

**Rational Pharmaceutical Management Plus  
Course on Pharmaceutical Management of Multidrug-resistant  
Tuberculosis: Trip Report  
Romania, January 24 - 28, 2005**

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Edgar Barillas  
Robert Burn  
Susanna Khachatryan

February 4, 2005

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Rational Pharmaceutical Management Plus  
Center for Pharmaceutical Management  
Management Sciences for Health  
4301 N. Fairfax Drive, Suite 400  
Arlington, VA 22203  
Phone: 703-524-6575  
Fax: 703-524-7898  
E-mail: [rpmpius@msh.org](mailto:rpmpius@msh.org)

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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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### **Abstract**

RPM Plus is collaborating with the Stop TB Green Light Committee (GLC) to promote pharmaceutical management of multidrug-resistant tuberculosis (MRD-TB). One of the collaborative activities is to conduct training workshops for TB and essential medicines for directors of countries that have applied to the GLC. The course “*Pharmaceutical Management of Multidrug-Resistant Tuberculosis*” described in this report was conducted in Bucharest, Romania on January 24-28, 2005. Participants who attended were from the National TB Program and other departments within the Ministry of Health (MoH), the National Insurance House, pharmaceutical distributors and representatives of international agencies. The course covered the following subjects: selection, procurement, distribution, use, and management support. Facilitators of the course were from Management Sciences for Health, Green Light Committee and Partners in Health.

### **Recommended Citation**

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### **Key Words**

Tuberculosis, multi-drug resistant tuberculosis, pharmaceutical management, GLC, Romania

# Contents

ACRONYMS .....	v
BACKGROUND .....	1
Purpose of Proposed Visit .....	2
Scope of Work for the facilitators and participants.....	2
ACTIVITIES.....	3
Collaborators and Partners.....	4
Next Steps.....	5
Annex 1: Course Proceedings.....	7
Annex 2: Request for Country Clearance.....	37
Bibliography .....	41



## ACRONYMS

DOTS	Directly Observed Treatment – Short Course
GLC	Green Light Committee
MDR-TB	Multidrug-Resistant TB
MoH	Ministry of Health
MSH	Management Sciences for Health
NHIH	National Health Insurance House
NTP	National Tuberculosis Program
RPM Plus	Rational Pharmaceutical Management Plus
TOT	Training of Trainers
WHO	World Health Organization



## BACKGROUND

By definition Multi-Drug Resistant Tuberculosis (MDR-TB) patients have developed resistance to at least isoniazid and rifampicin, currently the most powerful anti-TB medicines. The number of multidrug-resistant tuberculosis cases in many parts of the world is increasing due to poor treatment, non compliance of patients, and poor access to pharmaceuticals. Also expected to impact the increasing number of MDR-TB patients is the growing incidence of HIV/AIDS. If MDR-TB continues to spread, treatment costs will increase, many more global health resources will be required to combat TB, and patients will suffer for longer periods or die.

To confront this growing public health menace, the World Health Organization (WHO) and its partners have established the DOTS Plus strategy which provides technical support to countries and regions to build on existing DOTS programs (for primary TB). The WHO DOTS Plus strategy provides technical support through the Green Light Committee (GLC) and concessionary prices for second-line medicines needed to treat MDR-TB. Medicines to treat one MDR-TB patient can cost upwards of US\$ 10,000 or more, per treatment, if purchased on the open market. By purchasing through the GLC procurement agent a country program can reduce costs to as little as US\$ 2,000 per patient.

Management Sciences for Health (MSH) and its Rational Pharmaceutical Management Plus Program (RPM Plus) are partners with the WHO Stop TB program and the GLC. One of the RPM Plus streams of activities is to provide support in pharmaceutical management of MDR-TB medicines with the GLC and its partners. Financial support is provided by the U.S. Agency for International Development (USAID).

In Romania, RPM Plus has been collaborating with the Ministry of Health (MOH), the Institute of Pneumology "Marius Nasta" and the National Health Insurance House (NHIH), to strengthen the drug management information system (DMIS) for the National Tuberculosis Control Program (NTP). This work has focused to date on the DOTS program for the delivery of first line treatment of tuberculosis with activities including, in 2004 collaboration with the NTP to organize a series of one-day regional meetings for TB program staff from each judet (county) which have lead to the development of a common understanding of the issues facing the TB medicine supply. Subsequently, the NTP, with RPM Plus assistance is developing a Drug Management guide (targeted at judet level TB program staff) that, when complete, will provide the foundation for the planned RPM Plus activities of training of trainers (TOT) and judet level drug management training.

In order to support the Romanian application to the Green Light Committee and the implementation of a DOTS Plus Project, RPM Plus' work plan for FY03 focuses on the specific pharmaceutical management issues for second-line TB medicines. As part of this program RPM Plus proposed, with the participation of GLC and Partners in Health, to conduct a training course in Pharmaceutical Management for MDR-TB for staff from the Institute of Pneumology, MOH and other key partners in the delivery of second-line

medicines. The course materials were developed by RPM Plus and its partners, Partners in Health and GLC. The course was designed to provide technical information and to develop skills on specific managerial practices for managing a continual supply of quality MDR-TB medicines.

Senior program associates Robert Burn, Susanna Khachatryan and Edgar Barillas, traveled to Romania to conduct the workshop on January 24-28, 2005. Collaborative partners Michael Rich of the Partners in Health (Boston, USA) and Fabienne Jouberton (WHO GLC Secretariat, Geneva) facilitated several of the course sessions.

### **Purpose of Proposed Visit**

Carry out the training course on Pharmaceutical Management for MDR-TB. The goal of the course is to provide information and develop skills that are useful for planning and implementing the pharmaceutical management component of a DOTS Plus Project.

### **Scope of Work for the facilitators and participants**

Scope of work for Robert Burn:

- Oversee and liaise with local company contracted to organize and manage the logistics and support to the course
- Facilitate the Overview and Quantification sessions
- Plan implementation of future work plan activities (Drug Management Guide, Training of Trainers course, regional training and technical assistance relating to drug management of MDR-TB)

Scope of work for Susanna Khachatryan for this visit is as follows:

- Lead the training course
- Facilitate a number of sessions including the introductory session, Monitoring session, field visit exercise, and Quality Assurance session
- Coordinate with international collaborators, including GLC and PIH

Scope of work for Edgar Barillas:

- Facilitate Procurement and Distribution sessions
- Provide technical support during the course.

## ACTIVITIES

### 1. Pharmaceutical Management of Multi-drug Resistant Tuberculosis Course

The course initiated on Monday 24<sup>th</sup> with the attendance of 18 participants from public and private institutions involved in pharmaceutical management of 2<sup>nd</sup> line TB drugs. The course was held in two locations: Sinaia, Prahova from the 24<sup>th</sup>-26<sup>th</sup> January and in Bucharest the 27<sup>th</sup> and 28<sup>th</sup> January.

