

**RPM Plus Moldova Activities Coordination and Global Drug Facility
Monitoring Mission: Trip Report January 26–February 4, 2004**

Robert Burn

February 2004

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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

National Tuberculosis Program, anti-tuberculosis drugs, drug management information system, management, Moldova.

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ACRONYMS

AIHA	American International Health Alliance
DMIS	drug management information system
DOTS	directly observed therapy short-course (WHO TB Control Strategy)
DTC	Drug and Therapeutics Committee
GDF	Global Drug Facility
GFATM	The Global Fund to Fight AIDS, Tuberculosis & Malaria
GLC	Green Light Committee
MDRTB	multi-drug resistant tuberculosis
M&E	Monitoring and Evaluation
MOH	Ministry of Health of Moldova
MSH	Management Sciences for Health
NGO	Non-governmental organization
NTP	national tuberculosis program of Moldova
RPM Plus	Rational Pharmaceutical Management Plus Program [MSH]
SPCPHSM	Scientific Practical Center of Public Health and Sanitary Management
SO	strategic objective
TA	technical assistance
TB	tuberculosis
TRC	Technical Review Committee
UNAIDS	Joint United Nations Program on HIV/AIDS
USAID	United States Agency for International Development
WHO	World Health Organization

ABSTRACT

Tuberculosis is a growing health issue in Eastern Europe and an inexpensive and effective treatment regimen exists promulgated by World Health Organization (WHO). The United States Agency for International Development (USAID) is funding Rational Pharmaceutical Management Plus (RPM Plus) to strengthen the drug management aspects of national tuberculosis programs. In October 2002, RPM Plus assessed drug management information needs for program managers and other stakeholders of the Moldova national tuberculosis program. The findings of the assessment were verified and validated with Moldova counterparts during a post-assessment mission in January 2003 in preparation for a policy options workshop held in April 2003. Stakeholders in the tuberculosis (TB) drug management information system (DMIS) reviewed the current status of TB DMIS, gained a better understanding of the DMIS issues facing the national TB program (NTP) and proposed future steps to strengthening the system. These steps include establishing drug management indicators, as a component of the GFATM project monitoring and evaluation system, for assessing the performance of this function of the NTP and guiding decisions for improvement. Since October 2003 RPM Plus, with the expertise of a local consultant hired in January 2004, prepared a preliminary set of drug management indicators, and began the process of institutionalizing their implementation.

EXECUTIVE SUMMARY

The Rational Pharmaceutical Management (RPM) Plus program of Management Sciences for Health (MSH) assessed drug management information system (DMIS) needs for program managers of the national tuberculosis program and other stakeholders in Moldova in October 2002. The assessment reviewed existing drug management information policies, procedures and capacity, identified information flows and means of communication, and defined data and information gaps, leading to the development of recommendations for strengthening information and its use for decision-making.

Several national institutions and international organizations have a stake in data collection, analysis and reporting on the national tuberculosis program (NTP), with each having particular information needs. There are multiple sources of information for TB program management, the organization of information is fragmented, and the appropriate operational data required for drug management is not collected systematically. Gaps in the collection and analysis of data required for the optimum management of a drug supply system were identified. These findings supported the view that investment in the development of a consolidated DMIS would be beneficial to all stakeholders.

RPM Plus organized the workshop “*Informed Decision-Making for Drug and Supply Management within the National Tuberculosis Program: Current Status and Options for Strengthening*” in April, 2003, in Chisinau, with 40 participants from stakeholder organizations attending. By the close of the two-day event, the participants had an improved understanding of the strengths and weaknesses of the drug management information procedures and practices within the NTP and participated in an initial discussion identifying and recommending options for strengthening informed decision-making for drug and supply management.

In July 2003, RPM Plus conducted follow-up discussions with the MOH to determine the timing of the next step: a workshop to select drug management indicators to monitor performance and to review and redesign aspects of the DMIS to improve data collection, analysis and use in decision-making. RPM Plus’ Monitoring and Evaluation Coordinator continued the discussion with the Manager of the NTP on drug management indicators, and reached agreement on an appropriate set to be implemented by the program.

In January 2004 MSH recruited a local pharmacist to provide a full time support to the RPM Plus activities in Moldova.

As part of MSH/RPM Plus collaboration with the WHO Global Drug Facility, RPM Plus jointly conducted a monitoring visit to Moldova to assess compliance with the conditions of the GDF support and to determine the program’s 1st-line drug requirement for the next year.

BACKGROUND

The RPM Plus program, implemented by MSH, has received funds from the United States Agency for International Development (USAID) Bureau for Europe and Eurasia for activities in the region which support the Bureau's strategic health objectives (SOs), including supporting countries to improve the control of TB. Tuberculosis is increasing in the region and the situation in Eastern Europe and the Newly Independent States is of particular concern. The number of reported tuberculosis patients in the WHO Europe Region rose from 280,000 in 1995 to over 373,000 in 2002¹.

Moldova initiated the directly observed therapy short-course (DOTS) strategy in three pilot areas: the municipality of Chisinau, and Orhei and Lapusna judets (counties). In November 2001 and by January 2004 the DOTS strategy was implemented in all judets including Transnistria. The countywide adoption of the DOTS approach has been complimented by the agreement of the Global Drug Facility (GDF) to provide first line anti-TB drugs for all DOTS areas. In January 2004 the GDF conducted a monitoring mission to review compliance with GDF grant conditions and with the National Tuberculosis Program (NTP), determined the drug requirements for the third year of support.

