

Rational Pharmaceutical Management Plus
Drug Management Indicators for the National Tuberculosis Control
Program, Moldova: Trip Report

Robert Burn

November 2004

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: rpplus@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, 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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Abstract

Tuberculosis is a growing health issue in Eastern Europe and an inexpensive and effective treatment regimen exists promulgated by World Health Organization. The United States Agency for International Development is funding Rational Pharmaceutical Management Plus (RPM Plus) to strengthen the drug management aspects of national tuberculosis programs. RPM Plus has assessed drug management information needs for program managers and other stakeholders of the Moldova national tuberculosis program (NTP). A policy options workshop held in 2003 reviewed the current status of the TB drug management information system (DMIS), gained a better understanding of the DMIS issues facing the NTP and proposed future steps to strengthen the system. These steps include establishing drug management indicators for assessing the performance of this function of the NTP and guiding decisions for improvement. In 2004, RPM Plus developed and agreed with counterparts upon a set of drug management indicators, and begun the process of institutionalizing their implementation. In 2004, RPM Plus initiated technical assistance in pharmaceutical management for 2nd-line drugs, to complement the MOH and NTP's application to the Green Light Committee for support to the treatment of multi-drug resistant TB patients through a DOTS Plus program.

Recommended Citation

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Key Words

Tuberculosis, national tuberculosis program, tuberculosis drugs, drug management indicators, 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)
E&E	Europe and Eurasia (Bureau of USAID)
GFATM	The Global Fund to Fight AIDS, Tuberculosis & Malaria
M&E	Monitoring and Evaluation
MDR-TB	Multi-Drug Resistant Tuberculosis
MOH	Ministry of Health of Moldova
MSH	Management Sciences for Health
NTP	National Tuberculosis Program of Moldova
RPM Plus	Rational Pharmaceutical Management Plus Program [MSH]
SPCPHSM	Scientific Practical Center of Public Health and Sanitary Management
TB	Tuberculosis
USAID	United States Agency for International Development
WHO	World Health Organization

BACKGROUND

Moldova has one of the highest rates of tuberculosis (TB) within 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) established a DOTS program in 2002. RPM Plus conducted an assessment in 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 held in 2003, after which RPM Plus developed a set of steps for consideration by the MOH and National Tuberculosis Program (NTP). As a component of these steps, the NTP and RPM Plus identified a set of pharmaceutical indicators and discussed integrating these with the MOH's Health Statistics planned monitoring and evaluation (M&E) system being supported by the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM).

With MSH/RPM Plus assistance, the drug management indicators have been comprehensively defined and reviewed by staff of the National Tuberculosis Control Program, the Institute of Pneumology, the Ministry of Health and the Scientific Practical Center for Public Health and Sanitary Management (SPCPHSM). In particular, a sub-set of the drug management indicators will be integrated into the computerized health statistics program. A meeting of stakeholders to initiate putting these indicators into operation is planned. Once institutionalized, the indicators will facilitate the MOH and NTP in responding to monitoring requirements of the Global Drug Facility and GFATM.

Purpose of Trip

- (a) Conduct a one-day meeting of stakeholders in the drug management information system to initiate the implementation of a set of indicators to strengthen drug management in the National Tuberculosis Control Program.
- (b) With the MSH/RPM Plus local consultant, prepare for the planned regional workshop on the Pharmaceutical Management of MDR-TB Treatment.

Scope of Work

- Brief/debrief the USAID Mission on the RPM Plus Program activities in Moldova
- Complete the preparations for and facilitate the stakeholder meeting on implementing the DM indicators
- Discuss the need for additional TA on the design of data collection forms, and data analysis and reporting processes for drug management indicators that may be identified during the meeting
- Plan logistical arrangements for the Pharmaceutical Management of MDR-TB Treatment course with the MSH/RPM Plus consultant and counterparts
- Further discussions on collaboration with the American International Health Alliance (AIHA) *Strengthening Tuberculosis Control in Moldova* project.

ACTIVITIES

- Brief/debrief the USAID Mission on the RPM Plus Program activities in Moldova

Robert Burn and Rita Seicas met with staff from the USAID Mission in Moldova to debrief them on the meeting on drug management indicators, informing them of the outcome of the meeting and the next steps for the implementation of the indicator monitoring process. It was also agreed that RPM Plus would prepare a press release for the up-coming course on Pharmaceutical Management for Multi-Drug Resistant Tuberculosis for approval by USAID. A copy of the draft work plan for FY04 was shared with USAID and the planned activities discussed. USAID requested that the final agenda for the December course be sent to them and that RPM Plus prepare a short note on achievements in 2004.

- Complete the preparations for and facilitate the stakeholder meeting on implementing the DM indicators

The RPM Plus team (Robert Burn and Rita Seicas) met with the hotel staff and finalized the arrangements for the one-day meeting. The meeting was held as planned on Thursday, November 18 and attended by 13 staff of stakeholder organizations and institutions (see Annex 2 of attached Report for details).

Following presentations by Dr. Safta, Director of the National Institute of Pharmacy, and Mr. Ciocanu of the Scientific Practical Center of Public Health and Sanitary Management, the group reviewed the descriptions, data collection and requirements of the selected indicators and affirmed the planning for the implementation of the indicators. During his remarks, Mr. Ciocanu informed the group that addressing tuberculosis was the #1 priority for the MOH and that his aim was to have the health statistics monitoring system functioning by the end of the next 18 months.

See the *Report on TB Drug Management Indicator Working Group Meeting, 18th November 2004, Chisinau, Moldova*, attached as Annex 2 to this trip report for full details.

- Discuss the need for additional TA on the design of data collection forms, and data analysis and reporting processes for drug management indicators that may be identified during the meeting

The RPM Plus team met with Dr. Sain and agreed that Rita Seicas would continue to work closely with the NTP staff to develop data collection procedures and practices to ensure that the required data would be available to implement the indicators. This effort would link directly with the monitoring system being developed by the SPCPHSM for the health field since a sub-set of the drug management indicators are being incorporated into the SPCPHSM computerized system.

- Plan logistical arrangements for the Pharmaceutical Management of MDR-TB Treatment course with the MSH/RPM Plus consultant and counterparts

Robert Burn and Rita Seicas met with hotel staff to discuss the conference accommodation and arrangements for the forthcoming Pharmaceutical Management for Multi-Drug Resistant Tuberculosis workshop planned for 6-10 December 2004. The RPM team completed other administrative and material preparations for this workshop.

- Further discussions on collaboration with the American International Health Alliance (AIHA) Strengthening Tuberculosis Control in Moldova project

The RPM Plus team met with Dr. Viorel Soltan and exchanged information on the progress of the respective projects. Whenever appropriate and possible the RPM Plus consultant, Rita Seicas, will participate in TB meetings, especially concerning issues of procurement and distribution of pharmaceutical and laboratory products, and also collaborate with the development of the MOH monitoring software which AIHA is also directly supporting.

Collaborators and Partners

Dr Sain, National Tuberculosis Control Program Coordinator

Rita Seicas, RPM Plus local consultant

See the attached meeting report for full list of counterparts participating in the workshop (Annex 2).

NEXT STEPS

Immediate Follow-up Activities

1. Prepare the final descriptions of the selected and agreed indicators, taking into account the comments of the workshop participants, and distribute.
2. Collaborate with the company hired by the SPCPHSM to create the software for the monitoring and evaluation system for the Ministry of Health to ensure that the sub-set of drug management indicators is successfully incorporated.
3. Prepare a press release on Pharmaceutical Management for MDR-TB workshop for USAID approval.
4. Draft note on RPM Plus achievements in 2004 for USAID

Agreements or Understandings with Counterparts

RPM Plus will continue to work with the SPCPHSM and the software company to incorporate the TB drug management indicators into the health statistics system.

Important Upcoming Activities or Benchmarks in Program

Pharmaceutical Management for multi-drug resistant TB workshop, 6-10 December, 2004.

ANNEX 1. REQUEST FOR COUNTRY CLEARANCE

TO: Vasile Filatov, 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 November 16-21, 2004. RPM Plus Cooperative Agreement No.: HRN-A-00-00-00016-00

COPY: Anthony Boni/ Global HSPR/CTO RPM Plus
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Mark Levinson, USAID/Moldova
Olena Radziyevska, USAID/Ukraine
Douglas Keene, Director, MSH/RPM Plus Program
Maria Miralles, Deputy Director, MSH/RPM Plus Program
Andrey Zagorskiy, Project Manager for TB, MSH/RPM Plus Program
Robert Burn, Senior Program Associate, 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 November 16-21, 2004.

2. Background:

Moldova has one of the highest rates of tuberculosis (TB) within 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) established a DOTS program in 2002. The MOH, recognizing that drug supply is a crucial element of the TB control strategy, sought assistance in improving TB drug management. RPM Plus conducted an assessment in 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 held in April 2003, after which RPM Plus developed a set of steps for consideration by the MOH and National Tuberculosis Program (NTP). As a component of these steps, the NTP and RPM Plus identified a set of pharmaceutical indicators and discussed integrating these with the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) project's planned monitoring and evaluation (M&E) system.

