

WHO Training Course for TB Consultants: RPM Plus Drug Management Sessions in Sondalo, Italy September 28 – October 1, 2006: Trip Report

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October 18, 2006



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About RPM Plus

The Rational Pharmaceutical Management Plus (RPM Plus) Program, funded by the U.S. Agency for International Development (cooperative agreement HRN-A-00-00-00016-00), works in more than 20 developing countries to provide technical assistance to strengthen drug and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, family planning, HIV/AIDS, Tuberculosis, Malaria and other infectious diseases, and in promoting the appropriate use of health commodities in the public and private sectors.

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Key Words

Tuberculosis, TB pharmaceutical management, WHO TB Consultants

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Contents

Acronyms	v
Background	1
Purpose of the Trip.....	1
Scope of the Work	1
Activities	3
Collaborators and Partners	3
Adjustments to Planned Activities and/or Additional Activities	3
Next Steps	5
Annex 1: List of Participants	7
Annex 2: Agenda	11
Annex 3: Presentation “Assessing Management of TB Pharmaceuticals”	13
Annex 4: Presentation “Valuable Tips for a TB Drug Management Consultant” ...	21
Annex 5: Worksheet for group work	25

Acronyms

DOTS	WHO Strategy to break the transmission of Tuberculosis
HIV	Human Immunodeficiency Virus
MSH	Management Sciences for Health
NGO	Non-governmental organization
PAHO	Pan American Health Organization
RPM Plus	Rational Pharmaceutical Management Plus
TB	Tuberculosis
TB CTA	Tuberculosis Coalition for Technical Assistance
USAID	United States Agency for International Development
WHO	World Health Organization

Background¹

WHO, Stop-TB Partners, and NGOs that support country programs for DOTS implementation and expansion require capable consultants in assessing the capacity of countries to manage TB pharmaceuticals in their programs, developing interventions, and providing direct technical assistance to improve availability and accessibility of quality TB medicines. Beginning in 2001, RPM Plus, in addition to its own formal courses on pharmaceutical management for tuberculosis, has contributed modules and facilitated sessions on specific aspects of pharmaceutical management to the WHO Courses for TB Consultants in Sondalo.

The WHO TB Course for TB Consultants was developed and initiated in 2001 by the WHO-Collaborating Centre for Tuberculosis and Lung Diseases, the S. Maugeri Foundation, the Morelli Hospital, and TB CTA. The main goal of the course is to increase the pool of international level TB consultants. As of December 2005, over 150 international TB consultants have participated in the training, a majority of whom have already been employed in consultancy activities by the WHO and international donors.

In 2006 fiscal year RPM Plus received funds from USAID to continue supporting the Sondalo Course, which allowed RPM Plus to facilitate sessions on pharmaceutical management for TB at four courses in May, June, July, and October of 2006.

Purpose of the Trip

RPM Plus Senior Program Associate, Edgar Barillas, traveled to Sondalo from September 28 to October 1 to facilitate the TB pharmaceutical management session at the WHO course for TB Consultants in Sondalo, Italy.

Scope of the Work

Participate as facilitator during the first week of the training course and conduct two sessions on pharmaceutical management for TB on October 1.

¹Background information based on: Zagorskiy, Andrey. 2005. Trip Report. WHO Training Course for TB Consultants: RPM Plus TB Drug Management Sessions. Sondalo, Italy. 19 – 22, May 2005. Submitted to the U.S. Agency for International Development by the Rational Pharmaceutical Management Plus Program. Arlington VA: Management Sciences for Health.

Activities

The Course was attended by 23 participants from 12 countries (Annex 1 includes the list of participants). The session on pharmaceutical management for TB consisted of a slide presentation on the pharmaceutical management cycle and a discussion of issues in pharmaceutical management, which participants may face when in a consultant's capacity. The agenda of the course is included in Annex 2.

Edgar Barillas used slides and materials specifically developed for this course (annex 3), updated and revised to prepare the consultants for their simulated mission to an invented country – Fictitia - on which all the exercises and discussions are based.

The second presentation provided the participants with additional information to analyze the pharmaceutical management problems in Fictitia and propose tentative interventions to face them. Additionally, Edgar Barillas prepared a presentation on “Useful Tips for a TB Drug Management Consultant” (annex 4). Following the presentation, a small group exercise was held to identify the strengths and weaknesses of the Fictitia National TB Program, using the pharmaceutical management logic (Annex 5), and to elaborate on the tentative interventions to solve them. Additional materials were provided for the exercise, including RPM Plus' *Managing Pharmaceuticals and Commodities for Tuberculosis: A Guide for National Tuberculosis Programs*.

