PROGRESS REPORT

TO THE UNITED STATES AGENCY FOR INTERNATIONAL DEVELOPMENT

FROM THE STOP TUBERCULOSIS DEPARTMENT OF THE WORLD HEALTH ORGANIZATION ON THE ADVANCED DEVELOPMENT OF THE TUBERCULOSIS CONTROL PROJECT IN THE RUSSIAN FEDERATION

June – November 2006

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LIST OF ATTACHMENTS

GLOSSARY

ACSM	Advocacy, Communication, Social Mobilization
AIDS	Acquired Immunodeficiency Syndrome
CDC	Centers for Disease Control and Prevention
CTRI RAMS	Central Tuberculosis Research Institute of the Russian Academy of Medical Sciences
DOTS	Directly Observed Treatment, Short-course
DRS	Drug Resistance Surveillance
DST	Drug Susceptibility Testing
FQ	Fluoroquionolones
FCEQA	Federal Centre of External Quality Assurance in Laboratory Medicine
FCS	Federal Correctional Service
FILHA	Finnish Lung Health Association
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GHC	General Health Care
GLC	Green Light Committee
GMP	Good Manufacturing Practice
HIV	Human Immunodeficiency Virus
HLWG	High Level Working Group
ICC-TB	International Interdepartmental Coordination Committee on Tuberculosis
IFRC	International Federation of Red Cross and Red Crescent Societies
KNCV	Royal Netherlands Tuberculosis Foundation
LHL	Norwegian Heart and Lung Association
MDGs	Millennium Development Goals
MDR-TB	Multidrug-resistant Tuberculosis
MoH	Ministry of Health of the Russian Federation
MoHSD	Ministry of Health and Social Development of the Russian Federation (former MoH)
NTP	National Tuberculosis Programme
NTRI	Novosibirsk Tuberculosis Research Institute
OTBD	Oblast TB Dispensary
PATH	Programme for Appropriate Technology in Health
PT	Proficiency Testing
PIH	Partners in Health
RF	Russian Federation
RHCF	Russian Health Care Foundation
RIPP MMA	Research Institute of Phthisiopulmonology of Sechenov Moscow Medical Academy
SP RIPP	St. Petersburg Research Institute of Phthisiopulmonology
TB	Tuberculosis
TWG	Thematic Working Group
UNION	International Union against Tuberculosis and Lung Disease
URIPP	Ural Research Institute of Phthisiopulmonology
USAID	United States Agency for International Development
WB	World Bank
WHO	World Health Organization
WHO/EURO	World Health Organization Regional Office for Europe
WHO/HQ	World Health Organization headquarters

1. GENERAL INFORMATION

1.1. Project title

Advanced Development of the Tuberculosis (TB) Control Project in the Russian Federation (RF).

1.2. Timeframe of the project

27 August 1999 – 31 December 2008.

1.3. Project sites

Ivanovo Oblast, Orel Oblast, Vladimir Oblast, the Russian Republic of Chuvashia, Central TB Research Institute of the Russian Academy of Medical Sciences (CTRI RAMS), Research Institute of Phthisiopulmonology of Sechenov Moscow Medical Academy (RIPP MMA).

1.4. Reporting period

1 June – 30 November 2006.

2. EXECUTIVE SUMMARY

This document describes the progress made in implementing the WHO TB Control Programme in the RF during the six-month period from 1 June to 30 November 2006. The implementation of the Programme is financially supported by the United States Agency for International Development (USAID). This report presents the main activities carried out during the above-mentioned period, states the achievements, and describes the challenges and the next steps in the project.

Capacity-building and institutional support for a sustainable TB control model was pursued by continued active cooperation with the Russian Government through the mechanism of the High Level Working Group on TB in the RF (HLWG) and a number of Thematic Working Groups (TWGs) established under the HLWG umbrella. The HLWG liaised with the Russian Ministry of Health and Social Development (MoHSD) and the Federal Correctional Service (FCS) regarding the implementation of a comprehensive External Review of Internationally Supported TB Control Projects in the RF, which took place with the Programme's financial and logistical support from 3 to 14 July 2006. The Review activities consisted of evaluation missions to several Russian regions implementing TB control activities with international support and interviews at different levels, including questioning of high-level Russian health authorities and international partners working in Russian TB control.

The importance of the Review activities was underlined during the 13th HLWG meeting held on 13 July 2006. Preliminary results from the Review evidenced that TB control projects with international support facilitated the exchange of expertise, knowledge and technology transfer in Russia. They collected evidence for the introduction and expansion of revised TB control and new approaches suitable for the Russian context. However, the quality of the implemented revised TB control activities in the country and remaining divergences between Russian and international approaches to active case-finding, management of multidrug-resistant TB (MDR-TB) and TB monitoring challenge the effective implementation of the country plan for reaching the Millennium Development Goals (MDGs).

The 4th meeting of the International Interdepartmental Coordination Committee on TB (ICC-TB) and the International Scientific and Practical Conference co-organized by the WHO TB Control Programme in the RF and the Ural Research Institute of Phthisiopulmonology (URIPP) in Yekaterinburg, Russia, from 28 November to 1 December 2006, focused on identifying the next steps that should be taken in order to improve Russian TB control in the light of the Global Stop TB Partnership's strategic plans for 2006-2015.

The assistance given by the Programme to the Russian Government, the Russian Health Care Foundation (RHCF) and federal TB research institutes with implementation of the World Bank (WB)-supported project was recognized during the Mid-term Review of the project by the WB team from 2 to 13 October 2006. The Review resulted in a positive appraisal, and among other outcomes, it recommended that the WHO TB Control Programme in the RF should continue its assistance with training, planning and monitoring activities within the project.

The Programme continued with its assistance to the RHCF in DOTS-Plus expansion in the framework of the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM)-supported project. These activities focused on technical assistance to Russian regions with applying to the Green Light Committee (GLC), and consultancy and training of regional staff in international principles of managing MDR-TB patients. Twelve Russian regions received GLC approval to implement DOTS-Plus projects in 2007. It is urgent that the Programme continue its technical assistance to Russian regions with DOTS-Plus implementation and the establishment of MDR-TB centres of excellence in the civilian and prison sectors.

Special attention was given by the Programme to strengthening the national capacity for rational drug management. The goal of the activities performed was to facilitate Good Manufacturing Practice (GMP) certification for Russian manufacturers of anti-TB products and increase their knowledge of the Global Drug Facility (GDF) procedures. The Programme provided technical support and invited facilitators from WHO headquarters (WHO/HQ) and the WHO Regional Office for Europe (WHO/EURO) to take part in three workshops on drug management and GMP certification conducted during the period for about 70 representatives from eight Russian anti-TB drug manufacturers. WHO also participated in the work of the Expert Committee, which selected Russian candidates for GMP inspection.

During the reporting period, the Programme actively cooperated with the Federal Centre of TB Care for HIV-infected Persons in the development of training curricular in TB/HIV collaborative activities, national recommendations on TB control among the HIV-infected population, and the first Bulletin on TB Control among People with HIV-infection. The Programme intends to produce the Bulletin on a semi-annual basis to highlight major national and international approaches to TB/HIV control and the progress of the GFATM-supported project in this field in Russia.

The joint DOTS and DOTS-Plus pilot project supported by WHO through USAID funds (Orel and Vladimir Oblasts and the Republic of Chuvashia) facilitated the expansion of revised TB control in the country. During the reporting period, a new system of targeted social support for TB patients was launched in the pilot projects, based on the results of the operational research that was conducted by the Programme and RIPP MMA in 2004-2005. The regions have cooperated with WHO and CTRI RAMS on the establishment of the TB Demonstration Centre in Orel Oblast and the Infection Control Demonstration Centre in Vladimir Oblast to disseminate the lessons learned and international recommendations on TB control. Preparations were made for launching operational research on performance-based incentives for TB and GHC staff in the WHO pilot projects, with potential expansion to several other Russian regions in order to increase the overall effectiveness of TB detection and treatment in Russia. Regional training activities continued with USAID financial support, based on the revised WHO training modules on managing TB at the district level and new modules on unified methods of microscopy testing for acid-fast bacilli (AFB) intended for laboratory staff in the general health care (GHC) service.

The current project covers a broad range of activities that respond to the challenges of TB, MDR-TB and TB/HIV in the country. However, several reviews performed during the reporting period by international and national experts demonstrated that much needs to be done to improve the expansion and quality of the revised TB control strategy in the country and achieve the MDGs, so continuous support from the international community and WHO technical assistance are necessary to overcome the remaining challenges in national TB control.