With MSH/RPM Plus assistance, the drug management indicators have been comprehensively defined and reviewed by staff of the National Tuberculosis Control

Programme, the Institute of Pneumology, the Ministry of Health and the Scientific Practical Center for Public Health and Sanitary Management (SPCPHSM). In particular, the integration of a sub-set of the drug management indicators into the developing computerized GFATM project monitoring and evaluation system has been discussed with the SPCPHSM. A meeting of stakeholders to initiate putting these indicators into operation is planned. Once institutionalized, the indicators will facilitate the MOH and NTP in responding to monitoring requirements of the Global Drug Facility and GFATM.

3. Purpose of Proposed Visit:

- (a) Conduct a one-day meeting of stakeholders in the drug management information system to initiate the implementation of a set of indicators to strengthen drug management in the National Tuberculosis Control Program.
- (b) With the MSH/RPM Plus local consultant, prepare for the planned regional workshop on the Pharmaceutical Management of MDR-TB Treatment.

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
- Complete the preparations for and facilitate the stakeholder meeting on implementing the DM indicators
- Discuss the need for additional TA on the design of data collection forms, and data analysis and reporting processes for drug management indicators that may be identified during the meeting
- Plan logistical arrangements for the Pharmaceutical Management of MDR-TB Treatment course with the MSH/RPM Plus consultant and counterparts
- Further discussions on collaboration with the American International Health Alliance (AIHA) *Strengthening Tuberculosis Control in Moldova* project

5. Anticipated contacts: Mr. Vasile Filatov (USAID/Moldova); Dr. Turcanu, First Vice Minister and other officials and specialists from the Moldovan Ministry of Health; Dr. Sain, (National TB Program); Dr. Sofroni, (National TB Institute); Ms. Rita Seicas, MSH consultant, Dr. Dumitru Laticevschi, GFATM, and Mr. Viorel Soltan, Project Director, AIHA.

6. Logistics: Robert Burn will arrive in Chisinau on Tuesday, November 16, 2004 and depart Moldova on Sunday, November 21, 2004. No Mission assistance is required.

7. Funding: The in-country RPM Plus work will be paid for with USAID/Moldova Mission and E&E Regional 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 Kama Garrison at kgarrison@usaid.gov, Andrey Zagorskiy at azagorskiy@msh.org, Robert Burn at rburn@msh.org, Douglas Keene at dkeene@msh.org and Meriel Jimenez at mjimenez@msh.org.

Thank you in advance for Mission cooperation.

ANNEX 2. REPORT ON TB DRUG MANAGEMENT INDICATOR WORKING GROUP MEETING

18th November 2004, Chisinau, Moldova

Background

The United States Agency for International Development (USAID) is funding Management Sciences for Health's Rational Pharmaceutical Management Plus (RPM Plus) to strengthen the drug management aspects of national tuberculosis (TB) programs (NTP). In October 2002, RPM Plus assessed drug management information needs for program managers and other stakeholders of the Moldova national tuberculosis program. In April 2003, RPM Plus held, together with the MOH and NTP, the workshop "Informed Decision-Making for Drug and Supply Management within the National Tuberculosis Program: Current Status and Options for Strengthening". The findings of the assessment were presented, participants reviewed the current status of TB Drug Management Information System (DMIS), gained a better understanding of the DMIS issues facing the NTP, and initiated steps to define a plan to strengthen the existing system. One finding highlighted that data was neither aggregated nor analyzed using a systematic, indicator-based approach.

One key step was to establish drug management indicators for assessing the performance of this function of the NTP and guiding decisions for improvement, which would be included as a component of the Scientific Practical Center for Public Health and Sanitary Management (SPCPHSM) of the MOH monitoring and evaluation system (M&E). Since October 2003, RPM Plus, with the expertise of a local consultant, has developed and agreed with counterparts upon a set of drug management indicators, and has begun the process of institutionalizing their implementation.

This working group meeting of key implementers was held to:

- To share information on drug management indicators as a method to monitor performance and evaluate the impact of drug management interventions
- To understand how to implement selected performance indicators for monitoring tuberculosis drug management
- To plan for the introduction of systematic data collection and timely analysis (relevant to the determination of indicator values) for drug management decision-making

The agenda of the meeting is attached as Appendix 1.

Session 1: RPM Plus outlined the program for the day and the participants introduced themselves to the group.

Session 2: Presentation by Dr Safta Deputy Director National Institute of Pharmacy:
Monitoring of National Policies for Drugs

Dr. Safta set the scene for the later exchanges and group work on the indicators of drug management within the national tuberculosis control program. He explained the priority objectives of the monitoring of national drug policies—of ensuring a pharmaceutical market with efficient, inoffensive, and quality products, accessible according to the real necessity of society, the incidence of diseases, and the development program of the public health system.

The results of a study (conducted with WHO input) focusing on legislation, access to medicines and prescribing, and using regularly prepared indicators, were presented. The purpose of the study was to assess the capacity of the pharmaceutical sector to implement the medical insurance assistance, emphasizing legislation, access to medicines and prescribing.

- Analysis of state regulations found a need to establish equilibrium between excessive regulations (that were reducing the financial and economic access to drugs) and insufficient regulations (that were encouraging a black market, illegal importation and counterfeit products);
- Analysis of indicators on the development of warehouse and pharmacies networks, drugs import dynamic, volume of the pharmaceutical market, and drugs price dynamic in Moldova, highlighted a the high growth of outlets per capita and the low expenditure per capita in comparison with other countries.
- The indicators on use/prescribing of medicines suggested low prescribing of generics, above average use of antibiotics and high use of injectable medicines.

Session 3: Presentation by Dr. Ciocanu Director Scientific Practical Center for Public Health and Sanitary Management (SPCPHSM)

Dr. Ciocanu described the monitoring and evaluation system that is being developed in the SPCPHSM which involves:

- the creation of a network of 85 computers based in the raions (administrative areas)
- the preparation of custom-built software for data entry at the raion and analysis at the central level
- the training of health personnel in the system's use.

The network is intended to improve access to the health database by doctors (e.g. of WHO standard treatment guidelines for TB).

The transfer of data on line will be key to data being timely for decision-making.

He mentioned the interest of donors in indicators and timely data on the real situation, which the current information system was not able to provide.

The aim was to tender with a software company to write the program and have this developed by the end of April 2005.

Session 4: The rationale for implementing an the indicator approach to monitoring

TB control programs face many new and existing challenges.

- A lack of political commitment to TB control by some countries in the past. This, in turn, leads to weak support of TB control activities from the health system and society;
- Public sector health services need to enhance their capacity to implement, expand, and sustain DOTS-based services without compromising the quality of case detection and treatment;
- The impact of the HIV/AIDS epidemic on TB;
- The exponential increase in MDR-TB.

WHO and partners developed the expanded DOTS strategy in 2002 which includes the following key operations:

1. Establish a national tuberculosis program with a strong central unit
2. Prepare a program development plan and a program manual, and establish the recording and reporting system allowing cohort analysis of treatment outcomes
3. Plan and initiate a training program
4. Set up a microscopy services network in close contact with primary health care (PHC) services and subject to regular quality control to ensure that detection and cure of smear-positive TB cases remain a priority, through effective decentralization of diagnosis
5. Organize treatment services within the PHC system where directly observed short course chemotherapy is given priority
6. Secure a regular supply of drugs and diagnostic material
7. Design and implement a plan of supervision of key operations at the intermediate and district levels.

An important feature of the expanded framework is that it broadens the scope of monitoring and evaluation (M&E) of TB activities to include both traditional program outcome indicators such as case detection and treatment success rates, and indicators that measure the technical, managerial, social, and political dimensions of DOTS. Consequently, the expanded framework demonstrates why it is necessary to routinely collect information on a standard set of programmatic inputs, processes, and outcomes to better identify strengths and weaknesses and track progress. Indicators are one component of a monitoring and evaluation system

Why monitor?

- In order to assess whether or not stated aims are being achieved:
 - In the broadest sense, to attain the targets of the WHO, through the implementation of DOTS programs, of 85% detection rate and 75% cure rate;
- One of the five original pillars of the DOTS initiative is an uninterrupted supply of quality anti-TB drugs
 - Therefore in a narrower sense monitoring takes place to ensure the continuity of supply of appropriate drugs to TB patients;

- If the TB control program is successful, there should eventually be a diminishing number of TB patients and a lower demand for anti-TB drugs, so the supply system needs to be monitored to avoid overstocking;
- Quality for anti-TB drugs—as for all—is critical for successful treatment outcomes;
- Timely and cost effective procurement is important for avoiding disruptions in supply (for example: delayed tendering, poor specification of requirements, weak oversight of contractual obligations of suppliers)
- Ministers are responsible for the use of public funds;

Few countries are addressing TB alone and the international health scene has increasingly focused efforts on stopping TB and allocating finance and technical assistance to the development and support of DOTS programs. It is not only necessary for MOHs to report on the progress of the NTP to national government and the public, but also to a range of international technical agencies and donor organizations: WHO (# of cases, treatment outcomes), GDF (1st line drug needs, stocks), GFATM (project implementation, expenditures), GLC (drug use), etc. So, implementing a competent monitoring system is not only important for domestic audiences but also to support and justify programs to external partners.