The results of the group work were presented in plenary session. The discussion focused on the feasibility of the interventions and strategies to present the evidence taking into consideration different audiences.

Collaborators and Partners

The Course was facilitated by WHO Collaborating Centre for Tuberculosis and Lung Diseases, S. Maugeri Foundation, Tradate and Morelli Hospital, Sondalo, in collaboration with WHO/Geneva. Giovanni Battista Migliori, Director of the WHO Collaborating Center was the organizer and main facilitator of the course.

Adjustments to Planned Activities and/or Additional Activities

No adjustments were necessary

Next Steps

For project year 7 (October 2006 – September 2007), RPM Plus will propose to USAID to continue to conduct the TB pharmaceutical management portion of the WHO consultant training workshop. If the work plan is approved, four courses will be held during that period.

ANNEX 1: LIST OF PARTICIPANTS

	WHO Global DOTS course on TB and TB/HIV management Sondalo, 27 September – 10 October 2006 List of participants
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	Name	Institution	Phone / Fax number / Email
1	Mr. Adama Jallow	Program Manager NLTP Gambia	Mail address: adamahaddyjatau@hotmail.com
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4	Omuniyi Amos Fadare	National TB/ Leprosy Control Programme, Abuja, Nigeria	Mail address: ominivifadare@yahoo.com
5	Asady Chukwuemeka Charles	National TB/ Leprosy Control Programme, Abuja, Nigeria	Mail address: ecasadu@yahoo.com
6	Kefas Samson	WHO staff in Nigeria (NPO – TUB for the North – East Zone) Nigeria	Mail address: samsonk@ng.afro.who.int samsonkefas@yahoo.co.uk samsonkefas@hotmail.com

	Name	Institution	Phone / Fax number / Email
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8	John Osho	Damien Foundation Nigeria. GRA Ibadan Nigeria	Mail address: dfbnig@skannet.com dfbnig@multilinks.com
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11	Delia Goletti	Clinical Investigator II Division of the Health Department Translational Research Unit of the Research Department National Institute of Infectious Diseases Italy	Mail address: d.goletti@tiscali.it
12	Rashidul Hasan	Medical Officer National TB control programme, Leprosy. Mohakhali Hospital, Dhaka Bangladesh	Mail address: Baku21@yahoo.com
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20	Maria Almiron	PAHO Consultant, Asuncion Paraguay	Mail address: Almironma@par.ops-oms.org
21	Jaafar Mansur Kabir	National Coordinator, National TB and Leprosy Control Programme, Federal Ministry of Health. Abuja Nigeria	Mail address: jfrmkabir@yahoo.co.uk jfrmkabir@hotmail.com

	Name	Institution	Phone / Fax number / Email
22	Michael Jose	National Professional Officer- Tuberculosis. WHO, Port Harcourt Nigeria	Mail address: josem@ng.afro.who.int
23	Emanuele Borroni	Stop TB, Milan Italy	Mail address: Borroni.lele@gmail.com

ANNEX 2: AGENDA
WHO Global Training course on TB and TB/HIV management
Sondalo, Italy, 27 Sept - 10 October, 2006

Time	Wednesday 27	Thursday 28	Friday 29	Saturday 30	Monday 2	Tuesday 3
08.30 - 10.30	*Travel	Part 1, Unit 1-4: Course presentation	<u>Unit 4:</u> Assess epidemiology	<u>Unit 7:</u> Assess drug management	<u>Unit 10:</u> Assess the laboratory network	<u>Unit 11:</u> Assess in-country supervision <u>Unit 12:</u> Assess the NTP organization
10.30 - 11.00		Coffee	Coffee	Coffee	Coffee	Coffee
11.00 - 13.00		Part 2, Unit 1 Preparing the mission	<u>Unit 5:</u> Assess Case management & DOT	<u>Unit 7:</u> continued	<u>Unit 10:</u> continued	<u>Unit 12:</u> continued
13.00 - 14.30		Lunch	Lunch	Lunch	Lunch	Lunch
14.30 - 15.30	<u>Arrival in Sondalo and registration</u> <u>Reading Fictitia background document</u>	<u>Unit 2:</u> How to prepare the report	<u>Unit 6:</u> Assess recording and reporting	<u>Unit 7:</u> continued	<u>Unit 10:</u> continued	Unit 13: Debriefing
15.30 - 16.00		Coffee	Coffee	Coffee	Coffee	Coffee
16.00 - 18.00		<u>Unit 3:</u> Presentation of Fictitia Today	<u>Unit 6:</u> continued	<u>Unit 8:</u> Assess partner co-ordination <u>Unit 9:</u> Assess advocacy	<u>Unit 10:</u> continued	Part 3, Unit 1: Assess TB DOTS Plus implementation
18.00 - 19.00		Free time	Free time	Free time	Free time	Free time
19.00 - 20.00	Dinner	Dinner	Dinner	Dinner	Dinner	Dinner
20.00 - 21.00	Free time	Free time	Free time	Free time	Q&A on human resources	Free time

