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## USE OF NALTREXONE IN THE TREATMENT OF OPIOID DEPENDENCE IN THE RUSSIAN FEDERATION



*Situation Analysis*

This publication was prepared by Nicole Judice  
of the Health Policy Project.

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# Use of Naltrexone in the Treatment of Opioid Dependence in the Russian Federation: Situation Analysis

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This publication was prepared by Nicole Judice<sup>1</sup> of the Health Policy Project.

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# CONTENTS

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**Executive Summary**..... v

**Abbreviations**.....vii

**Introduction**..... 1

**Background** ..... 1

    Epidemiological Situation Related to HIV and Opioid Addiction in the Russian Federation..... 1

    Drug Addiction Treatment (Narcology) as a HIV Prevention Strategy ..... 2

    Naltrexone Formulations and Use in Relapse Prevention to Opioid Use..... 3

**Findings of the Naltrexone Situation Analysis**..... 1

    Narcology in the Russian Federation..... 1

    Organization and Coordination of Services for People Who Inject Drugs..... 4

    Opinions and Viewpoints of Naltrexone in the Russian Federation..... 6

    Opinions on the Application and Use of Vivitrol in the Russian Federation ..... 7

    Access to Vivitrol (extended-release, injectable naltrexone) ..... 9

**Conclusions and Recommendations**..... 12

**Annex A. List of Key Informants** ..... 14

**Annex B. Interview Questions** ..... 18

**References** ..... 21



# EXECUTIVE SUMMARY

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## Background

The Russian Federation has one of the fastest growing HIV epidemics in the world, with the number of diagnosed HIV cases doubling since 2001. The country's epidemic remains concentrated among key populations—primarily people who inject drugs (PWID), sex workers (SWs), and males who have sex with males (MSM) (PEPFAR, 2010a). Injecting drug use accounts for 63 percent of all HIV cases, while 35 percent of cases are attributed to heterosexual sex. It is important to note that incidence attributed to heterosexual sex is often related to sexual contact with a PWID. Researchers estimate that there are up to 2 million PWID in the country—of which, more than one-third (37%) are believed to be HIV positive (UNAIDS, 2010).

The Russian Federation faces a difficult public health challenge because of the dual epidemics of opioid dependence and HIV infection. An important intervention for individuals who are opioid dependent is drug treatment. Drug treatment provided to those at risk for HIV infection is a well-established and recognized HIV prevention intervention. Therefore, the Russian Federation can address opioid dependence and HIV infection together through the implementation and scale-up of evidence-based drug treatment for opioid dependence.

Currently, three formulations of naltrexone have been approved to treat both alcoholism and opioid dependence in the Russian Federation. Oral naltrexone has been available and used for the longest period of time, but its effectiveness has been limited by both its cost, an insufficient number of rehabilitation programs, and the lack of adherence by opioid dependent individuals. To address medication adherence, two longer-lasting formulations have been developed and approved for use: an implantable formulation lasting up to six months and an injectable formulation lasting up to one month.

## Objectives and Methodology

The Health Policy Project (HPP) conducted a situation analysis to identify the perspectives, attitudes, and understanding of practitioners and civil society representatives on how naltrexone and its formulations can be used to address HIV and opioid dependence in the Russian Federation. The analysis comprised (1) a global literature review of naltrexone use and its formulations, focusing on the effectiveness of naltrexone for treating opioid dependence and (2) interviews with 39 key informants, such as clinicians and government, private sector, and nongovernmental organization (NGO) leadership. The interviews took place in Moscow, Leningrad Oblast, the city of St. Petersburg, and other regions from December 5–16, 2011.

## Findings of the Naltrexone Situation Analysis

The findings confirm that naltrexone in oral and injectable forms are being used by narcologists throughout the Russian Federation and that practicing narcologists were familiar with the different formulations and evidence of their effectiveness. While Vivitrol is available in many regions, narcologists expressed interest in using Vivitrol more widely. While NGO representatives were familiar with naltrexone and Vivitrol, they had inconsistent information about its effectiveness and indicated that policymakers may not be familiar with this new development in opioid dependence treatment.

Internationally, practitioners, government, donors, international organizations, and Russian NGOs still have various views on what is the most effective treatment paradigm for opioid dependence. Interviewees consistently cited the importance of a strong rehabilitation program to prevent relapse after detoxification, and many respondents noted that Vivitrol would be most effective as a part of a comprehensive

Use of Naltrexone in the Treatment of Opioid Dependence  
in the Russian Federation: Situation Analysis

rehabilitation program. Maintaining abstinence from opioid use will help individuals stay adherent to antiretroviral therapy and reduce high-risk injecting drug use and other behaviors that may put an individual at risk of HIV.

The findings further illustrate that narcologists appear eager to integrate Vivitrol into their package of narcology services but that the cost of Vivitrol is a limiting factor. While the cost has declined dramatically over the past two years, the price per injection is still prohibitively high for many clients receiving services in the government sector. Interviewees cited instances when the government funded a small number of doses, but the funding has been insufficient to meet demand.

This report focuses on the potential for expanding the use of naltrexone formulations in the government-financed Russian Federation healthcare system. The use of naltrexone and its formulations appear to be a viable option for pharmaceutical treatment of opiate dependence as an HIV prevention intervention. The analysis findings, along with data from ongoing pilot projects, will help to inform policy, resource allocation, and clinical approaches to opioid dependence treatment programs in the Russian Federation.

## ABBREVIATIONS

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AIDS	acquired immune deficiency syndrome
HAART	highly active antiretroviral therapy
FDA	Food and Drug Administration
Global Fund	Global Fund to Fight AIDS, Tuberculosis, and Malaria
HIV	human immunodeficiency virus
HPP	Health Policy Project
IDU	injecting drug user
MOHSD	Ministry of Health and Social Development (from June, 21, 2012, the Ministry of Healthcare)
MSM	males who have sex with males
NGO	nongovernmental organization
NHMRC	National Health and Medical Research Council
OST	opioid substitution therapy
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
PLHIV	people living with HIV
PWID	people who inject drugs
STI	sexually transmitted infection
TB	tuberculosis
UNAIDS	Joint United Nations Program on HIV/AIDS
UNODC	United Nations Office on Drugs and Crime
USAID	United States Agency for International Development
WHO	World Health Organization

Use of Naltrexone in the Treatment of Opioid Dependence  
in the Russian Federation: Situation Analysis

# INTRODUCTION

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The Russian Federation faces a difficult public health challenge because of the dual epidemics of opioid dependence and HIV infection. An important intervention for opioid dependent individuals is drug treatment. Further, drug treatment for those at risk of HIV infection is a well-established and recognized HIV prevention intervention. Therefore, the Russian Federation has an opportunity to address opioid dependence and HIV infection together through the implementation and scale-up of evidence-based drug treatment for opioid dependence.

In support of efforts by USAID and the Russian Federation to implement evidence-based drug treatment paradigms for opioid dependent individuals, the Health Policy Project conducted a situation analysis to identify the perspectives, attitudes, and understanding of practitioners and civil society representatives about how naltrexone and its formulations can be used to address HIV and opioid dependence. This report presents the findings of the analysis and focuses on the potential for expanding the use of naltrexone formulations in the federally financed Russian healthcare system. Three formulations of naltrexone have been approved to treat both alcoholism and opioid dependence. Thus, the use of naltrexone and its formulations appear to be a viable option for pharmaceutical treatment of opiate dependence as an HIV prevention intervention.