Moreover a monitoring system allows action to take place promptly to rectify any problems that occur—because the issues can be identified quickly and routinely and often before serious consequences have developed.

If indicators are to be used effectively, action needs to be taken when “flags” are raised. Positive feedback or corrective feedback can be initiated appropriate to the nature of the problem—might involve reassigning staff or responsibilities, adjusting the TB drug supply targets, or requesting additional information to better understand the issue.

Session 4 (continued): Review of progress to date in identifying appropriate indicators

- 2002 RPM Plus DMIS assessment suggested:
 - Data is neither aggregated nor analyzed using a systematic, indicator-based approach.
 - Monitoring and reporting on drug supply and utilization trends is ad hoc and/or irregular. Similarly, the monitoring and reporting on the use and status of laboratory supplies is weak.
 - The requirement of GDF support that there be monitoring and evaluation of anti-TB drug supply is currently applied only to drugs from the GDF.
 - It appears that there are no processes in place to verify the quality of data.
- RPM Plus suggests that steps be taken to introduce an indicator-based approach to the monitoring of the implementation and the evaluation of the performance of the TB drug program as part of NTP. (At least one or two major indicators for such areas of drug management as drug selection, registration, procurement, financing, distribution and use should be selected and introduced.)
- A supplier performance monitoring system needs to be introduced.

- RPM Plus offered forward a list of tested indicators that MSH had experience with in a number of countries.
- Link to overall monitoring and evaluation system (discussed by Dr. Ciocanu) SYMERTA.
- List reviewed by NTP and selection from list made by NTP (January 2004).
- Development of detailed descriptions of indicators and calculations (2004).
- Preliminary analysis of data requirements and availability of data (September 2004)

Session 5/6: Group Work

The participants were divided into two groups (based on area of drug management addressed by each indicator and the role of each participant in the drug supply cycle) and asked to review nine indicators based on the following characteristics:-

- *Indicator title*
- *Definitions of terminology*
 - **Users of the indicator**
 - **Rationale for the indicator (strategic)**
 - **Rationale for the indicator (operational)**
- *Calculation of indicator*
- *Data requirements (to effect calculation)*
 - **Source of data**
 - **Current practice (re obtaining data)**
 - **Proposed method for obtaining data**
- *Frequency of reporting indicator*
- *Gaps in data collection*
 - **What needs to be done to collect data effectively and efficiently?**

Session 7: Review of group work

Each group reported back on the nine indicators they had reviewed. This session was useful because it was the first time that many of the participants had the opportunity to understand the nature and use of the indicators which had been selected by the coordinator of the NTP.

The groups confirmed that each indicator was clearly defined, its purpose understood and the method of computation logical. For the majority of the indicators the source of data was correctly identified though in a few cases additional comments were made which improved the description of how and where to obtain the necessary data. Suggestions for secondary sources and for updating the source of particular data (for example, on an organization's website) were also made. The need to design and introduce a new recording format was recognized for one indicator. For the indicator on adverse reactions, it was recognized that data was deficient because of the unsatisfactory reporting rate of such cases.

Session 8: Planning next steps (outcome of meeting)

The group confirmed that the indicators were applicable and useful.

The indicator descriptions would be updated to reflect the groups' comments on data availability and how to resolve any identified gaps in data availability.

There was agreement to implement the indicators in a phased manner, taking into account those that are more immediately useful, those requiring modification to procedures or data collection practice to implement and the frequency of preparation (annual, quarterly, etc.).

The NTP agreed to write to the MOH to request that appropriate backing be given to the implementation of the indicators and advising where new or modified practices would need to be introduced.

MSH/RPM Plus agreed to provide further support in the short term.

The final, updated indicator descriptions are attached as Appendix 3 and a list of these indicators classified according to the current availability of data can be found in Appendix 4.

Appendix 1: Agenda

Session 1:	9:00-9:20am	Introductions and review of meeting agenda
Session 2:	9:20-9:40am	Dr. Safta: Monitoring of the National Drug Policy
Session 3:	9:40-10:00am	Dr. Ciocanu: Health Information System
Session 4:	10:00-10:30am	Overview of the performance improvement process Review of progress to date in identifying appropriate indicators
	10:30-10:45am	Coffee break
Session 5:	10:45-12:00am	Operationalising Indicators
	10:45-11:15am	Introduction to group work
	11:15-12:00pm	Group work
	12:00-1:00pm	Lunch
Session 5:	1:00-2:45pm	Group work (continued)
	2:45-3:00pm	Refreshments
Session 6:	3:00-3:30pm	Group work (wrap up)
Session 7:	3:30-4:15pm	Review of group work in plenary
Session 8:	4:15-5:00pm	Planning next steps

Appendix 2: Participants

Organization	Department (sub department)	Name of participants	Position
Ministry of Health	Department of Medical Technologies	V.Tapu	Consultant
National Institute of Pharmacy		V.Safta	Deputy director
	Pharmaceutical Management and Marketing Laboratory	A. Danilov	Chief
	Clinic Evaluation and Pharmacovigilance Center	L.Turcanu	Chief
National Tuberculosis Programme		D.Sain	NTP Coordinator
	M& E Department	E.Axenti	TB physician
	Org/Method Department	A. Donica	TB physician, Responsible for DM
Institute of Phtysiopneumology	Hospital Pharmacy	A. Djugostran	Chief
Scientific Practical Center for Public Health and Sanitary Management		M. Ciocanu	Director
	Monitoring and Evaluation of National Programmer Department	V.Plesca	Specialist
SanFarmPrim JC		A. Ciobanu	Deputy director
AIHA Project		V. Crudu	Lab Specialist
Caritas Luxemburg		V. Laticevschi	Medical Officer

Appendix 3: Final indicator descriptions

Indicator#1: Percentage of TB drugs used in NTP that are registered in the country.	
Rationale: users of indicator	<ul style="list-style-type: none"> • National Tuberculosis Control Programme (NTP) • Ministry of Health(MOH) • National Institute of Pharmacy (NIP)
Rationale: use for decision-making (strategic)	Ensure that the NTP only uses drugs that are registered in Moldova for distribution in Moldova following evaluation of quality, safety etc. in accordance with government regulations.
Rationale: use for decision-making (operational)	Measure taken to reduce import of unregistered TB drugs non depending on supply sources: state procurement, donations, grants.
Data requirements	<ol style="list-style-type: none"> 1) Number of TB drugs used in NTP that are registered 2) Number of TB drugs used in NTP
Source of required data	<ol style="list-style-type: none"> 1) NTP –NTP coordinator- List of TB drugs used in national tuberculosis control programme 2) National Institute of Pharmacy –chief of the Pharmaceutical Management and Marketing Laboratory- List of TB drugs registered in Moldova 3) MOH –secretary of Humanitarian Aid Committee- List of donated TB Drugs
Current practice	<ol style="list-style-type: none"> 1) NTP <ul style="list-style-type: none"> • Receives quarterly report from health facilities containing following information: name of TB drugs, dosage, strength, the received, used and left quantities and the source: out of donations or public money. 2) National Institute of Pharmacy <ul style="list-style-type: none"> • State list of registered drugs 3) MOH <ul style="list-style-type: none"> • List of donated drugs
Method of collecting required data	<ol style="list-style-type: none"> 1) NTP: <ul style="list-style-type: none"> • Continue to obtain the list of anti-TB drugs used by all health facilities, but additionally include in the health facilities quarterly report information on the manufacture name and country of origin. 2) National Institute of Pharmacy (Information-Statistics Department) <ul style="list-style-type: none"> • Continue to publish list of registered anti-TB drugs, according to ATC classifications. The list is updated monthly. 3) Ministry of Health: <ul style="list-style-type: none"> • For donations, Humanitarian Aid Committee to prepare on a regular basis a list of TB drugs and name of manufacturers based on packing list (or invoice), <p>Extract from the Working Group of MOH reports on decisions relating to approval of drugs to be bought with public funds and information to include manufactures name, etc.</p>