3. BACKGROUND INFORMATION

3.1. Epidemiological situation

The TB notification rate in Russia in 2005 reached 83.8 per 100 000 (source: federal surveillance of TB patients). Despite the stabilization of TB notification rates in the country, TB mortality remained relatively high and constituted 22.5 per 100 000 in 2005 (source: federal surveillance of TB patients). This number is highest among the age group of 24-45 (46.9-47.1 per 100 000), which demonstrates the unfavourable TB situation in the country.

Multidrug-resistant tuberculosis (MDR-TB) in Russia

According to Russian MoHSD statistics, the proportion of new TB cases diagnosed with MDR-TB in the civilian sector increased from 8.1% (2004) to 9.5% (2005), while the proportion of all (new and re-treated) TB cases diagnosed with MDR-TB increased from 16.5% (2004) to 18.7% (2005). In cumulative figures, 22 820 MDR-TB cases (among all sputum-positive TB patients) were registered at the end of 2005, with 4167 new cases (source: federal surveillance of TB patients). However, care must be taken when interpreting the data due to the remaining inadequacies of the national TB laboratory services, standards and quality.

TB epidemiology in Russian prisons

The TB situation in the prison sector has shown a steady improvement over the last five years. The absolute number of TB cases decreased from 98 767 (2001) to 48 370 (2005). The TB notification rate decreased from 1614 (2004) to 1591 (2005) and mortality from 118 (2004) to 103 (2005) per 100 000 inmates. In 2005 the absolute number of cases of HIV-infection in the prison sector was 35 317 and the number of TB/HIV cases was 2566. These rates have remained stable over the last few years. However, 17.8% among new and 32.9% among re-treated cases were diagnosed with MDR-TB in 2005 (source: FCS surveillance of TB inmates).

HIV and its possible impact on the TB epidemic in Russia

According to the Federal Centre of TB Care for HIV-infected Persons, the cumulative number of people with HIV infection registered in the country increased within one year from 297 988 (2004) to 333 730 (2005). The number of HIV-related deaths during the same period increased from 7093 to 8157.

3.2. Expansion of the WHO TB control strategy in the RF

Following the objectives of the project, the WHO TB Control Programme in the RF continued with technical assistance to the Russian Government in DOTS and DOTS-Plus expansion in cooperation with international and Russian partners and using the lessons learned from the WHO pilot projects.

Supported by the Programme and the WB and GFATM projects, 83 out of 86 Russian regions have now implemented the revised components of TB control following WHO recommendations (90% population coverage). Throughout the period, the Programme facilitated the expansion of the new recording and reporting system for TB introduced by Prikaz # 50, which is in accordance with international recommendations. As the results for 2005, 67 Russian regions submitted TB notification data and 29 submitted data on treatment outcomes to federal monitoring centres using the new recording and reporting forms.

With the Programme's support, the TWG on Surveillance and Monitoring adjusted two forms from the existing Russian surveillance documentation (# 8 and # 30-4/y), so that they report data on TB/HIV cases and patient follow-up. The Federal Statistics Committee approved these forms in early 2006. The new reporting format is hoped to improve the system of HIV surveillance among TB patients in the country.

The TWG on Laboratory Diagnosis of TB, which includes WHO experts, leads the development of new guidelines and training modules for GHC and TB laboratory staff. The technical manual "Unified Methods of Microscopy Testing for Acid-Fast Bacilli", intended for clinical and diagnostic laboratory staff in GHC services, has been approved and is expected to be published in 2007. The draft guidelines entitled "Microscopy Testing for Acid-Fast Bacilli" were submitted to the Russian MoHSD for finalization and approval. Training modules on culture, identification and DST are currently under preparation and are expected to be finalized in early 2007.

Since June 2005, three rounds of proficiency testing (PT) for drug susceptibility testing (DST) of *M. tuberculosis* have been conducted in selected TB laboratories in Russia. The PT project was initiated by WHO in collaboration with the TWG on Laboratory Diagnosis of TB, the Swedish Institute for Infectious Disease Control in Stockholm (supranational reference laboratory and WHO collaborating centre), and the Federal Centre of External Quality Assurance in Laboratory Medicine (FCEQA). The PT results will help identify the Russian laboratories that are capable of conducting high quality DST; they will take part in the global Drug Resistance Surveillance (DRS) project initiated by WHO/HQ in 2005, and underpin the expansion of a reliable EQA system in the RF. Twenty Russian laboratories were tested during the first PT round from November 2005 to January 2006 and thirty were tested during the second PT round in April 2006.

Through the Programme's efforts, operational research conducted in seven Russian regions, including WHO pilot sites, provided evidence for the development of a special social support programme tailored to manage risk groups of TB patients. Based on the research findings, five articles were prepared and submitted for publication in the international and national press. Using this evidence, the Programme has also been looking at ways of establishing performance-based remuneration for staff involved in early detection and successful treatment of infectious TB patients in Russian regions.

4. PROJECT GOAL

The overall goal of the project is to reduce TB morbidity and mortality, prevent disease transmission and stop the development of drug-resistant forms of TB in the community.

5. PROJECT OBJECTIVES

The project has the following specific objectives:

1. Capacity-building and institutional support for a sustainable TB control model at the regional and national levels;
2. Assistance to the Russian Government with DOTS expansion through the WB-supported project on TB and AIDS control;
3. Assistance to the Russian Health Care Foundation, the Principal Recipient, with DOTS and DOTS-Plus expansion through the GFATM project on promoting the strategic response to TB treatment and care for vulnerable populations in the Russian Federation;
4. Development of a sustainable regional model of TB/HIV control;
5. Assistance with the development of a sustainable regional model for DOTS and DOTS-Plus;
6. Assistance with the revision of the national anti-TB drug policy;
7. Information, education and communication strategy to strengthen diagnosis and treatment outcome results.

6. TARGET GROUPS

1. TB patients in Categories I, II and III, according to WHO definitions, in four designated oblasts, and Category IV (MDR-TB) in Orel and Ivanovo Oblasts;

2. National TB control service personnel in four designated oblasts;
3. Designated federal TB research institutes.

7. PROGRESS TO DATE

7.1. Capacity-building and institutional support for a sustainable TB control model at the regional and national levels

The WHO TB Control Programme in the RF pursued its active cooperation with the Russian Government and federal TB institutions through the HLWG mechanism and collaboration with the governing authorities in the health sector at different levels.

From 3 to 14 July 2006, the Programme took part in the comprehensive External Review of Internationally Supported TB Control Projects in the RF in the context of 10 years of international collaboration. The Review was initiated by international partners and approved by HLWG members during its 12th meeting on 13 December 2005. WHO and the Open Health Institute (OHI) co-organized the Review with support from a number of international agencies. The objectives of the Review were to:

a. assess the progress made in TB control during the period 1994-2005 with emphasis on the role of international projects;
b. summarize the experience, lessons learned and methods of work used for achieving success within TB control projects with international cooperation;
c. study the sustainability of effects produced by projects with international cooperation;
d. develop recommendations for ministries and proposals for donor and technical organizations upon the results of the Review.

Experts from such international agencies as USAID, the Royal Netherlands Tuberculosis Foundation (KNCV), the New Jersey Medical School National TB Center, WHO Regional Office for Europe, Stop TB Partnership and the WHO/HQ Stop TB Department, took part in the Review. They cooperated with TB specialists-observers from FCS, CTRI RAMS, RIPP MMA, Novosibirsk TB Research Institute (NTRI) and St. Petersburg Research Institute of Phthisiopulmonology (SP RIPP).

From 2 to 6 July 2006, the Review participants visited five Russian regions (Archangelsk, Vladimir, Tomsk and Samara Oblasts and the Republic of Khakassia) and interviewed representatives from regional health departments, civilian and prison TB services and the GHC service. From 10 to 11 July 2006, the participants conducted interviews at the federal level and met with partner organizations. This included meetings with representatives of the Russian MoHSD, the Federal Service for Healthcare and Social Development, FCS, FCEQA and RHCF, along with interviews of representatives from the WB, Partners in Health (PIH), International Federation of Red Cross and Red Crescent Societies (IFRC) and GFATM. From 12 to 14 July 2006, an additional mission was performed to Tula Oblast. This region has implemented a TB control programme without international support and its results were used for comparison analysis.