Time	Wednesday 4	Thursday 5	Friday 6	Saturday 7	Monday 9	Tuesday 10
08.30-10.30	<u>Unit 2:</u> Assess TB control in the private sector	<u>Unit 2:</u> How to prepare a plan (8.30-9.30) <u>Unit 3:</u> Epidemiology of TB & HIV/AIDS (9.30-10.30)	<u>Unit 7:</u> The WHO 3x5 initiative	<u>Unit 11:</u> Surveillance of HIV prevalence among TB patients	<u>Unit 15:</u> TB/HIV Monitoring & Evaluation	<u>Unit 19:</u> Discussion of selected TB/HIV plans
10.30 – 11.00	Coffee	Coffee	Coffee	Coffee	Coffee	Coffee
11.00-13.00	<u>Unit 3:</u> Assess GFATM proposal	<u>Unit 4:</u> Principles of TB & HIV/AIDS control	<u>Unit 7:</u> The clinical management of HIV/AIDS	<u>Unit 12:</u> Capacity building for TB/HIV	<u>Unit 16:</u> Strengthening TB and HIV/AIDS collaboration <u>Unit 17:</u> Costing & budgeting for TB/HIV planning	<u>Unit 20 :</u> Course evaluation & Closing
13.00 – 14.30	Lunch	Lunch	Lunch	Lunch	Lunch	Lunch
14.30-15.30	Individual finalization of reports	<u>Unit 5:</u> News on DOTS (PPM/ communities & universal standards of care)	<u>Unit 8:</u> TB/HIV interim policy	<u>Unit 13:</u> Field visit	<u>Unit 17:</u> Continued	**Departure to Tirano station
15.30 - 16.00	Coffee	Coffee	Coffee	Coffee	Coffee	
16.00 – 18.00	Discussion of selected reports & registration participants 2 nd week	<u>Unit 6:</u> Clinical management of TB	Unit 10: Recording & Reporting	<u>Unit 14:</u> Service delivery for TB/HIV	<u>Unit 18:</u> Individual finalization of TB/HIV plans	
19.00 - 20.00	Dinner	Dinner	Dinner	Dinner	Dinner	
20.00 – 21.00	Part 4, Unit 1: Introduction (ice-breaker)	Free time	Free time	Free time	Free time	

ANNEX 3: PRESENTATION “ASSESSING MANAGEMENT OF TB PHARMACEUTICALS”

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Pharmaceutical Management for TB
Document No. 2.7.2



WHO Training Course
for TB Consultants and Managers
Sondalo, Italy

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Closing the gap between what is known about public health problems and what is done to solve them



RPM Plus | Rational Pharmaceutical Management Plus Program



Expanding DOTS:
Assessing Management of
TB Pharmaceuticals

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DOTS Strategy

- Sustained political commitment
- Access to quality-assured sputum microscopy
- Standardized short-course chemotherapy for all cases of TB under proper case management conditions, including *direct observation of treatment (DOT)*
- *Uninterrupted supply of quality-assured medicines*
- Recording and reporting system enabling outcome assessment of all patients and assessment of overall program performance