Indicator #2: Percentage of TB drugs used in NTP and included on the National Essential Medicines List.	
Definition	The National Essential Medicines List is the list which has been defined, adapted and published at country level
Rationale: users of indicator	<ul style="list-style-type: none"> • National Tuberculosis Control Programme (NTP) • Ministry of Health (MOH) • National Institute of Pharmacy
Rationale: use for decision-making (strategic)	Ensure continuous and improved TB drug supply at all times in adequate amounts, in appropriate dosage forms, adequate quality based on the limited essential drugs at all level.
Rationale: use for decision-making (operational)	Facilitates procurement of TB drugs by NTP through referral to the National Essential Medicines List. Will increase efficiency of each step of supply cycle e.g.: the selection of the main drugs, optimal utilization of funds, selection of relevant suppliers.
Data requirements	<ol style="list-style-type: none"> 1) List of TB drugs used in NTP 2) The National Essential Medicines List
Source of required data	<ol style="list-style-type: none"> 1) NTP <ul style="list-style-type: none"> • List of TB drugs used in national tuberculosis control programme 2) National Institute of Pharmacy <ul style="list-style-type: none"> • Published the National Essential Medicines List 3) MOH <ul style="list-style-type: none"> • The National Essential Medicines List
Current practice	<ol style="list-style-type: none"> 1) NTP <ul style="list-style-type: none"> • Receives quarterly report from health facilities containing following information: name of TB drugs, dosage, strength, the received, used and left quantities and the source: out of donations or public money. 2) National Institute of Pharmacy <ul style="list-style-type: none"> • Publish the National Essential Medicines List in the “Informational Bulletin” of the National Institute of Pharmacy 3) Ministry of Health <ul style="list-style-type: none"> • the MOH decision which approves the National Essential Medicines List and sent officially to all health facilities
Method of collecting required data	<ol style="list-style-type: none"> 1) NTP <ul style="list-style-type: none"> • Continue to obtain the list of anti-TB drugs used by all health facilities, but additionally include in the health facilities quarterly report information on the manufacture name and country of origin. 2) National Institute of Pharmacy (Information-Statistics Department) <ul style="list-style-type: none"> • Continue to publish list of National Essential Medicines. 3) Ministry of Health
Indicator calculation	<p>Variable(A): Number of TB drugs used by the NTP that are included on the National Essential Medicines List.</p> <p>Variable(B): Number of TB drugs used in NTP</p> <p>Formula: $A*100/B$</p>
Frequency of reporting	Annual

<p>Gaps in data collection</p> <p>What needs to be done to collect data effectively and efficiently</p>	<ul style="list-style-type: none"> • The National Essential Medicines List is not reviewed on a regular basis. <p>1)NTP:</p> <ul style="list-style-type: none"> • to follow the modifications of the NEML, • to receive regular reports from TB facilities, • accurate examination of TB facilities reports • to subscribe to “Informational Bulletin” of the National Institute of Pharmacy <p>2)MOH:</p> <ul style="list-style-type: none"> • assure the presents of the NEML
<p>Target</p>	<p>Optimum indicator value = 100 %.</p>
<p>Comments</p>	<p>All drugs used in the NTP are officially listed as Essential Medicines for the Moldovan public health</p>

Indicator #3: Percentage of TB drugs used in NTP and included on the WHO Essential Medicines List.	
Definition	Essential drugs are those that satisfy the health care needs of the majority of the population and therefore should be available at all times. The WHO Essential Medicines List includes those drugs that meet the criteria recommended by WHO.
Rationale: users of indicator	<ul style="list-style-type: none"> • National Tuberculosis Control Programme(NTP) • Ministry of Health (MOH) • National Institute of Pharmacy(NIP)
Rationale: use for decision-making (strategic)	Convergence of state treatment guidelines and selection of TB drugs with WHO Essential Medicines List (which contains a limited number of drugs selected based on public health relevance, on efficacy, safety and cost efficient principles)
Rationale: use for decision-making (operational)	Monitoring of drugs used in relation to international standards (WHO Essential Medicines List) and drug selection.
Data requirements	<ol style="list-style-type: none"> 1) Number of TB drugs used in NTP included on the WHO Essential Medicines List 2) Number of TB drugs used in NTP
Source of required data	<ol style="list-style-type: none"> 1) NTP <ul style="list-style-type: none"> • List of TB drugs used in national tuberculosis control programme 2)WHO EDM Dept website <ul style="list-style-type: none"> • Regularly updated list of essential medicines
Current practice	<ol style="list-style-type: none"> 1) NTP Receives quarterly report from health facilities containing following information: name of TB drugs, dosage, strength, the received, used and left quantities and the source: out of donations or public money 2) The WHO Essential Medicines List is not examined on regular basis
Method of collecting required data	<p>NTP</p> <ul style="list-style-type: none"> • Review the quarterly report from health facilities • Check the WHO website
Indicator calculation	<p>Variable(A): Number of TB drugs used in NTP included on the WHO Essential Medicines List</p> <p>Variable(B): Number of TB drugs used in NTP</p> <p>Formula: $A*100/B$</p>
Frequency of reporting	Annual (depending on changes in drugs used in the NTP and periodic updating of the WHO Essential Medicines List)

Gaps in data collection	Lack of the WHO Essential Medicines List and absence of information of the last revisal.
What needs to be done to collect data effectively and efficiently	NTP <ul style="list-style-type: none">• Check WHO EDM Dept web site
Target	Indicator value of 100% indicates all TB drugs used in NTP are recommended by WHO for use in public health programmes.
Comments	Countries may not follow WHO EML in full depending upon local public health needs and medical experience, so a figure below 100% is acceptable. However, a very low figure would indicate the use of drugs for the treatment of TB well out of line with WHO recommendations.

Indicator #4: 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.	
Definition	The Batch Certificate of a Pharmaceutical Product, WHO format is a document by which producer unit or national competent authority guaranty that the individual drugs lot comply with the specification accepted at the time of product registration.
Rationale: users of indicator	<ul style="list-style-type: none"> • National Tuberculosis Programme (NTP) • Ministry of Health (MOH) • National Institute of Pharmacy (NIP)
Rationale: use for decision-making (strategic)	To measure the performance of: <ul style="list-style-type: none"> - quality assurance system - the level of compliance of national quality standards to the international quality standards as a tool to ensure the quality of drugs.
Rationale: use for decision-making (operational)	To implement acceptable quality standards for: <ul style="list-style-type: none"> • TB drugs, • suppliers , <p>To ensure distribution of quality, efficacy and inoffensive anti-TB drugs to TB patients.</p>
Data requirements	<ol style="list-style-type: none"> 1) List of TB drugs used in NTP 2) Number 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 3)Number of TB drugs received in shipments during the last year
Source of required data	<ol style="list-style-type: none"> 1)NTP – person in charge for management of anti-TB drugs – the list of anti-TB drugs 2) Drugs Quality Control Laboratory, National Institute of Pharmacy -chief of the laboratory - list of total anti-TB drugs received in shipment in the last year and the list of anti-TB drugs received in shipments that were accompanied with an individual batch certificate meeting the requirements of the WHO certification scheme.
Current practice	Currently this data are not collected.
Method of collecting required data	PNT <ul style="list-style-type: none"> • obtain and review a report under a standard form and record TB drugs received in shipments during the last year and those that were accompanied with an individual batch certificate meeting the requirements of the WHO certification scheme.
Indicator calculation	<p>Variable(A): Number 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</p> <p>Variable(B): Number of TB drugs received in shipments during the last year</p> <p>Formula: $A*100/B$</p>

Frequency of reporting	Annual
Gaps in data collection	Lack of: <ul style="list-style-type: none"> • assess the authenticity or validity of the certificate of a pharmaceutical product submitted; • recording of drugs received in shipments during the last year that were accompanied with an individual batch certificate meeting the requirements of the WHO certification scheme; • the drug registration requirements doesn't ask for the individual batch certificate meeting the requirements of the WHO certification scheme • confuse of the individual batch certificate meeting the requirements of the WHO certification scheme with certificate of pharmaceutical product
What needs to be done to collect data effectively and efficiently	<p>NIP:</p> <ul style="list-style-type: none"> • to modify the Drug Registration Requirements with individual batch certificate, <p>QCCL:</p> <ul style="list-style-type: none"> • to request the individual batch certificate meeting the requirements of the WHO certification scheme • improving staff knowledge concerning WHO certificates, • modification of the record system of drugs tested by the QCDCCL that contents the difference of those that comply and don't comply to WHO certification scheme.
Target	The 100% figure will confirm the delivery of quality drugs according to the WHO standard.
Comments	

Indicator #5: Percentage of TB drugs samples that failed quality-control testing out of the total number of TB drug samples tested during the past year.	
Rationale: users of indicator	<ul style="list-style-type: none"> • National Tuberculosis Program (NTP) • Ministry of Health(MOH) • National Institute of Pharmacy(NIP)
Rationale: use for decision-making (strategic)	Ensure the availability of high quality TB drugs
Rationale: use for decision-making (operational)	Monitoring of drug selection and procurement and supplier performance
Data requirements	1)List of anti-TB drugs used in NTP 2)Total number of anti-TB drugs samples tested during the past year 3)Number of anti-TB drugs samples that failed quality-control testing
Source of required data	1)NTP – NTP coordinator- List of anti-TB drugs used in NTP 2)DQCL, National Institute of Pharmacy -chief of the DQCL- standard report and the lists with total number of drugs samples tested during the past year and with number of drugs samples that failed quality control testing. 3) Pharmaceutical Management and Marketing Laboratory, NIP –chief of the department –“Informational Bulletin of the NIP” (provide the lists of all drugs samples tested ant those that failed quality control testing monthly)
Current practice	1)NTP doesn't collect data 2) DQCL has the results of all drugs tested 3) The “Informational Bulletin” of the National Institute of Pharmacy provides the list of all drugs samples tested published only by the brand name, which sometimes would create difficulties to select of those that are anti-TB drugs.
Method of collecting required data	NTP: <ul style="list-style-type: none"> • inform the DQCL with the anti- TB drugs list used by NTP • obtain and review the standard report of the DQCL with results of tested the anti-TB drugs
Indicator calculation	Variable(A): Number of TB drugs samples that failed quality-control testing Variable(B): Total number of TB drugs samples tested during the past year Formula: $A*100/B$
Frequency of reporting	Annual

