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Executive Summary

Pollution, poor health and a growing rate of HIV infections has contributed to Russia’s declining population. In spite of these issues, Russia’s economy has experienced a prolonged period of growth. The Russian economy has grown each year following the 1998 default. Political stability and rising incomes have lead to greater purchasing power for consumers.

The economic growth, plus the public health concerns, is likely to form a major market for modern medicine. In fact, the Russian pharmaceutical market has experienced double-digit increases in recent years reaching US$11 billion in 2006. The sector is attracting greater interest from foreign manufacturers and those looking to invest in pharmaceutical distribution and sales. The increase in demand for pharmaceutical products will likely lead to a corresponding demand for safer medicines of higher quality and government policies designed to meet these needs.

Russia is known as a haven for counterfeit products, ranging from compact discs and software to clothing. The prevalence of counterfeit pharmaceuticals is no different. The problem is acknowledged by the government, and the penetration of the legitimate pharmaceutical supply chain is a major concern. The Russian Health and Social Protection Minister estimated the number of counterfeit drugs amounts to 3 to 4 percent of the Russian market. Counterfeits are found of domestic as well as popular international brands. “Look-alike” patent infringing products are also frequently found on the market.

PSI data indicates that Russia ranks second worldwide in the number of pharmaceutical crime incidents and first in the number of seizure/discoveries of fake medicines. Incidents of counterfeiting are increasing. Between CY 2004 and CY 2006, PSI has documented 336 counterfeiting incidents linked to Russia. The increase in number of counterfeiting incidents between CY 2004 and CY 2006 is 166 percent.
Counterfeiting operations have targeted a number of different types of drugs. In the 336 counterfeiting incidents occurring between CY 2004 and CY 2006, 114 different pharmaceutical products were identified. The top three therapeutic categories linked to counterfeiting incidents in Russia were alimentary (25%), anti-infectives (24%), and central nervous system (20%).

Counterfeit pharmaceuticals have been found in more than thirty of Russia’s eighty-nine regions. The vast majority of the counterfeit discoveries involve products within the legitimate supply chain.

Despite high counterfeit incident totals, minimal Russian law enforcement actions have been documented. Between CY 2004 and CY 2006, PSI has documented only nine incidents that involved Russian law enforcement action. Also, only twenty-four (24) arrests have been record in relation to pharmaceutical crime during the same period. This is in stark contrast with the level of law enforcement action in China, which is much greater.

The lack of law enforcement action can be traced to a breakdown in communication between government agencies, low priority, and corruption. A further contributing factor to complacency is the non-existence of investigative reporting.

Despite recording a comparable number of incidents, the pharmaceutical counterfeiting situation in Russia differs drastically from China. While China is a major producer of counterfeits for international markets, Russia’s counterfeiting problem is very insular. The vast majority of counterfeiting incidents linked to Russia involve product found in Russia. There are very few confirmed incidents of counterfeit medicine found in other regions of the world in which the product was sourced in Russia.
I. Russia: The People and Economy

Since the fall of the Soviet Union, lower birth rates and higher death rates have reduced Russia’s population. Alcoholism, pollution and environmental degradation, leading to birth defects and miscarriages, have also played a significant role in Russia’s declining population. According to an intelligence agency’s 2007 statistics, Russia’s population is 141.4 million, with a growth rate of -0.484%. The life expectancy is 65.87 years, and the infant mortality rate is 11.06 deaths/1,000 live births. The fastest-growing section of the population is the 60- to 64-year-olds, which is expected to expand by 78.5% over 2006-2016, while the second fastest-growing group, 50- to 64-year-olds, should increase by 39.3 percent, according to a report by Moscow-based investment bank Troika Dialog.

Although Vladimir Putin has put in place government measures to halt the declining population, elevated death rates from substance abuse and the fact that Russia has the highest growth rate of HIV infections in the world outside of Africa indicates this trend will continue.

Despite the declining population, Russia ended 2006 with its eighth straight year of growth, averaging 6.7 percent annually since the financial crisis of 1998. This growth is buoyed by a favorable trade balance, which, in turn, is supporting a boom in domestic consumption. Specifically, gross domestic product (GDP) is US$733 billion. Exports stand at 43 percent of GDP, and imports are 23 percent of GDP. Over the last five years, personal incomes have achieved real gains more than 12 percent per year. The number of Russians living in poverty has halved since the economic crisis following the disintegration of the Soviet Union. Political stability, high oil prices and a cheap ruble have contributed to the recent economic expansion in Russia.
II. Pharmaceutical Market Overview

At the end of 2006, Russia remained one of the most dynamic of the large pharmaceutical markets in the world. According to Pharmexpert, the volume of the Russian pharmaceutical market amounted to US$11 billion in 2006, which is 30 percent greater than in 2005. The consumption per capita was US$81, which is equal to 2 percent of the average allocated income per one Russian citizen. For reference, in European countries this index is 7 percent and 9 percent in the United States.

According to a United States Commercial Service report in July 2005, in the last ten years, the total volume of the Russian pharmaceutical market increased nine times. This growth is driven by rising incomes and consumer spending. Also, the growth has been supported by the appearance of a relatively new market segment, the DLO Reimbursement Program (Dopolnitelnoye Lekarstvennoye Obespecheniye). The DLO Reimbursement Program is a federal government program that was launched in 2005, and it provides pensioners and low-income families with free medicine. In 2006, the program accounted for approximately 24 percent of the total market volume.

In late 2006, the expectation of continued 20+ percent increases annually in the Russian pharmaceutical market was tempered by the government’s decision to severely cut the number of higher priced, imported medicines covered by the DLO Reimbursement Program. This decision is expected to impact the market in 2007.