In 2001 the number of registered new TB patients increased by 33 percent over 2000, and in 2002 there were 4,149 registered cases. The expansion of DOTS strengthened case finding and diagnostic practices, and sufficient availability of first-line TB drugs through Ministry of Health (MOH) central procurement and GDF assistance have all contributed to the increased registration of new patients. Drug resistant strains of tuberculosis are an increasing problem in Moldova with estimates that almost 40 percent of patients have developed resistance to at least one of the five main first-line drugs.² This resistance has arisen and evolved in parallel with the increasing failure of the TB drug management supply system to cover in full proper treatment. The MOH responded to this concern by tendering the first procurement for second-line drugs in fall 2002.

RPM Plus activities in Moldova during 2001–2002 were focused on strengthening tuberculosis drug management and on antimicrobial resistance. These activities included assessments of TB drug procurement and distribution practices, GDF assessments, a Drug and Therapeutics Committee (DTC) course in Moldova, and a regional training course on TB drug procurement held in Sinaia, Romania. RPM Plus prioritized the drug management information system (DMIS) as a key area to be strengthened following the assessment of tuberculosis drug procurement.

Centralization of anti-TB drug procurement has been evolving since 2001, with the MOH in the lead role as a policy and decision maker. At the same time, supply from the Global Drug Facility has dramatically improved anti-TB drugs availability and has provided a crucial opportunity for maintaining positive outcomes in TB control. With improved availability of anti-TB drugs, it is even more important that drug management capacity and practice be strengthened. The current multi-year support of the GDF provides the Moldova leadership with the opportunity to plan for sustaining a full supply situation into the future through reliance on internal resources and

¹ WHO Global TB Control Report 2003.

² Zagorskiy, Andrey and Alix Beith. 2002 *RPM Plus Moldova Trip Report: Brief Assessment of Tuberculosis Drug Procurement in Moldova*.

domestic capacity. Strengthening the TB DMIS to support decision-making is a key factor, along with the development of a full understanding of contemporary drug management practices, to the program's ability to manage anti-TB drugs in a systematic way that will ensure uninterrupted supply and 100 percent availability.

The NTP has made promising steps in reorganizing the distribution of TB drugs from the central store to a quarterly schedule, replacing the single annual issue procedure. In accordance with the Global Fund to Fight AIDS, Tuberculosis & Malaria (GFATM) monitoring requirements, the NTP is developing, with RPM Plus support, a set of drug management indicators, a sub-set of which will feed into the monitoring and evaluation scheme (M&E) for the GFATM project.

Purpose of Trip

RPM Plus Senior Program Associate Robert Burn visited Moldova from January 26—February 4, 2004 in order to:

- (a) Continue progress on the RPM Plus work plan for Moldova, by initiating the activities of the local RPM Plus consultant, integration of drug management components into the TB MIS of the GFATM project, and discussions with the NTP on planned activities for the pharmaceutical management for second line drugs.
- (b) Technical assistance to the WHO to undertake a monitoring mission in Moldova on behalf of the Global Drug Facility.

Scope of Work

Scope of work for Robert Burn:

For the RPM Plus/Moldova program:

- Brief/debrief the USAID Mission on the RPM Plus Program activities in Moldova
- Orientate the RPM Plus consultant
- Prepare a task list with deliverables and timeframes for this consultant
- Finalize the selection and elaboration of key drug management indicators for incorporation into the GFATM M&E system
- Initiate design work on data collection forms, and data analysis and reporting processes for drug management indicators
- Discuss future RPM Plus work plan activities with the NTP

As a member of the RPM Plus/GDF TB team:

- Brief/debrief USAID/Moldova officials as requested
- Assess adherence to GDF terms and conditions of support
- Obtain specific information to respond to issues raised by the GDF Technical Review Committee (TRC) or during previous GDF visits
- Clarify the numbers of patients to treat, quantities and specifications of drugs required, and the preferred date of delivery
- Assess the current TB drug procurement and distribution system within the country

A list of persons met during the visit appears in Annex 1 and the full text of the Request for Country Clearance for this visit in Annex 2.

ACTIVITIES

- 1. Orientate the RPM Plus consultant, and prepare a task list with deliverables and timeframes for this consultant.*

Ms. Rita Seicas, a qualified pharmacist formerly with the Pharmaceutical Procurement section of the MOH, was recruited by RPM Plus to provide technical input to the implementation of the RPM Plus program in Moldova. She commenced full time with RPM Plus on 12 January 2004. During this trip R. Burn described the RPM Plus work plan to Ms. Seicas, outlined her role, advised her on administrative matters, and introduced her to counterparts at USAID and the National Tuberculosis Control Program at the Institute of Pneumology.

The idea of linking up RPM Plus and the American International Health Alliance (AIHA) TB activities in Moldova more closely by locating Ms. Seicas in the AIHA Project's office was explored with the AIHA Project Director, but was not feasible at this time. Alternative space was available at the Caritas Luxembourg office and essential office equipment was obtained.

Immediate tasks for Ms. Seicas involved advancing the development of the drug management indicators previously agreed upon with the National Manager of the NTP and engaging in discussions with the NTP on proposed activities relating to pharmaceutical management for second line treatment of MDR-TB.

- 2. Finalize the selection and elaboration of key drug management indicators for incorporation into the GFATM M&E system.*

The list of drug management indicators developed jointly by the NTP and RPM Plus following the visit of RPM Plus' M&E Coordinator in October 2003, was reviewed by R. Burn, Ms. Seicas and Dr. Victor Burinschi and a final list determined (see annex 3). R. Burn and Ms. Seicas met with Dr. Mihai Ciocanu, Director of the Scientific Practical Center of Public Health and Sanitary Management, to introduce her as the RPM Plus consultant, to inform him of progress made with the NTP on the selection of drug management indicators, and to determine how to best proceed with the integration of the mentioned indicators into the M&E system being developed for the GFATM project.