On 13 July 2006, the HLWG held its 13th meeting. The preliminary results of the Review were on the agenda. At this meeting the participants acknowledged the impact of international collaboration and support on TB control in Russia. They emphasized that the most important aspects of the projects with international partners were expertise, knowledge exchange and technology transfer. These projects produced evidence for the introduction and expansion of revised TB control and new approaches suitable for Russia. They also served as a catalyst for expanding revisions and provided leverage for significant budget increases (federal and regional). Among the remaining issues on the meeting agenda were the efforts of the Global Stop TB Partnership and the Russian TB community to raise the profile of TB control at the G8 Summit held from 15 to 17 June 2006 in St. Petersburg, as well as the establishment of a new TWG on Infection Control and the need for national guidelines on managing MDR-TB in line with international recommendations.

From 9 to 10 November 2006, Programme experts took part in the roundtable meeting on Approaches to Monitoring the TB Epidemic co-organized by the WHO TB Control Programme in the RF and the Chief TB Expert of the Russian MoHSD, Academician Perelman. This meeting aimed to harmonize some approaches related to TB detection, monitoring and global reporting, which at present differ in the Russian and international TB communities. The international TB community was represented by TB specialists from WHO/HQ, the Foundation for Innovative New Diagnostics, the Norwegian Heart and Lung Association (LHL) and the New Jersey Medical School. Representatives of the Russian MoHSD, the Central Research Institute for TB Statistics, as well as the heads of all TB research institutes, attended the meeting to share knowledge and practices existing in Russia with their international counterparts. As a result of the meeting, a summary of recommendations was developed that would be shared with partners at the next HLWG meeting in February 2007.

On 28 November 2006, the 4th ICC-TB meeting was co-organized by the WHO TB Control Programme in the RF and URIPP in Yekaterinburg. The participants reviewed the progress achieved since the previous meeting (Novosibirsk, 10 November 2004) and the challenges faced by the RF in pursuing the MDGs. As a result, they identified the following steps that should be supported by national and international partners:

- Improve the quality of the implemented revised TB control activities in accordance with DOTS principles (complete DOT coverage; complete recording and reporting based on cohort analysis, etc.).
- Sustain the positive implementation of the Five-year National Plan to Stop TB in 2002-2006 by establishing a TWG and developing a National Plan to Stop TB in 2007-2015 in order to reach the MDGs.
- Increase the response and derive effective strategies to address the challenges posed by the emerging threats of MDR & XDR-TB, HIV and TB/HIV.
- Contribute to health system strengthening with special focus on laboratory capacity in order to expand quality assured culture examinations, DST and DRS.
- Increase and broaden the involvement of federal TB research institutes, the Federal Service for Public Health and Social Development, and all other respective bodies at the Russian MoHSD in the planning, monitoring and evaluation activities performed by the RHCF with WHO's assistance within the WB- and GFATM-supported projects.
- Promote human resource development (international collaboration in education and training; new training curricula, etc.).
- Promote the engagement of all care providers and communities in TB control (strengthened training on TB for GHC staff; social mobilization; peer-to-peer activities, etc.).
- Promote and support operational research in TB control.

The ICC-TB meeting was followed by the International Scientific and Practical Conference, "Prioritized Areas to Ensure Effectiveness of TB Control in Today's Social and Epidemiological Environment", Yekaterinburg, 28 November to 1 December 2006. The WHO TB Control Programme in the RF provided logistical and financial support for the event. About 200 delegates from all over the country, including representatives from all Russian regions (civilian and prison sectors), the Russian MoHSD, FCS, RHCF, federal TB research institutes and federal TB university departments, took part in the conference. Also participating were international partners, including the US Centers for Disease Control and Prevention (CDC), Médecins sans Frontières Belgium, Médecins sans Frontières Holland, Project HOPE in Uzbekistan, USAID, IFRC, PIH, LHL and WHO.

During the conference, the participants elaborated on the recommendations from the ICC-TB meeting (28 November 2006). There remain certain divergences between the approaches used in the Russian and international TB communities in such areas of TB control as active case-finding,

MDR-TB treatment and TB monitoring. There is an urgent need to continue with efforts to move towards a consensus regarding these issues in the light of the Stop TB Partnership's strategic directions and objectives for 2006-2015.

The above-mentioned activities contributed to motivating partners to improve the quality of the implemented revised TB control strategy in the country. It was also recognized that there is a need to enhance international cooperation in those areas of TB control which challenge the effective implementation of the country plan for reaching the MDGs.

7.2. Assistance to the Russian Government with DOTS expansion through the WB-supported project on TB and AIDS control

According to the agreement with the RHCF, the Programme continued to provide technical assistance to the country with the implementation of the WB-supported project. This included:

- Assistance with implementing the Mid-term Review of the project
- Assistance with establishing EQA mechanisms for the laboratory network in the RF.

From 2 to 13 October 2006, the WB team led by Mr Marquez, WB Project Team Leader, performed the Mid-term Review of the project. The objectives of the Review were to assess the progress made in the project by the second semester of 2006 in terms of input, output and initial outcomes, and to determine the measures that should be taken to ensure that the project achieves its goal. WHO assisted with the preparation of the mid-term report of the project to the WB and took part in the independent external evaluation of project activities.

The Review team was nominated by the WB and worked in Moscow, Vladimir and Novosibirsk. They had a number of meetings at federal, regional and municipal levels (both in the civilian and prison sectors). On 13 October 2006, a wrap-up meeting with the Deputy Health Minister, Mr Khalfin, was held. The Coordinator of the WHO TB Control Programme in the RF was the only UN representative at the meeting.

As a result of the Review, the intermediate targets were revised and the following recommendations were made:

- Replace the key WB project performance indicator, "Levelling off or decrease of new MDR-TB cases", by "Availability of effective assessment system for DR and data of the public statistics", and "TB mortality among new cases" by "TB mortality among general population".

- Consider human resource development a crucial element for the success of the project. Prioritize training of staff at district (rayon) level. WHO could share training expenditures with the WB and GFATM.

- Undertake urgent actions to increase motivation of medical staff involved in TB control. The WHO TB Control Programme in the RF plans to pilot a model of performance-based incentives for regional staff in Vladimir and Orel oblasts through potential expansion to other regions and a possible WB grant.

- Facilitate supervision and monitoring of the project performed by the federal TB research institutes through the coordination offices established by WHO within their structure. A draft Ministerial Order to mandate these activities was prepared within the WB project with involvement of the Programme's staff and submitted to the Russian MoHSD for approval.

- Facilitate harmonization of the WB and GFATM indicators and activities through joint planning and coordination of activities by the RHCF, WHO, WB, GFATM, sub-contractors, five institutes and federal agencies.

- Strengthen the drug management system in the country.

- Continue to monitor performance of the project with the Programme's support.

The Review resulted in a positive appraisal. It was underlined that the project had advanced considerably since the second half of 2005, particularly within the TB component, with over 22 000 items of equipment procured, mainly for microscopy and culture laboratories in the civilian and prison sectors.

The RCHF signed agreements for participation in the project (TB component) with 85 out of 86 regional administrations in Russia. This cooperation implies implementation of the WHO-recommended approaches to TB control in concordance with Prikazes # 109 and # 50 and related guidelines and protocols.

Four training courses were conducted at federal TB institutes on Managing TB at the Municipal Level (NTRI, 6-10 June 2006, 75 participants; CTRI RAMS, 12-16 June 2006, 31 participants; RIPP MMA, 19-23 June 2006, 51 participants; and SP RIPP, 26-30 June 2006, 50 participants). This training curriculum, based on WHO principles and the most recent Russian regulations on TB, was recently approved by the Russian MoHSD and has been used for cascade training of Russian TB staff within the WB-supported project.

The third and final round of the PT project was implemented from September 2006 to January 2007 in collaboration with the FCEQA and the Swedish Supranational Reference Laboratory, and through technical and logistical support from the Programme. Forty laboratories at federal and regional levels have been participating. The results of the second PT round testified to the improvement of DST quality, which can be explained by improvements in the infrastructure of laboratory services and the skills of Russian laboratory staff through respective procurement and training.

7.3. Assistance to the Russian Health Care Foundation, the Principal Recipient, with DOTS and DOTS-Plus expansion through the GFATM project on Promoting the Strategic Response to TB Treatment and Care for Vulnerable Populations in the Russian Federation

The WHO TB Control Programme in the RF assists the RHCF with DOTS and DOTS-Plus expansion through the GFATM-supported project. During the reporting period, the Programme's assistance focused on the strengthening of TB/HIV control and the development of a quality assurance system for TB drugs (detailed in sections 7.4. Development of a sustainable regional model of TB/HIV control and 7.6. Assistance with the revision of the national anti-TB drug policy), and on support for the expansion of DOTS-Plus in Russian regions.

