Fighting Drug-Resistant TB in the 21st Century: Novel Approaches to Improving Access to anti-TB Medicines and Pharmaceutical Services
1st Conference on Pharmaceutical Management for TB and M/XDR-TB for WHO European Region

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Antalya, Turkey. December 10-13, 2013

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SIAPS Systems for Improved Access to Pharmaceuticals and Services

World Health Organization REGIONAL OFFICE FOR Europe

Stop TB Partnership

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

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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

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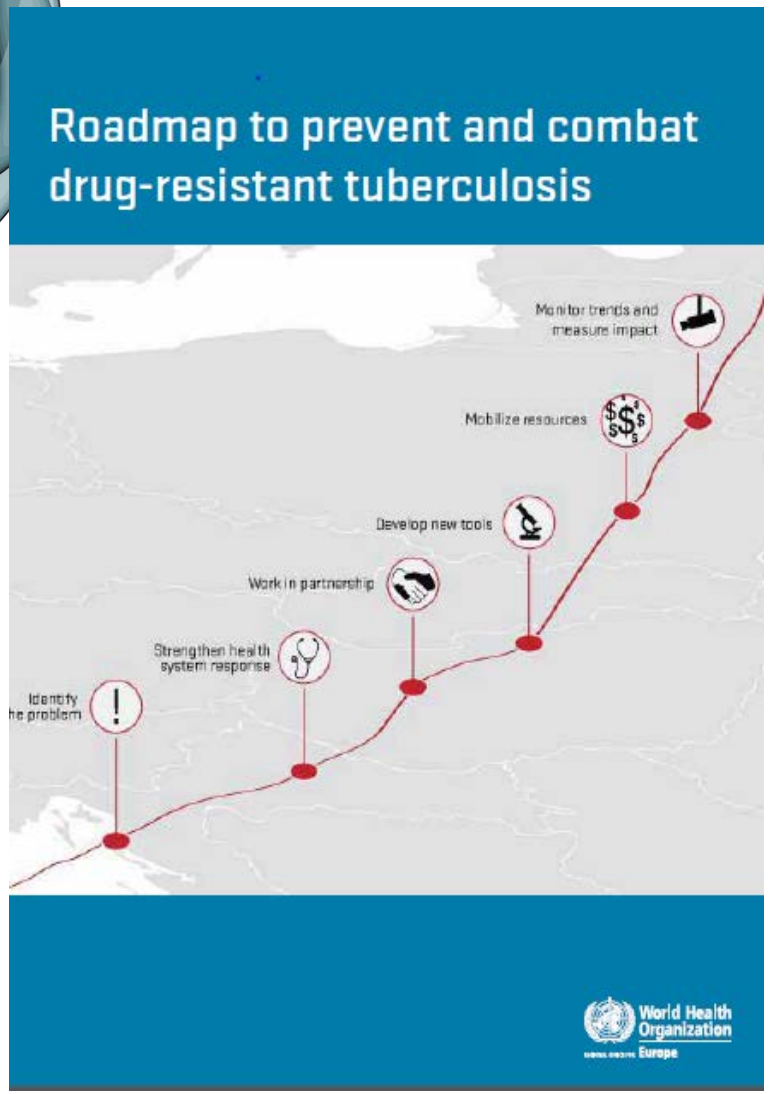

The Consolidated Action Plan to Prevent and Combat Multidrug- and Extensively Drug-Resistant Tuberculosis in the WHO European Region, 2011-2015

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."