Dr. Ciocanu informed the RPM Plus team of the status of plans and implementation of this monitoring system. The aim is for a computerized network to link the raion (district) health facilities to the center by 2006; the latter has the responsibility to assess, monitor and report. This is being funded by the GFATM project, though additional funding was being sought from the Joint United Nations Program on HIV/AIDS (UNAIDS). Dr. Ciocanu advised that program indicators for TB and AIDS had been selected, which at this time did not include any drug management indicators. He would be looking for indicators to help confirm that the drugs were consumed by the patient and to be able to monitor stocks of anti-TB drugs at the facility level to avoid disruptions in supply for treatment. The Scientific Practical Center of Public Health and Sanitary Management (SPCPHSM) was starting to elaborate the requirements for a software

program to manage the indicator data, which would be contracted out for development over the next six months. RPM Plus agreed to collaborate closely to ensure the inclusion of useful drug management indicators.

3. Initiate design work on data collection forms, and data analysis and reporting processes for drug management indicators.

There was insufficient time available to address this task during the visit and thus it was deferred. However, the local consultant, Ms. Seicas, was briefed on the next steps to be taken and this would form the major component of her activities over the next few months. This would include assessing the current information system's ability to provide the data required to compute the indicators and, as necessary, suggest modifications to existing procedures to ensure complete data capture.

4. Discuss future RPM Plus work plan activities with the NTP.

RPM Plus learnt during the visit that Dr. Victor Burinschi, the National Manager of the NTP, was likely to be leaving the program to join the GFATM Project staff. Dr. Timbaralu, Director of the TB Institute, advised RPM Plus that another staff member of the TB Institute, Dr. Sain would likely take over the role of manager. RPM Plus met with Dr. Sain and began to establish a working relationship. It was agreed that Dr. Sain and Ms. Seicas would keep in regular contact and Ms Seicas would brief him on the development of the drug management indicators.

Dr. Sain and Dr. Vangheli were briefed on the RPM Plus proposal for activities to support the strengthening of drug management for MDR-TB treatment. Dr. Vangheli confirmed that they were in discussion with the Green Light Committee (GLC) about securing the supply of 2nd-line drugs and the implementation of a DOTS Plus program for Moldova. It is planned for Moldova to submit an application to the GLC by July.

5. Debrief the USAID/Moldova Mission and the MOH on the visit, discuss and decide on next RPM Plus TA steps in Moldova.

Robert Burn, Rita Seicas and Dumitru Laticevschi met with the USAID Project Manager Specialist for the RPM Plus Program, Mr. Vasile Filatov and Diana Cazacu, Project Management Assistant and debriefed them on RPM Plus activities and the current visit.

GDF Monitoring Visit

Over the period January 26-31, Robert Burn participated in the GDF monitoring visit to Moldova, which assessed adherence to GDF terms and conditions of support, obtained specific information to respond to issues raised by the GDF Technical Review Committee (TRC) or during previous GDF visits, clarified the numbers of patients to treat, quantities and

specifications of drugs required, and the preferred date of delivery, and assessed the current TB drug procurement and distribution system within the country.

The full report submitted to the GDF is attached as Annex 4 to this report.

In summary, the team recommended that the GDF provide the third year's grant of 1st line anti-TB drugs to the National Tuberculosis Control Program in Moldova since the program was in compliance with the conditions of the Grant Agreement.

Collaborators and Partners

Dr. Timbalaru, Director TB Institute

Dr. Victor Burinschi, National Manager, National Tuberculosis Program

Dr. Dumitru Laticevschi, Project Manager, Project Coordination Unit TB/AIDS Project

Mr. Vasile Filatov, USAID Moldova, Project Manager

Ms. Rita Seicas, RPM Plus Consultant

NEXT STEPS

Immediate Follow-up Activities

1. Complete a detailed list of agreed drug management indicators with the NTP.
2. Facilitate agreement between NTP and Scientific Practical Center of Public Health and Sanitary Management (CPHSM) on mechanism to integrate TB drug management indicators into GF monitoring system.
3. Reach agreement in principle with NTP and MOH on MSH/RPM Plus proposed 2nd line drug management activities for FY03.
4. Document current rayon quarterly reporting system (data collection and analysis) for TB drugs and explore opportunities for RPM Plus technical assistance.

Annex 1. Persons Met

Persons met during TDY	
Ministry of Health	Dr. Larissa Catrinici, Deputy Minister
National Tuberculosis Control Programme/ Institute of Pneumology	Dr. Victor Burinski, National Manager NTP Professor Timbalaru, Director Institute Dr. Vangheli, Vice Director Institute Dr. Sain
Scientific Practical Center of Public Health and Sanitary Management	Dr. Mihai Ciocanu, Director
AIHA Project Office	Dr. Peter Metzger, Chief of Party Ms. Ina Lisnic, Project Administrator Dr. Valeru Crudu, Laboratory and Surveillance Specialist
Project Coordination Unit, TB/AIDS Project in Moldova	Dr. Dumitru Laticevschi, Project Manager
USAID	Mr. Vasile Filatov, Project Management Specialist Ms. Diana Cazacu, Project Management Assistant
RPM Plus Consultant	Ms. Rita Seicas