In 2006 the GLC approved seven new DOTS-Plus projects in Russia (Vladimir, Belgorod, Samara and Novosibirsk Oblasts and the Republics of Chuvashia, Khakassia and Mari-El), and Novgorod Oblast received the approval of the GLC to launch DOTS-Plus in January 2007. Therefore, 12 GLC-approved DOTS-Plus projects are to be implemented in Russia in 2007 with the enrolment of 3068 MDR-TB cases in the framework of the GFATM-supported project. The Programme has been providing technical assistance to Russian regions with applying to the GLC and further consultancy in line with international principles.

Five MDR-TB centres of excellence in the civilian sector and eight in the prison sector are to be established through the GFATM-supported project. It is urgent to prepare a set of documents that would authorize the legal status of such centres and their operation. As a practical step towards this goal, a special workshop was co-organized for 35 participants by WHO and the RHCF from 11 to 13 September 2006. The audience consisted of deputy heads of federal TB research institutes, and representatives from FCS, regional TB services, the RHCF and WHO. As a result of the workshop, a draft Regulation on the Status of an MDR-TB Centre of Excellence in the RF was prepared.

The experience of implementing social support programmes within the WHO pilot projects in Russia was used to develop a social support model in the framework of the GFATM-supported project. In the 4th Quarter of 2006, the RHCF allocated funds for regional social support. According

to their technical protocol, social support is intended for drug-sensitive TB cases (DOTS projects). Discussion was started between WHO and the RHCF to consider a possible modification of the protocol in order to include items on social support for TB patients with drug-resistant TB.

From 26 to 27 June and from 29 to 30 June 2006, two training courses on "Strengthening management competencies of TB control in Russia" were conducted for 50 participants from civilian and prison TB services in Russian regions. They were co-organized by WHO, the RHCF, and the Russian Academy of Medical Postgraduate Education. The training materials were developed by the course facilitator, Dr Kombe, USA, and facilitators from the Academy. The Programme provided logistical and financial support for this training.

The activities performed by the Programme facilitated the efforts of the RHCF in pursuing the objectives of the GFATM-supported project.

7.4. Development of a sustainable regional model of TB/HIV control

The WHO TB Control Programme in the RF invests its efforts in the process of establishing effective coordination mechanisms at the federal and regional levels to improve collaboration between the national TB and HIV/AIDS services.

As a practical step towards the accomplishment of this task, the respective TWG on TB in HIV-infected Patients developed a training course on TB/HIV collaborative activities in the framework of the WB- and GFATM-supported projects and in cooperation with leading national and international agencies in TB/HIV control. Its curriculum includes materials from WHO/HQ on the WHO European Framework for TB/HIV and the WHO-recommended interim strategy to decrease the burden of TB/HIV, modified in line with key Russian regulations on TB/HIV control. With the Programme's logistical and technical support and using this curriculum, five training courses were conducted from September to November 2006 by experts from the Federal Centre of TB Care for HIV-infected Persons and the Federal AIDS Centre. Regional TB/HIV coordinators and focal points for TB and HIV at regional health departments received this training. The overall goal was to gain the commitment of regional health authorities to supporting the recently established mechanism of TB/HIV coordinators.

The WHO TB Control Programme in the RF initiated the development of national recommendations on TB control among the HIV-infected population, which was implemented in cooperation with the Federal Centre of TB Care for HIV-infected Persons. A draft was submitted to WHO/EURO for review and will be finalized based on the comments received.

Another initiative launched with the Programme's support is the issue of the Bulletin on TB Control among People with HIV-infection. According to the plan, the Bulletin was drafted in cooperation with the Federal Centre of TB Care for HIV-infected Persons and submitted for publication. The Programme intends to produce the Bulletin on a semi-annual basis and have it provide the latest surveillance data on TB/HIV, update on the progress of the implementation of the GFATM-supported project, and highlight major national and international events and approaches in the field.

7.5. Assistance with the development of a sustainable regional model for DOTS and DOTS-Plus

The three joint DOTS project sites supported by WHO through USAID funds (Orel and Vladimir Oblasts and the Republic of Chuvashia) demonstrated a sustainable improvement in TB-related rates through effective implementation of the projects.

The joint TB control programme in Ivanovo Oblast has been scaled down. There was a serious deterioration in the political environment in Ivanovo Oblast due to the incident involving CDC staff in February 2005 and the changing of the regional administration and the Governor. Soon afterwards, in April 2005, law-enforcement officers inspected the Oblast TB Dispensary (OTBD) and confiscated financial documents and US$ 7192 cash from the OTBD safe. WHO had provided this money for implementing social support for regional TB patients in 2004 in accordance with the Agreement for Performance of Work between WHO and OTBD (dated 18 March 2004,

EU/04/049789). Although nearly two years have passed since that time, the incident has still not been resolved. In 2006 four visits were performed to Ivanovo Oblast by representatives of the Programme, CTRI RAMS and the donor agency to discuss the situation with the regional authorities and the return of the unspent funds against the above Agreement for Performance of Work between the OTBD and WHO. As a result of the lack of progress towards resolving this incident, USAID has now decided to withdraw from that aspect of the project funded by them, and not to advance any additional funds for the project. An official letter from the WHO TB Control Programme in the RF to the Governor of Ivanovo Oblast regarding the termination of the joint TB control programme in the region and the necessity to resolve the incident is currently routing in the WHO/EURO Legal Department. When approved, the letter will be delivered to the Governor with official copies to all national and international partners in this project.

On 7 June 2006, the Programme hosted a meeting of project directors from the civilian and prison services in the five WHO pilot regions, including the project in Kaliningrad oblast funded by the Swedish Agency for International Development. Representatives from WHO, USAID, FCS, RHCF, CTRI RAMS and RIPP MMA took part in the meeting. Altogether, 30 participants met to discuss the performance of the projects, the managerial and technical challenges faced and the actions needed to overcome the problems. Representatives from the supervising federal TB institutes (CTRI RAMS and RIPP MMA), the donor agency (USAID) and FCS took an active part in the discussion devoted to the launch of operational research projects in Orel and Vladimir Oblasts for piloting a model of performance-based incentives for GHC and TB staff to improve TB detection and treatment results. RHCF representatives led the discussion on coordinated interactions of several partners (RHCF, WHO, GLC and regional administrations) when implementing DOTS-Plus projects approved by the GLC. As a result of the meeting, the project directors improved their understanding of the issues discussed and the next steps in the projects.

7.5.1. WHO TB control strategy (DOTS) implementation

Ivanovo Oblast

The project has been suspended and did not provide epidemiological data on TB for the reporting period. The WHO TB Control Office in Moscow receives these data from CTRI RAMS, which supervises the region and collects the quarterly reports in accordance with Prikaz # 50.

- TB detection by smear microscopy remained insufficient in the civilian sector and did not exceed 54.4% in the 2nd Quarter of 2006. Culture confirmation of TB also remained suboptimal and was 70.9% among all new TB cases. In the prison sector TB detection by microscopy varied from 33.3% (2nd Quarter 2006) to 64% (3rd Quarter 2006). Culture confirmation of TB in the prison sector did not exceed 60.6% (2nd Quarter 2006).
- The treatment success rate remained suboptimal and varied from 72.4% (1st Quarter 2005) to 69% (3rd Quarter 2005). Such results were caused by a high number of deaths, up to 17.3% (1st Quarter 2005) and failures, up to 13.7% (2nd Quarter 2005). Treatment success in the prison sector was 85.7% (2nd Quarter 2005) and 90.7% (3rd Quarter 2005). The Programme did not analyse the performance due to the suspended joint activities in the project.

Orel Oblast

- TB detection by smear microscopy continued to grow and reached 69% in the 3rd Quarter of 2006. Culture confirmation of TB remained high at around 80% (2nd Quarter 2006). In the prison sector TB detection by microscopy among smear-positive pulmonary cases varied significantly by quarter, from 45% (4th Quarter 2005) to 25% (2nd Quarter 2006), owing to the relatively small number of prisoner-patients. Culture confirmation of TB among pulmonary cases was around 45%, which is a satisfactory rate.
- The treatment success rate in new sputum smear-positive patients varied from 75% to 81% during the last four years of the project. The treatment success rate among TB patients registered in the 3rd Quarter of 2005 was the highest among all pilot projects and constituted 86.3%, reaching the global target for treatment success. The treatment success rate in

patients treated in the prison sector in the reporting period varied from 80% (1st Quarter 2005) to 76.6% (3rd Quarter 2005). However, the representative value of these data is low due to the relatively small number of prisoner-patients.