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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

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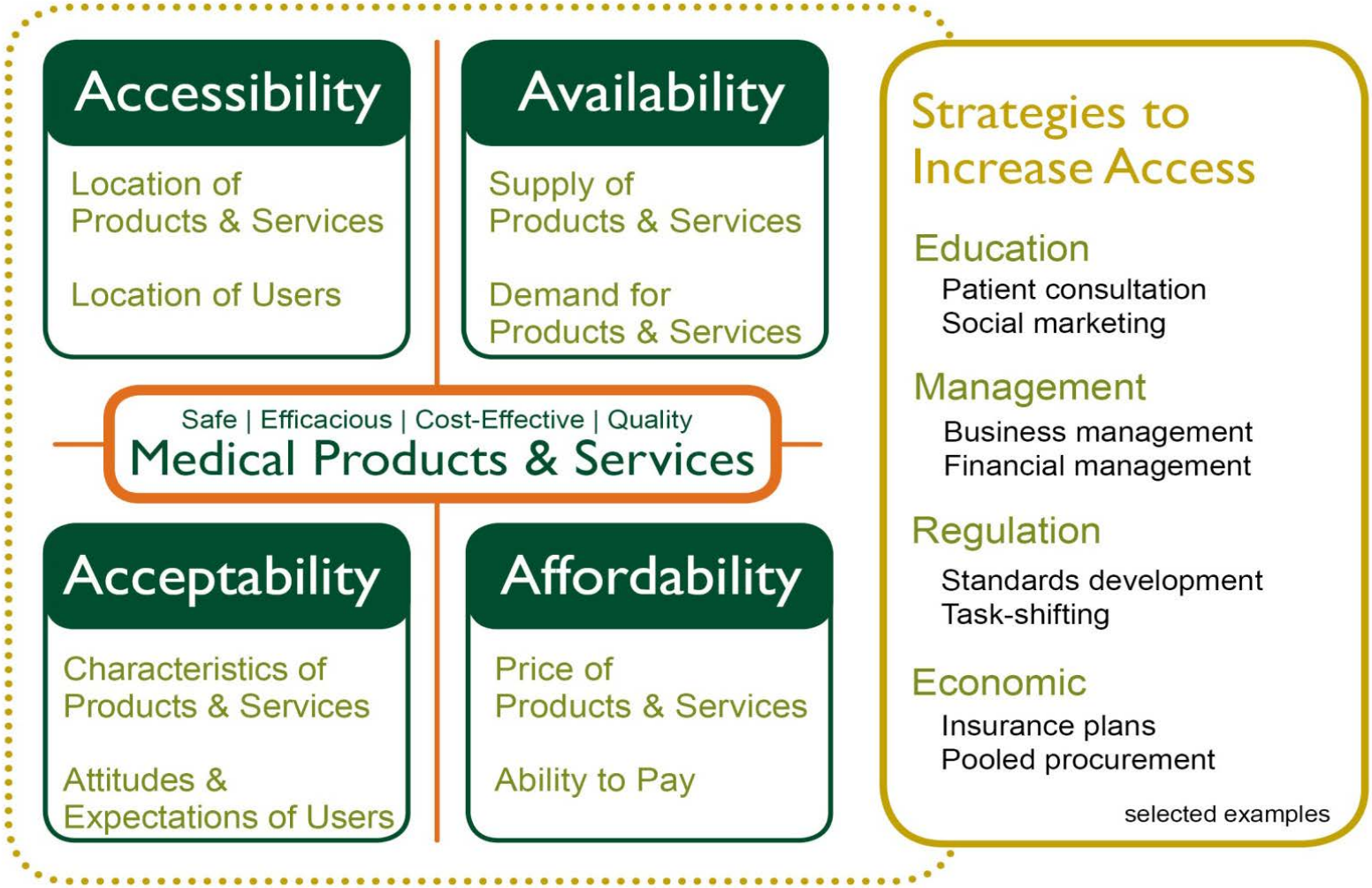
Increasing Access to Products and Services



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The Pharmaceutical Management Framework

Management Support

Organization and Management
- Program planning and implementation approaches
- Program monitoring and evaluation
- Community participation