<p>Gaps in data collection</p> <p>What needs to be done to collect data effectively and efficiently</p>	<ul style="list-style-type: none"> • All tested drugs are recorded in a common list, not being classified according ATC principle. <p>NTP:</p> <ul style="list-style-type: none"> • Inform DQCL with clear determined anti- TB drugs used within the program. <p>DQCL:</p> <ul style="list-style-type: none"> • improve the existing recording system of tested drugs by systematization of drugs according ATC classification
<p>Target</p>	<p>The figure of zero (0) will imply all drugs are of appropriate quality (providing testing procedures and expertise are competent).</p>
<p>Comments:</p>	<p>Indicator values above zero will confirm delivery of drugs of unsatisfactory quality (potentially causing shortages of drugs through the necessity of waiting for a new delivery).</p>
<p>Terms</p>	<p>Quality control is concerned with sampling, specifications, and testing and with the organization, documentation, and acceptance/ rejection procedures which ensure that the necessary and relevant tests are actually carried out and the finished product are not accepted for use, sale or supply until their quality has been judged to be satisfactory.</p>

Indicator #6: Average percentage of time out of stock for TB drugs in TB facilities (including warehouses) for last year.	
Definition	Time out of stock 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 assessment takes place). To be considered a stock out there must have been none of an unexpired drug 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 presentation of days a 12 month period that a drug has been out of stock(based inventory records)
Rationale: users of indicator	<ul style="list-style-type: none"> • National Tuberculosis Control Programme (NTP) • Ministry of Health (MOH) • TB health facilities • Warehouse
Rationale: use for decision-making (strategic)	Confirm the procurement and distribution system's capacity to maintain an uninterrupted supply of drugs.
Rationale: use for decision-making (operational)	Identification of whether distribution, stock-keeping and reporting practices are satisfactorily performed.
Data requirements	<ol style="list-style-type: none"> 1) Total number of stock-out days for all TB drugs 2) Total number of TB drugs normally stocked
Source of required data	<ol style="list-style-type: none"> 1)NTP – person in charge of drug management -quarterly report 2)TB facilities – coordinator rayon TB – record register 3) Warehouse - chief of the Marketing Department – record register
Current practice	NTP doesn't collect total number of stock out days for TB drugs.
Method of collecting required data	<p>NTP:</p> <ul style="list-style-type: none"> • Review quarterly reports <p>TB Facilities and warehouse</p> <ul style="list-style-type: none"> • Check the stock, register the results in existing record tools and fill in the quarterly reports
Indicator calculation	<p>Variable(A): Total number of stock-out days for all TB drugs</p> <p>Variable(B): Total number of TB drugs normally stocked (B)</p> <p>Formula: $A*100/365*B$</p>
Frequency of reporting	Quarterly

<p>Gaps in data collection</p> <p>What needs to be done to collect data effectively and efficiently</p>	<p>The list of TB drugs used in NTP is not clear. The misunderstanding of the term “stock-out days” Inaccurate inventory record system.</p> <p>1)National Tuberculosis Control Programme (NTP):</p> <ul style="list-style-type: none"> • regular basis evidence , • staff should be trained in inventory management <p>2)TB health facilities:</p> <ul style="list-style-type: none"> • applying of standard, unique evidence tools such as: cards, registers, blanks etc • accurate use of the notion,, stock-out days,,
<p>Target</p>	<p>An indicator value of zero would be optimum.</p>
<p>Comments</p>	<p>Values close to zero would suggest the non-availability of TB drugs is a manageable problem, but there is still room for improvement. Values higher than, say 10%, would suggest that there are problems in the distribution of TB drugs which could well affect the treatment of patients.</p>

Indicator #7: Average percentage of normally stocked, unexpired TB drugs available in TB facilities and medical stores (C/F).	
Definition	A drug is defined as available if even one unit of unexpired product is in stock. Since expired drugs are inappropriate for use in almost all situations, they are not counted as stock available for use.
Rationale: users of indicator	<ul style="list-style-type: none"> • National Tuberculosis Control Programme (NTP) • TB facilities • Warehouse
Rationale: use for decision-making (strategic)	Ensure successful implementation of the TB treatment strategy, by ensuring availability of viable (that is, unexpired) TB drugs.
Rationale: use for decision-making (operational)	Facilitates the identification of health facilities or medical stores that may have problems in the management (quantification, ordering, stock control, record-keeping) of TB drugs.
Data requirements	<ol style="list-style-type: none"> 1) The list and total number of TB drugs normally stocked, 2) Number of unexpired TB drugs in stock in each facility.
Source of required data	<ol style="list-style-type: none"> 1) ME Department of the NTP – person in charge of monitoring - monitoring reports 2) TB Facilities -TB physicians – inventory records and stock count 3) Warehouse - chief of the Store Department – inventory records and stock count
Current practice	The Evaluation and Monitoring Department from TB Institute, makes physical counts of anti-TB drugs stored at the health facilities within monitoring visits. But the results of monitoring are not reflected
Method of collecting required data	Evaluation and Monitoring Department, TB Institute: <ul style="list-style-type: none"> • Monitoring visits, review the registration register and stock inventory
Indicator calculation	<p>I. To determine the percentage for a single facility:</p> <p>Variable(A): Number of normally stocked, unexpired anti-TB drugs in stock</p> <p>Variable(B): Total number of anti-TB drugs normally stocked</p> <p>Formula: $A*100/B$</p> <p>II. To determine the average % of TB drugs availability:</p> <p>Variable(C): Sum of % for each facility</p> <p>Variable(D): Total number of facilities</p> <p>Formula: C/D</p>
Frequency of reporting	Quarterly

Indicator #8: Average percentage of stock records that correspond with physical counts for TB drugs in TB storage facilities.	
Definition	This is the average percentage of in stock TB drugs inventory record that correspond exactly with physical stock count for a set of TB drugs
Rationale: users of indicator	<ul style="list-style-type: none"> • National Tuberculosis Control Programme • TB facilities • Warehouse
Rationale: use for decision-making (strategic)	One indication of the ability of facility staff to manage the TB drugs properly.
Rationale: use for decision-making (operational)	Identifies the ability of facility staff to record and monitor drug use and suggests potential training needs.
Data requirements	<ol style="list-style-type: none"> 1) List of anti-TB drugs used in NTP 2) Data concerning the method of recording stocks 3) The results of physical count of unexpired stock levels that include: the number of stock records with No discrepancies, total number of records examined and total number of facilities.
Source of required data	<ol style="list-style-type: none"> 1) TB Facilities <ul style="list-style-type: none"> - TB physicians – record instruments 2) Warehouse <ul style="list-style-type: none"> - chief of the stock department – record instruments 3) ME Department of the NTP <ul style="list-style-type: none"> - person in charge of monitoring - monitoring reports
Current practice	The Evaluation and Monitoring Department from the TB Institute, makes physical counts of anti-TB drugs stored at the health facilities within monitoring visits. But the results of physical count are not put into base data.
Method of collecting required data	<p>Evaluation and Monitoring Department from the TB Institute:</p> <ul style="list-style-type: none"> • Monitoring visits • reviewing the record instruments and carrying out a physical count <p>Org/ Meth. Department</p> <ul style="list-style-type: none"> • Review the monitoring reporting form
Indicator calculation	<p>I. To determine the value for an individual facility:-</p> <p>Variable(A): Number of stock records that correspond with physical counts</p> <p>Variable(B): Total number of products that are stocked and examined</p> <p>Formula: $A*100/B$</p> <p>II. To determine the average percentage</p> <p>Variable(C): Sum of % for each facility</p> <p>Variable(D): Total number of facilities</p> <p>Formula: C/D</p>
Frequency of reporting	<ul style="list-style-type: none"> • Warehouse – annual • TB facilities- quarterly.

Gaps in data collection	<ul style="list-style-type: none">• Comparison of physical account with stock records,• Lack of reporting tool for the results of monitoring visits.
What needs to be done to collect data effectively and efficiently	Evaluation and Monitoring Department from the TB Institute: <ul style="list-style-type: none">• to design a reporting form for results obtained during the monitoring visits,• to create a database for these results separately in conformity with sources(donation, centralized or local budget procurement
Target	An indicator value of 100% indicates full compatibility of stock records with physical counts for TB drugs and suggests inventory control is being well managed.
Comments	Comments from group: Additional sources than centralized distribution should be included: local budget, donation, etc.