- According to regional data, 99% (427) of all newly detected TB patients (433) were tested for HIV infection in 2006. Six (1.4%) of them were diagnosed as HIV-positive. In total, 23 (2.35%) TB patients among 977 TB cases (new and retreated) registered for treatment in regional TB services in 2006 were diagnosed as HIV-positive.

Republic of Chuvashia

- TB detection by smear microscopy in patients registered for treatment in the civilian sector was satisfactory and constituted 56.3% (1st and 2nd Quarters 2006). Culture confirmation of TB increased through the improved performance of the central clinical and diagnostic laboratory. As a result, confirmation by culture increased to 69.8% (2nd Quarter 2006). Detection by smear microscopy and confirmation of TB by culture among new pulmonary TB patients in the prison sector remained insufficient: 19.6% (2nd Quarter 2006) and 17.2% (3rd Quarter 2006), and 46.7% (2nd Quarter 2006) and 33.3% (3rd Quarter 2006), respectively, due to the relatively small number of prisoner-patients.

- The treatment success rate among new sputum smear-positive patients in the civilian sector varied by quarter from 66.3-66.4% (1st and 3rd Quarters 2005) to 81.6% (2nd Quarter 2005). The project had a relatively high failure rate (over 20%) due to 1) persistent problems with correct registration of treatment results; and 2) 15% of new cases were diagnosed with MDR-TB after improvements in the performance of the central clinical and diagnostic laboratory in the 1st and 2nd Quarters of 2005. Treatment success in the prison sector was 76.5% (2nd Quarter 2005) and 80% (3rd Quarter 2005).

- According to regional data, 91% (800) of all newly detected TB patients (875) were tested for HIV infection in 2006. Seven (0.88%) of them were diagnosed as HIV-positive. In total, 14 (0.65%) TB patients among 2138 TB cases (new and retreated) registered for treatment in regional TB services in 2006 were diagnosed as HIV-positive.

Vladimir Oblast

- TB detection by smear microscopy in patients registered for treatment in the civilian sector increased from 36.9% (2nd Quarter 2006) to 47.2% (3rd Quarter 2006). Culture confirmation constituted 63.2% (1st Quarter 2006) and 53.5% (2nd Quarter 2006). The situation is impaired by the insufficient laboratory capacity in the region. The oblast plans to centralize all culture confirmation of TB in the central bacteriological department of the Oblast TB Dispensary (OTBD) and abandon all district culture units. This will help the oblast to significantly improve the culture confirmation rate. Culture confirmation of TB in the prison sector was 40% (1st Quarter 2006) and 42.7% (2nd Quarter 2006).

- The treatment success rate in sputum smear-positive TB patients remained stable at around 68.9% (2nd Quarter 2005) and 68.7% (3rd Quarter 2005). According to the regular quarterly cohort reviews, there are a relatively high number of failures and deaths (12.3% and 14.1%, respectively, in the 2nd Quarter of 2005). The increase in the number of MDR-TB cases and improvements in the performance of the central clinical and diagnostic laboratory led to the growth of the TB failure rate because every new TB case diagnosed with MDR-TB should be registered as a failure case according to WHO recommendations.

- The treatment success rate in patients registered for treatment in the prison sector varied by quarter from 50% (2nd Quarter 2005) to 84.6% (3rd Quarter 2005) due to the relatively small number of prisoner-patients (10-11 cases).

- According to regional data, 100% of all newly detected TB patients (898) were tested for HIV infection in 2006. Twelve (1.34%) of them were diagnosed as HIV-positive. In total, 18

(0.83%) TB patients among 2158 TB cases (new and retreated) registered for treatment in regional TB services in 2006 were diagnosed as HIV-positive.

7.5.2. DOTS-Plus at WHO project sites in the RF

One DOTS-Plus project in the RF (Orel Oblast) was supported by WHO, CDC and USAID in 2006.

The DOTS-Plus project in Orel Oblast had enrolled all 200 MDR-TB patients approved by the GLC by the end of 2005. The intermediate results of the project in November 2006 were the following: 102 cases completed treatment with success (51%), 18 cases remained under treatment (9%), 28 patients had treatment failure (14%), 26 patients had defaulted treatment (13%), 6 patients were transferred out (3%), 18 patients died (9%), and 2 patients discontinued treatment due to adverse effects (1%).

In 2006 after Orel Oblast had received approval from the GLC for the continuation of the project and enrolment of an additional 200 patients, 46 MDR-TB patients were enrolled for treatment. From October to November 2006, the project witnessed a potential shortage of para-amino salicylic acid for treatment due to poor coordination between the Oblast TB Dispensary (OTBD) and the GLC supplying agency, and difficulties with customs clearance of imported drugs. It has been agreed to supply the project with further second-line drugs through the GFATM-supported project, which has established mechanisms for regular drug supplies.

The DOTS-Plus project in Ivanovo Oblast, launched in November 2004, enrolled for treatment only 42 out of the 50 MDR-TB cases approved by the GLC. By June 2006, the drugs for MDR-TB patients purchased initially through the GLC and later covered by the regional budget were depleted. The oblast, however, did not submit repeat requests for the continuation of second-line drug supplies due to unfavourable changes in the political environment in the oblast. The project was scaled down in 2006 and did not submit data or reports on implementation to the WHO Moscow Office. The oblast administration rejected the hosting of a GLC mission from May to June 2006. However, in November 2006 the WHO Moscow Office received a letter from the Regional Health Commissioner expressing the region's willingness to host a GLC mission in December 2006.

The other two WHO pilot projects with USAID financial support in Vladimir Oblast and the Republic of Chuvashia received GLC approval for launching DOTS-Plus in their areas in 2007. Currently, they are cooperating with the RHCF on the preparation of necessary agreements for second-line drug supplies in the framework of the GFATM-supported project.

The WHO TB Control Programme in the RF provides overall technical support for the implementation of the current and planned DOTS-Plus projects in 12 Russian regions approved by the GLC and will pursue the expansion of DOTS-Plus in Russia.

7.5.3. Training

The Programme has continued to provide assistance with strengthening the federal and regional capacity for modern TB control and operational research through training courses with the involvement of WHO international experts.

Federal

- **4-6 July 2006:** Thematic conference co-organized by WHO and NTRI for 35 civilian and prison TB doctors from the institute's supervision zone (Far-East and Siberian federal "okrugs"). The conference had a roundtable session organized by WHO to discuss ways of enhancing cooperation and communication between partners (WHO, NTRI, FCS and regional authorities) in order to improve the implementation of the recent federal TB regulations (Prikaz # 109, Prikaz # 50) and the GFATM-supported project at the regional level.
- **24-25 July 2006:** Training course for 150 TB laboratory staff in Stavropol Krai. The course aimed to improve the knowledge and skills of local TB laboratory staff in microscopy and culture diagnosis of TB according to international standards. A WHO TB Control

Programme representative, as well as specialists from FCEQA and the Munich Supranational Laboratory, took part in this course with presentations and practical recommendations.

- **18-19 September 2006:** Workshop on "Organization of Social Support for TB Patients" arranged by RIPP MMA for 30 social and administrative staff of Orel Oblast. A Programme officer took part in the workshop as a facilitator and distributed WHO information materials on the topic.
- **16-21 October 2006:** Basic training course for 84 people from NTRI and its area of supervision. The revised WHO modules on managing TB at the district level were used as training material. WHO Moscow experts took part in the course and provided recommendations.

Regional

Ivanovo Oblast

During the reporting period, WHO did not provide funds for training and other activities in the region because implementation of the project was suspended due to the deterioration in the political environment in the area. The Regional TB Control Programme in Ivanovo Oblast did not organize refresher training courses on TB, as they had done previously, and did not report on training activities in the regional TB service.

Orel Oblast

- **12 September 2006:** Refresher training course for 30 nursing staff of the regional TB services on managing TB at the district level.
- **11 October 2006:** Refresher training course for 30 technicians from GHC clinical and diagnostic laboratories on unified methods of AFB microscopy and infection control. The technical manual "Unified Methods of Microscopy Testing for Acid-Fast Bacilli" was used as core material for the course.
- **18-19 October 2006:** Refresher training course for 60 nursing staff of district feldsher points on managing TB at the district level.
- **23-23 November 2006:** Refresher training course for 60 GHC physicians on managing TB at the district level in the GHC service.