## Naltrexone Situation Analysis

In the Russian Federation, naltrexone and its formulations have been used to treat alcoholism and/or opioid dependence for a limited period of time. Oral naltrexone has been available and used for the longest period of time, but its effectiveness has been limited by both its cost and the lack of adherence by opioid dependent individuals. To address medication adherence, two longer-lasting formulations have been developed and approved for use: an implantable formulation lasting up to six months and an injectable formulation lasting up to one month. Both of these formulations present challenges to the medical healthcare system, as they are both new products and Russian policymakers and medical providers have limited knowledge regarding their effective use in the Russian healthcare system.

### *Purpose*

The Health Policy Project (HPP) conducted the situation analysis to gather information and general knowledge regarding the effective implementation and scale-up of extended release naltrexone formulations in treating opioid dependence as an HIV prevention intervention. The goal is to use this information to improve the treatment and care of HIV-positive people and people who inject drugs (PWID) in the Russian Federation. The situation analysis comprised (1) a global literature review of the use of naltrexone and its formulations and (2) key informant interviews with leading clinical and policy experts on drug dependence in the Russian Federation. This information, along with data from ongoing pilot projects, will help inform policy, resource allocation, and clinical approaches to opioid dependence treatment programs.

### *Methodology*

The HPP team first reviewed current global literature regarding the use of naltrexone and its formulations, while focusing on the effectiveness of naltrexone for treating opioid dependence. The findings were used to develop data collection instruments for key informant interviews and to inform this final report. Following the literature review, the team interviewed 39 key informants regarding the policy environment and the acceptability of the use of naltrexone and its formulations for treating opioid dependence, as well as its availability to clients. Key informants responded to different in-depth questions depending on their area of expertise and experience. The HPP team used a semi-structured interview guide to collect the data.

## Use of Naltrexone in the Treatment of Opioid Dependence in the Russian Federation: Situation Analysis

Specifically, informants were asked to respond to the following questions (see Annex B for a full list of interview questions):

- How and in what settings are oral and Vivitrol (d-NTX) methods currently being used in the Russian Federation?
- How do oral and/or Vivitrol (d-NTX) methods fit into an overall HIV prevention and treatment program?
- To what extent are oral and Vivitrol (d-NTX) methods available and accessible to individuals overcoming opiate addiction?
- What are the benefits and challenges of using Naltrexone in a package of interventions?
- What barriers exist to the use of Vivitrol throughout drug dependence treatment programs in the Russian Federation?

The team conducted the interviews in Moscow, Leningrad Oblast, the city of St. Petersburg, and other regions from December 5–16, 2011. All interviews were conducted in Russian or English. The key informants were identified by HPP in collaboration with USAID/Russia and the consultants involved in the analysis. The informants included representatives of international organizations, nongovernmental organizations (NGOs), women's groups, networks of people living with HIV or representative organizations, advocates, clinicians, and leaders in the field of narcology in the Russian Federation (see Annex A for a full list of interviewees).

Several interviews were recorded with permission of the key informant and transcribed into the language of the recording (Russian). Detailed notes were handwritten for those interviews not recorded. The interviewer read through each transcript or set of interview notes to develop a list of themes and findings.

### ***Limitations***

The situation analysis was not conducted as a program or implementation evaluation and only focused on the national level and one oblast. Thus, the findings cannot be used to evaluate specific projects, nor can the findings provide adequate insight into opioid dependence treatment and HIV prevention efforts in the country's other regions. Further, results of the interviews may be subject to biases of personal opinion and recollection.

## BACKGROUND

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### Epidemiological Situation Related to HIV and Opioid Addiction in the Russian Federation

The Russian Federation has one of the fastest growing HIV epidemics in the world, with the number of diagnosed HIV cases doubling since 2001. Eastern Europe and Central Asia has experienced the largest increase in HIV prevalence of any region in the world. Together, the Russian Federation and Ukraine account for almost 90 percent of newly reported HIV cases in the region (UNAIDS, 2011a).

Injecting drug use accounts for 63 percent of all HIV cases, while 35 percent of cases are attributed to heterosexual sex.

The estimated number of people living with HIV (PLHIV) in the Russian Federation is 750,000—an estimate supported by both the Joint United Nations Program on HIV/AIDS (UNAIDS) and the Russian Federal AIDS Center. In 2009, 471,000 people were registered as living with HIV in the Russian Federation (56% male, 44% female)—up from 420,000 individuals in 2007. There has been a steady increase of newly registered cases, with approximately 58,000 individuals diagnosed with HIV in 2009 and 2010 (Federal Scientific-Methodological Center for the Prevention of HIV and AIDS, 2011a). It is estimated that approximately 62,000 people will be diagnosed by the end of 2011 (Federal Scientific-Methodological Center for the Prevention of HIV and AIDS, 2011b). However, these data do not accurately demonstrate the extent of the country's HIV epidemic, as they only include individuals entered into the official government register of HIV cases.

The Russian Federation's epidemic remains concentrated among key populations—primarily PWID, sex workers (SWs), and males who have sex with males (MSM) (PEPFAR, 2010a). Injecting drug use accounts for 63 percent of all HIV cases, while 35 percent of cases are attributed to heterosexual sex. It is important to note that incidence attributed to heterosexual sex is often related to sexual contact with a PWID. Researchers estimate that there are up to 2 million PWID in the country—of which, more than one-third (37%) are believed to be HIV positive (UNAIDS 2010; Mathers et al., 2008).

Beginning in 2007 with the Federal Targeted AIDS Program, the number of patients receiving highly active antiretroviral therapy (HAART) increased from 15,000 in 2006 to 71,916 in 2009 (UNAIDS, 2009). Despite these significant increases in coverage of PLHIV with life-saving treatment and large-scale investments in HIV treatment, federal HIV prevention efforts are lagging. The Russian Federation has not adopted a comprehensive national HIV prevention strategy, and the rate of new HIV infections continues to increase. The allocation of resources to the prevention of HIV transmission among groups most at risk is limited with only US\$8 million of the US\$181 million spent on HIV prevention in 2008 being invested in PWID, MSM, or SWs (UNAIDS, 2011b). UNAIDS has also reported that the funding allocated for HIV prevention among key populations for 2010 was not released by the government for allocation and spending (UNAIDS, 2009).

Drug dependence, and specifically opioid dependence, poses a significant burden to the Russian Federation public health system, as well as to the global economy. There are substantial medical and social consequences of drug abuse and dependence, including HIV and hepatitis C virus transmission, criminal activity, occupational absenteeism, lost productivity, family dysfunction and breakup, and increased healthcare costs, which can be alleviated by evidence-based drug treatment (Tetrault and Fiellin, 2012).

In 2008, total Russian government spending for the provision of healthcare to patients with diseases associated with drug use was 19.9 billion Russian Rubles (US\$606 million) or 2 percent of all government spending for healthcare (Higher School of Economics, Institute of Healthcare Economics, 2011).

In 2009, the Ministry of Health and Social Development of the Russian Federation reported 555,272 registered drugs users, with a total of 357,759 registered cases of “*narcomania*” or narcotic addiction (dependence). Of this total, 310,960 are federally registered cases of opioid dependence (Ministry of Health and Social Development, 2010). Opioids are by far the predominant narcotic of choice, but there is a steady rise over the past decade in the number of registered cases of dependence on multiple narcotics or on “other forms” to include narcotic prescription abuse. Narcotic prescription abuse also carries a risk for HIV infection through the trading of narcotic prescribed medications for sex. PWID can be polysubstance abusers that are at risk of contracting or transmitting HIV and/or hepatitis through unsafe injection practices. There were 386,279 registered PWID in 2009 (69.6 percent of all registered drug users in the country). According to the Ministry of Health and Social Development, 50,994 of registered PWID are HIV positive, which is 13.2 percent of all registered PWID (Ministry of Health and Social Development, 2010).