Indicator #9: Percentage of TB drug shipments received at the contracted delivery date for the last (three) procurements.	
Rationale: users of indicator	<ul style="list-style-type: none"> • National Tuberculosis Control Programme • Ministry of Health
Rationale: use for decision-making (strategic)	To assess the procurement efficiency
Rationale: use for decision-making (operational)	To monitor a suppliers, performance Participant prequalification
Data requirements	1) Contracted delivery terms. 2) Payment terms (usually for centralized procurement is using prepayment conditions and delivery is done within 30 days after prepayment) 3) The expected arrival dates of shipments 4) Actual delivery dates. 5) Number of procurements last year.
Source of required data	1) MOH – secretary of Working Group, Pharmaceutical Department - information concerning contract delivery terms stipulated in bid documents and shipments from supplier; -chief-the economical planning and accounting department- payment receipt and contracted terms provided by contract; 2) Warehouse –chief of the Marketing Department -actual delivery dates
Current practice	Data exists in different documents and departments but are not selected and evaluated.
Method of collecting required data	NTP <ul style="list-style-type: none"> • Review the procurement contracts, payment receipt , invoices and information note of the supplier concerning availability of shipment
Indicator calculation	Variable (A): The number of shipments received at the contracted delivery date. Variable(B): The total number of last year procurements (3 if we take into consideration only last 3 procurements) Formula: $A * 100 / B$
Frequency of reporting	Annual
Gaps in data collection	Inaccurate collecting of information concerning payment, delivery terms and actual delivery data.
What needs to be done to collect data effectively and efficiently	NTP <ul style="list-style-type: none"> • Precise collection and review of following data and documents : the contract terms , payment date, invoices and information note of the supplier concerning availability of shipment, contract developing
Target	The 100 % ensure complies of the shipment with contracted terms.
Comments	Following up the contract terms will ensure the achievement of uninterrupted drug supply and treatment.

Indicator #10: Average lead time for orders placed for TB drugs from sources during the last year, measured from the time order is submitted to procurement department or office for purchasing (Working group of MOH) to the time order is received in warehouse	
Definition	The lead time is defined as the interval between submitting an order and receiving the goods. It includes the bidding process, the selection of suppliers, the evaluation of the bids, sign of contracts by parties etc. The average lead time should be calculated on the basis of orders during the last year.
Rationale: users of indicator	<ul style="list-style-type: none"> • National Tuberculosis Control Programme • Ministry of Health
Rationale: use for decision-making (strategic)	Assess the efficiency of procurement practice
Rationale: use for decision-making (operational)	Evaluation of procurement and supplier performance. Confirm average lead time necessity to accomplish procurement cycle of TB drugs.
Data requirements	<ol style="list-style-type: none"> 1). Submitted date of order to procurement office 2). Actual delivery date 3). Number of procurements
Source of required data	<ol style="list-style-type: none"> 1)NTP –NTP coordinator- submitted order. 2)MOH – the secretary of the Working Group, Pharmaceutical departments – register with registration dates of the order list of TB drugs and information about TB drugs received by the warehouse and delivery availability 3) Warehouse –chief of the Marketing Department- information note about TB drugs received and delivery availability.
Current practice	<ol style="list-style-type: none"> 1) NTP doesn't collect data. 2) MOH -the pharmaceutical department- registers the order list of TB drugs and the information note about TB drugs received by the warehouse 3) Warehouse - informs about the delivery availability
Method of collecting required data	NTP: <ul style="list-style-type: none"> • Review the registration dates of the order list of anti-TB drugs, information note from warehouse concerning received drugs
Indicator calculation	<p>Variable(A): Submitted date of order to procurement office</p> <p>Variable(B): Actual delivery date</p> <p>Variable(C): Number of contracts ($C_1, C_2, C_3, \dots, C_n$)</p> <p>Formula: $B_1 - A_1 = C_1$, then, $B_2 - A_2 = C_2$ $(C_1 + C_2 + C_3 + \dots + C_n) / n$</p>
Frequency of reporting	Annual

<p>Gaps in data collection</p> <p>What needs to be done to collect data effectively and efficiently</p>	<ul style="list-style-type: none"> • the absence of the order registration and delivery date • the information note of warehouse doesn't provide the delivery date <p>NTP:</p> <ul style="list-style-type: none"> • authorized person (unit) who will supervised the whole process starting with order submission and ended with order received in warehouse, • create a register that will contain all the data concerning the supply process • standardized content of information warehouse letter
<p>Target</p>	
<p>Comments:</p>	<p>Average lead time needed for the drug to be in warehouse from sources is an average term to achieve a well organized supply process. The 5/6 month is optimal figure.</p>

Indicator #12: Percentage of median international price paid for TB drugs that was part of the last year regular procurement	
Definition	Median International Price is the median free on board (FOB) price from a set of international suppliers, adjusted to CIP prices. The last regular procurement price refers to the CIP price paid during the last regular MOH procurement. One source of price information is the MSH International Drug Price Indicator Guide.
Rationale: users of indicator	<ul style="list-style-type: none"> • National Tuberculosis Programme (NTP) • Ministry of Health(MOH) • National Institute of Pharmacy(NIP)
Rationale: use for decision-making (strategic)	Contribute towards effective use of public funds
Rationale: use for decision-making (operational)	To monitor and improve procurement effectiveness.
Data requirements	1)List of anti-TB drugs used in NTP 2) Recent prices paid for anti-TB drugs by MOH. 3)Median International Price
Source of required data	1)NTP - person in charge for management of anti-TB drugs - List of anti-TB drugs used 2) MOH – secretary of the Working Group, Pharmaceutical Department - the decision of Working Group of MOH, or procurement contract signed by MOH and approved by the National Agency for Public Procurement 3) Management Sciences for Health –website www.msh.org - International Drug Price Indicator Guide(prices are adjusted up ward by 20-25 % (CIP)
Current practice	NTP: <ul style="list-style-type: none"> • has the information about procurement prices for anti- TB drugs • evaluation of procurement prices for anti- TB drugs with international prices are not done.
Method of collecting required data	NTP review the following documents: <ul style="list-style-type: none"> • the decision of Working Group of the MOH or procurement contract(copy) • the International Drug Price Indicator Guide.
Indicator calculation	I) For individual drug: Variable(A): MOH unit price Variable(B): Median international unit price Formula: $A*100/B$ II) For all drugs Variable(C): Sum of percentages of all drugs Variable(D): Total number of drugs procured used in NTP Formula: C/D

Frequency of reporting	Annual
Gaps in data collection	<ul style="list-style-type: none"> • lack of the information about international prices • the wrong determination of median international price • comparing prices for products different by generics name, strength, pharmaceutical forms • comparing prices data based on different years and currency; • wrong use of exchange rates • lack of knowledge about „median,, definition
What needs to be done to collect data effectively and efficiently	<p>MOH, NTP:</p> <ul style="list-style-type: none"> • establishing the source for obtaining the international prices, • an update of information about international prices, • the correct evaluation of median international price, • an accurate comparison of the prices of the same year, product that have the same name, strength and doses. • use of common comparison currency; • use of exchange rates established by the National Bank at the time of contract sign; • use the last INCOTERMS
Comments:	The compared ratio 1:1 achieved between the MOH procurement price and the international price confirms the efficacy of funds use.

Indicator #13: Value of expired drugs last quarter (year).	
Rationale: users of indicator	<ul style="list-style-type: none"> • National Tuberculosis Control Programme (NTP) • National Institute of Pharmacy (NIP) • TB facilities • Warehouse
Rationale: use for decision-making (strategic)	Confirm the efficiency of the drug management distribution system.
Rationale: use for decision-making (operational)	Contribute to improvement of quantification, distribution, use and inventory practices.
Data requirements	<ol style="list-style-type: none"> 1) Quantities of expired drugs (in period) 2) Unit cost of expired TB drug 3) Total sum of expired TB drug
Source of required data	<ol style="list-style-type: none"> 1)NTP <ul style="list-style-type: none"> • person in charge of drug management – health facilities' and warehouse's quarterly reports 2) TB Facilities <ul style="list-style-type: none"> • local TB coordinator – registers records, invoices and inventory records 3) Warehouse- <ul style="list-style-type: none"> • chief of the Marketing Department – registers records, invoices and inventory records
Current practice	Currently data are not collected.
Method of collecting required data	<ol style="list-style-type: none"> 1) TB facilities Check the current stock, Review the registers and calculate the sum of expired TB stock and fill in the quarterly report 2)Warehouse Check the current stock, Review the registers and calculate the sum of expired TB stock and fill in the quarterly report 3)NTP Review the quarterly reports
Indicator calculation	<p>By facility/warehouse: Multiply quantity of each expired drug from last quarter by selected unit cost (for example—average unit cost or latest unit cost).</p> <p>Sum value of expired quantities for all drugs.</p>
Frequency of reporting	Quarterly
Gaps in data collection	<ul style="list-style-type: none"> • Recording and inventory lack.
What needs to be done to collect data effectively and efficiently	<p>NTP/TB facilities/Warehouse</p> <ul style="list-style-type: none"> • to include in TB drugs record register a new column for registration the validity period of TB drugs and unit price • to complete the design of quarterly report with additional column which reflect the value of expired anti- TB drug • to establish a constant inventory program of stock
Target	An indicator figure equal to zero (0) will show that the distribution and inventory system is performing without loss due to expiry of products.