Republic of Chuvashia

- **12 November 2006:** Refresher training course for 25 deputy chief TB doctors from the civilian and prison GHC services on improvement of TB detection and treatment in the Republic of Chuvashia.
- **14 November 2006:** Refresher training of 45 TB doctors on improvement of TB detection and treatment in the Republic of Chuvashia.
- **15-16 November 2006:** Refresher training course for 25 heads of GHC clinical and diagnostic laboratories in the civilian and penitentiary sectors on unified methods of AFB microscopy and infection control. The technical manual "Unified Methods of Microscopy Testing for Acid-Fast Bacilli", prepared by the relative TWG on Laboratory Diagnosis of TB, which includes WHO experts, was used as training material.
- **16 November 2006:** Refresher training course for 40 nursing staff from district GHC services on improvement of detection and treatment of TB. The revised WHO modules on managing TB at the district level were used as training material.
- **17 November 2006:** Refresher training course for 51 nursing staff from district TB civilian and penitentiary services on the principles of directly observed chemotherapy of TB patients.

- **22-23 November 2006:** Refresher training course for 29 laboratory technicians from the civilian sector on microscopy of *M. tuberculosis* and infection control measures. The technical manual "Unified Methods of Microscopy Testing for Acid-Fast Bacilli" was used as training material.
- **12 December 2006:** Refresher training course for 25 social workers on improvement of TB detection and treatment in the Republic of Chuvashia.

Vladimir Oblast

- **20 September 2006:** Refresher training course for 45 social workers and TB doctors from the civilian and prison sectors on "The Role of Social Workers in TB Control".
- **27 September 2006:** Refresher training course for 47 heads of district GHC facilities in the civilian and prison sectors on "Managing TB at the Municipal Level".
- **19-20 October 2006:** Refresher training course for 30 TB doctors from the civilian and prison TB services on "Managing TB at the Municipal Level".
- **26-27 October 2006:** Refresher training course for 30 laboratory technicians and paramedical laboratory personnel from the civilian and prison sectors on "TB Laboratory Diagnosis".
- **21-24 November 2006:** Refresher training course for 86 paramedical staff from the TB and GHC services and the prison system on "The Organizational Framework for Early Detection of TB in GHC and Prison Systems".
- **29 November 2006:** Refresher training course for 28 physicians and pulmonologists from the GHC and prison systems on "The Organizational Framework for Early Detection of TB in GHC and Prison Systems".

7.5.4. Outreach and follow-up

Following the results of the operational research on social support which was conducted by the WHO TB Control Programme in the RF in cooperation with RIPP MMA in 2004-2005, new principles and methods of social support for TB patients were launched in the WHO pilot regions. One of the key requirements is to target social support for TB patients depending on their risk factors for treatment default. These risk factors should be identified before treatment onset. Screening for risk factors is performed using a questionnaire that was piloted during the above operational research. The cost-effectiveness of the activities implemented will be investigated through the Programme's support and in cooperation with one of the five federal TB research institutes and regional authorities in order to sustain the established model beyond the period of the Programme.

Noteworthy is the fact that the RHCF began to provide funds for social support to Russian regions in the 4th Quarter of 2006 in the framework of the GFATM-supported project. It is hoped that additional funds will enable Russian regions to decrease the number of TB patents defaulting from treatment.

Ivanovo Oblast

The oblast administration continued to provide social support to TB patients from the local budget. The region did not provide any reports on social support to the WHO Moscow Office in 2006 because the implementation of the WHO pilot project in Ivanovo Oblast was suspended.

Republic of Chuvashia

In 2006 the social support programme in the area was implemented with USAID funds and WHO support. The Republican Department for Social Affairs manages the purchasing, packing and distribution of food parcels to TB patients. The Department reports to the WHO Moscow Office on the activities performed and cooperates with the OTBD regarding lists of TB patients eligible for

social support. In 2006, 538 560 roubles were provided by the Programme for social support of TB patients in the Republic of Chuvashia.

Orel Oblast

In 2006 all TB patients with below-average incomes were fully covered by the local social support programme, which is financed from the local budget. The budget for social support in the region includes payments (13%) to the local branch of the Russian Red Cross for purchasing and packing food parcels for TB patients.

MDR-TB patients received monthly food packages worth 100 roubles each and food packages on successful completion of the intensive phase and the whole course of treatment worth 1000 roubles each. These activities were administered with CDC financial support and OTBD logistical support. According to the reports from the region, the project faces consistent problems with irregular transfer of funds from CDC. The Programme started negotiations with the RHCF regarding allocation of funds to support MDR-TB patients in Orel Oblast in 2007 using the GFATM mechanism.

Vladimir Oblast

In 2006 social support for TB patients with below-average incomes was financed from the regional budget in full. The WHO TB Control Programme in the RF provided consultancy and training of regional staff in terms of screening of TB patients and identifying risk factors for default before they start treatment in order to target social support and increase its effectiveness.

7.5.5. Logistical support and procurement of goods and services

Drug and supply management

Drug stock reports were collected from the projects and processed on a quarterly basis (1st, 2nd and 3rd Quarters 2006). Data on regional drug stocks in the 4th Quarter of 2006 were requested for monitoring purposes. As a result, the Programme confirmed that all WHO project sites had sufficient stocks of first-line anti-TB drugs.

Vehicles

With USAID funds, the Programme procured two vehicles for the civilian (one car) and the prison (one car) TB services of Orel Oblast and three vehicles for the civilian (two cars) and prison (one car) TB services of Vladimir Oblast. These vehicles will facilitate implementation of DOTS-Plus activities in the regions and the performance of DOTS and DOTS-Plus Demonstration Centres, which will be established in the oblasts in 2007.

The procurement of two vehicles for the Republic of Chuvashia is underway.

Office equipment

During the reporting period, the Programme accomplished the procurement of office partitions and equipment (AIKO ASM-30 safe) for the WHO TB Control Programme in the RF.

Twenty-two Dell desktops and six laptops for Programme staff were ordered, with their cost shared between several allotments, including USAID funds.

7.5.6. On-site monitoring and technical assistance

During the reporting period, Programme staff conducted regular monitoring visits to the DOTS and DOTS-Plus project sites in cooperation with experts from the federal TB research institutes, FCS and donor agencies.

The Programme increased the number of monitoring visits to the Republic of Chuvashia and performed monitoring on a quarterly basis due to deviations from the DOTS technical protocol at the project site following the change in the leadership of the Regional TB Control Programme. The

Programme did not monitor the performance of the Regional TB Control Programme in Ivanovo Oblast because the implementation of the WHO pilot project in the area was suspended.

Republic of Chuvashia

- **13-16 June 2006:** Joint monitoring mission to the DOTS project in the Republic of Chuvashia for monitoring and training purposes in the light of the DOTS-Plus activities that are expected to start in the region. Two experts from the WHO DOTS-Plus project in Orel Oblast took part in the mission upon the invitation of the Programme and shared their experience of the practicalities of MDR-TB diagnosis and treatment monitoring.

- **24-25 August 2006:** WHO monitoring mission. The WHO supervisor of the Republican TB Control Programme met with members of the Republican TB Coordination Committee for personal consultations and evaluation of their performance. The mission aimed to improve the performance of the Coordination Committee on TB in the Republic of Chuvashia.

- **10-13 October 2006:** Joint WHO/RIPP MMA/USAID monitoring visit to evaluate the performance of the DOTS project in the Republic of Chuvashia and discuss coordination of activities in the framework of the other two projects supported by the WB and GFATM in the area. The mission participants met with the local Health Minister, members of the Republican TB Coordination Committee and representatives of the Republican Department for Social Affairs. They shared their findings and recommendations regarding the improvement of cooperation between partners at different levels.

- **13-15 November 2006:** Joint WHO/FCS monitoring mission to the penitentiary TB services to evaluate the quality of laboratory performance in TB microscopy, culture and DST at each level of the laboratory network. The mission shared their findings and recommendations with local responsible staff and focused on quality control measures and organization of laboratory supplies for the Republican prison services.

Vladimir Oblast

- **19-21 June 2006:** Duty trip to meet with regional health authorities and TB staff in order to discuss the logistics and technical issues related to the field visit of international TB experts to Vladimir Oblast in the framework of the External Evaluation Review of Internationally Supported TB Control Projects in the Russian Federation (Russia, 1-12 July 2006). During the visit, regional TB staff also received consultancy to ensure that regional quantitative and qualitative data would be available during the forthcoming field visit.

Orel Oblast

- **19-22 September 2006:** Joint WHO/FCS/CTRI RAMS monitoring mission to the DOTS and DOTS-Plus projects in Orel Oblast to evaluate the implementation of the projects and discuss the establishment of the TB Demonstration Centre in the oblast. Among the key issues discussed during the wrap-up meeting were recommendations to ensure regular supplies of second-line anti-TB drugs in the DOTS-Plus project.

