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PHARMACEUTICAL SUPPLY SYSTEMS AND ACCESS TO ANTI-TB MEDICINES IN THE ENVIRONMENT OF GROWING DRUG RESISTANCE
Session outline

• Countries’ TB medicines supply goals
• Elements of the medicines supply system and access to TB medicines
• Global and regional situation with TB medicines
• New TB tools: what should we expect?
• Countries’ readiness for the implementation of new TB tools
• The conference themes: discussions and experience sharing
• Working groups: roadmaps and recommendations
• Expected conference outcomes

Milestone:

- “by the end of 2013, provision by all Member States of an uninterrupted supply of quality-assured first and second-line drugs for treatment of all TB and M/XDR-TB patients.”
Goals of National TB programs (NTPs)

• Ensure access to TB medicines of guaranteed quality for all diagnosed cases at all levels of the health system

• Continuously improve use of TB medicines:
  – Improve efficacy
  – Ensure safety
  – Reduce waste
Increasing Access to Products and Services

**Accessibility**
- Location of Products & Services
- Location of Users

**Availability**
- Supply of Products & Services
- Demand for Products & Services

**Acceptability**
- Characteristics of Products & Services
- Attitudes & Expectations of Users

**Affordability**
- Price of Products & Services
- Ability to Pay

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**Medical Products & Services**

**Strategies to Increase Access**

**Education**
- Patient consultation
- Social marketing

**Management**
- Business management
- Financial management

**Regulation**
- Standards development
- Task-shifting

**Economic**
- Insurance plans
- Pooled procurement

(selected examples)
The Pharmaceutical Management Framework

Management Support
- Organization and Management
  - Program planning and implementation approaches
  - Program monitoring and evaluation
  - Community participation
- Financing
  - Pharmaceutical financing strategies, including revolving funds
  - Analyzing and controlling expenditures
  - Financial planning and management
  - Donor financing
- Information Management
  - Information-based decision making
  - Pharmaceutical management information systems
  - Indicator-based monitoring
- Human Resources
  - Personnel management
  - Preservice education
  - Continuing education
  - In-service training

Use
- Drug information services
- Rational prescribing
- Use of antimicrobial resistance data
- Drug use evaluation
- Good dispensing practices
- Patient information/counseling
- Behavior change strategies
- Curriculum reform

Selection
- Marketing approval/registration
- Therapeutic formularies and essential medicines lists
- Standard treatment guidelines

Procurement
- Morbidity vs. consumption quantification
- Tendering and contracting
- Quality assurance and supplier prequalification
- Supplier performance monitoring and evaluation
- Price monitoring
- Pooled procurement/group purchasing
- Donor coordination
- Medicine donation guidelines

Policy, Law, & Regulation

Policy, Law, and Regulation
- Generics policies
- Decentralization
- Use of private services
- Integration of services/supply systems
- Availability by level of care

Pharmaceutical Laws and Regulations
- Accreditation/licensing (hospitals, pharmacies, providers)
- Procurement laws
- Pharmacopeial standards
- Pharmacy benefits

Policy Support
- Central medical stores vs. alternative models
- Vertical vs. integrated programs
- Inventory management
- Kit system
Quality assured TB medicines: Global picture

Quality assured TB medicines:
- WHO pre-qualified; or,
- approved by stringent regulatory authority (SRA); or,
- approved by Expert Review Panel (ERP)

• Limited demand for quality-assured* TB medicines – mostly through the Global Fund procurement
  - but GDF could rapidly double its supply of SLDs

• Limited/slow market of quality-assured TB medicines:
  - Low incentives for manufacturers of finished products and active pharmaceutical ingredient
  - But the GDF prices are generally lower than countries’

• Unknown quality of non-GDF TB medicines
TB medicines: Regional specifics

Although TB incidence generally is going down, there is a notable growth in demand for second-line TB medicines (SLD), and Group 5 medicines for XDR-TB and compassionate use.