## Drug Addiction Treatment (Narcology) as a HIV Prevention Strategy

Effective drug addiction treatment is one key recommended component of HIV prevention programs for PWID (PEPFAR, 2010b). Guidance from the U.S. President’s Emergency Plan for AIDS Relief on comprehensive HIV prevention for PWID advises that the potential impact of drug dependence treatment on preventing HIV is borne from the following:

- Reduced injecting drug use
- Reduced sharing of injecting equipment
- Reduced exposure to high-risk environments, such as prisons
- Reduced high-risk behaviors related to sexual transmission of HIV
- Increased opportunities for HIV education and medical care
- Improved adherence to HIV care and treatment

Narcology is a medical sub-specialty of psychiatry dealing with addictions, primarily addictions to illicit drugs and alcohol. In the Russian Federation, the current government-funded medically based drug treatment program comprises medical detoxification followed by entry into rehabilitation programs. The rehabilitation programs are abstinence-based and can be either government supported with government program staff or private programs administered and run by local nongovernmental or faith-based organizations. The government services are provided free to registered drug users, and the private programs usually require a fee. There are reports of substantial client attrition after detoxification, since the detoxification and rehabilitation programs are separately managed. There is also a lack of sufficient, high-quality rehabilitation programs (using best practices) to support abstinence from drug use after detoxification, which further contributes to recidivism to drug and alcohol use and to HAART-related adherence problems. There are no chronic medical care models for opioid treatment after detoxification in the Russian Federation, which would promote the use of medication-assisted treatment in all its forms. Currently, only naltrexone (an opioid antagonist) is a legal treatment option post-detoxification. Methadone and buprenorphine (opioid agonists) are not viable medical care options, as methadone is an

illegal drug in the Russian Federation, and buprenorphine, while a legal medication, is illegal to prescribe to opioid dependent persons.<sup>1</sup>

The World Health Organization (WHO) recommends methadone maintenance treatment and buprenorphine treatment for opiate dependence. Many Russian and international scientists, clinicians, advocates, and patients have advocated to the Russian government to legalize methadone maintenance treatment for opioid dependence. Many of these individuals, as well as the WHO, publicly criticize (in literature and mass media) the current approaches to drug dependence treatment in the Russian Federation, stating that the approaches violate bioethical principles and do not adhere to international best practices (Elovich and Drucker, 2008; Mendelevich, 2011; Audoin and Beyrer, 2012; Bart, 2011).

However, new medications and formulations of current medications provide a resource for scientists and clinicians in the country, as well as internationally, to conduct clinical trials and evaluations and develop models of care to provide evidence-based treatment for PWID with opioid dependence. This includes the extended release formulations of naltrexone recently approved for treatment of opioid dependence—particularly the extended release, injectable naltrexone (Vivitrol).

## Naltrexone Formulations and Use in Relapse Prevention to Opioid Use

Naltrexone is a non-narcotic opioid receptor antagonist for relapse prevention without abuse liability or reinforcing effects. Naltrexone attenuates or completely blocks, reversibly, the subjective effects of intravenously administered opioids. Naltrexone is not associated with the development of tolerance or dependence, but in patients physically dependent on opioids, naltrexone will precipitate withdrawal symptomatology. Thus, naltrexone is used exclusively after detoxification from opioids to prevent relapse to opioid use. Naltrexone is available as naltrexone hydrochloride in oral, daily formulations from Merck Pharmaceuticals, brand name Revia, or as a generic equivalent. Long-acting, sustained-release formulations (injectable and implantable) are also available and approved for opioid treatment in the Russian Federation. Each formulation has been documented to have positive and negative attributes from the clinical and client perspectives. Positive attributes overall include a lack of abuse potential and mild side effects (Krupitsky et al., 2010). In addition, a recent study has shown that sustained release formulations can reduce all-cause mortality and overdose in the first four months post-treatment (Kelty and Hulse, 2012). Negative attributes for the oral formulation include poor patient medication adherence, a potential risk of liver complications on overdosing, and a risk of opioid overdose on relapse to heroin use after long-term naltrexone use (Krupitsky, 2011).

### *Oral naltrexone*

Oral naltrexone hydrochloride is a non-narcotic dose-dependent, opioid antagonist that blocks opioid binding to the  $\mu$ -opioid receptor. It was approved for use in the treatment of opioid dependence in the United States in 1984. Clinical studies indicate that 50 mg of naltrexone hydrochloride will block at the  $\mu$ -opioid receptor the pharmacologic effects of 25 mg of intravenously administered heroin for periods as long as 24 hours. Other data suggest that doubling the dose of naltrexone hydrochloride provides blockade for 48 hours, and tripling the dose of naltrexone hydrochloride provides blockade for about 72 hours. There is no negative reinforcement (opioid withdrawal) upon discontinuation. Due to naltrexone's

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<sup>1</sup> Opioid substitution therapy (OST) includes treating addicts using methadone and/or buprenorphine. These drugs have been found to be effective in reducing illicit opioid use as well as increasing retention in drug abuse treatment. OST has been found to reduce drug-related HIV risk behaviors, including the frequency of injecting and sharing of equipment. Studies also show that effective maintenance treatment is associated with protection against HIV sero-conversion. Both buprenorphine treatment and methadone maintenance treatment have been shown to lead to greater initiation of HAART among HIV-positive opioid-dependent injecting drug users as well as higher subsequent antiretroviral adherence.

opioid antagonism, patients must abstain from opioids for a minimum of seven days prior to starting treatment to avoid the precipitation of opioid withdrawal. The effectiveness of naltrexone treatment depends on the patient's motivation and social support system. Thus, in environments where there is strong family or social support for the patient in care, oral naltrexone hydrochloride has been shown to be effective in the prevention of relapse to heroin use. Because of a lack of positive reinforcing effects with naltrexone and low motivation on the part of many patients, as well as, poor clinician acceptability, oral naltrexone is not widely prescribed for the treatment of opioid dependence in the United States and thus is not seen as a good maintenance treatment medication for opioid treatment. In the Russian Federation, where family support has been shown to promote effectiveness, a main barrier to use is medication cost.

### ***Long-acting naltrexone formulations***

*Dermal implants*—Several types of naltrexone implants are available, can provide sustained release of naltrexone hydrochloride for up to 12 months, and are used mainly in private clinics. All implants are surgically inserted into subcutaneous tissue in an outpatient setting. In the Russian Federation, an implant containing 1 gram of naltrexone (Prodetoxon) is available from Fidelity Capital, Moscow, and has been approved for use to prevent relapse to opioid use. This implant can provide sustained release naltrexone hydrochloride for up to two months. In a study of 102 heroin dependent patients, individuals receiving the naltrexone implant were noted to be retained in treatment longer, have substantially greater number of opioid-free urines, and be five times more likely to be in remission six months post-treatment. Limitations regarding use of the naltrexone implant include the need for a surgical procedure, the risk of wound infections, and cosmetic skin marks from surgery.