The course included presentations, group discussions and activities, and a field visit to public and private institutions involved in pharmaceutical management of MDR-TB. During the last day of the course the participants presented the results of their visits along with recommendations to improve the performance of the pharmaceutical management system. The proceedings of the course are included as an annex of this report which includes a brief description of the sessions, the prime areas of discussion and the key issues raised by the participants.

The lengthy time frame for approval of the DOTS Plus application by the GLC and procurement of 2<sup>nd</sup> line pharmaceuticals through the GLC mechanism was discussed, because of practical concerns, by some of those attending the course. The NTP program with the technical assistance of the regional WHO TB advisor are considering drafting a note to the GLC addressing the obstacles that the NTP has faced so far and explaining what they perceive to be the strengths and weaknesses of the GLC mechanism for the procurement of second-line TB medicines. As mentioned by the regional WHO TB advisor, the intention is to turn this process into a learning experience for all the institutions involved.

### 2. Implementation of future RPM Plus activities in Romania

RPM Plus has been contracted by the Programme Implementation Unit (PIU) of the Romanian Global Fund Project to provide technical input into the development of a drug management guide for district level staff. A working group, established by the NTP, submitted draft chapters of the document which were consolidated by MSH into the first complete draft by the end of December 2004. The draft was reviewed by the working group and further comments, suggestions and text incorporated into a second version.

R Burn discussed the revised draft in detail with Cristi Popa, Lucica Ditiu and Cassandra Butu and collated a further round of areas for revision. It is planned to prepare the final draft, in English, by 21<sup>st</sup> February 2005.

The Drug Management guide will form the basis for a series of regional trainings for district level staff from health facilities, district health insurance houses and territorial pharmacies. RPM Plus will in advance conduct a training of trainers (TOT) course to capacitate a cadre of local experts, who will subsequently facilitate the regional training

courses. Following discussion it was agreed to hold the TOT course and the first regional training during the week of 17<sup>th</sup> April. A group of 8 to 10 participants for the TOT course will be identified by the NTP.

RPM Plus has also been developing a spreadsheet based tool designed to (1) improve the flow of data on stocks, receipts and consumption of anti-TB drugs by district TB managers; (2) simultaneously act as a monthly order form; (3) automatically prepare standard indicators to monitor specific drug management activities; and (4) report systematically to the Central Unit at the NTP on all aspects of drug management.

The essence of this tool is included in the Drug Management guide and the spreadsheet tool will also be demonstrated during the TOT and regional training workshops.

### **Collaborators and Partners**

Dr. Michael Rich, Partners in Health, Boston, USA

Dr. Fabienne Jouberton, GLC secretariat, WHO, Geneva, Switzerland

Prof. Ioan Paul Stoicescu, "Marius Nasta" Institute of Pneumology

## **Next Steps**

1. Complete the next draft of the Drug Management guide for presentation at the planned working group meeting (8-9 February).
2. Make the arrangements for the training of trainers course in April.
3. Explore opportunities for RPM Plus to assist in the design and implementation of a monitoring system for second-line pharmaceutical management. Since this is a critical element of any DOTS-Plus Project, the NTP will have to implement a monitoring system for their decision making process and to report to the GLC. The indicators and methodologies presented during the course may be a starting point for its development.



## **Annex 1: Course Proceedings**

### **Introduction/background to the course**

Although the incidence of MDR-TB in Romania is lower than other East European countries (2.8% among new patients), 978 cases were reported in 2003. RPM Plus is providing technical assistance to the National TB Program in Romania in the implementation of DOTS and, recently, DOTS Plus. RPM Plus proposed, with the participation of GLC and Partners in Health, to conduct a training course in Pharmaceutical Management for MDR-TB for staff from the Institute of Pneumology, MOH and other key partners in the management of second-line medicines.

The course materials were developed by RPM Plus and its partners, the Partners in Health and GLC. To date RPM Plus has conducted this course in Russia, Mexico, South Africa and Moldova. The course was designed to provide technical information and to develop skills on specific managerial practices for managing a continual supply of quality MDR-TB medicines. Financial support was provided by the U.S. Agency for International Development (USAID).

### **Aim of the course**

The goal of the course is to provide information and develop skills that are useful for planning and implementing the pharmaceutical management component of a DOTS Plus Project. During the course, participants will discuss the implications for a DOTS Plus Project for all aspects of pharmaceutical supply management, including selection, procurement, distribution, use, and quality assurance. Practical exercises using local data will be undertaken.

### **Course Activities**

The activities opened on Monday 24 at the Anda Hotel in Sinaia with attendance of 18 participants. The agenda of the course is included in the next section of this report. This is a summary of the content of the sessions and dynamics of the activities and discussions.

1. **Overview and introduction:** This presentation provided the background of the course, including the countries where it was previously held, and the specific goals and objectives of the course in Romania. The organizer of the workshop, Senior Program Associate Susanna Khachatryan, and co-facilitator, Senior Program Associate Edgar Barillas were introduced. After the opening remarks and the self-

introduction of each of the participants, they shared their expectations of the course. A complete list of the participants is included the next section.

2. **MDR-TB Situation in Romania:** Prof. Ioan Stoicescu and Dr. Cristi Popa presented an overview of the “*Situation of MDR-TB in Romania*”. This presentation was particularly useful for participants not working in the MDR Center, and for the facilitators. It served as an introduction to the current status of the procurement process through GLC, and provided valuable information for the organization of the field visit.
3. **Introduction to Pharmaceutical Management of MDR – TB:** In this session the participants were presented with an overview of the pharmaceutical management cycle, emphasizing the close relationship between the components. This session was particularly useful since, the session on *Selection and Use and Procurement by the GLC* did not follow the logical sequence illustrated in the pharmaceutical management cycle<sup>1</sup>. After the presentation the participants presented and discussed their participation on the different components of pharmaceutical management and the current challenges to improve pharmaceutical management in their respective working areas.
4. **Procurement:** This session presented the different competitive and non competitive modalities to purchase second-line TB medicines, and medicines for the treatment of adverse drug reactions. During the exercise that followed the presentation, the working groups analyzed Romania’s pharmaceutical procurement system and the prices of second-line medicines. They compared the prices of the last tender with average international prices<sup>2</sup> and the prices offered by the GLC.
5. **Distribution:** The different components of the distribution cycle (port clearance, storage, inspection, transportation, and inventory control) were explained. Since an independent company will be contracted for port clearance, storage and transportation of GLC-second-line drugs, the participants were particularly interested in the *pros* and *cons* of a direct delivery system versus a prime vendor system. These other options were discussed. In the final exercise of this session, the participants filled by consensus a matrix to understand Romania’s public distribution system, according to different options ( decentralized vs. centralized; public vs. private; push vs. pull ordering; delivery vs. pick-up transportation; etc.,)

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<sup>1</sup> Both Michael Rich and Fabienne Joubertone arrived to Sinaia on Tuesday and Wednesday, respectively, so their presentations were moved, as showed in the agenda (annex 1)

<sup>2</sup> From MSH’s International Drug Price Indicator Guide.

