

## 2<sup>nd</sup> Line TB Medicine Manufacturers' Symposium at the Man & Drug Conference

Moscow, Russia  
April 14-16, 2010

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### *Trip Report*

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### **Promoting the Quality of Medicines Program**

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**Cooperative Agreement #** GHS-A-00-09-00003-00

**Sponsoring USAID Missions:** USAID/Russia

**Grantee:** Promoting the Quality of Medicines (PQM) Program

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**Language:** English

**Date of Publication:** May 21, 2010



This report is made possible by the generous support of the American people through the United States Agency for International Development (USAID), under Cooperative Agreement No. GHS-A-00-09-00003-00. The contents are the responsibility of the *Promoting the Quality of Medicines* Program, implemented by the U. S. Pharmacopeia, and do not necessarily reflect the views of USAID or the United States Government.

## **About PQM**

The Promoting the Quality of Medicines (PQM) program, funded by the U.S. Agency for International Development (USAID), is the successor of the Drug Quality and Information (DQI) program implemented by the United States Pharmacopeia (USP). PQM is USAID's response to the growing challenge posed by the proliferation of counterfeit and substandard medicines. By providing technical leadership to developing countries, PQM helps build local capacity in medicine quality assurance systems, increase the supply of quality medicines to priority USAID health programs, and ensure the quality and safety of medicines globally. This document does not necessarily represent the views or opinions of USAID or the United States Government. It may be reproduced if credit is given to PQM and USP.

## **Abstract**

In conjunction with the World Health Organization (WHO) Prequalification Team, WHO-Euro Russia office, the Global Drug Facility (GDF) and Roszdravnadzor (Russian FDA), PQM conducted a symposium in Moscow, Russia for 2<sup>nd</sup> Line TB Medicine Manufacturers at the Man and Drug Conference. The symposium's main objectives were to encourage Russian and Ukrainian manufacturers to pursue 2<sup>nd</sup> Line TB medicines prequalification under the WHO Prequalification Program and access the PQM technical assistance (TA) that is available to such manufacturers to expedite the prequalification process.

## **Recommended Citation**

Chibwe, K.M., Burimski, K, O., April 2010 *2nd Line TB Medicine Manufacturers' Symposium at the Man & Drug Conference, Moscow, Russia, April 14- 16, 2010* Submitted to the U.S. Agency for International Development by the Promoting the Quality of Medicines Program. Rockville, Maryland: United States Pharmacopeia.

## **Key Words**

WHO Prequalification, WHO, GDF, dossier, second-line anti-TB medicines

## Table of Contents

<b><u>Acknowledgements</u></b> .....	4
<b><u>Acronyms</u></b> .....	5
<b><u>Background</u></b> .....	6
<b><u>Purpose of Trip</u></b> .....	6
<b><u>Source of Funding</u></b> .....	6
<b><u>Overview of Activities</u></b> .....	6
<b><u>Conclusions</u></b> .....	8
<b><u>Annex 1: Participant List</u></b> .....	9
<b><u>Annex 2: Participants' Evaluations</u></b> .....	10

## **ACKNOWLEDGEMENTS**

The authors would like to thank:

- Dr. Kaspers Lunte, Team Leader MDR-TB, Global Drug Facility (GDF), speaker
- Mr. Anthony R. Gould, Auditor, WHO Prequalification Program, speaker
- Dr. Konstantin Y. Belanov, Roszdravnadzor, Symposium co-chair
- Dmitriy D. Pashkevich, WHO-Euro, Russia office, speaker
- Dr. Nikita Y. Afanasiev, USAID/Russia – Symposium co-chair
- PQM editors and administrative staff for editing this report and assisting with logistics
- Mr. Anthony Boni and Ms. Veerle Coigneux at USAID HQ for their support and advice

## ACRONYMS

ATB	Anti-Tuberculosis
DQI	Drug Quality and Information Program
GDF	Global TB Drug Facility
GLC	Green Light Committee
GMP	Good Manufacturing Practices
MDR-TB	Multi-drug resistant tuberculosis
PQM	Promoting the Quality of Medicines Program
TA	Technical Assistance
TB	Tuberculosis
USAID	United States Agency for International Development
USP	United States Pharmacopeia
WHO	World Health Organization