Annex 2. Request for Country Clearance

TO: Mark Levinson, USAID/Moldova
Diana Cazacu, USAID/Moldova
Olena Radziyevska, USAID/Ukraine
Vasile Filatov, USAID/Moldova
Veronica Mihailiuc, USAID/Moldova

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

SUBJECT: Travel of MSH/RPM Plus Senior Program Associate Robert Burn, to Chisinau, Moldova from January 26—February 5, 2004. RPM Plus Cooperative Agreement No.: HRN-A-00-00-00016-00

COPY: Anthony Boni/ Global HSPR/CTO RPM Plus
Marni Sommer/ USAID Washington
Julia Wallace/ USAID E&E Bureau
Douglas Keene, Director, MSH/RPM Plus Program
Andrey Zagorskiy, Project Manager for TB, MSH/RPM Plus Program

1. The RPM Plus Program requests country clearance for MSH/RPM Plus Senior Program Associate Robert Burn to Chisinau, Moldova from January 26—February 5, 2004.
2. Background:
 - (a) Moldova has one of the highest rates of tuberculosis (TB) of the former Republics of the USSR. With assistance from the World Health Organization, (WHO), the Stop TB Initiative, and USAID, the Ministry of Health (MOH) is currently implementing new approaches to tuberculosis (TB) control based on WHO recommendations. The MOH, recognizing that drug supply is a crucial element of the TB control strategy, is looking for assistance in improving TB drug management. RPM Plus conducted an assessment in October 2002 which identified a number of areas where TB drug management information needs and practices could be strengthened. Subsequently, a policy workshop on strengthening the TB Drug Management Information System (DMIS) was organized and took place in April 2003. In June 2003, during a visit to the region, RPM Plus developed a set of next steps for consideration by the MOH and National Tuberculosis Program (NTP). In October 2003, RPM Plus discussed integrating pharmaceutical indicators within the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) project's planned monitoring and evaluation (M&E) system.

Progress in strengthening the pharmaceutical management of first and second line drugs for the TB control program is being enhanced by the recruitment of a consultant to provide full time technical and logistical support in-country.

- (b) The Global Drug Facility (GDF) is an initiative of the Stop TB Partnership to increase access to high-quality tuberculosis (TB) drugs. The aim of the GDF is to provide drugs for 10 million patients over the next five years, and to treat 45 million patients over a 10-year period. WHO has called for a commitment to this initiative of at least US\$ 250 million by 2005.

The Technical Review Committee (TRC) of the Global TB Drug Facility is responsible for reviewing grant applications to the GDF. The GDF TRC makes recommendations to WHO on necessary steps for Programs to meet conditions for GDF support. One component of this review and recommendation process is a country visit. RPM Plus, as a part of its Global tuberculosis program, was asked to provide technical assistance to the GDF by participating in a number of country visits. The scope of such a visit is outlined below.

GDF support is provided in principle for a three year period, subject to availability of resources and satisfactory compliance with GDF conditions of support. GDF support to Moldova began in 2001. Provision of drugs for 2004 is dependent partly on a monitoring visit that has been coordinated with the National Tuberculosis Program for January 2004. The monitoring team will consist of Jerod Scholten, Technical Officer Tuberculosis Control WHO and Robert Burn, MSH/ RPM Plus Senior Program Associate.

3. Purpose of Proposed Visit:

- (a) Continue progress on the RPM Plus work plan for Moldova, by initiating the activities of the local RPM Plus consultant, integration of drug management components into the TB MIS of the GFATM project, and discussions with the NTP on planned activities for the pharmaceutical management for second line drugs.
- (b) Technical assistance to the WHO to undertake a monitoring mission in Moldova on behalf of the Global Drug Facility.

4. Scope of work for Robert Burn for this visit is as follows:

For the RPM Plus/Moldova program:

- Brief/debrief the USAID Mission on the RPM Plus Program activities in Moldova
- Orientate the RPM Plus consultant
- Prepare a task list, with deliverables and timeframes, for this consultant
- Finalize the selection and elaboration of key drug management indicators for incorporation into the GFATM M&E system
- Initiate design work on data collection forms, and data analysis and reporting processes for drug management indicators
- Discuss future RPM Plus work plan activities with the NTP

As a member of the RPM Plus/GDF TB team:

- Brief USAID/Moldova officials as requested
- Assess adherence to GDF terms and conditions of support

- Obtain specific information to respond to issues raised by the GDF Technical Review Committee (TRC) or during previous GDF visits
 - Clarify the numbers of patients to treat, quantities and specifications of drugs required, and the preferred date of delivery
 - Assess the current TB drug procurement and distribution system within the country
5. Anticipated contacts: USAID/Moldova (Mr. Mark Levinson, Mr. Vasile Filatov); officials and specialists from the Moldovan Ministry of Health (Dr. Turcanu, First Vice Minister); National TB Program (Dr. Victor Burinschi); National TB Institute (Professor Țâmbalari); donor agencies and representatives of their programs in the country (Dr. Dumitru Laticevschi, GFATM), RPM Plus local consultant (Rita Seicas).
 6. Logistics: Robert Burn will arrive in Chisinau on Monday January 26, 2004 and depart Moldova on Thursday February 5, 2004. No Mission assistance is required.
 7. Funding: The in-country RPM Plus work will be paid for with USAID/Moldova Mission funds. RPM Plus participation in the GDF monitoring visit is supported with USAID Global Funds.
 8. Action: Please advise Anthony Boni of country clearance for Robert Burn to travel to Moldova as planned. Please reply via e-mail to the attention of Anthony Boni, USAID/G/PHN/HN/HPSR tel. (202) 712-4789, fax (202) 216-3702, e-mail address aboni@usaid.gov. Please send carbon copies to Marni Sommer at msommer@usaid.gov, Andrey Zagorskiy at azagorskiy@msh.org, Robert Burn at rburn@msh.org, Douglas Keene at dkeene@msh.org and Fiona Abolade at fabolade@msh.org. Thank you in advance for Mission cooperation.