6. **Quantification:** Methods to estimate the needs of drugs for standardized regimens were described in this session. It was evident, during the presentation and discussion, that the estimation of needs for empiric/ individualized regimens is complicated because of the use of multiple regimens and the difficulty to predict the consumption. As presented in this session, the best estimates should be based on the calculation of the number (or percentage) of patient receiving each medicine. After the presentation the participants practiced the methods for medicine quantification in standardized regimens. This session went behind schedule, so the presentation of the consumption method was moved to the last day of the course.
7. **Quality Assurance:** This session outlined the importance of good selection, procurement and distribution practices in a comprehensive quality assurance program, particularly when laboratory facilities are not reliable or immediately available. At the end of the presentation the participants analyzed, using a check list that RPM Plus provided, the procedures in place to guarantee the quality of second-line drugs.
8. **Monitoring and Evaluation / Instructions for the field visit:** The facilitator emphasized the importance for a DOTS Plus Project, of a well designed monitoring system based on indicators. Three groups were formed for the field visits: 1. Selection and Quantification; 2. Procurement; and 3. Distribution. Following the instructions provided by the facilitator, each group carried out the following activities:
  - a. Identified the data and indicators needed in each area for monitoring purposes.
  - b. Identified the sources of information and the instruments for data collection.
  - c. Agreed on the logistics for the field work.
9. **Introduction to the GLC procurement mechanism:** Fabienne Jouberton, of the GLC secretariat in Geneva, presented the session *“Introduction to the GLC procurement mechanism”*. She presented the basic mechanism by which the country programs can purchase quality MDR-TB medicines from the GLC at the lowest prices. Romania was awarded with a grant from the Global Fund for AIDS, Tuberculosis and Malaria (GF). The GF requires the purchase of second-line TB medicines through the GLC mechanism. Romania has already applied to the GLC, but administrative procedures and requirement from both sides (GLC and the Ministry of Health) are delaying the first shipment of medicines. The participants discussed with Fabienne Jouberton the problems Romania have faced to fulfill GLC requirements. The course

provided the opportunity for an open discussion of the problems and potential solution.

10. **Selection:** During the third day of the course, Michael Rich, who has valuable experience in several DOTS Plus country programs, presented the sessions “*Selection of Pharmaceuticals for MDR-TB and Use of medicines to treat adverse reactions*”. Romania is currently using a combination of *empiric*<sup>3</sup> and *individualized*<sup>4</sup> regimens for the treatment of MDR-TB. Clinicians from the MDR Centre in Bucharest were particularly interested on systematic approaches to design empiric regimens.
11. **Field visit:** The field visit was carried out in Bucharest during the fourth day of the course. The participants planned to visit the following institutions.

<b>Group</b>	<b>Institution</b>
1. Selection and quantification	The Marius Nasta Institute of Pneumoptiziology // The MDR Center
2. Procurement	National Insurance House*
3. Distribution	Unifarm (private distribution company)
* Note: The group could not get an authorization to visit the National Insurance House. They completed their work using data the brought on medicine financing and the price of drugs.	

Once the data was collected, the participants gathered at The Marius Nasta Institute of Pneumoptiziology to process and analyze the information, and to prepare a presentation which included the main findings and the weaknesses and strengths of the system.

12. **Presentation of the findings:** The results of the field work and recommendations for improvement were presented during the morning of the fifth day of the course. During the discussions that followed each presentation the participants were able to use the concepts and methods presented during the course, and analyze, based on the information gathered during the field work, the current challenges that the MDR-TB project is facing.

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<sup>3</sup> Regimen based on the patient’s profile (contact history, previous treatments, etc.,) when drug susceptibility tests is not available yet.

<sup>4</sup> Regimen based on the results of the drug susceptibility test.

13. **Closing remarks:** Before the closing remarks of the course the participants review their expectations of the course (registered during the first day) and analyzed whether they were actually met. The overall conclusion was the expectations were progressively fulfilled during the course. The WHO representative commented that she is going to recommend a replication of the course for other countries in the region. During the closing remarks the facilitators thanked the participants for their dedicated work, and the National TB program staff for their support in the organization of the course, particularly for the field visit. RPM Plus provided CDs to each participant containing the training session materials, check lists, questionnaires, participant presentations, various documents relating to GLC technical and program requirements for the procurement of MDR-TB drugs, websites where additional information can be obtained, and a reference document for treating MDR-TB patients prepared by Partners in Health.



## Agenda

Day	Time	Activity
Jan 24	8:30-9:00	Registration
	9:00–9:30	Opening
	9:30–9:45	Overview of the course. Goals and objectives of the course.
	9:45–10:15	<b>MDR-TB Situation in Romania</b>
	10:15-10:30	Questions and Answers
	10:30-11:00	Break
	11:00 – 11:30	<b>Session 1: Introduction to Pharmaceutical Management for MDR-TB</b>
	11:30 – 12:00	Group Activity
	12:00 -13:00	<b>Session 2: Procurement</b>
	13:00 - 14:00	Lunch
	14:00 – 14:45	Group Activity
	14:45 – 15:30	<b>Session 3: Distribution</b>
	15:30 – 16:00	Break
	16:00 – 17:00	Group Activity
Jan 25	9:00 - 9:30	<b>Session 4: Quantification</b>
	9:30 – 10:30	Group Activity
	10:30 – 11:00	Break
	11:00 – 12:00	Group Activity
	12:00 – 13:00	<b>Session 5: Quality Assurance</b>
	13:00–14:00	Lunch
	14:00 – 14:30	Group Activity
	14:30 –15:30	<b>Session 6: Monitoring and Evaluation. Instructions for field visit.</b>
	15:30 -16:00	Break
	16:00 -17:00	Group Activity: preparing for field visit
Jan 26	9:00–10:00	<b>Session 7: Introduction to the GLC procurement mechanism</b>
	10:00–10:30	Questions and answers
	10:30-11:00	Break
Jan. 26	11:00 – 13:00	<b>Session 8: Selection</b>

**Course on Pharmaceutical Management of Multidrug-resistant Tuberculosis: Trip Report  
Romania, January 24 - 28, 2005**

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<b>Day</b>	<b>Time</b>	<b>Activity</b>
cont.	13:00 – 14:00	Lunch
	14:00 – 15:30	Group activity. Developing participant field visit plans/preparing data collection instruments
	15:30 – 16:00	Break
	16:00 – 17:00	Review participant field visit plans/ data collection instruments
Jan 27	10:30–13:30	<b>Fieldwork</b>
	13:30–14:30	Lunch
	14:30–17:00	Group work—analyze data, prepare presentation of findings and recommendations
Jan 28	9:00–10:30	Plenary - groups present findings and recommendations
	10:30–11:00	Break
	11:00–12:00	Individual work—prepare plans for Improvement
	12:00–12:30	Individual activity -course evaluation
	12:30–13:00	Closing comments
	13:00:14:00	Lunch