*Injectable sustained release*—Vivitrol is an injectable extended-release (one-month) naltrexone hydrochloride preparation that has recently been approved for the treatment of opioid abuse and dependence in the United States and Russian Federation. The United States Food and Drug Administration (FDA) approved Vivitrol, the long-acting, extended-release, injectable version of naltrexone hydrochloride, on October 12, 2010, for the prevention of relapse to opioid dependence following opioid detoxification (U.S. FDA, 2010). The Russian Federation approved Vivitrol for use in treating opioid dependence on April 8, 2011. Vivitrol addresses the concern of medication adherence as a monthly injectable formulation, and this extended formulation has been shown to be more effective than oral naltrexone hydrochloride. This was also shown in a recent Phase 3 clinical trial performed in the Russian Federation that confirmed Vivitrol's safety and efficacy in the prevention of relapse to heroin use in a cohort of PWID. A higher retention in care and higher rates of opioid-free urine screens were observed, along with a significant reduction in opioid craving compared with placebo. Patients treated with Vivitrol were more likely to stay in treatment and to refrain from using illicit drugs (Krupitsky, 2011). Additional studies are underway to determine the most efficacious service model(s) for the use of Vivitrol in the treatment of relapse prevention to heroin use.

# FINDINGS OF THE NALTREXONE SITUATION ANALYSIS

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A total of 39 individuals were interviewed in Moscow, the city of St. Petersburg, Leningrad Oblast, and other regions. Of the 39 individuals interviewed, 22 are narcologists or rehabilitation specialists, whether practicing or serving in administrative functions. Other interviewees represented international NGOs, Russian NGOs, AIDS centers, and pharmaceutical companies.

## Narcology in the Russian Federation

Narcology is a medical sub-specialty of psychiatry dealing with addictions, primarily focusing on addictions to illicit drugs and alcohol. Drug dependence treatment is provided by government narcology programs, while drug and alcohol dependence rehabilitation is provided by government narcology programs, private practicing narcologists, and rehabilitation specialists at rehabilitation centers. As noted earlier, independent viewpoints about the differences between the practice of narcology in the Russian Federation and drug and alcohol dependence treatment programs in Western countries are well documented in literature and mass media, as well as concerns about the effectiveness and ethics of the Russian approach.

### *Philosophy of Russian narcology*

HPP interviewed 22 practicing narcologists or individuals with training in narcology or rehabilitation working in the government and private sectors and with donor-funded projects. Many narcologists interviewed had been exposed to European and American approaches to drug addiction treatment and rehabilitation through study tours, conferences, and exchanges. Interviewees described the differences between the Russian model of narcology and the European and American models of drug addiction treatment by noting that the “Russian model focuses on abstinence-based therapy.” The practicing narcologists interviewed shared a common viewpoint:

*“Russian model is focused on actual treatment of the patient, while foreign models are more interested in stopping the consequences of drug use.”*

### *Rehabilitation programs*

Key informants explained that the Russian model of care for drug dependence begins with detoxification for approximately seven days, followed by rehabilitation. The HPP team interviewed three rehabilitation specialists in St. Petersburg and Moscow. These rehabilitation specialists, as well as nine representatives of international and Russian NGOs, described the importance of a strong rehabilitation program as well as a comprehensive set of interventions:

*“Rehabilitation focuses on the whole person and not just symptoms and consequences of drug dependence. It’s holistic care. Narcology focuses primarily on the biological, but there are other aspects.”*

*“Rehabilitation lasts from 1 to 6 months, and roughly one half of the people who enter rehabilitation complete the course of care. During rehabilitation, they receive care from several different specialists. Social workers help the individual to get rid of old friends and links to drug use. The rehabilitation specialist (“rehabilitologist”) works with the family to understand how the family affects the addict. Looking at drug dependence from all these different angles is what helps to keep a person from relapsing.”*

All 39 interviewees acknowledged that the quality and effectiveness of detoxification and rehabilitation approaches in the country differ. Interviewees noted the following reasons for limited access to high-quality rehabilitation programs:

- Lack of a government system and specialty in rehabilitation
- Absence of strong, evidence-based protocols or standards for rehabilitation<sup>2</sup>
- Widely held views among both providers and clients that detoxification is a substitution for rehabilitation
- Insufficient number of high-quality rehabilitation programs
- Barriers that a client faces to stepping away from his life for inpatient rehabilitation services
- Client's inability to pay for the services

According to key informants, government narcology hospitals and clinics do not always have a rehabilitation program but do provide referrals to rehabilitation programs that can address clients' needs. While interviewees cited strong rehabilitation programs funded by the government in St. Petersburg, Murmansk, and Tatarstan, they reported that many of these programs are not sufficient for helping a PWID avoid relapse after detoxification. Instead, comprehensive, high-quality rehabilitation programs are often commercial or supported by a religious group. One informant noted the following:

*“The government declares that they have a rehabilitation program, but it is mostly focused on medical rehabilitation to stabilize a craving for drugs. A PWID needs more than that. They need assistance in obtaining secure housing and employment, psychological counseling, services for family members, and a spiritual component to help provide motivation and build commitment to prevent relapse.”*

One rehabilitation specialist interviewed is confident that the government rehabilitation system will eventually improve:

*“The government is definitely interested in moving toward establishing a rehabilitation system within the government health system. It's not the physical center and location, but having trained specialists to provide these services. Russia doesn't have the appropriate training programs for rehabilitation specialists.”*

### **Barriers to accessing narcological and rehabilitation services**

According to the practicing narcologists and rehabilitation specialists interviewed, there is no one consistent profile of a PWID in the Russian Federation. They described an aging epidemic of opiate use that spans socio-economic groups. With drug use no longer seen as primarily a problem among youth, professional and lifestyle concerns and consequences of being formally registered in the government drug dependence treatment system can be a concern to PWID. For example, a person formally enrolled (“registered”) in narcology treatment may have his driver's license revoked and may be unable to apply for a driver's license for up to five years:

*“People don't want to register in the system because they would have to relinquish their driver's license.”*

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<sup>2</sup> Currently, a protocol does exist: Реабилитация больных наркоманией” (Приказ МЗ от 22.10.2003) №500; however, key informants note that it is not sufficient to support high-quality, evidence-based rehabilitation services.

Interviewees reported that clients may have trouble obtaining or maintaining employment or a position in an educational institution/program:<sup>3</sup>

*“Taking extensive leave from employment or school to participate in a detox and rehabilitation program could result in dismissal. Addicts that are in this position may not want to enroll in a full rehabilitation program even if they are able to afford it.”*

Additionally, all 39 key informants interviewed expressed concern that many PWID cannot afford a high-quality rehabilitation program:

*“You can get into a rehab program for around \$700 per month, but a \$3,000 per month program is much better.”*

*“Religious rehab centers are typically free, but there are waiting lines and people may not be interested in being a part of a church-oriented program.”*

*“If a patient wants to avoid the government system altogether, he can seek services in the commercial sector. Detoxification care costs 15,000–30,000 Russian rubles (US\$500–1,000) for a week, depending on the amount of medications and the approach needed. Inpatient rehabilitation for approximately one and a half months with food and medications costs 70,000 rubles (US\$2,400).”*

No matter the cost, high-quality rehabilitation programs are in short supply and are full with long waiting lists. Narcologists acknowledged that without access to a rehabilitation program, a patient that leaves treatment following detoxification is likely to relapse.

### **Pharmaceutical treatment of opiate addiction**

The only pharmaceutical treatment available for opioid dependence in the Russian Federation is the opioid antagonist naltrexone in its different formulations: short-term, oral form and long-acting injections and implants. Opinions about the current forms of legal pharmaceutical treatment for drug addiction in the country vary. Most of the narcologists and rehabilitation specialists interviewed noted that an ideal package of services for treating opioid dependence would include a “variety of interventions,” including medication-assisted treatment and other biomedical approaches, psychological counseling for the patient and family, and social support and services.