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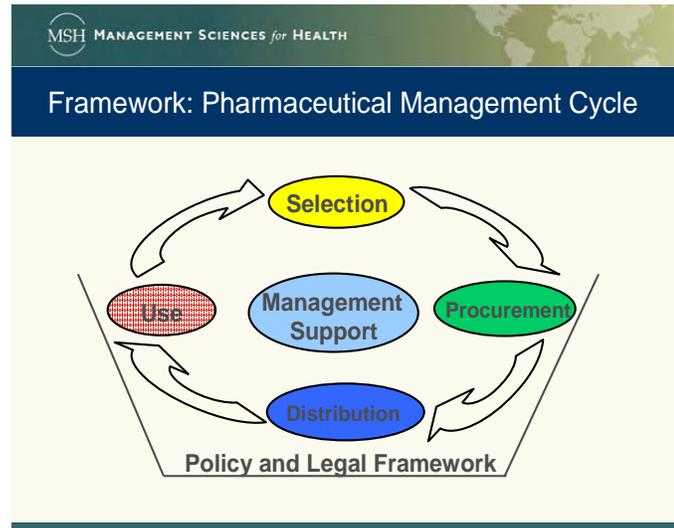
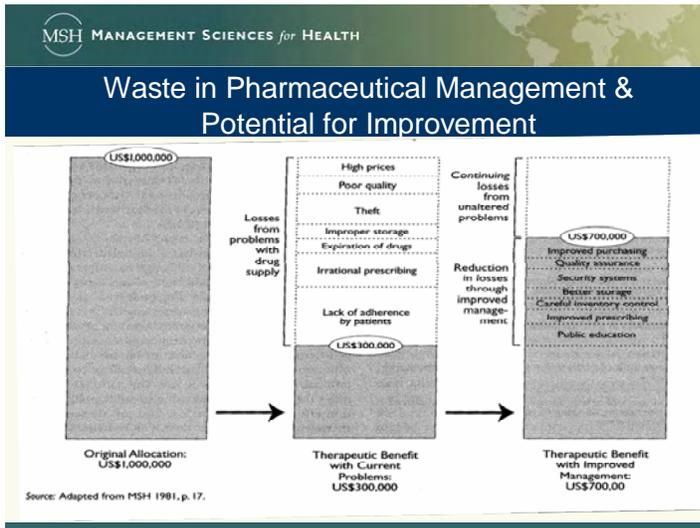
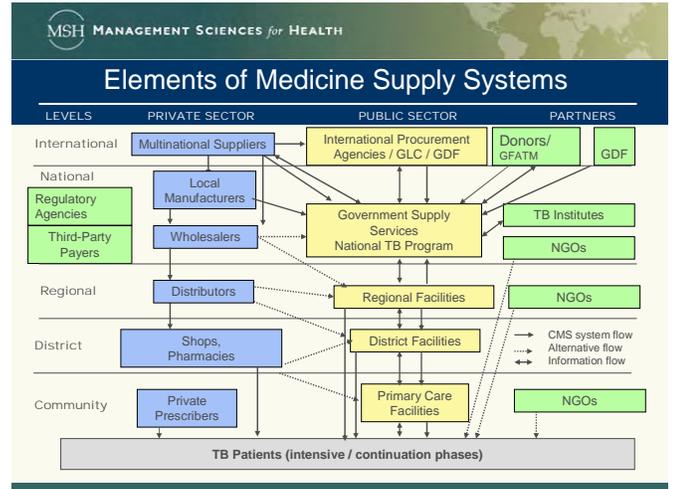
Pharmaceutical Management--defined

- Pharmaceutical management is the set of practices aimed at:
 - ensuring the timely availability and appropriate use of safe, effective, quality medicines
 - appropriate use of related supplies (ex. syringes)
 - appropriate management services for all health care settings

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Good TB Pharmaceutical Management--results

- Full set of quality TB medicines is available at all facility levels of the NTP when patients need them
- Patients more likely to complete their treatments promoting the NTP targets (85% treatment success)
- TB medicines are of guaranteed quality
- TB medicines are prescribed, dispensed, and administered correctly (under DOT) throughout full course of treatment



Policy Framework

- Government TB policy and support of NTP
- Decentralization
- Integration of services/supply systems
- Use of private services
- Essential medicines
- Generics versus brand names
- Support of domestic manufacturing
- Availability by level of care

Legal Framework

- Registration of pharmaceuticals
 - Proof of safety, efficacy, and quality
 - Pharmacopoeia standards
- Accreditation/licensing
 - Hospitals, clinics, pharmacies, and providers
- Pharmaceutical sector regulations/laws
 - Procurement, retail sales, importation

Policy, Laws: Challenges for NTP

- Political will is not translated into actual legal and financial support
- Gaps exist in pharmaceutical regulations
- Laws exist but are not enforced
- TB program management
 - Lack of skills and resources for effective pharmaceutical management, poor QA program, poor drug management information system (DMIS) for feedback analysis and planning