7.6. Assistance with the revision of the national anti-TB drug policy

The WHO TB Control Programme in the RF continued its assistance to the GFATM-supported project with strengthening the national capacity for rational drug management. The interim objectives are to identify Russian manufacturers of quality anti-TB products and develop training materials on drug management at different levels. Lessons learned from the WHO pilot projects and GMP training of Russian experts and manufacturers within the GFATM-supported project will facilitate the expansion of rational drug management in the country.

From 5 to 9 June 2006, a training course on drug management was conducted for 25 health managers at the federal level who are responsible for TB drug supply issues. The course was co-organized by the RHCF and MMA and launched a series of training courses on drug management

at all levels planned within the GFATM-supported project. The Programme provided logistical support for the course and took part in the development of training materials.

Further to the first meeting on the WHO prequalification programme (21-23 March 2006), the Programme organized a seminar on GMP from 6 to 8 September 2006 for 32 representatives from the Association of Russian Pharmaceutical Manufacturers, FCS and the Directorate for State Control in the Sphere of Medical Procedures and Rehabilitation (Roszdravnadzor). A WHO/HQ-invited expert conducted lectures and practical classes related to GMP on-site inspections and GDF procedures. This seminar was followed by a workshop co-organized by WHO and Roszdravnadzor from 15 to 17 November 2006 for 15 representatives from Russian pharmaceutical manufacturers. Three WHO/HQ-invited experts conducted lectures and practical classes. The workshop aimed to facilitate GMP certification for Russian manufacturers. It was conducted in view of the forthcoming GMP inspection of several local anti-TB drug manufacturers performed from 27 November to 1 December 2006 (1st round) by Danish experts from "Farmakon" and WHO/EURO. The premises of "Makiz-farma" and "Zio-Zdorovie" companies were inspected. These activities were conducted in close collaboration with the Federal Service for Surveillance in Public Health and Social Development. WHO participated in the work of the Expert Committee, which selected pharmaceutical manufacturers for GMP inspection.

On 29 November 2006, the Programme organized a symposium on "Use of Fluoroquionolones (FQ) in MDR-TB Treatment: Latest Approaches" in the framework of the Scientific Conference, "Prioritized Areas to Ensure Effectiveness of TB Control in Modern Social and Epidemiological Environment", in Yekaterinburg, Russia. The key issue of the symposium was the discussion on the long-term use of FQ in the treatment of new and re-treated patients diagnosed with MDR-TB. Representatives from CTRI RAMS, RIPP MMA, the Institute for Drugs and Medical Products' Preclinical and Clinical Trials, WHO, CDC, the Latvian State Centre of TB and Lung Diseases, as well as TB staff from DOTS-Plus projects in Archangelsk, Orel and Tomsk Oblasts, took part in the symposium. As a result of the symposium, the participants decided to create a working group which would work on the technical protocol for long-term treatment of MDR-TB using FQ. This protocol will be submitted to the Russian MoHSD for approval and further use in DOTS-Plus projects.

Through the above activities, WHO can be seen to have contributed to the strengthening of collaboration between the Russian MoHSD, other health agencies and the Russian Pharmacological Committee on drug management issues.

7.7. Information, education and communication (IEC) strategy

The WHO TB Control Programme in the RF, in cooperation with WHO/HQ, WHO/EURO and partners, provided further assistance with the translation, editing and preparation for publishing of international guidelines and materials on TB. Among the key publications translated into Russian during the period were:

1. WHO Guidelines for the Programmatic Management of Drug-Resistant Tuberculosis
2. International Standards for TB Control
3. Global Plan to Stop TB 2006-2015: Actions Towards Life.

These materials were widely distributed to around 200 representatives of the Russian TB community during the Scientific Conference, "Prioritized Areas to Ensure Effectiveness of TB Control in Modern Social and Epidemiological Environment", co-organized by WHO and URIPP in Yekaterinburg from 28 November to 1 December 2006.

The Programme continued to support the participation of Russian experts in a number of international TB-related events:

- **4-11 July 2006:** WHO training course on collaborative TB/HIV activities in Europe, TB Hospital "E. Morelli", Sondalo, Italy. The overall goal of the course was to develop the necessary skills to plan and implement collaborative TB/HIV activities in Europe. The Head of

the Federal Centre of TB Care for HIV-infected Persons and a representative from the Programme took part in the course.

- **17-21 July 2006:** Site tour to the Latvian State Centre of TB and Lung Diseases in Riga for seven Russian TB experts (representatives from all federal TB institutes and FCS), accompanied by a Programme officer. The overall goal of the tour was to share advanced international experience in DOTS-Plus and thus to facilitate the establishment of MDR-TB centres of excellence in the civilian and prison sectors in Russia.
- **14-23 August 2006:** International course on TB control, organized by FILHA in Tartu, Estonia. The Programme covered the trip expenses for the participation of four nurses from Tula, Stavropol and Volgograd Oblasts to strengthen the capacities of regional nursing staff and improve their cognitive, technical and communication skills.
- **21 August-2 September, 2-13 October 2006:** WHO/EURO advanced training courses at the WHO Collaborating Centre for Research and Training in Management of MDR-TB for nine countries of the WHO European Region in Riga (Latvia). The Programme supported the travel and participation of representatives from Vladimir and Novosibirsk Oblasts and the Republics of Booryatia and Mari-El in order to improve the skills and knowledge of Russian TB managers in planning, implementing and evaluating TB control activities in accordance with DOTS-Plus principles.
- **4-10 October 2006**: International course in TB control for nurses, Tartu and Tallinn, organized by FILHA. The Programme covered the trip expenses for the participation of four nurses from the OTBDs in Vladimir Oblast (two people), Orel Oblast and the Republic of Chuvashia.
- **16-20 October 2006**: 2nd training course, International Principles of TB and HIV Control, London, UK, organized by the National Mycobacterium Reference Unit, the Clinical TB and HIV Group Barts and Queen Mary's School of Medicine in London. The Programme covered the expenses for the participation of two federal representatives from CTRI RAMS and NTRI.
- **30-31 October 2006:** Meeting of the Stop TB Partnership Core Groups (DOTS Expansion; TB/HIV; MDR-TB; and ACSM) in Paris, France. The first day was devoted to a joint discussion and the second day was organized as a symposium within the 37th UNION World Conference in Paris. This meeting followed up on the results of the Joint Working Group Meeting held last year in Versailles, France, to ensure continued momentum in global, regional and national efforts to accelerate and improve global TB control, so that the TB-related MDGs and related Stop TB Partnership targets are met by 2015. The Programme's Coordinator and two representatives from the Russian MoHSD took part in the meeting with the Programme's support.
- **31 October-4 November 2006:** 37th UNION Conference, "Strengthening Human Resources for Better Lung Health", in Paris, France. The Programme took part with four poster presentations on the results of operational research on social support and other social support initiatives carried out with the Programme's support. WHO covered the expenses for the participation of two representatives from the Russian MoHSD.
- **13-21 November 2006:** WHO-KNCV regional training on TB control programme management in Warsaw, Poland. Four Russian experts (one from the Republic of Ingushetia and three from RIPP MMA) attended the course with WHO support.

From 7 to 9 June 2006, the Programme's Coordinator took an advocacy tour to Washington D.C. upon an invitation from RESULTS USA to raise awareness of the global TB epidemic among UK and US policy-makers and to encourage the UK and US governments to increase their financial contribution to global TB control. RESULTS UK and RESULTS USA are international grassroots lobbying groups working to build public and political will to end hunger and the worst aspects of poverty. During the tour, the Coordinator met with leading media outlets in the US and abroad. Among them were USA Today (with the largest circulation of any US newspaper), US News and World Report (weekly news magazine), Associated Press (wire service), ITAR-TASS (leading

Russian wire service), the German News Agency (leading German wire service), the Christian Science Monitor (national newspaper for the intellectual community), and the Chicago Tribune.

The next steps will aim to expand cooperation with the mass media community in Russia and abroad in order to draw their attention to the problem of TB and raise awareness of TB among the general public and the authorities through advocacy and health promotion in Russia.

8. MANAGEMENT AND COORDINATION

8.1. Management

The TB Programme Coordinator of the WHO TB Control Programme in the RF is responsible for the implementation and monitoring of the project. Five full-time national professional officers, one part-time medical officer and one technical officer (international professional) on laboratory issues (since November 2006), and one full-time and two part-time TB assistants aided the Coordinator with the implementation, evaluation and monitoring of the project, including supply and procurement. A part-time financial assistant is responsible for financial issues. Three part-time secretaries and an office driver also assisted.