Comments	<p>Any system may experience some expired stocks and a figure of less than 5% may be acceptable. Figures above 5% will suggest improvements can be made in distribution and inventory control.</p> <p>Comments from group: Additional source for data collection: National Institute of Pharmacy—where they keep information on quantities of drugs actually destroyed. Documentation includes price for these drugs.</p>
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Indicator #14: Percent of annual MOH TB drug needs met by annual MOH TB drug budget.	
Rationale: users of indicator	<ul style="list-style-type: none"> • National Tuberculosis Control Programme (NTP) • Ministry of Health(MOH)
Rationale: use for decision-making (strategic)	Evaluation of self-sufficiency
Rationale: use for decision-making (operational)	Indicates how budget for TB drugs needs to be developed (or to what extent donated product is needed to implement national program)
Data requirements	1) Annual MOH TB drug budget 2) Estimate of the annual quantity of TB drugs needed by the MOH/NTP
Source of required data	1)NTP –NTP coordinator – estimation of the annual quantity of TB drugs needed by the MOH/NTP 2) MOH - chief of the economical planning and accounting department - estimated budget spending for TB drugs, pre-approved by Min of Finance
Current practice	1) NTP <ul style="list-style-type: none"> • computes the annual MOH TB needs 2) MOH <ul style="list-style-type: none"> • has data concerning the total budget and estimated budget spending, inclusive for TB drugs, pre-approved by Ministry of Finance
Method of collecting required data	NTP : <ul style="list-style-type: none"> • Interview the chief of the economical planning concerning the estimated budget spending for TB drugs • Estimate the annual quantity of TB drugs needed by using appropriate quantification bases and price data base.
Indicator calculation	Variable(A): Annual MOH TB drug budget Variable(B): Annual MOH TB drug needs Formula: $A*100/B$
Frequency of reporting	Annual

<p>Gaps in data collection</p> <p>What needs to be done to collect data effectively and efficiently</p>	<ul style="list-style-type: none"> • Unqualified quantifications of drug needs • Lack of base data about medium prices for anti- TB drugs of the pharmaceutical market <p>NTP:</p> <ul style="list-style-type: none"> • Update the standard treatment scheme according to international standard • selection of most appropriate quantification method • developing the abilities of using quantifications methods <p>NIP:</p> <ul style="list-style-type: none"> • to establish a price data base for TB drugs
<p>Target</p>	<p>The optimal result is 100 %.</p>
<p>Comments</p>	<p>The result will reflect full commitment by and self sufficiency of the MOH in addressing TB drug needs for the national tuberculosis control programme.</p>

Indicator #15: Months of buffer stock available (C) C = central level	
Definition	Months of buffer stock available is the capacity of current buffer stock at the central level to cover anti- TB drugs necessity represented by number of months.
Rationale: users of indicator	<ul style="list-style-type: none"> • National Tuberculosis Programme (NTP) • Ministry of Health (MOH) • National Institute of Pharmacy (NIP) • Pharmaceutical warehouse (ex .Sanfarprim)
Rationale: use for decision-making (strategic)	To measure the capacity of the procurement unit and the efficiency of inventory management to ensure continuous anti- TB drug supply through the prevention of stock outs.
Rationale: use for decision-making (operational)	Effective maintenance of stock levels to avoid stock-outs Minimize stock holding
Data requirements	<ol style="list-style-type: none"> 1) List of anti-TB drugs 2) Data of annual consumption and average consumption per month for anti-TB drugs 3) Stock on hand
Source of required data	<ol style="list-style-type: none"> 1) NTP – person in charge of anti -TB drug management –quarterly reports 2) Pharmaceutical Warehouse – chief of the Marketing Department - quarterly reports concerning stock on hand
Current practice	Collected data are not complete.
Method of collecting required data	NTP: <ul style="list-style-type: none"> • Review and obtain the annual consumption for anti-TB drugs, average consumption per month and stocks on hand based on the quarterly reports of warehouse
Indicator calculation	Variable(A): Stock on hand at central level Variable(B): Average consumption per month Formula: A/B
Frequency of reporting	Twice per year.
Gaps in data collection	<ul style="list-style-type: none"> • Inadequate calculation method and indicators using: average consumption per month, stock on hand • Inaccurate quarterly reports.
What needs to be done to collect data effectively and efficiently	Warehouse: <ul style="list-style-type: none"> • improve reports practice, NTP: <ul style="list-style-type: none"> • accurate determination of average consumption per months • have a clear image about term,, stock on hand,, • receive a precise information about stock on hand
Target	
Comments:	Availability of anti-TB drug stock for 6 month without replenishment will avoid the danger of uninterrupted drug dispensing.

Indicator #16: Months of buffer stock available at TB facilities	
Definition	Months of buffer stock available is the capacity of current buffer stock at the TB facilities level to cover anti- TB drugs necessity represented by number of months. Average consumption per month is consumption figures for a period divided by the number of months in that period.
Rationale: users of indicator	<ul style="list-style-type: none"> • National Tuberculosis Programme (NTP) • TB facilities
Rationale: use for decision-making (strategic)	To measure the efficiency of inventory management and distribution system to ensure continuous anti- TB drug supply through the prevention of stock outs.
Rationale: use for decision-making (operational)	<ul style="list-style-type: none"> • Effective maintenance of stock levels • Minimize stock holding
Data requirements	<ol style="list-style-type: none"> 1) List of TB drugs 2) Stock on hand 3) List of annual consumption and average consumption per month for TB drugs
Source of required data	<ol style="list-style-type: none"> 1)NTP <ul style="list-style-type: none"> – person in charge of anti -TB drug management –quarterly reports 2) TB facilities <ul style="list-style-type: none"> - rayon TB coordinator– quarterly report and evidence register.
Current practice	Data collection is partly.
Method of collecting required data	PNCT <ul style="list-style-type: none"> • Review the quarterly reports of health facilities and obtain the annual consumption for anti-TB drugs, average consumption per month and stocks on hand.
Indicator calculation	<i>Variable(A):</i> Stock on hand <i>Variable(B):</i> Average consumption per month <i>Formula:</i> A/B
Frequency of reporting	Quarterly
Gaps in data collection	<ul style="list-style-type: none"> • Inadequate calculation method and indicators using: average consumption per month, stock on hand, • Inaccurate quarterly reports.
What needs to be done to collect data effectively and efficiently	<ul style="list-style-type: none"> • improve reports practice, • accurate determination of average consumption per months, • have a clear image about term,, stock on hand,, receive precise information about stock on hand, accurate information of TB physicians by the medical staff from the ,health center or family doctor office about anti-TB drug consumption
Target	
Comments:	A 3 month of buffer stock available at the rayon level is an optimal result to avoid the danger of uninterrupted drug dispensing.

Indicator #17: Percentage of new smear positive patients with pulmonary TB who received full unchanged regimen of treatment in intensive and continuous phase.	
Rationale: users of indicator	<ul style="list-style-type: none"> National Tuberculosis Control Programme (NTP) TB facilities
Rationale: use for decision-making (strategic)	Ensure application of standard treatment
Rationale: use for decision –making(operational)	Monitoring of treatment guidelines implementations
Data requirements	<ol style="list-style-type: none"> Total number of new smear positive pulmonary TB cases who received full unchanged regimen of treatment in intensive and continuous phase Total number of new smear positive pulmonary TB
Source of required data	<ol style="list-style-type: none"> NTP - coordinator -standard treatment regimens TB facilities - TB physicians- Patients records and quarterly reports
Current practice	<p>NTP:</p> <ul style="list-style-type: none"> collects data about the total number of new smear positive pulmonary TB cases, based on quarterly report of TB facilities (TB form 08). Total number of new smear positive pulmonary TB cases who received full unchanged regimen of treatment in intensive and continuous phase is not collected.
Method of collecting required data	<p>TB Health facilities:</p> <ul style="list-style-type: none"> Examine the patients records and fill in the reports form <p>NTP:</p> <ul style="list-style-type: none"> Review the reports form <p>Comments from group: Re data collection: Patient form #089/1 can serve as source, but has the same information as TB01.</p>
Indicator calculation	<p>Variable(A): Total number of new smear positive pulmonary TB cases who received full unchanged regimen of treatment in intensive and continuous phase</p> <p>Variable(B): Total number of new smear positive pulmonary TB cases</p> <p>Formula: $A*100/B$</p>
Frequency of reporting	Quarterly

<p>Gaps in data collection</p> <p>What needs to be done to collect data effectively and efficiently</p>	<ul style="list-style-type: none"> • Inaccurate patients records; • Lack of daily registration of TB drugs prescription • Lack of staff knowledge • Reporting standard form is not fill in <p>TB health facilities:</p> <ul style="list-style-type: none"> • correct records of TB patients on categories • precise examination of the patients records • accurate fill in the report form, • to have an evidence register of permanent use of drugs. <p>NTP:</p> <ul style="list-style-type: none"> • improve report form TB 0-89/1
<p>Target</p>	<p>The result 100% will reflect the medical staff capacity in correct diagnosis of the patient, prescribing drugs according to the standard treatment; upholding the standard treatment concept.</p>
<p>Comments</p>	