While this assessment did not include questions referring to methadone maintenance treatment or buprenorphine treatment, 11 narcologists interviewed noted that these treatment regimens can be effective tools in an opioid treatment program but should never be considered the only tools or the most important tools. Narcologists practicing in the Russian government sector expressed concern that methadone maintenance treatment, applied in models that they are familiar with in Europe and the United States, is often used long term and for too many patients. One key informant noted that even if methadone maintenance treatment were allowed in the country, the model for using this treatment tool would be different:

*“OST [opioid substitution therapy] would be just one of the tools in an ideal package of services, but it is not appropriate for everyone.”*

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<sup>3</sup> On January 1, 2012, the list of employment positions drug addicts are prohibited from obtaining was extended. For example, the list now includes bank and medical positions, yard-keeping positions, and positions in educational institutions.

*“International experts who are against the Russian model would want you to think that every addict can and should have methadone. That’s not the case. Abstinence-based treatments are clinically indicated for many and can also be a preference for an addict.”*

This is an important observation, as in the United States, two important characteristics of the opioid treatment programs are (1) providing treatment options for patients so they can “select” their treatment option and thereby have ownership of that treatment option and (2) matching the patient to the treatment option, where patients and healthcare providers match the treatment needs of the patient to a specific treatment regimen.

Pharmaceutical treatment for opioid dependence in the Russian Federation is discussed in more detail in the sections below.

## Organization and Coordination of Services for People Who Inject Drugs

According to international guidance by the WHO, the United Nations Office on Drugs and Crime (UNODC), UNAIDS, and other global agencies, comprehensive programs targeting the needs of PWID should provide the following components (WHO et al., 2009):

1. HIV counseling and testing
2. Antiretroviral treatment
3. Prevention and treatment of sexually transmitted infections (STIs)
4. Programs for distribution of condoms to PWID and their sexual partners
5. Target programs in the field of information, awareness building, and communication, specifically targeting PWID and their sexual partners
6. Vaccination, diagnosis, and treatment of viral hepatitis
7. Prevention, diagnosis, and treatment of tuberculosis (TB)
8. Programs for needle and syringe distribution and exchange
9. Opiate substitution treatment and other types of drug addiction treatment

In the Russian Federation, many of these components, when provided, are provided by separate vertical programs. For instance, narcology provides drug addiction treatment services; infectious disease specialists oversee HIV counseling and testing and HAART; NGOs and social workers are responsible for HIV prevention, psychological and social support services, outreach, and case management; venerology provides STI diagnosis and treatment; and tuberculosis facilities provide TB-related services. Additionally, private clinics can provide a variety of specialty services anonymously and confidentially.

The HPP team asked key informants about how narcological services are provided to HIV-positive PWID or PWID with other co-morbidities. All the narcologists interviewed described the vertical structure as one that “does not prioritize narcological services.” Key informants consistently agreed that coordination between vertical programs is weak in many parts of the country and at the national level. Many stated that coordination is more often “dependent on motivation and the personalities of those involved.” One narcologist noted the following:

*“It is not a secret—there is a lack of coordination between vertical health programs. For instance, if I am treating a patient on HAART, I am not required to communicate his/her status and health updates to the AIDS Center caring for them. So, the AIDS center may not know that he/she is in narcological care at all.”*

Another stated that:

*“People on HAART have difficulty getting narcological assistance. In some places, a person on HAART cannot be admitted to the narcology hospital because they aren’t supposed to take medications and they don’t want very sick patients or patients with OIs [opportunistic infections] that could be passed on to others.”*

Each of the 39 key informants noted that existing regulations “neither facilitate nor hinder” communication and data sharing between these vertical programs. One key informant stated the following:

*“If something is dependent on personalities and individual motivation, this is not a system. A system should be able to operate effectively no matter which personalities are involved.”*

Existing Ministry of Health and Social Development recommendations do establish positions for a variety of specialists, within an AIDS Center (MOHSD, 2007), but otherwise, access to these services is provided within the individual specialty. Although a key informant referred to these recommendations as specifying a narcologist, in fact, the recommendations highlight a psychiatrist as a provider to include in the AIDS center. If a PWID is not already in the care of an AIDS center, it may be more difficult to gain access to the full spectrum of care available. One key informant expressed the consequences of this challenge:

*“The lack of coordination can result in dangerous health outcomes for the client as well as society. If a client is diagnosed with TB in the narcology unit, he is sent to the TB facility and is not likely to receive narcological care. The TB facility may hospitalize the patient, and the patient will begin to experience withdrawal and no one helps him. So, then the patient leaves TB treatment without undergoing the full course of medications.”*

Several key informants in the field of narcology described HIV as a “consequence of drug dependence” and expressed frustration that narcology is not seen as a place to treat other medical conditions. For instance, one interviewee questioned why “there is no mandate for an infectious disease specialist to provide HIV-related services at narcology hospitals or dispensaries.”

Some oblasts organize different models of coordination among vertical programs to try to overcome these barriers, but the coordination is dependent on the interest and willingness of different specialties to collaborate and fund a position for specialists from a different vertical program. Key informants highlighted the following oblasts as having strong models of coordination or comprehensive care: Murmansk, Altai Krai, Kemerovo, Tatarstan, Khanti-Mansisk, Leningrad Oblast, and Moscow City’s specific focus on co-morbidities.

Only a small number of key informants represented AIDS centers and the infectious disease program. HPP approached several key informants to represent the program, but they were unable to participate or did not see the relevance of Vivitrol to their program.

## Opinions and Viewpoints of Naltrexone in the Russian Federation

*“People want to talk about naltrexone as OST [opioid substitution therapy], but it’s not. It’s a variation on abstinence treatment. It’s a step forward, and it allows someone to put a wall between them and heroin.”*

Naltrexone is an opioid receptor antagonist and can prevent relapse to opioid use, thus maintaining abstinence to opioids. While naltrexone blocks the effects of opioids, key informants noted that pharmaceutical treatments, such as naltrexone, methadone, and buprenorphine do not address underlying medical, psychiatric, or social conditions. Thus, it is important to provide other supportive services, such as psychological counseling, group therapy, medical care for co-morbidities, and services to help the client secure employment, housing, and other social needs.

A significant concern cited by the narcologists and rehabilitation specialists (22) about all forms of naltrexone is that if the client discontinues naltrexone and immediately returns to his usual dose of heroin, s/he could suffer an overdose due to a reduced tolerance of the opioid, which is true for other forms of drug treatment, such as methadone and buprenorphine. At least two key informants noted that services would be improved by incorporating the distribution of naloxone to clients to use in case of overdose.

### **Knowledge of naltrexone**

Interviewees were asked to describe their knowledge of different forms of naltrexone, evidence of the effectiveness of naltrexone, and whether their colleagues in other regions of the Russian Federation are familiar with naltrexone in long-acting forms. Representatives of international and Russian NGOs were familiar with naltrexone and Vivitrol, but did not have extensive experience or information about the use of Vivitrol in the country. Narcologist respondents unanimously reported that their colleagues throughout the country are familiar with naltrexone in different forms. When asked how narcologists learn about new pharmaceuticals, the narcologists and rehabilitation specialists interviewed (22) reported that naltrexone, in particular, has been discussed during conferences and presentations by narcologists paid to represent the pharmaceutical company promoting Vivitrol in the Russian Federation, Janssen-Cilag. While interviewees were questioned about naltrexone in different formulations, the majority of questions focused on Vivitrol.

