Structure of the presentation

- International regulatory framework for narcotic / psychotropic substances
- Procurement procedures
- Supply chain mechanism
- OST Delivery System
International regulatory framework for narcotic / psychotropic substances
• **Convention on Narcotic Drugs (1961)**

• **Convention on Psychotropic Substances (1971)**

• **Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988)**

**Common objectives:**

• Provide legal foundation for action in drug control

• Ensure that drug production, distribution and consumption is limited to medical and scientific purposes

• Prevent diversion to illicit channels
International regulatory framework

- Different mechanism for narcotics / psychotropics
  - Methadone
    - Covered under the 1961 convention
    - Prior quota and annual consumption reporting required
  - Buprenorphine
    - Covered under the 1971 convention
    - Annual quota not required to be allocated
    - Annual reporting for Buprenorphine (optional)

- Essential medicine list – WHO
  - Methadone and buprenorphine in the list
Laws / policies of countries

• Drawn in accordance to the conventions
• Support the use of narcotics/psychotropics for medicine and scientific purpose
• Example
  – India: use of opioids for OST (de-addiction) mentioned under NDPS act
  – Nepal: harm reduction and OST endorsed in the National Drug policy
Supply chain mechanism

- Procurement
- Supply
- Stock management
- Replenishment of stocks
Procurement procedures

1. **Determining type of medicine required**
   - Methadone: syrups
   - Buprenorphine tablets: 8 mg, 2 mg, 0.4 mg, 0.2 mg

2. **Determining the quantity**
   - No. of patients X no. of days X average dose per patient per day
3. Request for **QUOTA**

- Required only for Methadone
- Nodal Ministry requests INCB for a quota for Methadone
- Example
  - Department of Narcotics Control (Bangladesh)
  - Ministry of Home Affairs (Nepal)
  - Central Bureau of Narcotics (India)
Procuring agency

• Each country has a nodal agency for procurement of goods and supplies
  – Maldives → State Trading Organization
  – Nepal → ‘Sajha’ trust
  – India → NACO through its procurement agency (UNOPS/RITES) (for NACO sponsored OST programme)
Bidding agency

- Agency
  - Manufacturer / supplier

- Must have a WHO-GMP certificate or equivalent certificate

- For export, supplier would need “Certificate of Pharmaceutical Product” (COPP) as recommended by WHO.
Eligibility criteria

• Manufacturers
  – incorporated in country of manufacture & licensed by regulatory authority
  – evidence of its technical, financial and production capability

• Distributors
  – Duly authorised by the manufacturer to supply goods within a country

• Finalise vendor
  – Technical and financial qualification

Negotiate Rates
Supply Chain Mechanism
Establishing a supply chain mechanism

**Supply chain – A**
Vendor

Clinic

Patient

**Supply chain – B**
Vendor

Central Stock

Clinic

Patient
Stock management

- Licenses from relevant authorities for storage and transport

- Central stocks
  - Storage area of central stock
  - Responsible officer for central stock
  - Safe keeping: secure system

- Flow of stocks from central to OST clinic
  - Chain of custody

- Clinic stocks
  - Storage area
  - Secure system
  - Staff-in-charge?
Record maintenance for stock management

**Central stock register**
- Inventory of the stock to be maintained
- Signed by the officer supplying the stock to clinic

**Clinic stock register**
- Inventory of the stock to be maintained
- Signed by the officer receiving the stock in clinic

**Dispensing register**
- Total quantity of methadone dispensed in the clinic in the given day

**Daily stock register**
- Information on the daily stock transaction being made
OST Delivery
Directly observed treatment strategy in South Asia
Securing sustained supply: considerations

- Clear understanding of the various Ministries/departments dealing with quota, licensing and procurement

- Ensure clear commitment from the ministries – licensing, narcotics control / home

- Ensure procurement is made well in-advance

- Prepare a standard supply chain protocol / guideline
Securing sustained supply: considerations

- Stock replenishment
  - Stock projection
  - Rotate stocks with eye on expiry dates

- Establish a strong supply chain mechanism
  - Identify officers responsible in-charge of the stock at every point

- Maintain records strictly
  - Check at regular intervals
Further areas & Conclusion

• Advocacy for inclusion of narcotics/psychotropics in the national essential medicine list
  – Removal of import duties

• Use of computer based software for stock management (copy right issues, monopoly of pvt sector !)

• Robust supply chain an important part of scale up plan for OST
Thank you