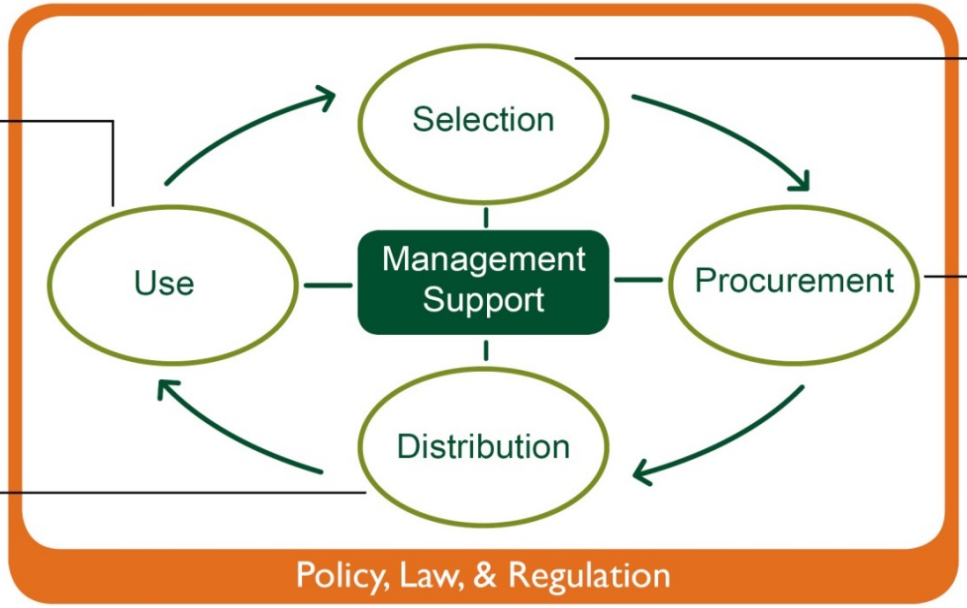
Financing
- Pharmaceutical financing strategies, including revolving funds
- Analyzing and controlling expenditures
- Financial planning and management
- Donor financing

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

Distribution
- Central medical stores vs. alternative models
- Vertical vs. integrated programs
- Inventory management
- Kit system



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, and Regulation

Policies
- 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

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

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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

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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

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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

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New TB tools: How to put them to practice?

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

Adapted from presentation: New Technologies for Tuberculosis Control: Programme Perspective. Retooling Task Force Meeting, Geneva, Switzerland, 15-16 January 2008

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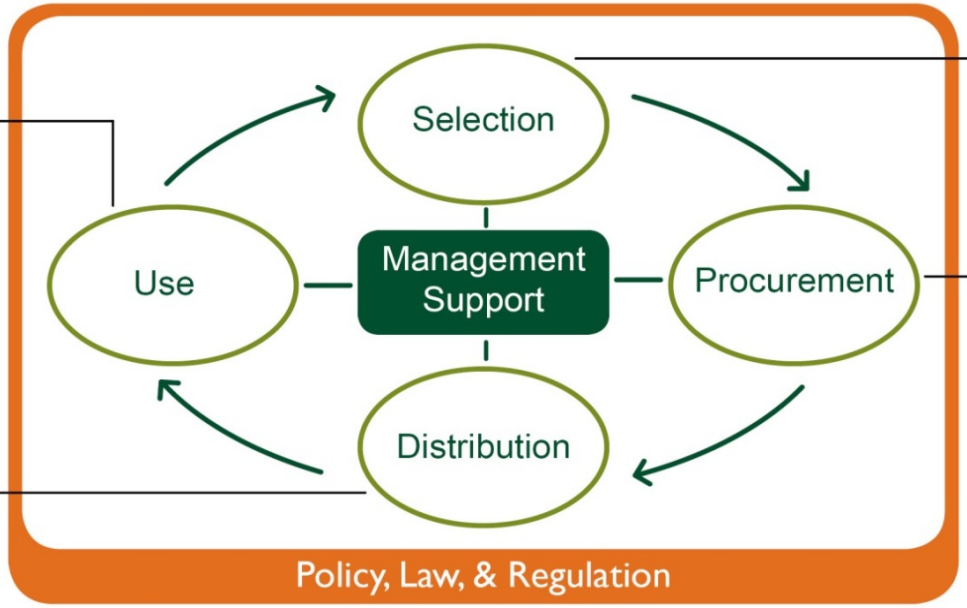

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Minimum requirements for PSCM systems

- 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

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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)

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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