Despite widespread familiarity with the use and effectiveness of naltrexone in oral, injectable, and implant formulations, current use of naltrexone to treat opiate addiction is limited. As a narcologist in St. Petersburg noted, “each form has its own pluses and minuses for treatment of drug addiction.” The following summarizes current viewpoints of different forms of naltrexone among the key informants interviewed.

*Oral naltrexone (antaxone).* The oral form of naltrexone was registered in 1998 and has been more prevalently used than other form, according to the narcologists interviewed. The oral form of naltrexone is effective and affordable to some PWID at approximately US\$100 per month, but adherence to this daily form of naltrexone is challenging:

*“Every day someone has the choice about whether they want to take the oral naltrexone pill.”*

The narcologists interviewed stated that the most effective model of care for providing oral naltrexone is during inpatient care or daily visits to the health facility, as oral naltrexone as typically administered is only effective for 24 to 36 hours. According to interviewees and current literature, effective treatment with oral naltrexone is limited by poor treatment adherence and subsequent relapse.

Extended release naltrexone (via injection or implant) can overcome one of the major drawbacks of oral naltrexone—patient compliance with a daily regime.

*Implant (prodetoxon).* In the Russian Federation, prodetoxon<sup>4</sup> has only been used in clinical trials and not in routine clinical practice, according to interviewees—though four narcologists interviewed expressed concern about “black market implants.” There is evidence of the effectiveness of naltrexone implants in clinical trials (Hulse, 2009; NHMRC, 2010). The implant is active for a longer period of time—from 2 to 3 months—and can be removed in the event of side effects or client dissatisfaction. The Australian implant has been widely studied and has the most significant evidence of efficacy. Key informants were not aware of any initiatives to register the Australian implant in the Russian Federation or conduct a trial of the Australian implant in the country.

Narcologists described the greatest concerns about the implant: (1) the implant insertion involves minor surgery and requires specific expertise, equipment, and accreditation for a facility to be able to provide the implant; (2) the implant can be removed by a client, which can result in significant wound infections and dangerous opiate overdose. As described above, it is unlikely that a client will inject enough heroin to overcome the blockade that naltrexone provides. However, interviewees expressed concern that if the client discontinues naltrexone or removes the implant and immediately returns to his usual dose of heroin, he could suffer an overdose due to a reduced tolerance to the opioid.

*Injection (Vivitrol).* Vivitrol was registered for use in treating opiate dependence in April 2011 and was included in the list of essential drugs in the Russian Federation in 2010 (based on registration for treatment of alcohol abuse). As of March 2012, it has not been included in the WHO Model List of Essential Drugs.

According to interviewees, Vivitrol is used primarily in private clinics, clinical trials, and as a part of small-scale projects or special studies to treat alcohol and opiate addiction. It is not yet used routinely in clinical care. There is evidence of its effectiveness for preventing relapse among people who have recently undergone detoxification from opiate use (as described in the background section of this report).

Interviewees had mostly a positive view of Vivitrol as a potential biomedical tool to fight opioid dependence. In addition to a concern about overdose among PWID that return to opioid use after taking naltrexone, interviewees cited a few potential concerns or barriers to more widespread use. Barriers or concerns related to Vivitrol include its cost and the lack of an ideal mechanism for integrating it into service delivery. These issues will be addressed below.

## Opinions on the Application and Use of Vivitrol in the Russian Federation

The HPP team asked key informants to discuss the use of Vivitrol in the Russian Federation and the models of care they would recommend for providing Vivitrol. Key informants described it as the preferred formulation of naltrexone in most situations and cited its strengths, such as prevention of relapse, minor side effects, and long-acting effectiveness. Rather than taking a daily oral form of naltrexone, clients can take monthly injections of Vivitrol—though clinical trials do note a reduction in blood levels of naltrexone after three weeks. Interviewees recommended that clients continue psychological counseling and monitoring throughout the month, a form of comprehensive treatment for opioid dependence practiced in Western countries. A few narcologists interviewed (5) specifically expressed the importance of not waiting a full month for the next injection. It is important to note that

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<sup>4</sup> See <http://www.prodetocon.ru>.

while all narcologists interviewed had some experience prescribing and monitoring the use of Vivitrol, only the narcologists involved in clinical trials had extensive experience. To date, Vivitrol while approved in the Russian Federation, has not been scaled up throughout the Russian Federation, and national treatment guidance has not been issued for Vivitrol use in narcology hospitals or clinics.

### ***Issues mentioned with the use of Vivitrol***

Interviewees noted that as with treatment for other medical conditions, clients should be informed of the risks associated with taking naltrexone, if any risks are present. Interviewees cited what has been discussed in the literature, including the recommendation that clients should be educated about the increased risk of overdose if the client uses opioids during or immediately after discontinuation of long-acting naltrexone (as with treatment discontinuation when using methadone and buprenorphine). Some interviewees (6) suggested that the addition of naloxone and education about the use of naloxone in case of overdose would improve the model of care.

The primary issue expressed by all interviewees about Vivitrol was its cost, routinely cited by key informants at 17,000 rubles per injection (per month) or nearly US\$600. In the United States, a monthly cost for Vivitrol is cited as \$900 per month but is usually paid for by medical insurance (Kennedy et al., 2011). All of the interviewees explained that this is cost prohibitive for many opioid dependent persons and their families.

An additional issue cited is that clients may not participate actively in rehabilitation if they believe that Vivitrol alone will prevent them from using opiates. NGO representatives highlighted the need for psycho-social support for PWID using Vivitrol, as with all other medications used to treat opioid dependence. Several experts interviewed by the HPP team expressed caution at seeing naltrexone as a silver bullet—instead preferring that it serve as one “tool in the toolbox”:

*“Too often, they get the shot and don’t want rehab because they see Vivitrol as the silver bullet. Instead, it would make more sense to provide Vivitrol at the end of rehabilitation before they are released.”*

*“Many people consider that when they take naltrexone, they don’t need rehabilitation.”*

*“Clients may consider it a panacea and may not be willing to receive other important services.”*

*“It’s very difficult to expect someone to be cured with naltrexone. It has to go hand-in-hand with other services—social and psychological services. We have to help them to see that they can get a high elsewhere—finding a high out of people and events in their lives.”*

*“Pharmaceuticals and blockers may seem like an easy fix or an easier way to get to remission, but it isn’t the full solution.”*

Additionally, five key informants noted that heroin is now more difficult to find than it was in the past due to more control along the country’s borders. Several interviewees expressed concern that naltrexone will not address addictions to other drugs that a PWID is using alongside opiates. However, recent studies have shown that sustained-release formulations may be effective in the treatment of polysubstance abuse, particularly opioids and stimulants.

*“Many drug addicts do not just use opiates. Naltrexone does not block the effects of other drugs, though, so there is a need for treatment that addresses the addiction to other substances.”*

*“Heroin is now not very clean, and some drug effects may get through if used with naltrexone.”*

### **Models of care for prescribing Vivitrol**

Different models for prescribing naltrexone were described by interviewees. Interviewees cited these models of care for providing naltrexone in different forms:

- Immediately following detoxification, while waiting for admission to rehabilitation
- As a part of inpatient (oral naltrexone cited) and/or outpatient rehabilitation programs
- Immediately following rehabilitation, upon release
- Instead of receiving services at a rehabilitation center

Several narcologists interviewed agreed that naltrexone would be most effective either as a part of a comprehensive rehabilitation program or toward the end of an intensive, comprehensive rehabilitation program:

*“If you are geared to the full recovery of the patient, this means that they need a full spectrum of services that addresses all their needs.”*

*“We know that detoxification rarely brings remission. Vivitrol is just one quarter of what’s needed for full remission. There need to be psychological, spiritual, and social services.”*

*“Without establishing a strong system, Vivitrol and naltrexone alone will not have good results. Financing is insufficient for Vivitrol, but it’s also insufficient for a strong system, including quality rehabilitation.”*

When asked if the ideal model of care would differ if the client were HIV positive and receiving HAART, key informants noted that the timing of providing Vivitrol, the involvement of a narcologist, and the need for rehabilitation would not be affected by the client’s HIV status. Key informants did note that an HIV-positive status would simply require coordination and active communication with the AIDS center about the most appropriate approaches for providing both narcological care and HIV-related care.