Selection

- Treatment regimens for 1st and 2nd line therapies should be determined by expert committees using:
 - Epidemiological profile including category mix, morbidities, drug resistance patterns
 - Evidence-based medicine to show effectiveness
 - Bio-equivalence data (especially Rifamp. in FDCs)
 - Applied pharmaco-economics for cost-effectiveness
 - Appropriate packaging such as selection of fixed-dose combination (FDCs), blisters and patient kits
- Marketing approval/registration

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Selection (The Essential Medicines Target)

Source: WHO/EDM

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Good Procurement Practices

- Reliable estimate of actual needs
- Research of pharmaceutical market
- Procurement by generic name (INN)
- Supplier qualification and performance monitoring
- Competitive bulk procurement
- Sole-source commitment
- Guaranteed payment to suppliers
- Transparency (SOPs, audits, published results)
- Separation of key functions
- Product quality assurance program

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Selection: Challenges for NTP

- Lack of quality TB drugs registered in the country
- Pressure from manufacturers and suppliers
- Branded versus generic drugs (non-informative brand names)
- Local biases: schools of thought, personal interests
- Lack of skills to use selected drugs (e.g., FDC)
- Unjustified selection of second-line drugs

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Procurement: Challenges for NTP

- Wrong drugs, dosage forms, packaging, labeling, quantities = overstock or stock outs)
- Lack of drug-quality specifications in tender documents: lowest prices = poor quality
- “Rigged” tenders caused by lack of competition or poorly designed and enforced standard operating procedures
- Port clearance delays
- Potential for corruption due to lack of transparency and procurement performance monitoring
- No competition – high prices

International Sources of TB Medicines

- Global Drug Facility (GDF) <http://www.stoptb.org/gdf/>
 - 1st line medicines at special prices
 - Governments and organizations can buy since 2002
 - Countries can apply to GDF for free grants
- Green Light Committee (GLC) www.who.int/gtb/policyrd/DOTsplus.htm
 - 2nd line medicines at special prices
- International agencies
 - UNICEF
 - PAHO
 - Nonprofit suppliers (IDA and others)
 - Donors

GDF Impact on TB drug prices

To treat one Category I or III patient of medium weight (40-54 kg):

- GDF **US\$ 15 - 17** (CIF) (as of May 2005)
- Other suppliers **US\$ 30 - \$50 in 2004 (no data yet for 2005; prices will go up by 20-30% for RIF and FDCs in 2005)** (CIF)

GLC Price Comparison

	Price status									
	Ethambutol	Cycloserine	PAS	Ethionamide	Prothionamide	Amikacin	Kanamycin	Ciprofloxacin	Ofloxacin	
International reference price (Boston, USA)	25.04	8.42	2.50	7.95		16.61	6.38	8.91	8.54	
High-income country average price	21.17	3.38	2.50	1.84	6.60	7.46	1.79	2.71	2.60	
Low-income country average price	12.00	1.50	5.00	0.26	0.16	5.75	0.89	0.53	0.60	
Green light committee (GLC) price	1.02	0.14	1.51	0.10	0.10	0.11	0.36	0.05	0.33	
Difference: international reference versus GLC price	95.93%	98.34%	39.60%	98.88%		99.34%	94.36%	99.33%	96.14%	
Difference: high-income country average versus GLC price	95.18%	95.86%	39.60%	94.57%	83.33%	98.53%	79.89%	97.79%	87.31%	
Difference: low-income country average versus GLC price	91.50%	90.67%	69.80%	61.54%	37.50%	96.09%	59.55%	88.69%	45.00%	

GDF Stop TB Patient Kits



Distribution

- Vertical vs. integrated programs
- Central medical stores vs. alternative models
- Push vs. Pull system
- Storage—environmental conditions
- Good storage practices
- Transportation method and frequency
- Inventory management

Distribution: Challenges for NTP

- Parallel TB network vs. existing MOH network
- Different goals of NTP and distribution network
- Lack of management skills / no pharmacists in NTP
- Absence of pipeline data
- Medicines expiry and stock-outs
- Lack of transportation means
- Inadequate distribution of donated TB drugs
- Waste and pilferage
- Poor inventory control skills

Poor Storage



Use

- Drug information services to providers and patients
- Rational prescribing
- Feedback of anti-microbial resistance data
- Drug use evaluation to determine effectiveness
- Good DOT
- Patient information/counseling
- Packaging—blisters and patient kits
- Curriculum reform in medical/nursing schools

