

World Health  
Organization TB  
Consultant  
Training in  
Sondalo, Italy

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*Trip Report*

Management Sciences for Health  
is a nonprofit organization  
strengthening health programs worldwide.



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Moore, Thomas  
*October 2005*

## **Trip Report: World Health Organization TB Consultant Training in Sondalo, Italy**

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October 6 – 8, 2005

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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, HIV/AIDS, infectious diseases, and family planning 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

## Contents

|   |    |
|---|----|
| Acronyms .....  | vi |
| Background .....  | 1  |
| Purpose of the Visit.....   | 1  |
| Activities .....  | 3  |
| Next Steps .....  | 5  |
| Annex 1: List of Participants .....   | 7  |
| Annex 2: List of Slides “Expanding DOTS: Assessing Management of TB Pharmaceuticals” .... | 9  |
| Annex 3: List of Slides “Assessment of TB Drug Management: Fictitia Case Study” .....     | 11 |
| Annex 4: Framework for Practical Exercises .....  | 13 |





## Acronyms

|           |   |
|-----------|---|
| AFRO      | WHO African Regional Office                               |
| CDC       | United States Centers for Disease Control                 |
| DOTS      | WHO strategy to break the transmission of tuberculosis    |
| DOTS Plus | WHO department promoting treatment/drug access for MDR-TB |
| EMRO      | WHO Eastern Mediterranean Regional Office                 |
| FDC       | Fixed-dose combination (drug products)                    |
| GDF       | Global (TB) Drug Facility                                 |
| GLC       | Green Light Committee for MDR-TB                          |
| MDR-TB    | Multi-drug resistant tuberculosis                         |
| MSH       | Management Sciences for Health                            |
| PAHO      | Pan American Health Organization                          |
| PIH       | Partners in Health  |
| RPM Plus  | Rational Pharmaceutical Management Plus                   |
| SEARO     | WHO Southeast Asia Regional Office                        |
| TB        | Tuberculosis  |
| TB Union  | International Union Against TB and Lung Disease           |
| WHO       | World Health Organization                                 |
| WPRO      | WHO Western Pacific Regional Office                       |





## **Background**

USAID, through its SO5 TB global objective, promotes TB pharmaceutical management activities through the RPM Plus program. The global activities support the DOTS scheme, a WHO initiative, documented to break the transmission of TB when implemented correctly by national TB programs (NTP). One of the five primary elements of the DOTS scheme is an uninterrupted supply of TB drugs. RPM Plus provides technical assistance to the following WHO/Stop TB organizations:

- The Global TB Drug Facility (GDF): established in 2001 to provide free grants of TB medicines to countries unable to satisfy their medicine needs and to serve as a source of good quality TB drugs for those countries having their own funds.
- The Green Light Committee (GLC): technical support group for the DOTS Plus program. Initiated by the WHO and its partners to promote the correct treatment of multi-drug resistant (MDR) TB. The GLC makes medicines available to countries at affordable prices.

As part of the global support RPM Plus also provides training in Pharmaceutical Management for TB at various World Health Organization consultant-training courses promoted by the Stop TB Department.

### **Purpose of the Visit**

The Purpose of the visit was to conduct the pharmaceutical management portion of the WHO TB consultant-training course in Sondalo, Italy from October 6-8, 2005. RPM Plus's Principal Program Associate Thomas Moore carried out the assignment.



## Activities

Seventeen consultants attended the WHO consultant-training workshop that were from the following countries: Brazil, Kazakhstan, Italy, France, Angola, Switzerland, Bangladesh, Denmark, Pakistan, Armenia, Haiti, Afghanistan, South Sudan and Morocco. See Annex 1 for more details.

The pharmaceutical management portion consisted of two slide presentations and a practical exercise as follows:

1. Slide presentation on aspects of TB pharmaceutical management including challenges for a national TB program
2. Slide presentation on TB pharmaceutical management conditions in the country of “Fictitia” which participants use as the basis for all work done during the workshop
3. Small group case study of TB pharmaceutical aspects in Fictitia including: appropriateness of standard treatment guidelines, availability of TB medicines and supplies, appropriateness of local and international sources of TB medicines, drug registration requirements, product quality assurance system and appropriateness of storage and distribution systems

See Annex 2 for a list of slides used during the presentation: “Expanding DOTS: Assessing Management of TB Pharmaceuticals.”

See Annex 3 for list of slides for the presentation: “Assessment of TB Drug Management: Fictitia Case Study.”

During the case study each of the four groups was asked to identify strengths and weaknesses of the Fictitia TB pharmaceutical management system and suggest steps for improving the noted challenges. See Annex 4 for the framework used by participants during the practical exercise.