## Background

Despite efforts by the WHO Prequalification program, Global TB Drug Facility (GDF), and the Green Light Committee (GLC) to increase access to essential anti-tuberculosis medicines (ATBs), there are not enough WHO-prequalified second-line ATBs and an inadequate supply of products to treat patients with multi-drug resistant TB (MDR-TB). PQM assists the GDF in its efforts to increase the availability of good quality second-line ATBs. To expedite the prequalification process and thereby expand the pool of viable manufacturers, PQM is providing technical assistance to interested companies to:

- Prepare their product dossiers for submission to the WHO prequalification program
- Facilitate discussions with WHO to remedy incomplete dossiers or respond to comments
- Guide manufacturers onsite to comply with the principles and guidelines of WHO Good Manufacturing Practices (GMP) and the requirements of the prequalification program

## Purpose of Trip

- Conduct the 2<sup>nd</sup> Line TB Medicine Manufacturers' Symposium at the Man & Drug Conference for manufacturers from Russia, Belarus, and Ukraine
- Debrief USAID/ Russia on activities

## Source of Funding

The trip was funded by USAID/Russia under the terms of Cooperative Agreement GHS-A-00-09-00003-00.

## Overview of Activities

### Russia 2nd Line TB Medicine Manufacturers' Symposium – April 14, 2010

The speakers were Dr. Kaspars Lunte (GDF), Mr. Anthony R. Gould (WHO Prequalification), Dr. Dmitriy D. Pashkevich (Euro-WHO Russia Office), and Dr. Kennedy M. Chibwe (PQM).

There were at least 40 attendees and 14 firms represented at the 3-hr symposium (please see *Annex 1* for the complete List of Participants). The following table shows the firms and the ATB medicines that they currently produce:

Firm	Current ATB Medicines
<b>Russia</b>	
<b>1. Biocom</b>	<ul style="list-style-type: none"><li>• Ciprofloxacin</li><li>• Cycloserine</li></ul>
<b>2. Pharmasyntez</b>	<ul style="list-style-type: none"><li>• Prothionamide</li><li>• Ofloxacin</li><li>• Aminosalicyclic acid</li><li>• Terizidone</li><li>• Moxifloxacin</li></ul>
<b>3. Pharma-Center</b>	<ul style="list-style-type: none"><li>• Amikacin</li><li>• Ofloxacin</li></ul>
<b>4. Sintez</b>	<ul style="list-style-type: none"><li>• Kanamycin</li><li>• Amikacin</li><li>• Ofloxacin</li><li>• Ciprofloxacin</li></ul>

<b>5. Veropharm</b>	<ul style="list-style-type: none"> <li>• Ciprofloxacin</li> </ul>
<b>6. Shelkovo</b>	<ul style="list-style-type: none"> <li>• Prothionamide</li> <li>• Ciprofloxacin</li> <li>• Terizidone</li> <li>• Levofloxacin</li> </ul>
<b>Ukraine</b>	
<b>7. Borshgovskii Khimiko-pharmaceuticheskii</b>	<ul style="list-style-type: none"> <li>• Amikacin</li> <li>• Kanamycin</li> <li>• Ofloxacin</li> </ul>
<b>8. Arterium</b>	<ul style="list-style-type: none"> <li>• Amikacin</li> <li>• Kanamycin</li> <li>• Ofloxacin</li> </ul>
<b>9. Lekchime</b>	<ul style="list-style-type: none"> <li>• Ofloxacin</li> <li>• Amikacin</li> <li>• Capreomycin</li> <li>• Moxifloxacin</li> </ul>
<b>10. PharmaStart</b>	<ul style="list-style-type: none"> <li>• Levofloxacin</li> </ul>
<b>11. Zdorovie</b>	<ul style="list-style-type: none"> <li>• Levofloxacin</li> </ul>
<b>12. Farmak</b>	<ul style="list-style-type: none"> <li>• Ciprofloxacin</li> </ul>
<b>Belarus</b>	
<b>13. Gomel Med. Universitet</b>	<ul style="list-style-type: none"> <li>• Levofloxacin</li> <li>• Para-Aminosalicylic acid</li> <li>• Cycloserine</li> <li>• Capreomycin</li> </ul>
<b>14. Belmedpreparaty</b>	<ul style="list-style-type: none"> <li>• Levofloxacin</li> <li>• Ofloxacin</li> <li>• Cycloserine</li> </ul>