Use: Challenges for NTP

- Noncompliance with the treatment regimen
- Idiosyncratic prescribing
- Adverse reactions to medicines (~2% of 1st line patients)
- Lack of control over patient use (migrant population)
- Discontinuation due to non-confirmed adverse reaction or patient pressure

DOTS takes care of most of these issues

Management Support

- **Planning for implementation**
 - Situation analysis using assessment tools and DMIS
 - Strategic planning, program planning, work planning
- **Implementation**
 - Managing people, training, money, information flow, comprehensive quality assurance program
- **Monitoring and evaluation**
 - Monitoring program performance and outcomes
 - Evaluation of organizational effectiveness

Product Quality Assurance Elements

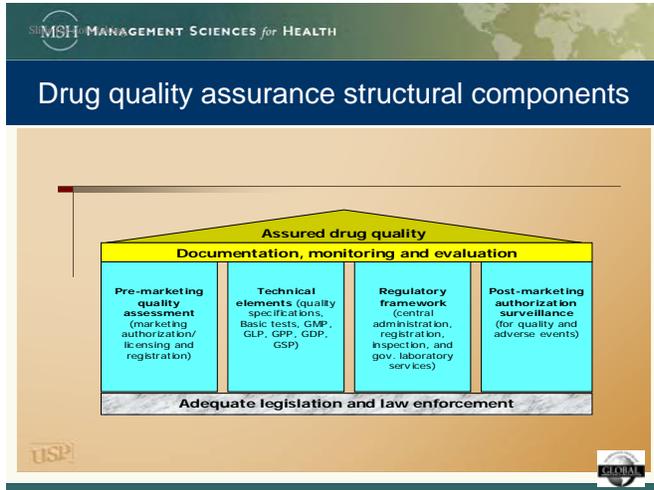
- Pre-qualification of suppliers
- Tender documents include international quality requirements:
 - Pharmacopeial standards
 - Proof of Good Manufacturing Practice (GMP)
 - WHO-type quality certificates
 - Proof of bioequivalence (RIF and FDCs)
- Supplier performance monitoring and evaluation
- Quality monitoring of products in facilities
- Physical inspection and laboratory testing on receipt
- Random sampling of distributed products

Product Quality Assurance System

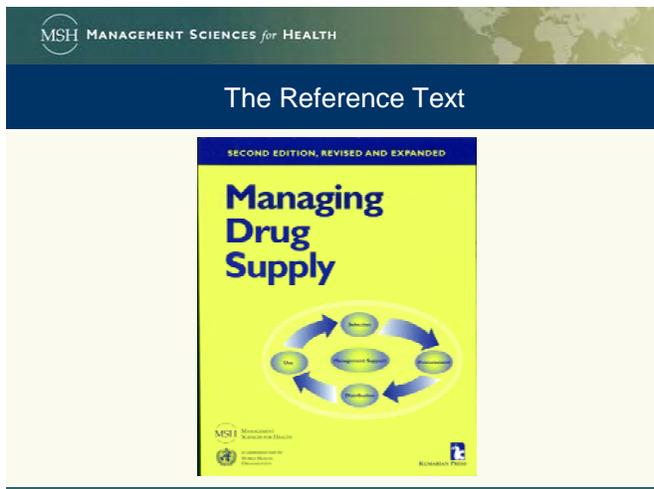


Stakeholders

- Drug regulatory authority
- Quality control laboratory
- Procurement agencies
- Local manufacturers
- Pharmaceutical importers
- Port of entry officials
- Pharmaceutical distributors
- Providers
- Patients



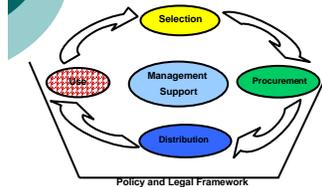
- MSH MANAGEMENT SCIENCES for HEALTH
- ### Summary
- Pharmaceutical systems are complex
 - Multiple interrelated components
 - Decision-making process is complex
 - Many stakeholders are involved
 - Systems operate in a dynamic environment
 - TB pharmaceutical supply is part of larger health system
 - The pharmaceutical management cycle framework guides the systematic analysis of pharmaceutical systems



ANNEX 4: PRESENTATION “VALUABLE TIPS FOR A TB DRUG MANAGEMENT CONSULTANT”

Useful Tips for a TB Drug Management Consultant

TIPS for the Consultant



•Pharmaceutical cycle offers a systematic approach to study TB pharmaceutical management.