## Course Participants

	Name	Institution/title	Work address	Telephone
1.	Prof. Dr. Ioan Paul Stoicescu	The "Marius Nasta" Institute of Pneumoftiziologie	# 90 Viilor Str, Bucharest 5 CP 050159	+ 40 21 335.82.01
2.	Dr. Iuliana Husar	The "Marius Nasta" Institute of Pneumoftiziologie	# 90 Viilor Str, Bucharest 5 CP 050159	+ 40 21 335.82.01
3.	Dr. Cristian Popa	The "Marius Nasta" Institute of Pneumoftiziologie	# 90 Viilor Str, Bucharest 5 CP 050159	+ 40 21 335.82.01
4.	Dr. Mirela Ciontu	MDR Center Bucharest	# 90 Viilor Str, Bucharest 5 CP 050159	
5.	Farm. Otilia Petrescu	MDR Center Bucharest	# 90 Viilor Str, Bucharest 5 CP 050159	
6.	Madalina Ciuciu	The "Marius Nasta" Institute of Pneumoftiziologie	# 90 Viilor Str, Bucharest 5 CP 050159	
7.	Dr. Lucica Ditiu	WHO Office for TB Control in the Balkans	# 85 – 87 Calea Dorobantilor Str, Fl. 6, Ap. 5, Bucharest 2 eter	+40 21 211 09 11
8.	Dr. Lucia Mihailescu	The National Administration of Penitenciaris	# 47 Maria Ghiculeasa Str, Bucharest 2 CP 023761	+40 745 779 228
9.	Dr. Elena Botezatu	MDR Center Bisericani	TB Sanatory, Bisericani, Neamt district	+40 744 222 945
10.	Dr. Margareta Ionescu	MDR Center Bisericani	TB Sanatory, Bisericani, Neamt district	
11.	Farm. Sorin Buruiana	MDR Center Bisericani	TB Sanatory, Bisericani, Neamt district	
12.	Farm. Elena Pascu	UNIFARM	#48 Aviator Sanatescu, Bucharest 1	+40 722 273 062
13.	Farm. Carmen Zaman	Ministry of Health The Pharmaceutical Products Directorate	#1-3 Cristian Popisteanu Entr, Bucharest 2	+40 21 310 49 66
14.	Farm. Ana Vasilescu	Ministry of Health The Pharmaceutical Products Directorate	#1-3 Cristian Popisteanu Entr, Bucharest 2	+40 21 310 49 66 +40 745 140 681
15.	Dr. Ady Popescu	National Insurance House	# 248 Calea Calarasilor Str. Bl. S19 Bucharest 3	+40 722 604 119
16.	Farm. Ioana Serban	Spit. Tunari	#11 Stefan cel Mare Str, Bucharest 2	+40 21 210 38 40/ 35
17.	Farm. Magda Costin	Spitalul de Pneumologie Iasi		
18.	Marius Ţicală	Ministerul Sănătăţii		+40 726 770 230

**Course on Pharmaceutical Management of Multidrug-resistant Tuberculosis: Trip Report  
Romania, January 24 - 28, 2005**

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	<b>Name</b>	<b>Institution/title</b>	<b>Work address</b>	<b>Telephone</b>
		UMP		
19	Psih. Ioana Novac	UIP – TB The “Marius Nasta” Institute of Pneumoftiziology	# 90 Viilor Str, Bucharest 5 CP 050159	+ 40 21 335.82.01

### Course facilitators

Khachatryan, Susanna	Senior Program Associate Rational Pharmaceutical Management Plus / Management Sciences for Health
Barillas, Edgar	Senior Program Associate Rational Pharmaceutical Management Plus / Management Sciences for Health
Burn, Robert	Senior Program Associate Rational Pharmaceutical Management Plus / Management Sciences for Health
Jouberton, Fabienne	Technical Officer, Stop TB Department World health Organization
Rich, Michael	World Health Organization/Partners in Health Harvard School of Medicine



## Course Logistics and Translation Support Team

	<b>Name</b>	<b>Institution/title</b>	<b>Work address</b>	<b>Telephone</b>
20	Dr. Cassandra Butu	WHO Office for TB Control in the Balkans	# 85 – 87 Calea Dorobantilor Str, Fl. 6, Ap. 5, Bucharest 2 eter	+40 21 211 09 11 +40 788 413 830
26	Raluca Teodoru	Totem Communication	#1 Burebista Blvd, Bl. D15 Sc. 4 Et. 3 Ap. 71, Bucharest 3, CP : 031106	+40 21 321 08 90 +40 744 311 115
27	Monica David	Totem Communication	#1 Burebista Blvd, Bl. D15 Sc. 4 Et. 3 Ap. 71, Bucharest 3, CP : 031106	+40 21 321 08 90 + 40 743 016 656
28	Laurentiu Andrei	Totem Communication	#1 Burebista Blvd, Bl. D15 Sc. 4 Et. 3 Ap. 71, Bucharest 3, CP : 031106	+40 21 321 08 90 +40 744 976 202

### **Course Evaluation by Participants**

Upon completion of the workshop, participants were asked to fill out an anonymous course evaluation form. The respondents were requested to rate each category (see below) of the final evaluation using a 1-5 scale, where 5 is the best/highest rating. The evaluations were provided for the workshop in general and for each session specifically. The final evaluation form for the course included the following questions.

<b>Course Evaluation</b>	<b>Ratings</b>				
	1	2	3	4	5
Session 1: Introduction to Pharmaceutical Management for MDR-TB	-	-	1	-	15
Group Exercises	-	-	1	1	13
Session 2: Selection of second-line medicines and selection of agents to	-	-	-	2	14
Session 3: Quality Assurance	-	-	1	1	14
Exercise to describe quality assurance system in participants' countries	-	-	1	1	14
Session 4: Procurement	-	-	-	3	11
Exercises to analyze procurement practices in participants' countries	-	-	2	12	-
Session 5: Distribution	-	-	-	4	12
Exercise: analyze distribution management cycle in participants' countries	-	-	4	12	-
Session 6: Monitoring	-	-	-	2	14
Exercise: participants prepare data collection instruments	-	-	-	3	13
Session 7: GLC procurement mechanism	-	-	1	1	14
Session 8: Quantification	-	-	-	2	12
Exercise: practicing quantification for own programs	-	-	-	2	12
Field Exercise	-	-	-	3	13
<b>General Evaluation</b>					
1. The course had importance to my future professional responsibilities	-	-	-	3	13
2. The course allowed me to better understand the concepts and use of tools to better perform my duties	-	-	-	2	14
3. The course gave me the opportunity to exchange useful experiences with participants from other countries	No info.	No info	No info	No info	No info
4. The theoretical content of presentations was useful and sufficient	-	-	-	2	14
5. The exercises and group activities were useful and sufficient	-	-	-	-	16
6. There was a good mix of presentations, discussions and group activities	-	-	-	1	15
7. The duration of the course was appropriate	-	-	-	1	15
8. Which three activities or sessions were most useful for you, starting from most useful? (see the summary of the responses below)	No info	No info	No info	No info	No info
9. Which three activities or sessions were least useful for you, starting from least useful? (see the summary of the responses below)	No info	No info	No info	No info	No info