Annex 3: Proposed list of drug management indicators

Proposed Drug Management Indicators for Moldova NTP M&E System		
	Responsible org.	
Drug Availability Indicators		NTP suggestion
Description	NTP	MOH
Percentage of TB drugs used in NTP that are registered in the country	x	x
Percentage of TB drugs used in NTP and included on the National Essential Medicines List (C)	x	x
Percentage of TB drugs used in NTP and included on the WHO Essential Medicines List (C)	x	x
Number of suppliers of NTP TB drug products registered in the country		
Percentage of TB drugs used in NTP on the last MOH procurement list (C)		
Percentage of TB drugs received in shipments during the last year that were accompanied with an individual batch certificate meeting the requirements of the WHO Certification Scheme . (C)	x	
Percentage of TB drug samples that failed quality-control testing out of the total number of TB drug samples tested during the past year. (C)	x	x
Average percentage of time out of stock for a set of TB tracer drugs in TB facilities (including warehouses) for last year (C/R/F)	x	x
Average percentage of a set of TB tracer drugs available in TB facilities and medical stores (C/R/F)	x	
Average number of days TB drugs were not available to patients after transfer due to distribution problems (for second-line drugs)		
Average percentage of stock records that correspond with physical counts for a set of TB tracer drugs in TB storage facilities. (C/R/F)	x	
Percentage of TB drug shipments received at the contracted delivery date for the last three procurements. (C)	x	x
Average lead time for orders placed for TB drugs from international sources during the last year measured from the time order is submitted to procurement department or office for purchasing to the time order is received in warehouse	x	
Average lead time for orders placed for TB drugs from local sources during the last year measured from the time order is submitted to procurement department or office for purchasing to the time order is received in warehouse	x	
Percentage of median international price paid for a set of TB drugs that was part of the last regular procurement. (C)	x	x
Value of expired drugs last quarter (year)	x?	
Total number of quality problems reported during the year by the storeroom, prescriber, and dispensing personnel and patients	?	
Percent of annual MOH TB drug needs met by annual MOH TB drug budget (C)	x	x
Months of buffer stock available (C)	x	x
Months of buffer stock available (F)	x	x?

Drug Use Indicators		
Percentage of new smear positive patients with pulmonary TB who were prescribed correct drugs in accurate dosages in accordance with treatment standards adopted by the surveyed country <could be two indicators separately for intensive and continuation phases> (F)		
Percentage of new smear positive patients with pulmonary TB who received full unchanged regimen of treatment in intensive and continuation phase	x	
Percentage of TB patients who reported regular observation of drug intake (F)		
Percentage of new smear positive patients with pulmonary TB with confirmed adverse reactions to TB drugs	x	
Percentage of new smear positive patients with pulmonary TB whose regimen was altered due to confirmed adverse reactions to TB drugs	x	
Percentage of TB outpatients who could correctly describe how the prescribed medication should be used (F) - if no DOT and HE is used in continuation phase		
Percentage of TB facilities visited where the latest official manual of treatment guidelines for TB was readily available (C/F)		
Percentage of prescribed TB drugs actually dispensed	x	

Annex 4: Report of GDF Monitoring Visit

GDF EVALUATION MISSION TO MOLDOVA 26 JANUARY - 30 JANUARY 2004

By Jerod Scholten (WHO-EURO)
and
Robert Burn (MSH-RPM Plus)

PRELIMINARY PROGRAMME

Date	Time	Event
Mon, 26 January	PM	Arrival
Tue, 27 January	9:00 – 10:00	Meeting with Dr. Timbalari Gh. - Director National TB Control Programme (NTP)
	10:00 – 11:30	Meeting with Dr. Burinschi V. - Manager National TB Control Programme (NTP)
	11:30 – 13:00	Visit to “San Pharm Prim” office and warehouse
	13:00 – 14:00	Lunch
	14:00 – 15:00	Meeting at MOH Pharmaceutical Department
	15:00 – 16:00	Meeting with Deputy minister, Ministry of Health, Republic of Moldova
	16:15 – 18:00	Donor’s meeting (GFATM, USAID/AIHA, Caritas, KNCV, WHO)
Wed, 28 January	08:00 – 18:00	<i>Visit to Falesti raion facilities, meeting with medical administration, TB and PHC workers</i>
Thu, 29 January	08:00 – 18:00	<i>Visit to TransDniester region of Republic of Moldova, meeting with medical administration, TB and PHC workers</i>
Fri, 30 January	9:00 – 13:00	Meeting at NTP, preliminary conclusions
	PM	Departure

IN COUNTRY MONITORING CHECKLIST

All recipients of GDF in-kind grants of first-line tuberculosis drugs agree, as a condition of support, to: *Regular assessments of program performance (including case finding & treatment outcomes), financing and drug management, to be carried out by an independent technical agency, with a complete assessment report provided to the GDF.*

MOLDOVA—3rd Year

This check-list will form the basis of the assessment report on the performance of GDF grantees within the *third year* of support. This report will be reviewed for completeness by an independent agent appointed by the GDF and then submitted to the Technical Review Committee, for review.