Dr. Kaspars reviewed the urgency to get at least three suppliers/manufacturers of each of key 2<sup>nd</sup> Line ATB medicine prequalified and explained how firms can bid on becoming a GDF supplier. Interested manufacturers need to become WHO Prequalified unless they are registered by a WHO-recognized stringent regulatory authority.

Mr. Gould's presentation explained the prequalification process. There is no charge for the process, and any firm is welcome to submit a product for prequalification. For further information, visit <http://apps.who.int/prequal/>

Dr. Pashkevich discussed the TB situation in Russia. He noted that Russia is one of 22 countries with a high burden of TB. While the number of registered cases and related morbidity is decreasing, the major concern is now multi-drug resistant TB (MDR-TB). According to WHO, 8% of all MDR-TB cases in the world are in Russia. Dr. Pashkevich also noted that effectiveness of treatment depends on the quality of ATB medicines.

Dr. Chibwe discussed how PQM becomes a TA resource for manufacturers. After submitting an Expression of Interest independently with GDF, PQM guides and assists interested parties with all steps of the submission process, working with the client until the medicine gets prequalified. PQM leverages its expertise and knowledge to expedite the prequalification process.

Dr. Elena Perezhogina of Sintez reported their progress with the WHO prequalification program as an industry case study. Sintez produces coated Leflobakt (levofloxacin) tablets and Kanamycin powder for solution for intramuscular injection, among others. In 2009, Sintez decided to participate in WHO prequalification. PQM provided TA and visited the plant. In February 2010, Sintez organized two audits. Dossiers on Leflobakt and Kanamycin are now complete, translated into English, and will be submitted for prequalification later this year.

Dr. Veniamin Potashnicov of Biocom provided another case study, speaking about Biocom's participation in the WHO prequalification program for Cycloserine capsules 250mg. In 2005, Biocom was certified by Pharmaplan GmbH for conformity to international quality standards for GMP in the European Union. With the assistance of Eli Lilly, Biocom expects to submit documents for prequalification in August 2010.



### **Presentation Materials**

If you would like copies of the presentations, please contact Dr. Chibwe ([kmc@usp.org](mailto:kmc@usp.org)).

### **Conclusions**

Based on evaluations (see *Annex 2*), the symposium was successful, with one firm preparing a request for PQM assistance and at least five others showing interest in becoming prequalified.

### **Meeting with USAID/Russia Office of Health – April 20, 2010**

Dr. Chibwe and Dr. Burimski met with Ms. Cheryl Kamin, Director, Office of Health, and Dr. Nikita Afanasiev, Senior Infectious Diseases Advisor. Dr. Chibwe briefed them on the successful 3-hr symposium at the Man & Drug Conference. There was discussion on follow-up and expectations for further engaging the manufacturers represented at the symposium. The group also discussed the Minilab<sup>®</sup> training, and Ms. Kamin asked that PQM keep key local stakeholders aware of our activities.