The WHO Regional Office for Europe provides technical and administrative support for the implementation of the project.

8.2. Local coordination

TB control in the RF is a good example of effective collaboration between national, international, governmental and nongovernmental organizations, and good coordination by donor and partner agencies.

Technical assistance to the DOTS and DOTS-Plus projects funded by USAID is now provided by CTRI RAMS, RIPP MMA and WHO.

Implementation of the revised TB control strategy is provided in close collaboration with the Russian MoHSD, FCS and RHCF.

TB interagency meetings continue to be held monthly at the WHO Moscow Office to facilitate information exchange, consultation and discussion among international agencies and partners.

The project is closely coordinated with HLWG activities, both contributing to the work of the various TWGs and benefiting from HLWG decisions on national TB control policy.

Special emphasis is given to collaboration and exchange of practical experience with TB control projects supported by IFRC. DOTS-Plus activities are closely coordinated with the PIH project in Tomsk.

Five coordination offices, established by the Programme at the federal TB research institutes in 2005, ensure proper technical assistance for the implementation of the WB-supported project and coordination of other activities at the regional level in harmonization with the GFATM-supported project.

9. DIFFICULTIES AND CHALLENGES

Major difficulties and challenges at the federal/national level

9.1. Commitment to TB control at different levels

The effective expansion of the revised TB control strategy in the country is challenged by continuing administrative reforms in public health and insufficient political commitment to exploring international principles of TB control. The country lacks an effective Central NTP Administrative Unit, which could improve cooperation between international partners and federal

health authorities and facilitate harmonization of TB control approaches that differ in Russian and international TB communities.

Some federal health-related authorities are lobbying to revise Russian MoH Prikaz # 109 and Prikaz # 50, which laid down principles for evaluating the implementation of the WB- and GFATM-supported projects in the country. This revision is supposed to improve the existing Russian regulations on TB, but additional time and effort will be required to implement the revision and train the relative staff in the revised documentation for management and monitoring of TB.

9.2. Coordination among different health sectors

Ongoing reforms in the public health sector and changing regulations on the responsibilities of health care providers involved in TB control at different levels challenge the continuity of TB control performed by different health care services. Insufficient integration of GHC services in TB control compromises the improvement of TB case detection and treatment results, especially among populations with risk factors for TB. Low rates of TB detection and treatment success among TB patients evidence the lack of proper management to ensure timely detection and effective, uninterrupted treatment of TB patients from different population groups.

9.3. DOTS expansion through the WB- and GFATM-supported projects

The implementation of the WB- and GFATM-supported projects revealed the insufficient capacity at the federal level of TB control to carry out proper surveillance of TB, including MDR-TB and TB/HIV. This situation is aggravated by the poor quality of the laboratory network for TB detection and treatment monitoring.

Growing rates of HIV/AIDS and MDR/XDR-TB pose a serious threat to the overall TB situation in Russia. Complete and reliable data on XDR-TB in Russia as a whole are not available because only a few Russian regions have the capacity to perform DST for second-line drugs. Most WHO demonstration projects have the necessary capacity to perform DST tests. According to data from Orel Oblast in 2006, 56.7% of re-treated TB cases were diagnosed with MDR-TB and 18.9% of them were diagnosed with XDR-TB. According to data from Vladimir Oblast in 2006, 5.7% of MDR-TB retreated cases were diagnosed with XDR-TB.

The expansion of the GLC-approved DOTS-Plus projects in Russian regions is challenged by the lack of national guidelines and an effective mechanism for provision of second-line drugs. The cooperative efforts of the RHCF, WHO and other partners in the projects should establish an effective mechanism to implement the revised TB control strategy at different levels through increasing the capacity of federal TB research institutes for monitoring, supervision and training.

Major difficulties and challenges at the regional level

Ivanovo Oblast

- The unfavourable political situation in the region resulted in the suspension of joint TB control activities in Ivanovo Oblast. Due to the difficult political situation, the oblast did not submit regional reports on TB epidemiology and TB control activities to the WHO Moscow Office, as they had done previously, and information exchange between the Ivanovo OTBD and the WHO Moscow Office was scaled down.

Orel Oblast

- The lack of federal regulations on financial mechanisms in the public health sector prevents the implementation of the proposed system of performance-based incentives for staff to reward effective TB detection and treatment in the GHC system.

Republic of Chuvashia

- The management of the Republican TB Control Programme needs further improvement. Not all the components of the joint project are satisfactory and in conformity with the DOTS technical protocol. The project's TB staff need further training, and the programme leadership needs to strengthen its managerial practices.

- The workload of OTBD staff has increased due to the forthcoming launch of the DOTS-Plus project in the Republic.

Vladimir Oblast

- The leadership of the Regional TB Control Programme needs further strengthening of its managerial capacity. Insufficient motivation of staff in both TB and GHC services due to low wages hinders the effective implementation of TB control in different health sectors.
- The problem with TB detection in the GHC service remains due to the uncertain distribution of responsibilities between TB versus GHC services in TB detection. Dramatic understaffing, particularly in the GHC service, aggravates this process.
- The workload of OTBD staff has increased due to the forthcoming launch of the DOTS-Plus project in the oblast.

10. FUTURE PLANS/NEXT STEPS

10.1. Federal/national level

Grant activities over the next six months will contribute to the progress of the following targets:

- To contribute to the revision and further development of national policies on:
  - state annual reporting forms (compatible with international standards)
  - MDR-TB management
  - TB/HIV collaborative activities.

- To facilitate the strengthening of the national TB laboratory network by technical assistance with:
  - 3rd round of PT involving TB laboratories that participate in implementation of DOTS-Plus projects
  - implementing EQA within the framework of global DRS
  - upgrading laboratory infrastructure and training of laboratory staff
  - expanding a new Prikaz for recording and reporting laboratory data.

- To continue cooperation with the existing network for postgraduate medical education and provide further assistance with:
  - training of trainers in the revised TB control strategy
  - training modules and educational materials on general management, drug management and laboratory diagnosis of TB, TB/HIV and MDR-TB in line with international requirements.

- To strengthen the national policy on rational drug management and facilitate GMP certification for Russian enterprises.

- To continue with technical support for the implementation of the WB- and GFATM-supported projects on TB and AIDS control.

- To ensure adequate infection control in federal and regional TB facilities with technical and financial support from international partners.

- To ensure regular monitoring missions to DOTS and DOTS-Plus project sites.

- To expand WHO operational research in the country.

10.2. Regional level

Ivanovo Oblast

- To arrange meetings with the Governor of Ivanovo Oblast to decide on the next steps and discuss the possibility of continuing international cooperation in regional TB control within the WB- and GFATM-supported projects.

Orel Oblast

- To approve the necessary documentation at federal and regional levels to start operational research in 2007 on the system of performance-based incentives for TB and GHC staff.

- To approve the necessary documentation at federal and regional levels regarding the establishment of the TB Demonstration Centre in Orel Oblast.

- To use the DOTS-Plus model developed in Orel Oblast as a training site for the new DOTS-Plus projects in Russia that will be implemented within the GFATM-supported project.

- To meet with the Governor and Administration of Orel Oblast and discuss the establishment of the TB Demonstration Centre as a branch of CTRI RAMS and the implementation of the performance-based incentive system.

Republic of Chuvashia

- To continue advising and training the administrative leadership of the Regional TB Control Programme in the Republic.

- To launch a DOTS-Plus project, approved by the GLC in November 2006.

- To continue with refresher training courses for local TB staff involving WHO experts and TB doctors and laboratory specialists from another joint TB control project in the RF. To visit the DOTS-Plus project in Orel Oblast and receive on-site training in the management of MDR-TB.

- To continue negotiations with the local health ministry to increase their budget for social support using the resources of the GFATM-supported project.

Vladimir Oblast

- To launch a DOTS-Plus project, approved by the GLC in May 2006.

- To visit the DOTS-Plus project in Orel Oblast and receive on-site training in the management of MDR-TB.

- To strengthen the system of monitoring and supervision of district TB services by the OTBD.

- To approve the necessary documentation at federal and regional levels to start operational research in 2007 on a system of performance-based incentives for TB and GHC staff.

- To approve the necessary documentation at federal and regional levels regarding the establishment of the Infection Control Demonstration Centre in Vladimir Oblast through a grant from CDC.