Country Visited	Republic of Moldova	Date	26-30 January 2004
Data Collector(s) Name(s)	(1) Jerod Scholten	(2)	Robert Burn
Data Collector(s) Signature(s)	(1) _____	(2)	_____

Note: To determine the best source of information for different questions in this checklist, ask the NTP manager. If additional pages are needed for any section of this checklist please append to this document, clearly indicating the section number to which the additional page corresponds.

CONTENTS

- Main achievements and constraints/problems in the year of the monitoring visit
- National TB program management
- Financial management
- Port clearance
- Drug registration and quality
- Stock management
- TRC recommendations
- Recommendations from pre-delivery country visit
- GDF request for next year
- Monitoring team feedback

Main NTP achievements and constraints in the year of the monitoring visit

1. Main achievements

- Moldova, as of 1 January 2004, has 100 percent DOTS coverage
- Moldova has developed a reliable network to deliver an uninterrupted drug supply through GDF on a quarterly basis including the introduction of a standardized WHO supplementary report to project drug needs (quarterly report on programme management Part C – Regional level)
- Standardized 1st line treatment regimens are provided and WHO recommended trainings have improved standards of overall care
- Laboratory capacity has improved with the replacement of old monocular microscopes with new binocular ones and continuous trainings

2. Main problems

- A new national health insurance plan was inaugurated in 2004 under which separate procurement mechanisms are outlined for the initial phase and the continuation phase. Hospitals will procure for initial phase and government will procure for continuation phase.
- The proposed structure of delivery will be inferior to the GDF system in that drugs will be distributed annually rather than quarterly based on quarterly projections
- Contribution of GPs and primary health care providers needs to be strengthened to the continuation phase of treatment
- International technical partners reported that the government has purchased 2nd line drugs and is using them to treat drug-resistant patients in a non-standardized fashion without GLC approval. A World Bank consultant subsequently asked the Ministry of Health to stop this practice. A GLC application will be submitted and technical visit is tentatively scheduled for the Fall of 2004
- High defaulter rates (partly a result of significant migration)

National TB program management

3. Has the annual WHO TB data collection form for 2002 been submitted to WHO?

YES X Data sent in August 2003 by Dr. Victor Burinschi

4. Collect the latest quarterly report on case findings and treatment outcomes of the NTP. Please provide comments on the data in these reports. (See Annex A)

- The proportion of new pulmonary patients who were sputum smear-positive increased slightly in the last two quarters (40%) compared to the first two quarters (36%). This was most likely due to improved laboratory capacity.
- The treatment success rate was 63% in the last quarter of 2002 compared with 59% in the 1st quarter of 2002. Defaulters decreased slightly in the last quarter while the proportion of patients who died increased compared to the 1st quarter.
- Compared with the 2001 treatment outcomes, there was a significant decrease in the failure rates in 2002 (19% vs. 10%). Part of this is artifact since a much larger proportion of 2001 cohort were prisoners compared to 2002 where more civilians were under DOTS.
- Strengthening of the programme is still needed to increase the treatment success to at least 85%

5. What evidence is there that drugs provided by the NTP are only used for people with TB?

- Inventory checks and quarterly reports accounted for all GDF drugs

6. **What evidence is there that TB drugs are provided free to TB patients?**
- Interviews were conducted with approximately 20 patients. All patients stated that their TB drugs were free
 - All TB personnel interviewed acknowledged this was the case
 - Both the mass media and the population were sensitised to the donated supply of TB drugs from the GDF.
7. **What evidence is there that GDF drugs were only used in DOTS programmes?**
- As of 1 Jan 2004, Moldova was 100% DOTS but all drugs were accounted for in DOTS programmes prior to 100% coverage e.g., drugs were not released in the last non-DOTS area of Moldova (Transnistria) until an official agreement was reached for them to become DOTS and essential DOTS trainings/infrastructure were in place.
 - Pharmacy checks were conducted in two pharmacies in Transnistria to determine if INH/RIF combination tablets were available for sale. No such combination drugs were available.

Financial management

8. **Is there any evidence that GDF has displaced resources that would otherwise have been available from the government or other donors? NO**

Provide the following indicators:

- **Proportion of total financial requirements for DOTS implementation/expansion available:**
 - Combined sources: 100% funding
- **Indicate the proportion of TB funding from government vs. other sources using the table below:**

Table 1: Proportion of TB funding from government vs. other sources

Budget/Expenditure (Expenditure for last year, budget for current and next year)		Last year, 2003		Current year, 2004		Next year, 2005	
		Amount and Currency	Period covered	Amount and Currency	Period Covered	Amount and Currency	Period Covered
A. Total TB budget from national government (non-donor funds & interest-bearing loans)	Drugs	~ 54,000. \$US	2003	~97,000. \$US*	2004	~97,000. \$US*	2005
	Other	~ 1,200,000. \$US (central funds)	2003	~ 1,200,000 \$US* (central funds)	2004	~ 1,200,000 \$US* (central funds)	2005
B. Total TB budget from donors (Specify name of donor(s))	Loans (non-interest bearing)						

<i>beside amount</i>)	Grant(s) in-kind	250,000 \$US (SIDA Sweden),	2003	1,280,000. \$US (GFATM)	2004	320,000 \$US (GFATM)	Jan-Mar
		400,000 \$US (GFATM)	2003	1,050,000 \$US (AIHA/USAID grant)	2004	1,050,000 \$US (AIHA/USAID grant)	2005
C. GDF grant (equivalent \$)		51,624 \$US	2003	~60,000 \$US	2004	-----	-----
D. Total TB budget from other sources (<i>specify</i>)		100,000 \$US (Caritas)	2003	200,000 \$US (Caritas)	2004	150,000 \$US (Caritas)	2005
		150,000 \$US (KNCV)	2003	130,000 \$US (KNCV)	2004	124,000 \$US (KNCV)	2005
		88,000 \$US (WHO)	2003	110,000 \$US (WHO)	2004	10,000 \$US (WHO)	2005
E. Total TB budget (A + B + C + D)		2,293,624 \$US	2003	4,127,000 \$US	2004	2,951,000 US\$	2005

* Note: from 01.01.2004 the payment will be realised by the Medical Insurance Company

Port clearance

9. Report the port clearance time for the last GDF drug shipment:

Date GDF shipment arrived in port,

19.05.2003

(-) Date drugs moved to warehouse, ready for distribution in-country,

20.05.2003

(=) Number of days to clear port.