- Lack of funding for TB medicines for all detected cases
- Stock-outs and interruptions, especially with SLDs and Group 5 medicines
- Wastage of TB medicines
  - Irrational use (e.g. outside treatment protocols)
  - Quantification mistakes
  - Delayed procurement
  - Expiry of medicines
- Availability of domestically manufactured medicines on local and regional markets
  - Domestic medicines oftentimes more expensive than from the GDF
  - Increased role of national authorities in ensuring quality
Medicines supply challenges

Management

• PSCM for new products not costed out and financed properly (funding not secured)
  – For all operations in entire pipeline; re-training, etc.
• Non-adherence to phase-in/phase-out plans
  – Waste of “old” products
  – Overuse of new products (stock-outs)
  – Over-ordering of new products (expiry, waste)

Selection

• Delays with registration (or waivers, permissions, etc.)
• Delays with the development and implementation of new protocols
Medicines supply challenges (2)

Procurement

- Quantification
  - Lack of data, skills, tools
- Regulatory issues preventing direct procurement
- Hectic lead times (including with the GF funding)
- Importation problems (customs fees, quarantine storage, etc.)
Medicines supply challenges (3)

Distribution

• Improper storage affecting quality of products
• Inventory control
  – Poor LMIS: no information on stock and consumption
  – Available stock and consumption not linked to actual cases on treatment and expected
  – Min/max, buffer levels not established/followed
  – No early warning system to signal about potential problems with supply
Medicines supply challenges (4)

Use

- Lack of information about TB medicine and new TB tools
- Resistance of providers (e.g. FDCs, pediatric TB formulations)
- Non-adherence to treatment guidelines
  - Reduces efficacy and treatment success
  - Complicates quantification and stock monitoring (early warning)
- Lack of ongoing programs for monitoring medicines use (Drug Use Review, active surveillance, risk management = Pharmacovigilance)
New TB tools: What to expect?

Possible scenarios:

• Changes in MDR-TB regimens
  – Add-on of 1-2 new medicines to old regimens
  – Repurposing of known medicines for TB
  – Reductions in the duration of treatment

• Changes in DS-TB regimens
  – e.g., introduction of regimens with fluoroquinolones

• Complete new MDR-TB regimens
  – With Bedaquiline, Delamanide, etc.

• Complete new regimens for any type of TB
# New TB tools: How to put them to practice?

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<thead>
<tr>
<th>Adoption</th>
<th>Introduction</th>
<th>Implementation</th>
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<tr>
<td>Analysis of benefits, risks, &amp; health system capacities; Decision-making to incorporate the new tool into the National Tuberculosis Programme; Communication of recommendation and policy</td>
<td>Regulatory &amp; registration compliance; Phase-in/phase-out plan preparation; Guidelines, tools, &amp; training materials revision; Financial resources mobilization; Procurement and logistics management; Staff training Advocacy, communication, social mobilization</td>
<td>Carrying out phase-in &amp; phase-out plans; On-going operational activities; Monitoring and evaluation of implementation progress &amp; new technology performance</td>
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Minimum requirements for PSCM systems

- Approved plan/roadmap for strengthening TB medicines supply based on the assessments of health systems and supply practices
  - National PSCM coordination group (or TF with clear TOR)
  - Policies for new medicines/regimens endorsed by key players
  - Multi-year finance secured, for all functions of PSCM, not only products (e.g. capacity building, infrastructure, LMIS)
  - National plan for supplying new medicines/regimens
  - Strategic long-term forecasting and quantification for the procurement
Minimum requirements for PSCM systems (2)

- Registration or importation waivers and other requirements secured
- M&E plan: performance indicators, data sources and data collection SOPs, reporting format, schedule
- Drug management SOPs available in pilot/roll-out sites; staff trained
- Distribution plan developed and approved (including QA)
- Proper inventory management (with SOPs): min/max/buffer stock levels for new products established, LMIS in place
- Functional Early Warning system for preventing stock-outs/over-stock
Conference themes

Substantial experience has been accumulated in the region and will be shared:

• Regional perspective on current strengths and challenges for TB diagnosis and treatment in WHO Europe region
• Regulatory and quality implications on procurement and management of TB medicines
• Rational use, pharmacovigilance and patient safety for TB medicines
• Strengthening TB supply chain systems
• Using information and Tools for effective decision making
• Transitioning from global to national financing mechanisms for TB control
• Adoption and impact of new TB technologies
• Tools for forecasting, quantification, and early warning (QuanTB)
Working groups

• Strategies for introduction of new TB technologies: a systems approach
• TB medicines supply strategies, planning and performance monitoring
• Using TB information system for effective decision making
• Options for enhancing patient safety and rational use of MDR-TB regimens in the context of existing pharmacovigilance systems
• Strategies for making pharmaceutical legislation and regulations to work for uninterrupted supply of quality ensured TB medicines
• Country strategic planning/update exercise (country working groups)
Expected outcomes

• Understanding and consensus on priority challenges and solutions
• Recommendations of the Conference
• Revision of TB medicines supply component of National Strategic plans
• Technical assistance needs formulated, and sources identified
• Post-conference feedback and communication mechanism established