In plenary each group presented their findings and RPM Plus led a discussion how best to provide this information to a NTP manager if it were a real consultant visit.

For facilitating the practical exercises, in addition to the above presentations and materials, participants were given copies of RPM Plus’s *Pharmaceutical Management for Tuberculosis: Assessment Manual* which includes indicators for national TB programs and two WHO publications to which MSH and RPM Plus experts have contributed as authors: (1) *Operational Guide For National Tuberculosis Control Programmes On The Introduction And Use Of Fixed-Dose Combination Drugs*, and (2) *Compendium of Indicators for Monitoring and Evaluating National Tuberculosis Programs*. These documents will serve as good references when participants are in the field serving as actual WHO consultants.



## **Next Steps**

- RPM Plus will provide follow-on technical assistance to participants by virtual means as needed and during in-country activities when possible
- RPM Plus will continue to conduct the TB pharmaceutical management portion of the WHO consultant training-workshops



## Annex 1: List of Participants

| Participant                | Affiliation                                  | Country     |
|----------------------------|--|-------------|
| Helenice Bosco de Oliveira | Hospital Chest Physician                     | Brazil      |
| Indira Aitmagambetova      | USAID mission                                | Kazakhstan  |
| Patricia Ann Paine         | USAID mission                                | Brazil      |
| Giovanni Sotgiu            | Hygiene and Preventive<br>Medicine Institute | Italy       |
| Dennis Falzon              | Institutue de Veille Sanitaire               | France      |
| Josef Nsuka                | Hospital Chest Physician                     | Angola      |
| Sylvia Wuest               | ICRC-Azerbaijan                              | Switzerland |
| Anwarul Azad               | Hospital Chest Physician                     | Bangladesh  |
| Soren Thybo M Se           | Infectious Disease Physician                 | Denmark     |
| Unaiza Shaikh              | WHO - NTP                                    | Pakistan    |
| Tatevik Kostanyan          | NTP  | Armenia     |
| Sara Pergolizzi            | National TB Institute                        | Italy       |
| Elsie Lafosse              | NTP  | Haiti       |
| Richard D/Meza             | NTP  | Haiti       |
| Sayed Amin Hamidi          | NTP  | Afghanistan |
| Ireanus Sindami            | NTP  | South Sudan |
| Ouafae Lahlou              | NTP  | Morocco     |



## **Annex 2: List of Slides “Expanding DOTS: Assessing Management of TB Pharmaceuticals”**

Unit Objective: What a TB consultant must know about the pharmaceutical management of TB

1. Objectives of the Session
2. DOTS Strategy
3. Pharmaceutical Management--defined
4. Results of Good TB Pharmaceutical Management
5. Waste in Pharmaceutical Management & Potential for Improvement
6. Framework: Pharmaceutical Management Cycle
7. Policy Framework
8. Legal Framework
9. Policy, Laws: Challenges for NTP
10. Selection (The Essential Medicines Target)
11. Selection: Challenges for NTP
12. Good Procurement Practices
13. Procurement: Challenges for NTP
14. International Sources of TB Medicines
15. GDF Impact on TB drug prices
16. GLC Price Comparison
17. GDF Stop TB Patient Kits
18. Distribution
19. Distribution: Challenges for NTP
20. Poor Storage
21. Use
22. Use: Challenges for NTP
23. Management Support
24. Product Quality Assurance Elements
25. Product Quality Assurance System Stakeholders
26. Summary
27. The Reference Text: Managing Drug Supply, 2<sup>nd</sup> Ed.



## **Annex 3: List of Slides “Assessment of TB Drug Management: Fictitia Case Study”**

1. Objectives of the Session
  - identify areas of concern in drug management
  - prioritize and plan interventions to improve drug availability and accessibility
  - group presentations
  - discussion of TB drug management issues
2. Background
3. Legal Framework
4. Financial Support for NTP
5. Drug Registration
6. Number of Registered Products: First-Line TB Drugs
7. Registered Combination Products
8. Registered Second-Line Drugs
9. Domestic Production
10. TB Drug Procurement Patterns
11. Reimbursement
12. Distribution
13. Availability of TB Drugs in District Facilities
14. Percentage of time out of stock in 2003
15. NGO 2002 Data
16. NGO unofficial estimate
17. NGO Unofficial Resistance Data in New Patients in Two Districts
18. In Groups: Use the Framework
  - Identify gaps and causes
  - Use the Cycle to think through different elements of Pharmaceutical Management
  - Suggest and prioritize interventions
  - Present your plan – be specific!!