10. What other subjects should have been included in the course?	No info				
11. What suggestions do you have to improve the course? (see the responses below)	No info				

Based on results of general evaluation, all participants rated the course as very useful/useful in performing their work with regard to theoretical content, exercises, and group activities. The respondents felt that the course had importance to their future responsibilities and allowed for better understanding of the concepts and tools needed to perform their duties better. There were numerous comments such as:

- “All sessions were very useful and allowed for understanding drug management”
- “All was interesting”
- “The course covered all subjects”
- “The training was very useful for my future activities for drug management”

Overall, the respondents gave “excellent” and “good” ratings for the course showing a high level of satisfaction with the course.

The participants provided a positive feedback with regard to all practical exercises, with a specific positive emphasis on quantification exercise to estimate drug needs. An example is a comment made by a participant: “Quantification session was very important especially for GLC procurement due to short shelf life of medicines”.

*The specific sessions* that participants particularly found to be most useful for them included the following:

- Quantification (8)
- Quality Assurance (6)
- Procurement (6)
- Distribution (5)
- Monitoring (4)
- Selection (4)
- GLC procurement (3)

Thirteen respondents stated that there were no sessions that they found to be *least useful*. The sessions listed by a few other respondents as *least useful*, included procurement (2 responses), distribution (2), monitoring (1) and quality assurance (1).

Some participants also suggested the following additional topics and improvements:

- Discuss difficulties encountered when procuring through GLC;
- Improvement in selection process within the context of Romanian specifics,

- Better correlation between theory and practice and more practical exercises/application;
- Add more experience from other countries;
- More clear descriptions of some sessions;
- MSH, based on previous experience, should specify participants for the training;
- Better selection of participants for the course;
- Change the breakdown of the workgroups.

The participant evaluations and practical observations of the facilitators during the course will be utilized by RPM Plus in improving preparation work, training approaches and materials for further trainings.

Summary: Review of the evaluation forms had shown that the training course was useful and relevant to the situation in Romania with regard to the pharmaceutical management component of the DOTS Plus program implemented by the TB program. All the participants benefited from learning concepts and the tools provided during the training and acquired skills will be useful for their future work performance.

## Appendix 1: Participant Presentations Following Field Visits (In Romanian, as presented in the last session of the course)

### Group 1: Selection

SELECTIA, UTILIZAREA SI DISPONIBILITATEA MEDICAMENTELOR DE LINIA A DOUA LA CENTRUL MDR BUCURESTI

#### MEMBRII GRUPULUI 1:

Farm. Ioana Pascu  
Farm. Carmen Zaman  
Farm. Ana Vasilache  
Dr. Margareta Ionescu  
Farm. Otilia Petrescu  
Dr. Elena Botezatu

#### MATRICE PENTRU SELECTAREA INDICATORILOR

<b>PARTEA 1:</b> Încercuiți funcția/funțiile managementului medicamentelor la care va lucra grupul vostru pentru un program specific selectat (ex. PNCT, regional, Clinica Institutului TB, spital)				
<b>PARTEA 2:</b>	<b>PARTEA 3:</b>	<b>PARTEA 4:</b>	<b>PARTEA 5:</b>	<b>PARTEA 6:</b>
Inserați o funcție:	Pentru ce indicatori veți avea nevoie să colectați date? (includeți indicatorii)	Numiți numărătorul și numitorul care permit calculul matematic al indicatorului.	Includeți sursele de informații (ex., informatori, înregistrări, etc.) de la care veți obține informații care să vă ajute în luarea deciziei.	Includeți instrumentele pe care le veți folosi pentru colectarea informațiilor (formulare de colectare a datelor, chestionare, etc.)
(Selectia )	Procentul din medicamentele TB MDR inregistrate in tara	Nr. medicamente TB MDR folosite/ nr medicamente TB MDR inregistrate $7/7 * 100 = 100\%$	Nomenclatorul medicamentelor de uz uman din 2004/ Ord Min San 180/2004	Formular de colectare a datelor
	<b>Indicator (C1)</b> Procentul de medicamente TB MDR incluse pe lista esentiala de medicamente	Nr. medicamente TB MDR incluse in lista de medicamente esentiale / nr. medicamente folosite in tratarea MDR TB $6/7 * 100 = 86\%$	Lista nationala de medicamente utilizate in PNCT – Ord Min San 573/2001/ CNAS 457/2001 Lista medicamentelor esentiale	Formular de colectare a datelor
(Utilizare și disponibilitate)	<b>Indicator K3</b> Procentul de pacienti BK+ TB MDR carora li s-au prescris medicamente corecte in doze corecte	Nr. pacienti BK+, TB MDR cu tratament corect si doze corecte / nr. bolnavi BK+ TB MDR aflati sub tratament in sectia MDR $14/14 * 100 = 100\%$	FO, fisa DOT, foaia de tratament	Formular de colectare a datelor care contine: rezultat ABG greutate medicamente folosite doze corecte nr. pacienti internati

**Course on Pharmaceutical Management of Multidrug-resistant Tuberculosis: Trip Report  
Romania, January 24 - 28, 2005**