1 Day

10. Is there evidence that the government took full responsibility for any import duties and taxes levied on drugs supplied by the GDF?

YES X Please explain your answer:

- The government declared the drugs humanitarian assistance. This provided the drugs exemption from import duties and taxes. We saw certification of this. Also, the drugs were stored free of charge.

Drug registration and quality

11. Did all the drugs provided by the GDF meet all national drug registration requirements? YES* X

*None of the drugs required registration because they were classified as humanitarian aid.

12. Does the government carry out quality control of drugs used in the NTP? YESX

If YES, please indicate the number of drugs that failed quality control testing out of the total number of drugs tested:

- Samples of each drug were tested in the State Laboratory. The samples were not returned. The testing took approximately 20 days. No drugs were reported to have failed the screening.

Stock Management

13. Total stocks at national level.

Date: 31 December 2003

PRODUCT	QUANTITY	Number of patients to treat
H 0,075 R 0,15	1,334,000	5,500
H 0,15 R 0,15	1,143,000	5,600
Z 0,4	148,000	660
E 0,4	573,000	1,100
H 0,1 R 0,15	49,000	100

Please provide data on the consumption of drugs if available (from National story):

Period: 01.01.2003 – 31.12.2003

PRODUCT	A Stock at the beginning of monitored period Date: 01.01.2003	B Quantity received during period (GDF only)	C Stock at the end of the monitored period Date: 31.12.2003	A+B-C Consumption
H 0,1 R 0,15	923,000	0	384,000	539,000
H 0,3	136,000	0	0	136,000
H 0,075 R 0,15	0	1,334,000	1,334,000	0
H 0,15 R 0,15	0	1,143,000	1,143,000	0
Z 0,4	292,000	1,230,000	312,000	1,210,000
E 0,4	519,000	645,000	645,000	519,000
S 1,0	69,500	0	0	69,500

14. Were any TB drugs out of stock³ in MOH national stores during the last 12 months? YES X NO

If YES, indicate the average percentage of time they were out of stock,

Z 0,4: 21.04-20.05.03 30/365= 8%

S 1,0: from 27.10.03 64/365=18%

and please provide additional details:

³ Time out of stock, or stock-out time, is defined as the number of days that a product was not present in a warehouse or health facility over a recent 12-month period (usually the 12 months preceding the one during which the monitoring takes place). To be considered a stock-out, there must have been none of an unexpired drug in stock. If even small quantities of an unexpired drug were present, the drug should be counted as in stock. Percentage of time out of stock is defined as the percentage of days during a 12-month period that a drug has been out of stock (based on inventory records).

- Almost everyone had enough stock of Z and S except for large hospitals and prisons. Hospitals bought their own Z and S and a donor (Caritas Luxemborg) purchased Z and S for prisons.
- The MOH had ordered limited Z and S in 2000 without considering DOTS (since this did not begin until later); the tender was delayed by a year due to major government transition. The order was based on the old Soviet scheme which excluded PZA and focused on two drugs (INH and RIF) for 15 months. Subsequently, the government decided to provide drugs for outpatient intensive and the continuation phase only; they bought only H, R and S, not PZA.
- The last GDF order underestimated the need slightly for Z and S. In the 1st year 2001, <500 patients were on the II regimen and GDF had provided enough S for 1000 patients; so, it was decided not to send any S in the 2nd shipment. But, in 2002, 1000 patients were on the II regimen and therefore there were shortages of S. Further, PZA had been provided as 3 x Z,04 but many patients were >50KG and required 4 x Z,04.

15. Did you find any expired TB drugs in the MOH national stores at the time of your visit?

YES NO

16. Indicate the value and quantity of any pending TB drug deliveries from all sources, by source (donor, government procurement e.t.c) expected to be received in-country over the next 6 months.

Table 2: Value and quantity of any pending TB drug deliveries from all sources

Drug	Source	Quantity	Value	Expected delivery date
H 0,1 *	MOH proc	90,000	-----	QIII-QIV.2004
Z 0,5	MOH proc	200,000	-----	QIII-QIV.2004
S 1,0	MOH proc	18,000	-----	QIII-QIV.2004
			Total 11,000 US\$	

*For INH chemoprophylaxis in children only. They will not purchase INH/RIF because there is enough in the national stocks.

17. Are the standard treatment guidelines for TB drugs comparable to the DOTS guidelines? YES

Technical review committee (TRC) recommendations

18. There were TRC recommendations for follow up: NO

19. If YES, using the TRC attachment to this checklist, write the recommendations below and the progress/expectations made by the NTP/government for fulfilling them. If no progress has been made on a specific recommendation, indicate what the NTP/government plans are to fulfil that obligation.