•Availability and good quality are the outcomes of an efficient pharmaceutical management

TIPS for the Consultant (2)

○ Preparation

- Be systematic in your approach:
 - What are the questions that you need to answer
 - What is the data / indicators you are going to base your arguments on
 - Create a tool

TIPS for the Consultant (3): Indicators

1	Procurement	Percentage of median international prices paid for a TB medicines from the last regular procurement
2	Inventory Control	Average percentage out of stock for TB medicines in health facilities (or warehouses)

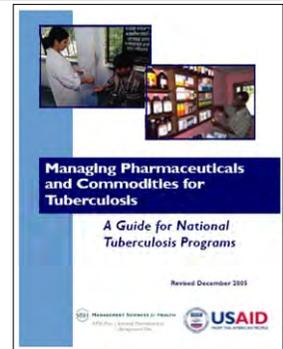
TIPS for the Consultant (9)

- Preparing the report and presenting the conclusions
 - Fill a predetermined outline
 - Be honest and explicit about your working hypothesis and data that is missing; address the limitations of your conclusions (if needed)
 - Write “backwards”
 - Adjust your presentation to the audience

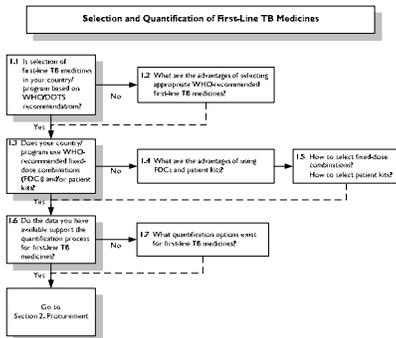
Managing Pharmaceuticals and Commodities for TB

Available in Spanish, English and French

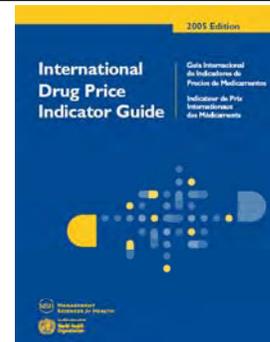
www.msh.org
 >Tuberculosis
 >Pharmaceutical Management



Managing Pharmaceuticals and Commodities for TB (2)



International Drug Price Indicator Guide



International Drug Price Indicator Guide (2)

Los precios se expresan en EEUU

Precios de proveedores			
Fuente	Paquete	Precio por Paquete	Precio Unitario
IMRES	100 Tab-cap (Tablets)	\$ 42.42	0.4242/Tab-cap
MERSON	100 Tab-cap (Tablets)	\$ 43.06	0.4306/Tab-cap
UNIFA	100 Tab-cap (Tablets)	\$ 46.00	0.4600/Tab-cap
IDA	100 Tab-cap (Tablets)	\$ 48.05	0.4805/Tab-cap
ORBI	100 Tab-cap (Tablets)	\$ 48.92	0.4892/Tab-cap
CLURB2	100 Tab-cap (Tablets, hydrochloride)	\$ 56.64	0.5664/Tab-cap
ELNHEM	10 Tab-cap (Tablets, hydrochloride)	\$ 6.97	0.7016/Tab-cap
JMS	1 Tab-cap (Tablets)	\$ 6.64	1.1588/Tab-cap
		Precio Mediano 0.4723/Tab-cap	Precio Más Bajo 0.4242/Tab-cap
		Proporción 2.73	Precio Más Alto 1.1588/Tab-cap
		Más Min	
Precios de compradores			
Fuente	Paquete	Precio por Paquete	Precio Unitario
DECSUPPS	0 Tab-cap (Tablets)	\$ 5.00	0.6750/Tab-cap
BDS	8 Tab-cap (Tablets)	\$ 16.56	2.0699/Tab-cap
		Precio Mediano 1.3474/Tab-cap	Precio Más Bajo 0.6750/Tab-cap
		Proporción 3.31	Precio Más Alto 2.0699/Tab-cap
		Más Min	

ANNEX 5: WORKSHEET FOR GROUP WORK

TB DRUG MANAGEMENT AREA	WEAKNESSES / GAPS	SOLUTIONS / ACTIVITIES
Selection		
Procurement (include Quantification, Quality Assurance)		
Distribution (include inventory control/stock management)		
Use (include irrational use, patient and provider adherence)		