<b>PARTEA 1:</b> Încercuiți funcția/funcțiile managementului medicamentelor la care va lucra grupul vostru pentru un program specific selectat (ex. PNCT, regional, Clinica Institutului TB, spital)				
<b>PARTEA 2:</b>	<b>PARTEA 3:</b>	<b>PARTEA 4:</b>	<b>PARTEA 5:</b>	<b>PARTEA 6:</b>
	<b>Indicator C6</b> Procentul de pacienti MDR TB care au raportat observarea regulate a luarii tratamentului	Nr. pacienti cu TB MDR la care s-a administrat tratament sub directa observare/ nr. pacienti cu TB MDR intervieati $14/14 * 100 = 100\%$	Bolnavi intervieati	Chestionar pentru pacient; intrebari: de cat timp primeste tratament daca cineva din personal urmareste administrarea tratamentului cate tablete din fiecare medicament ia cate zile pe saptamana face tratament daca stie cat timp trebuie sa ia medicamentele si ce se intampla daca nu ia medicamentele
	<b>Disponibilitatea medicamentelor MDR TB la momentul vizitei</b>	Nr. medicamente gasite in farmacie / nr. total medicamente folosite in MDR TB $7/7 * 100 = 100\%$	Inventarul farmaciei, in momentul vizitei	Formularul de colectare a datelor
	<b>Stoc disponibil la momentul vizitei</b> <b>1. Km</b>	Nr. flacoane Km aflate pe raft / nr. flacoane Km consumate mediu pe luna $963/ 370 = 2.61$ (necesar asigurat pentru aproximativ 3 luni)	Stoc faptic in momentul vizitei Fisa de raportare a consumului lunar al medicamentelor	Formular de colectare a datelor
	<b>2. Cs</b>	Nr. tablete Cs aflate pe raft / nr. tablete Cs consumate mediu pe luna $11.295/ 5.140 = 2.2$ (necesar asigurat pentru 2 luni)	Stoc faptic in momentul vizitei Fisa de raportare a consumului lunar al medicamentelor	Formular de colectare a datelor
	<b>3. Ptm</b>	Nr. tablete Ptm aflate pe raft / nr. tablete Ptm consumate mediu pe luna $10.890/ 6.450 = 1.69$ (necesar asigurat pentru aproximativ 2 luni)	Stoc faptic in momentul vizitei Fisa de raportare a consumului lunar al medicamentelor	Formular de colectare a datelor
	<b>4. Ox</b>	Nr. tablete Ox aflate pe raft / nr. tablete Ox consumate mediu pe luna $3600/ 1.150 = 3$ (necesar asigurat pentru 3 luni)	Stoc faptic in momentul vizitei Fisa de raportare a consumului lunar al medicamentelor	Formular de colectare a datelor

### Foia de lucru: Evaluarea calității datelor

Indicator folosit	Disponibilitatea datelor	Gradul de încredere	Frecvența colectării	Nivelul trimis pentru luarea deciziei	Partea responsabilă pentru colectare/procesare
Procentul din medicamentele TB MDR inregistrate in tara	Datele au fost disponibile: Nomenclatorul Medicamentelor de Uz Uman 2004	Da	Anual	UIP Ministerul Sanatatii CNAS	Manager DOTS Plus Ministrul Sanatatii - Oficiul Juridic Comisia de Licitatie CNAS
<b>Indicator (C1)</b> Procentul de medicamente TB MDR incluse pe lista nationala de medicamente din PNCT	Datele au fost disponibile: Lista Nationala a Medicamentelor pentru PNCT	Da	Anual	UIP Ministerul Sanatatii CNAS	Manager DOTS Plus Ministrul Sanatatii - Oficiul Juridic Comisia de Licitatie CNAS
<b>Indicator K3</b> Procentul de pacienti BK+ TB MDR carora li s-au prescris medicamente corecte in doze corecte	Datele au fost disponibile: FO Fisa DOT Fise de prescriere tratament	Da	Lunar	UIP	Manager PNCT (DOTS Plus)
<b>Indicator C6</b> Procentul de pacienti MDR TB care au raportat observarea regulate a luarii tratamentului	Datele au fost disponibile: FO Fisa DOT Chestionar pentru pacienti	Da	Lunar	UIP	Manager DOTS Plus
<b>Disponibilitatea medicamentelor MDR TB la momentul vizitei</b>	Datele au fost disponibile: Stocul la raft	Da	Lunar	UIP	Manager DOTS Plus
<b>Stoc disponibil la momentul vizitei</b>	Datele au fost disponibile: Stocul la raft Fisa de raportare a consumului lunar al medicamentelor	Da	Lunar	UIP	Manager DOTS Plus

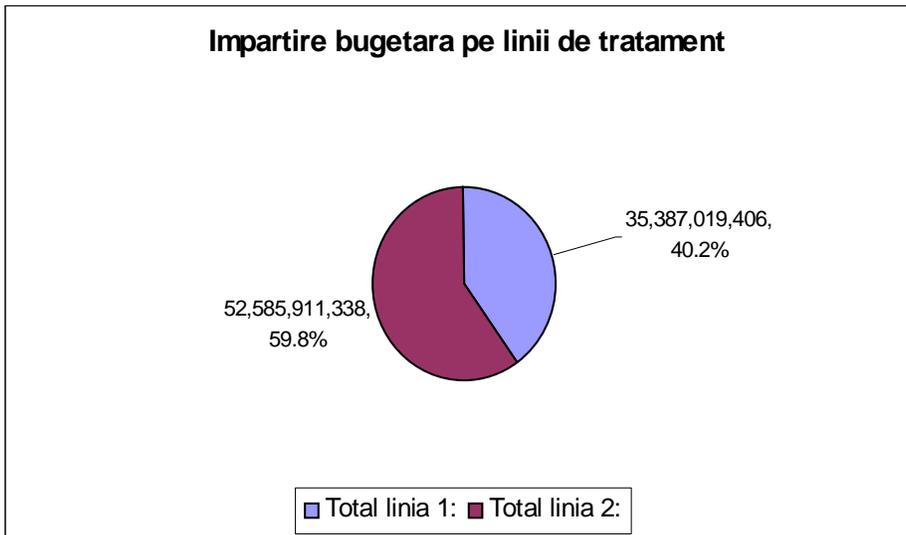
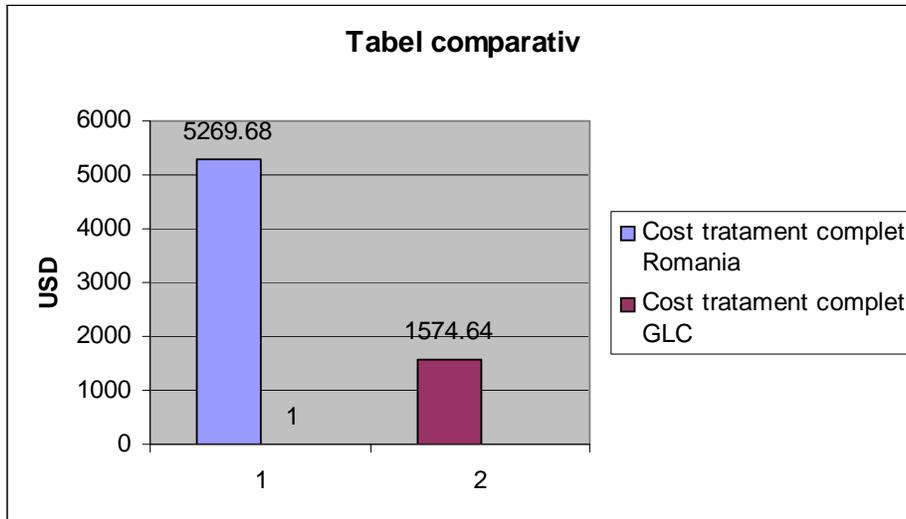
**ACTIVITĂȚI PLANIFICATE PENTRU ÎMBUNĂȚIREA SISTEMULUI DE  
MANAGEMENT AL MEDICAMENTELOR**

<b>ARIA DE PROCURARE</b>	<b>PUNCTE SLABE</b>	<b>ACTIVITĂȚI</b>	<b>RESPONSABIL</b>	<b>RESURSE</b>
<b>Seleție</b>	Indicator C1 – 86%	Reactualizarea listei medicamentelor esentiale din Romania. Introducerea tuturor medicamentelor de linia a doua pe lista medicamentelor esentiale.	Agentia Nationala a Medicamentului	Umane – personal.
<b>Utilizare si disponibilitate</b>	Nu.	Nu.	Nu.	Nu.

