTIA

<table>
<thead>
<tr>
<th>2921.46</th>
<th>Amfetamine(INN), Benzphetamine(INN), Dexamphetamine(INN), Ethylamphetamine(INN), Fenamfetamine(INN), Lefetamine(INN), Levamfetamine(INN), Mefenorex(INN), and Phentermine(INN); salts thereof, Bezylpiperazine(INN); salts thereof</th>
<th>Narcotic or Psychotropic Permit from DG: Department of Health</th>
<th>Medicines and Related Substances Act; Act 101 of 1965</th>
<th>Detain for Port Health, Endorse Permit</th>
</tr>
</thead>
<tbody>
<tr>
<td>2922.14</td>
<td>Dextropropoxyphene(INN) and its salts</td>
<td>Psychotropic Permit from DG: Department of Health</td>
<td>Medicines and Related Substances Act; Act 101 of 1965</td>
<td>Detain for Port Health, Endorse Permit</td>
</tr>
</tbody>
</table>
| 2922.31
2922.44 | Amfepramone(INN), Methadone(INN) and Normethadone(INN) salts thereof, Tildine (INN) and its salts | Narcotic Permit from DG: Department of Health | Medicines and Related Substances Act; Act 101 of 1965 | Detain for Port Health, Endorse Permit |
THANK YOU

Contact Details:
Mlungisi Wondo       Griffith Molewa
Tel: 012 395 8010     012 395 9318
Email: wondom@health.gov.za and
       molewg@health.gov.za