Interviewees were asked to describe their ideal client profile for using Vivitrol to help prevent relapse; they described a need to identify PWID who have experienced repeated attempts at sobriety, “really want to quit,” do not want to go through a lengthy or repeated rehabilitation, do not want to be in a religious rehabilitation center and are waiting for admission to an acceptable rehabilitation center, and have strong desire and strong social support.

*“For those that can go to the rehabilitation center, it would be better to provide naltrexone upon release. But for those who can’t leave work and can’t have inpatient rehabilitation, this would be a better reason to take naltrexone following detoxification or as a part of an outpatient rehabilitation program.”*

### **Access to Vivitrol (extended-release, injectable naltrexone)**

Given these considerations about Vivitrol, interviewees were then asked about clinicians’ and clients’ access to Vivitrol. Access is defined by a variety of frameworks in a variety of ways. For this analysis, HPP generally considered the factors that influence entry into care and use of care. The factors may include *availability* of a particular commodity or service; physical *accessibility* to the client; *affordability* to the client or health system; and *acceptability* of the commodity or service to the client and society.

Below, HPP addresses availability, accessibility, and affordability but does not address acceptability of the commodity to the client.

### ***Availability and accessibility***

Interviewees reported that naltrexone in its oral and extended-release injectable forms are widely available to order through pharmacies. Janssen Cilag, the pharmaceutical company responsible for marketing Vivitrol in the Russian Federation, is currently promoting it in 15 markets throughout the country, including Moscow, St. Petersburg, Nizhny Novgorod, Ufa, Khabarovsk, Vladivostok, Novosibirsk, Yekaterinburg, Kazan, and Rostov. A client can independently locate Vivitrol at local pharmacies in some larger cities by contacting a pharmacy telephone service, which will identify the closest pharmacy with the particular drug in stock. In rural areas and smaller municipalities, narcologists may be familiar with Vivitrol but would likely have to place special requests or orders to provide the medication at a pharmacy.

### ***Knowledge of effectiveness of naltrexone and its effect on access***

The majority of narcologists and rehabilitation specialists interviewed reported that medical professionals are familiar with different forms of naltrexone, including Vivitrol. They learn about Vivitrol from pharmaceutical representatives. However, note that only a small sample of narcologists, mostly based in large urban areas, were interviewed, and the use of naltrexone to treat opioid dependence may not be as widely understood or accepted outside of these areas. While interviews with medical professionals confirmed that physicians are informed about the use of naltrexone in the treatment of opioid dependence, interviewees reported that patients, policymakers, and planners are not familiar with naltrexone and its formulations. Specifically, eight interviewees noted that clients are not sufficiently knowledgeable about naltrexone and its formulations to be able to demand it from their local narcology clinic:

*“Medical personnel have to be interested in using a medication like this, and have to find a way to make it accessible.”*

*“Patients don’t always understand what different types of medications can do for them, and don’t always have the full information.”*

Several key informants at the national level expressed concern that this relatively new form of treatment for opioid dependence is not widely known or understood outside of clinical circles and also noted that some decisionmakers mistakenly view naltrexone as a form of substitution therapy.

*“There is confusion around Vivitrol as substitution treatment. This could become a problem if people continue to think about it that way.”*

*“If Vivitrol is now being developed and expanded, it’s very important to educate officials and the national drug control agency. If people label this medication as substitution treatment, nothing will really happen on expanding the use of this drug for years and people will suffer. It’s important to talk about the medication and describe it to people that don’t know—What is Vivitrol? Why is it important? Start education on it now.”*

Two narcologists and one NGO representative also noted that government commitment to provide funding for Vivitrol and improving the narcology and rehabilitation system are contingent on its understanding and knowledge about the treatment approaches needed to address drug dependence.

### **Cost of Vivitrol**

As described above, the cost of naltrexone in its extended-release formulation is high, but all interviewees reported that the cost of Vivitrol is particularly prohibitive for most clients entering government narcology clinics and hospitals. Interviewees noted that while the price of Vivitrol has reduced from 32,000 rubles to 17,000 rubles per injection, it is still unaffordable for most opioid dependent individuals and their families.

Narcologists in St. Petersburg and Leningrad Oblast noted that limited resources had been allocated for the procurement of Vivitrol, but that so far this had been on a small scale. One narcologist noted that a larger amount of funding had been allocated in last year's budget but, due to the financial crisis, had not been released for procurement of this medication. He described plans to initiate a "Vivitrol project" in the oblast government's 2013 budget. Two narcologists in St. Petersburg noted that Vivitrol had been procured in several other oblasts, but no information was collected from oblasts to get a full picture of the use of government funds to provide Vivitrol.

Narcologists in the government sector reported that they consider the drug's cost excessive; however, they noted that expensive treatments are funded to address other diseases:

*"If they would lower the price, we could actually buy it with government funding."*

*"If government considered it enough of a priority, they would find the funding."*

The HPP team interviewed representatives of Janssen Cilag as a part of this situation analysis. After reducing the price of Vivitrol from 32,000 to 17,000 rubles in the Russian market, Janssen Cilag reported no plans to lower the price further. The price includes the cost to produce, ship, and market the drug; royalties to the license holder of Vivitrol, Alkermes based in the United States; and the taxes and duties involved in importing and selling the drug. The representatives noted that "Vivitrol is a product with one of the lowest profits," and that if "Vivitrol is bought in bulk, price discounts can be provided."

## CONCLUSIONS AND RECOMMENDATIONS

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Several main findings can be drawn from the analysis:

**Naltrexone is being used.** The findings confirm that naltrexone in oral and injectable forms are being used by narcologists throughout the Russian Federation and that practicing narcologists are familiar with the different formulations and evidence of their effectiveness. Narcologists expressed interest in using Vivitrol more widely. While NGO representatives were familiar with naltrexone and Vivitrol, they had inconsistent information about its effectiveness and noted that policymakers may not be familiar with this new development in opioid dependence treatment.

**Vivitrol is most effective as part of a strong rehabilitation program.** Internationally, practitioners, government, donors, international organizations, and Russian NGOs continue to have different views on what is the most effective treatment paradigm for opioid dependence. Interviewees consistently cited the importance of a strong rehabilitation program to prevent relapse after detoxification, and many respondents noted that Vivitrol would be most effective as a part of a comprehensive rehabilitation program.

**Cost is a barrier to increased use.** The analysis findings illustrate that narcologists appear eager to integrate Vivitrol into their package of narcology services but that the cost of Vivitrol is a limiting factor. While the cost of Vivitrol has reduced dramatically over the past two years, the price per injection is still prohibitively high for many clients receiving services in the government sector. Interviewees cited instances of the government funding a small number of doses, but these funds have been insufficient to meet demand.