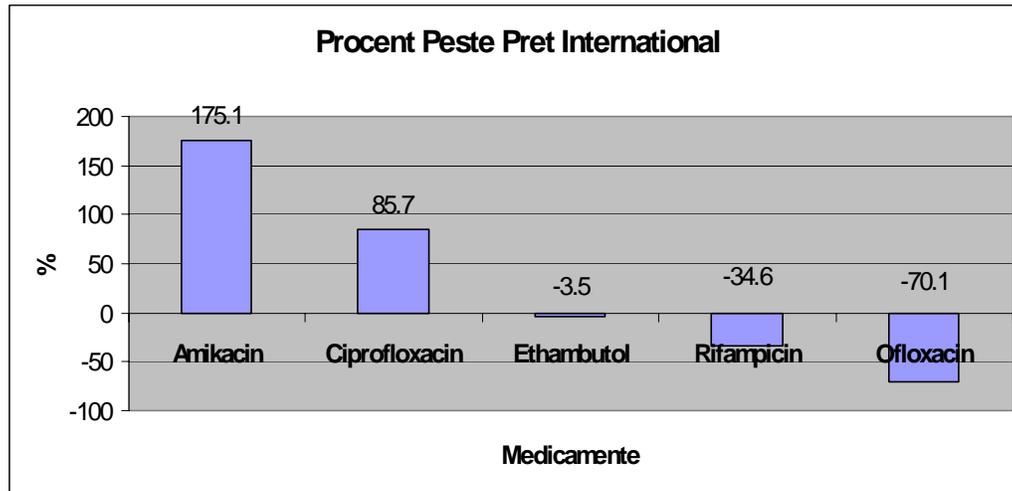
Concluzie:

Activitatea Centrului MDR TB Bucuresti se desfasoara in conditii foarte bune, din punct de vedere al selectiei, utilizarii si disponibilitatii medicamentelor de linia a doua. Daca activitatea va continua in aceleasi conditii, exista toate premisele ca Programul DOTS Plus sa fie implementat cu succes in Romania.

## Group 2: Procurement



## Tabel comparativ preturi



## Timp de livrare

Luna	F1	F2	F3
nov	14	13	13
dec	19	19	14
ian	29	35	33
Timp mediu livrare	21	22	20

## CONCLUZII SI RECOMANDARI

Aria de procurare	Slabiciune	Activitati	Responsabil	Resurse
Timp de livrare	Durata relativ mare de livrare a medicamentelor de catre furnizor	Respectarea perioadei de trimitere a comenzilor de medicamente catre CNAS si preluarea operativa a comenzilor de catre furnizori	Unitatile sanitare Furnizorii	Imbunatatirea comunicarii dintre unitati sanitare, furnizori si CNAS

## CONCLUZII SI RECOMANDARI

Aria de procurare	Slabiciune	Activitati	Responsabil	Resurse
Procurare	Pentru unele medicamente de linia a doua, preturile de licitatie sunt mai mari decat pretul mediu international, ceea ce determina cresterea costurilor tratamentelor care au in schema aceste medicamente.	Organizarea de licitatii deschise la care sa participe un numar cat mai mare de ofertanti, asigurandu-se posibilitatea selectarii unor medicamente cat mai ieftine la o calitate inalta.	MS	-Compararea preturilor -Asigurarea calitatii produselor prin certificare (GMP), studii de bioechivalenta, testari de laborator.

**Group 3: Distribution**

## **UNIFARM**

- Societate pe acțiuni
- acționar statul
- Nr. angajați 30
- Autofinanțare
- Furnizori interni și externi
- Beneficiari: unități sanitare, farmacii private, întreprinderi

## **UNIFARM**

### **- Misiune organizație -**

- Stoc de rezervă Ministerul Sănătății (calamități, epidemii)
- Distribuitor medicamente

## obiective

- Evaluare componentelor distribuției
- Identificarea punctelor slabe
- Propunere de îmbunătățire sistem

## Plan de lucru

ora	activități	Cu cine	logistică
11,00-11,30	Prezentare echipă, scop și obiective: Discuție despre proceduri de asigurare a calității – recepție, inspecție	Director economic Șef depozit	
11,30- 12,00	Vizită depozit, control calitate condiții	Director economic Șef depozit	
12,00-12,45	Inventar, verificare înregistrări cele 4 medicamente	Șef depozit gestionari	Formulare inventariere
12,45- 13,00	Prezentare concluzii	Director economic Șef depozit	
14,00-17,00	Analiză rezultate, propuneri recomandări, elaborare lucrare	echipa	Computer,

## **Evaluare componentelor distribuției - Componente evaluate -**

- Recepția și inspecția
- Depozitarea
- Transport
- Controlul inventarului

## **rezultate**

- Indicatori calitativi (Q) – generali
- Indicatori cantitativi (C) – pentru 1 drog antiTB de linia I și medicamente fol în tratamentul rr. adverse la drogurile antiTB
  - streptomycină (SM)
  - metoclopramid
  - scobutil
  - algocalmin

## Evaluare componentelor distribuției - Recepția -

activitate	Indicator Q – calitativ, C - cantitativ	sursa	responsabil
1. Comparare factură furnizor – comandă	(Q) Da	Factură	Departament comercial
2. Recepție cantitativă și calitativă: -Unitate -C% -Cantitate -Preț unitar -Preț total, -Seria -Data expirării - Organoleptic prin sondaj 5% - Certif de calitate	(Q) Da	Proces-verbal Recepție	Comisie recepție

## Evaluare componentelor distribuției - Depozitare -

Rotația stocului	Da
Securitate – acces limitat	Da
Ordonare – forme, c%, alfabetic	Da
Control temp	Da
Control umiditate	Nu
Ambalare	Da

## Evaluare componentelor distribuției - Transport -

- Livrare cu mijloace proprii
- Condiții transport corespunzătoare -  
Da
- Procedură feed-back asigurare calitate  
- Da

## Evaluare componentelor distribuției - Formular inventariere -

Medicamente	Formă prez	Stoc	Intrări ne-operate	Ieșiri ne-operate	Nr. scriptic	Nr. faptic	Nr. expirate
streptomicină	flacoane	4000	0	0	4000	4000	0
Algocalmin	Cutii 10 f	22000	0	0	22000	22000	0
Scobutil	Blister 10	40	0	0	40	40	0
Metoclopramid	Cutii 5 f	2600	0	0	2600	2600	0
Nr. TOTAL medicamente pentru care Nr scriptic = Nr faptic							4
Nr. TOTAL medicamente în stoc							4
% neexpirate							100
% scriptic corespunzător cu faptic							100