### **Next Steps**

- PQM will follow up with Ukrainian and Russian firms that expressed interest in receiving technical assistance towards WHO prequalification

### List of Participants/Manufacturers of Second line TB medicines

	NAME	Firm	Website
1.	Veniamin A. Potashnikov	Biocom, Stavropol	<a href="http://www.biocom.ru">http://www.biocom.ru</a>
2.	Olga A. Myachkova	Pharmasyntez, Irkutsk	<a href="http://www.pharmasyntez.com">http://www.pharmasyntez.com</a>
3.	Madina M. Sottaeva	Pharm-Center	
4.	Elena A. Perezhogina	Sintez, Kurgan	<a href="http://www.kurgansintez.ru/">http://www.kurgansintez.ru/</a>
5.	Larisa N. Mamonova Valenta Pharmatsevtika,	Shelkovo, Moscow region	<a href="http://www.hotlek.ru/">http://www.hotlek.ru/</a>
6.	Elena I. Arsenova	Veropharm, Moscow	<a href="http://www.veropharm.ru">http://www.veropharm.ru</a>
7.	Irina N. Kurilenko	Corp. Arterium	<a href="http://www.arterium.ua/ru">http://www.arterium.ua/ru</a>
8.	Sergey O. Fesenko	Borshagovskii Khimiko-pharmaceuticheskii Zavod	<a href="http://www.bhfz.com.ua/">http://www.bhfz.com.ua/</a>
9.	Mikhail A. Renskiy	Lekchime, Kiev	<a href="http://www.lekhim.ua/">http://www.lekhim.ua/</a>
10.	Inna A. Bocharova	PharmaStart	<a href="http://www.phs.ua">http://www.phs.ua</a>
11.	A. A. Gladilin	Zdorovie	
12.	Alexandr I. Kachaput	Farmak	<a href="http://www.farmak.ua/">http://www.farmak.ua/</a>
13.	Yulia G. Chernetskaya	Belmedpreparaty, Minsk	
14.	Dmitriy Y. Ruzanov,	Gomel Med. Universitet	

#### Other participants:

1. Andrey G. Kotov, Pharmacopeian Center, Ukraine, <fitex2@gmail.com>
2. Yurii Podpruzhnikov, Bioanalytical Laboratory “Klinpharm”, Ukraine.
3. Darya D. Pashkevich, City Hospital #4, Moscow, Russia
4. Davron M. Mukhamadiev, IF Red Cross, Moscow, Russia
5. Yuriy Y. Kokotov, IF Red Cross, Moscow, Russia
6. Tatyana V. Toichkina IF Red Cross, Moscow, Russia
7. Oksana G. Kirilenko Institute of Pharmaceutical Safety, Moscow, Russia <ifb@ifb-np.ru>
8. Olexandr (CPS)Polishchuk, WHO, Europe office <apo@euro.who.int>
9. Vadim Testov, WHO, Russia
10. Nina Khurieva, USAID|Russia

#### Co-chairs and instructors:

1. Nikita Y. Afanasiev, USAID|Russia
2. Konstantin Y. Belanov, Roszdravnadzor
3. Kennedy Chibwe, PQM
4. Kaspers Luntjes, GDF
5. Anthony R. Gould, WHO
6. Dmitriy D. Pashkevich, WHO, Russia

### Evaluations by Participants

Name of Symposium: Road Map to Increasing the Supply of Quality Assured second line ATBs

Participants are given evaluation forms at the beginning of the symposium and asked to rate its educational materials and associated activities. Participants are asked to rate all categories that apply and return the completed form to the instructor.

Indicator	Strongly Agree	Agree	Disagree Somewhat
1. Course objectives were relevant to my needs	11	10	
2. I was able to understand the content of the materials presented	17	4	
3. Overall the workshop was useful and will help my company get involved in Prequalification	12	8	1
4. The questions I had about WHO prequalification, GDF, Technical support by PQM have been answered.	9	11	1
5. The instructors were knowledgeable on the subject	18	3	
6. The instructors allowed an appropriate level of participation in the workshop	13	8	
7. Overall workshop rating. The workshop has been very useful.	15	6	

*Other comments/suggestions:*

**How soon will your company request PQM for technical support?**

- We have requested (2)
- Promptly (1)
- In 2010-2011 (1)
- In 2011-2012 (2)
- Do not plan to request PQM (1)
- We are very interested but do not know exactly (2)

**Why are you not currently involved in WHO medicines prequalification program?**

- Lack of knowledge on international programs and technical possibilities, we did not have information (2)
- Our company does not address all requirements (1)
- We are involved (2)