Policy makers, planners, and decisionmakers play an important role in allocating resources to treat opioid dependence and prevent HIV. The following key recommendations emerged from the analysis:

**Create incentives and guidelines to ensure coordination between vertical programs.** In addition to increasing funding for narcology and rehabilitation services, including the procurement of Vivitrol, interviewees called for improved coordination between vertical health programs (HIV, TB, narcology). Incentives and systematic guidelines are required to ensure that coordination and communication will occur regardless of the personalities leading the respective programs.

**Establish a stronger rehabilitation programs.** Interviewees called for the establishment of a government rehabilitation system, including standards, guidelines, and sufficient funding to support high-quality public rehabilitation programs and regulate the quality of services provided by private rehabilitation centers. Interviewees noted that naltrexone is not a solution to sub-optimal treatment options, including comprehensive psycho-social and behavioral support services.

**Inform infectious disease specialists at the AIDS centers and in the raions about Vivitrol.** While narcologists are overwhelmingly familiar with the existing evidence base around different formulations of naltrexone and have limited experience in applying Vivitrol, it is unclear to what extent infectious disease specialists across the Russian Federation are knowledgeable of the potential of Vivitrol to prevent relapse and improve adherence to HAART. The evaluation currently being conducted by St. Petersburg State Medical University and Yale University will include a strong component related to the dissemination of key findings on the use of Vivitrol to improve adherence to HAART. Increasing funding for coordination and information exchange between the two vertical programs of narcology and infectious disease would benefit clients that require treatment for drug dependence.

**Develop, adopt, and widely disseminate clinical guidelines on Vivitrol and HAART adherence.** As additional evidence is generated on the effectiveness of Vivitrol in improving HAART adherence and preventing relapse, Russian experts can develop evidence-based revisions to clinical standards and guidelines for the treatment of drug dependence, including the use of Vivitrol and the provision of naloxone to treat overdose.

**Consider ways to reduce the cost of Vivitrol to clients.** The cost of Vivitrol has been reduced by more than 50 percent over the past two years, but interviewees suggest that the price is still unaffordable for clients and their families. Considering the epidemic of opioid dependence in the Russian Federation, this pharmaceutical treatment could have a profound impact on the opioid abuse, HIV, and hepatitis epidemics. A few potential ways to reduce the price of Vivitrol include purchasing the medication in bulk, increasing government funding to subsidize the cost, increasing government advocacy to Janssen-Cilag and Alkermes to reduce the price, manufacturing Vivitrol in the Russian Federation, and reducing import duties and taxes on Vivitrol.

## ANNEX A. LIST OF KEY INFORMANTS

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### **Moscow & Moscow Region**

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## ANNEX B. INTERVIEW QUESTIONS

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Please describe your role and the role of your organization related to injecting drug use. How about HIV?

**How and in what settings are oral and Vivitrol d-NTX methods currently being used in the Russian Federation?**

- Please describe how drug dependence treatment services are currently provided. How are patients managed?
- Please describe the typical setting where oral naltrexone is provided (*in this series, probe also for use in treating alcohol abuse*). How about Vivitrol?
- Please describe how Vivitrol and oral naltrexone are currently provided in a clinical setting—the steps in service provision and the package of services typically provided.
- What are the benefits and challenges of using Naltrexone (Vivitrol) in a package of drug dependence treatment interventions? Oral naltrexone?
- Do government clinics and private providers have equal rights and opportunities to provide Vivitrol and oral naltrexone? Can any type of physician prescribe Vivitrol and oral naltrexone?
- Are Vivitrol and oral naltrexone available nationwide or in limited areas?
- When you interact with the average narcologist in the Russian Federation, is he/she providing Vivitrol? Oral naltrexone? Is he/she interested in providing these treatments?
- Do men and women have equal access to drug dependence treatment programs/rehabilitation?

**To what extent are oral and Vivitrol d-NTX methods accessible to individuals overcoming opiate addiction?**

- Are there any legal or regulatory barriers to PWID accessing healthcare and social services in general?
- Do you consider that existing policies present barriers to seeking and/or accessing drug dependence treatment services from the patient perspective? Naltrexone in particular?
- Do men and women have equal access to these treatments?
- If an individual wishes to access drug dependence treatment services, what types of barriers does he/she face to accessing treatment?
- If an individual wishes to use Vivitrol, what types of barriers does he/she face to accessing treatment?
- Is Vivitrol provided free of charge to the client? What costs to the client are associated with treatment?

- If an individual wishes to use oral naltrexone, what types of barriers does he/she face to accessing treatment?
- Is oral naltrexone provided free of charge to the client? What costs to the client are associated with treatment?

**How do oral and/or Vivitrol d-NTX methods fit into an overall HIV prevention and treatment program?**

- Are there any barriers to PWID (and their sexual partners) accessing HIV counseling and testing?
- Are facilities relying on provider-initiated opt-out counseling and testing or is voluntary and informed consent required in testing sites? Are rapid HIV tests used?
- Are appropriately trained and supervised lay workers allowed to provide counseling and testing services or does it require medical staff?
- Is there an effective referral system in place for clients identified as HIV positive at a narcology clinic or rehabilitation center?
- Is there an effective referral system in place for clients identified as possibly having an addiction when they are tested or in care for HIV or AIDS?
- Do PWID in treatment (either at a narcology facility or AIDS center) fully access STI, HAART, and opportunistic disease diagnostics and treatment when necessary?
- Are these services provided in one location and by one service or on a multi-disciplinary basis?

**What evidence has been generated to determine the effectiveness of naltrexone (Vivitrol) in preventing relapses and improving adherence to HAART among HIV-positive PWID?**

- Are you aware of evidence that has been generated either within or outside of the country to show that Vivitrol is effective in preventing relapses to opiate use? Please tell me about it.
- Are you aware of evidence that has been generated either within or outside of the country to show that Vivitrol is effective in improving adherence to HAART among HIV-positive PWID? Please tell me about it.
- Are you familiar with personal stories or experiences of clients who have used Vivitrol (either positive or negative)? Can you, please, share some of these experiences?

**What barriers exist to the use of naltrexone (oral or Vivitrol) throughout drug dependence treatment programs in the Russian Federation?**

- Do service providers face any barriers to prescribing or administering Vivitrol? What about barriers related to oral naltrexone? Implant naltrexone?

## Use of Naltrexone in the Treatment of Opioid Dependence in the Russian Federation: Situation Analysis

- Is there an adequate policy framework explaining how to integrate oral naltrexone and/or Vivitrol into a drug dependence treatment program?
- Do service providers have the skills and knowledge required to prescribe and dispense Vivitrol and monitor a client on that treatment?
- What are some of the reasons why opiate addicted individuals do not access drug dependence treatment services? What are some of the reasons why a client in drug dependence treatment might not access Vivitrol?
- How do think these obstacles can be addressed?

### **Policy and financing questions**

- Which organization/institution, in your opinion, has the most influence over policy decisions related to drug dependence treatment in the Russian Federation? HIV? Use of naltrexone?
- In your opinion, how do political factors at different levels facilitate or hinder the process of introducing new treatment regimens for drug dependence? Any specific factors related to naltrexone?
- What are the key priorities in policy development and policy implementation for expanding the use of naltrexone in the Russian Federation?
- In your opinion, are the funds available from the government (national and local) budgets sufficient for procurement of oral naltrexone? Vivitrol? Are there other ways to fund this treatment protocol?
- Are there any policy barriers to the procurement, supply chain, storage, or prescription of Vivitrol? Oral naltrexone? Implant naltrexone?

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