## Evaluare componentelor distribuției - Formular date pentru Ind K1 -

Nr crt	Medicament	1	2	3	4	5	6	7	8	9	10	11	12	Tot al
1	Streptomicină SM	0	0	0	0	0	0	0	0	0	0	0	0	0
2	Algocalmin	0	0	0	0	0	0	0	0	0	0	0	0	0
3	Scobutil	0	0	0	0	0	0	0	0	0	0	0	0	0
4	Metoclopramid	0	0	0	0	0	0	0	0	0	0	0	0	0
TOTAL zile stoc 0														0
TOTAL medicamente														4
% de timp cu stoc 0														0

## Evaluare componentelor distribuției - Indicatori Controlul inventarului -

Indicatori	Formulă	Surse informații Instrumente	rezultat
K1 - % din timpul cu stoc 0 pentru un set de 4 medicamente	$\frac{\text{Nr total zile cu stoc 0} \times 100}{365 \times \text{nr total medicam}}$	Fișa de inventar Formular de colectare	$\frac{0 \times 100}{365 \times 4} = 0\%$
K2 - % de disponibilitate pentru setul de 4 medicamente	$\frac{\text{Nr medicamente neexpirate} \times 100}{\text{Nr total medicamente}}$	Inventariere Formular de inventariere	$\frac{4 \times 100}{4} = 100\%$
C7 - % de înregistrări ce coresp cu facticul	$\frac{\text{Nr de înregistrări corecte} \times 100}{\text{Nr total înregistrări}}$	Fișe de raft (gestionar), evidențe intrări ieșiri, formular inventariere	$\frac{4 \times 100}{4} = 100\%$

## **Evaluare componentelor distribuției - puncte slabe -**

- **Recepție:**
  - nu toate medicamentele din stocul de rezervă au certificat de calitate
- **Depozitare:**
  - Nu există monitorizare umiditate

## **Annex 2: Request for Country Clearance**

TO: Gabriela Paleru, USAID/Romania

FROM: Management Sciences for Health (MSH) Rational Pharmaceutical Management Plus (RPM Plus) Program

SUBJECT: Travel of MSH/RPM Plus Senior Program Associates Susanna Khachatryan, Robert Burn and Edgar Barillas during the period of January 20<sup>th</sup> to February 4<sup>th</sup>, 2005. RPM Plus Cooperative Agreement No.: HRN-A-00-00-00016-00

COPY: Anthony Boni/ Global HSPR/CTO RPM Plus  
Kama Garrison / Global USAID  
Delna Gandhi / USAID E&E Bureau  
Douglas Keene, Director, MSH/RPM Plus  
Maria Miralles, Deputy Director, MSH/RPM Plus  
Andrey Zagorskiy, Project Manager for TB, MSH/RPM Plus  
Robert Burn, Senior Program Associate, MSH/RPM Plus

1. The RPM Plus Program requests country clearance for MSH/RPM Plus Senior Program Associates Susanna Khachatryan, Robert Burn and Edgar Barillas to Bucharest, Romania during the period January 20<sup>th</sup> to February 4<sup>th</sup>, 2005.

2. Background:

RPM Plus has been collaborating with in-country partners, the Ministry of Health (MOH), the Institute of Pneumology "Marius Nasta" and the National Health Insurance House (NHIH), to strengthen the drug management information system (DMIS) for the National Tuberculosis Control Program (NTP). This work has focused to date on the DOTS program for the delivery of first line treatment of tuberculosis. During the first half of 2004 the NTP organized a series of one-day regional meetings for TB program staff from each judet (county) which have lead to the development of a common understanding of the issues facing the TB medicine supply, informed about current procedures and discussed how to improve ordering practices at the judet level. RPM Plus surveyed the participants of these meetings in order to prepare a summary of drug management training needs. Subsequently, the NTP, with RPM Plus assistance is developing a Drug Management Guide (targeted at judet level TB programme staff) that, when complete, will provide the foundation for the planned RPM Plus activities of training of trainers (TOT) and judet level drug management training.

In order to support the Romanian application to the Green Light Committee (GLC) for assistance with a DOTS Plus program for Multi-drug Resistant TB (MDR-TB), RPM Plus' work plan for FY03 focuses on the specific pharmaceutical management issues for second line treatment. As part of this program RPM Plus will, with the GLC and Partners in Health, conduct a training course in Pharmaceutical Management for MDR-TB for staff from the Institute of Pneumology, MOH and other key partners in the delivery of second-line treatment. This course will also provide a foundation for future drug management activities in support of the DOTS Plus program.

3. Purpose of Proposed Visit:

Carry out the training course on Pharmaceutical Management for MDR-TB. The goal of the course is to provide information and develop skills that are useful for planning and implementing the pharmaceutical management component of a DOTS Plus Project. During the course, participants will discuss the implications for a DOTS Plus Project for all aspects of pharmaceutical supply management, including selection, procurement, distribution, use, and quality assurance. Practical exercises using local data will be undertaken.

4. Scope of work for Susanna Khachatryan for this visit is as follows:

- Lead the training course
- Facilitate a number of sessions including the introductory session, Monitoring session, field visit exercise, and Quality Assurance session
- Coordinate with international collaborators, including GLC and PIH

5. Scope of work for Robert Burn:

- Oversee and liaise with local company contracted to organize and manage the logistics and support to the course
- Facilitate the Overview and Quantification sessions
- Plan implementation of future work plan activities (Drug Management Guide, Training of Trainers course, regional training and technical assistance relating to drug management of MDR-TB)

6. Scope of work for Edgar Barillas:

- Facilitate Procurement and Distribution sessions
- Provide technical support during the course.

7. Anticipated contacts:

USAID/Romania; officials and specialists from the Romanian Ministry of Health and Family; National TB Program; National TB Institute.

8. Logistics:

No Mission assistance is required.

9. Funding:

The in-country work will be paid for with USAID Europe and Eurasia Bureau funds.

10. Action:

Please advise Anthony Boni, USAID/G/PHN/HN/HPSR, that Susanna Khachatryan, Robert Burn and Edgar Barillas have received country clearance to travel to Romania as planned by replying via e-mail to aboni@usaid.gov, tel. (202) 712-4789, fax (202) 216-3702. Please send carbon copies to Kama Garrison at kgarrison@usaid.gov, Robert Burn at rburn@msh.org; Andrei Zagorskiy at azagorskiy@msh.org, Douglas Keene at dkeene@msh.org, Maria Miralles at mmiralles@msh.org, Susanna Khachatryan at skhachatryan@msh.org, Edgar Barillas at ebarillas@msh.org and Meriel Jimenez at mjimenez@msh.org.

Thank you in advance for Mission cooperation.



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