Table 3: TRC recommendations and action taken

<i>Recommendation</i>	<i>Action Taken & Results</i>

Recommendations from the pre-delivery country visit

20. Please review the recommendations made during the pre-delivery country visit using the country visit attachment to this checklist; write below the recommendations and the progress/expectations made by the NTP/government for fulfilling them. If no progress has been made on a specific recommendation, indicate what the NTP/government plans are to fulfil that obligation.

Table 4: Pre-delivery country visit recommendations and action taken

Recommendation	Action Taken & Results

GDF request for next year (if applicable)

21. Estimates of patients to be treated with GDF drugs

Year: 2004

Date drugs required:

1 August 2004

Category	Regimen	Total estimated cases to be treated with DOTS	Estimated cases to be treated with GDF drugs
1	2 HRZE + 4 H3R3	2500	2500
2	2 HRZES/1HRZE + 5 H3R3E3	1100	1100
3	2 HRE + 4 H3R3	1200	1200

22. Calculation of drug needs (See annex B)

PRODUCT	A Drug needs for 1 year	B Buffer stock needed, 100 %	C Remaining stock*	D Pending deliveries	A+B-C-D GDF DRUG ORDER
RH 0,15/0,075	1,199,000	1,019,200**	814,000	0	1,582,000
RH 0,15/0,15	975,000	821,000**	728,000	0	1,221,000
Z 0,4	1,199,000	1,199,000	0	250,000	2,146,000
E 0,4	962,000	962,000	84,000	0	1,838,000
S 1,0	61,600	61,600	0	18,000	105,200***

Notes:

* Estimated as at 1 August 2004

** Less than 100% buffer because using up RH 0,15/0,1 stocks.

*** Without aqua for injection

Final column figures may not add across because of rounding.

Feedback

The independent consultant collecting these data will provide the following information as feedback to the GDF. The GDF will use the information to modify the data collection tool for future monitoring.

If you had difficulty collecting data for a particular item above, indicate the item below and the reason. From the possible *reasons* given below, choose the one most appropriate or indicate a different one in the space provided

Problem: _____ Reason: _____

Problem: _____ Reason: _____

Problem: _____ Reason: _____

Reasons:

- A. **Data not made available to you**
- B. **Data not easily retrievable**
- C. **Question not clear**
- D. **Other, indicate:** _____
- E. **Other, indicate:** _____

Annex A: Case finding and treatment outcomes

3. Case Finding		
Patients registered from:	1-Oct-03	to 31-Dec-03
	DOTS	Other
(a) New pulmonary smear-positive	273	
(b) New pulmonary smear-negative	402	
(c) New pulmonary: no smear or results unknown	0	
(d) New extra-pulmonary	156	
(e) Relapse smear-positive	155	
TOTAL NOTIFICATIONS	986	
<i>Re-treatment not included in WHO notifications:</i>		
(f) Pulmonary smear-positive re-treatment after failure	75	
(g) Other retreatment	180	

2002 cohorts with treatment outcomes

Teritoriu	New Cases-Smr+																				Success rate
	M	F	Total*	(1) Cured smr- %	(2) Treatment complete %	(3) Died %	(4) Failure (Smr+) %	(5)Default (Smr-) %	(6) Transferred %	(7) Not evaluated %	(8) Continued tx %	Total number evaluated (Sum of 1 to 8)									
Trimestrul I	99	24	123	54	44.3	18	14.8	10	8.2	17	13.9	15	12.3	7	5.7	1	0.8	0	0.0	122	59.0
Trimestrul II	94	25	119	71	59.7	6	5.0	9	7.6	10	8.4	20	16.8	2	1.7	1	0.8	0	0.0	119	64.7
Trimestrul III	118	36	154	78	50.6	16	10.4	7	4.5	16	10.4	31	20.1	5	3.2	0	0.0	1	0.6	154	61.0
Trimestrul IV	120	41	161	91	56.5	10	6.2	20	12.4	15	9.3	17	10.6	7	4.3	0	0.0	1	0.6	161	62.7
TOTAL	431	126	557	294	52.9	50	9.0	46	8.3	58	10.4	83	14.9	21	3.8	2	0.4	2	0.4	556	61.9

*Dintre care, 1 (număr) a fost exclus din evaluarea chimioterapiei din următoarele motive: Dg. Alt decât TB - 1

Teritoriu	2.SS+ Relapse cases																				Success rate
	M	F	Total*	(1) Cured smr- %	(2) Treatment complete %	(3) Died %	(4) Failure (Smr+) %	(5)Default (Smr-) %	(6) Transferred %	(7) Not evaluated %	(8) Continued tx %	Total number evaluated (Sum of 1 to 8)									
Trimestrul I	32	1	33	9	27.3	0	0.0	3	9.1	5	15.2	9	27.3	7	21.2	0	0.0	0	0.0	33	27.3
Trimestrul II	77	4	81	37	45.7	3	3.7	7	8.6	14	17.3	13	16.0	4	4.9	3	3.7	0	0.0	81	49.4
Trimestrul III	58	14	72	25	34.7	2	2.8	8	11.1	21	29.2	13	18.1	2	2.8	0	0.0	1	1.4	72	37.5
Trimestrul IV	56	14	70	27	38.6	3	4.3	11	15.7	12	17.1	12	17.1	1	1.4	0	0.0	4	5.7	70	42.9
TOTAL	223	33	256	98	38.3	8	3.1	29	11.3	52	20.3	47	18.4	14	5.5	3	1.2	5	2.0	256	41.4

*Dintre care, (număr) a fost exclus din evaluarea chimioterapiei din următoarele motive: Dg. Alt decât TB -

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