Indicator #18: Percentage patients with pulmonary TB with confirmed adverse reactions to TB drugs.	
Rationale: users of indicator	<ul style="list-style-type: none"> • National Tuberculosis Control Programme (NTP) • TB facilities • National Institute of Pharmacy (NIP)
Rationale: use for decision-making (strategic)	Assess the medical staff capacity to prescribe appropriate standard treatment and TB drug quality
Rationale: use for decision-making (operational)	<p>Checking the using patterns of drugs, drug prescribing practice</p> <p>Developing the following system of the adverse reactions on TB drugs</p>
Data requirements	<p>1) Total number of patients with pulmonary TB with confirmed adverse reactions to TB drugs</p> <p>2) Total number of patients with pulmonary TB registered.</p>
Source of required data	<p>1) NTP -coordinator NTP – report forms</p> <p>2) TB facilities - TB physicians -Patients records and Registration card of the drug adverse reactions,</p> <p>3) National Institute of Pharmacy - Pharmacovigilance Laboratory-Registration card of the drug adverse reactions</p>
Current practice	<ul style="list-style-type: none"> • NTP doesn't collect data about the number of patients with pulmonary TB with confirmed adverse reactions to TB drugs • TB facilities do not report on adverse reaction to TB drugs
Method of collecting required data	<p>TB facilities:</p> <ul style="list-style-type: none"> • examine the patients treatment record • fill in the registration card of the drug adverse reactions, • record the number of patients with pulmonary TB with confirmed adverse reactions to TB drugs • send the data through reporting forms <p>NTP:</p> <ul style="list-style-type: none"> • review the quarterly reports
Indicator calculation	<p>Variable(A): Total number of new smear positive patients with pulmonary TB with confirmed adverse reactions to TB drugs</p> <p>Variable (B): Total number of new smear positive patients with pulmonary of TB registered.</p> <p>Formula: $A*100/B$</p>
Frequency of reporting	Quarterly

<p>Gaps in data collection</p> <p>What needs to be done to collect data effectively and efficiently</p>	<ul style="list-style-type: none"> • inadequate training in determining and registration of adverse drug reactions • current report form doesn't provide the space for drug adverse data; • the registration card of the TB drug adverse reactions are not filled in <p>NIP-NTP</p> <ul style="list-style-type: none"> • to implement the communication mechanism of reporting adverse drug reactions, • to introduce report card of adverse reactions which will be fill in by TB patients • to attach the report card of adverse reactions to the TB patient's record <p>NTP</p> <ul style="list-style-type: none"> • to educate patients to communicate the adverse drug reactions • medical staff should have knowledge about adverse TB drug reactions • introduce updated form 0-89/1 <p>TB cabinet</p> <ul style="list-style-type: none"> • to introduce a register for registration of patients with adverse TB drug reactions • fill in the report card of adverse reactions
<p>Comments:</p>	<p>Comments from group:</p> <p>Gaps: Data about adverse side effects are not sent. There is a special card for information about side effects. This is not used and should be attached to the treatment card. Modify and simplify card for side effects that could be used by patient.</p>

Indicator #19: Percentage of patients with pulmonary TB whose regimen was altered due to confirmed adverse reactions to TB drugs.	
Rationale: users of indicator	<ul style="list-style-type: none"> National Tuberculosis Control Programme (NTP) TB facilities
Rationale: use for decision-making (strategic)	Elaboration of the alternative standard treatments
Rationale: use for decision-making (operational)	Developing the capacity of drug use.
Data requirements	1) Total number of patients with pulmonary TB whose regimen was altered due to confirmed adverse reactions to TB drugs 2) Total number of patients with pulmonary TB
Source of required data	1) NTP -NTP coordinator – standard treatment 2) TB facilities -TB physicians –patients records and record registers
Current practice	NTP doesn't collect requested data
Method of collecting required data	TB facilities: <ul style="list-style-type: none"> Examine the patients records and fill in the reports form NTP: <ul style="list-style-type: none"> Review the TB health facilities' reports form
Indicator calculation	Variable(A): Total number of patients with pulmonary TB whose regimen was altered due to confirmed adverse reactions to TB drugs Variable(B): Total number of patients with pulmonary TB Formula: $A*100/B$
Frequency of reporting	Quarterly
Gaps in data collection What needs to be done to collect data effectively and efficiently	<ul style="list-style-type: none"> Inefficient records of patients with pulmonary TB with adverse drug reactions Inefficient records of patients with pulmonary TB whose regimen was altered due to confirmed adverse reactions to TB drugs <ul style="list-style-type: none"> TB physicians and NTP: <ul style="list-style-type: none"> to record exactly of patients with pulmonary TB with adverse drug reactions, to apply register card of the drug adverse reactions, to fulfill permanently the register card of the drug adverse reactions, to note separately the patients with pulmonary TB from those whose regimen was altered due to confirmed adverse reactions to TB drugs
Target	
Comments	

Appendix 4: Proposed Indicators for Moldova NTP M&E System

Description	Comments
Indicators for which data is readily available in existing information flows or systems	
Percentage of TB drugs used in NTP and included on the National Essential Medicines List (C)	
Percentage of TB drugs used in NTP and included on the WHO Essential Medicines List (C)	
Percent of annual MOH TB drug needs met by annual MOH TB drug budget (C)	
Percentage of median international price paid for a set of TB drugs that was part of the last regular procurement. (C)	
Indicators for which data is available but requires effort to collect (for example: reviewing individual patient records to identify those with adverse reactions)	
Percentage of TB drugs used in NTP that are registered in the country	<p>The Humanitarian Aid Commission of the MOH collects the documents which on it is base drugs are imported as a donation for all drugs and they are separated by: the donors or entry period of time (monthly), but not by pharmacological groups. Sometimes one consignment could contain different kind of drugs and their names are listed together in the accompanying documents.</p> <p>So, to obtain the data about the anti -TB drugs imported as a donation and to know their manufacture is required to review all accompanying documents.</p>
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)	<p>QCDL has the list of all drugs samples tested during the past year and the list of all drugs samples that failed quality control testing, published only by the brand name, which creates difficulties to select of those that are anti- TB drugs.</p>

<p>Percentage of TB drug shipments received at the contracted delivery date for the last three procurements. (C)</p>	<p>The following data: contracted delivery terms, payment, the expected arrival dates of shipments (30 days after prepayment), actual delivery dates are not kept in one recording register but can be founded by reviewing different documents from different departments of the MOH.</p>
<p>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</p>	<p>The following data: submitted date of order to procurement office and actual delivery date are not kept in one recording register but can be founded by reviewing different documents from different departments of the MOH.</p>
<p>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</p>	
<p>Percentage of new smear positive patients with pulmonary TB who received full unchanged regimen of treatment in intensive and continuation phase</p>	<p>It is necessary to review treatment card (TB 08) to identify those who received full unchanged regimen of treatment in intensive and continuation phase</p>
<p>Percentage of new smear positive patients with pulmonary TB with confirmed adverse reactions to TB drugs</p>	<p>It is necessary to review individual patient records to identify those with confirmed adverse reactions</p>
<p>Percentage of new smear positive patients with pulmonary TB whose regimen was altered due to confirmed adverse reactions to TB drugs</p>	<p>It is necessary to review individual patient records and treatment card (TB 08) to identify those whose regimen was altered due to confirmed adverse reactions to TB drugs</p>
<p>Value of expired drugs last quarter (year)</p>	<p>If we know about some expired drugs from the existing report system we can not obtain the value of expired drugs. The quarterly report doesn't reflect separately quantities and the supply sources. So we couldn't know (at the NTP level) what price to use for calculation: centralized tender price, local tender price (which is known only at the rayonal level), price for donated</p>

	drugs (we can obtain the accompanying documents for donated drugs from MOH, but if the indicated price are very high, the rayonal health facilities may change it and indicate the price which is on the market for the same drug or symbolic price). Data is available to be collected but requires efforts or some changes of the quarterly report.
Months of buffer stock available (C)	It is necessary to review recording tools to obtain average consumption per month and stock on hand.
Months of buffer stock available (F)	
Indicators for which data is NOT currently collected or shared and hence new procedures will need to be established	
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)	The individual batch certificate meeting the requirements of the WHO Certification Scheme is not required by DRA.
Average percentage of stock records that correspond with physical counts for a set of TB tracer drugs in TB storage facilities. (C/R/F)	The Monitoring and Evaluation Department of NTP makes physical counts of anti-TB drugs stored at the health facilities within monitoring visits (<u>doesn't make at the central warehouse</u>), but the information note regarding the monitoring results doesn't contain the figures about the total number of products that are stocked and examined and the stock records with No discrepancies. The results of physical count are reflected only by expression "all anti -TB drugs are book-kept".
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)	Currently data are not collected.
Average percentage of a set of unexpired TB tracer drugs available in TB facilities and medical stores (C/R/F)	

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