Imports

The intensive growth of the Russian pharmaceutical market as a whole has made it very attractive for business development by large Western drug manufacturers. The share of imported drugs in Russia grew steadily during the past few years. Currently, imported medicines maintain nearly 76 percent of the market value. Domestically produced drugs own 24 percent of the value.
According to U.S. Government statistics, approximately 63 percent of the total pharmaceutical imports into Russia come from Western Europe, United States, Canada and Japan. The countries of Eastern Europe and the former Soviet republics, Asia, Australia and Latin America make up 25 percent. Also, products manufactured by Indian companies, such as Dr. Reddy’s Laboratories, are popular on the Russian market.

Manufacturers

There are no innovative domestic drug producers in Russia. All original products manufactured by Russian companies are a heritage of Soviet research institutes. There are approximately 700 enterprises of different sizes specializing in the manufacture of pharmaceutical products in Russia. The industry remains fragmented and focused on the production of generics and the handling of existing innovative drugs for profit. Currently, the cost of developing an original drug is commensurate with the market value of any Russian pharmaceutical manufacturer. Therefore, Russian manufacturers appear to not yet be in position for large-scale investment in the development of innovative drugs.

The top ten Russian manufacturers by production volumes in 2006 are listed below. It is of importance to note that Ferane, the manufacturing company owned by Vladimir Bryntsalov, dropped from a 5.13 percent share in 2005 to a 2.05 percent share in 2006, out of the top ten.\(^1\) Ferane’s drop from the top ten may be attributed to the legal proceedings alleging the company and its owner is involved in a large-scale pharmaceutical counterfeiting operation.

<table>
<thead>
<tr>
<th>Ranking</th>
<th>Company</th>
<th>Share %</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Microgen</td>
<td>13.08</td>
</tr>
<tr>
<td>2</td>
<td>Otechestvennye Lekarstva</td>
<td>11.86</td>
</tr>
<tr>
<td>3</td>
<td>Pharmstandart</td>
<td>9.1</td>
</tr>
<tr>
<td>4</td>
<td>Veropharm</td>
<td>5.81</td>
</tr>
<tr>
<td>5</td>
<td>Pharm-Center</td>
<td>5.49</td>
</tr>
<tr>
<td>6</td>
<td>Nizhpharm</td>
<td>4.98</td>
</tr>
<tr>
<td>7</td>
<td>Makiz-Pharma</td>
<td>4.49</td>
</tr>
<tr>
<td>8</td>
<td>Materia Medica</td>
<td>3.91</td>
</tr>
</tbody>
</table>
Besides the production of generics, domestic pharmaceutical producers specialize in the tableting and packaging of drugs made from imported substances. From 85 to 90 percent of all the substances used in pharmaceutical production are imported from Western Europe, China and India.\(^2\)

Another trend emerging in Russia is the acquisition of domestic manufacturers and the establishment of production facilities within Russia by foreign drug producers. This tendency appears to be quite definite since Gedeon Richter, a Hungarian pharmaceutical manufacturer, opened a Russian manufacturing plant in 2001. The establishment of subsidiaries allows foreign manufacturers to side-step logistic and customs issues.

**Distributors**

There are approximately 4,000 registered distributors of pharmaceutical drugs in Russia.\(^3\) The distribution network includes national distributors operating throughout Russia and interregional and regional distributors which primarily work in specific regions. Also, there are niche distributors which specialize in specific products or work closely with a limited group of producers whom they represent in the market.

According to Pharmexpert, there are seven major distributors in Russia that operate in all 89 regions. These national distributors include: Protek (Moscow), SIA International (Moscow), Shreya Corporation (Moscow), Rosta ZAO (Moscow), Apteka-Holding (Moscow), Biotec (Moscow), and Katren SRC (Novosibirsk).\(^4\) According to a U.S. government report in 2005, there are 250-300 medium-size pharmaceutical distributors. The remainders are small distributors that may be tied to specific projects or tenders.
Distributors operate expansive networks of contacts and work to control retail distribution channels. Some manufacturers prefer not to work with retail pharmacies in Russia, rather they rely on distributors in promoting their products to retail outlets. A number of the larger distributors even own their own pharmacy networks. For example, Protek owns Rigla and the O3 drugstore chain, two of Russia’s leading pharmacy networks.

All distributors in Russia must comply with regulations governing proper storage and recordkeeping. Although wholesale distributors are not required to provide purchasers with evidence of pedigree, the Federal Ministry of Health, which oversees pharmaceutical activities, has the authority to audit distributors on a random or for cause basis. Also, during the course of audits, the Ministry has the right to inspect documentation pertaining to origin of products.5

*Pharmacies*

According to Pharmabiz, the pharmacy chain of Russia as a system is represented by over 65 thousand pharmacy enterprises, including pharmacies, kiosks, medical points, and shops.6 More than 40 percent of all retail pharmacies are held privately, and this share is expected to rise. Without a change in market strategy, state-owned drugstores may be forced to close as competition with commercial drugstores is intensifying. The leading pharmacy networks in Russia include Apteki 36.6 (Moscow), Rigla (Moscow), Pharmacor (St. Petersburg), Implozia (Samara), and O3 (Moscow).

Foreign pharmaceutical retailers are not, as yet, active in the Russian market. However, foreign retailers are taking a keen interest in the industry’s growth, and have participated in a number of tenders where drugstore chains were put on sale.7

Pharmacies and pharmacists maintain a substantial amount of power in the sale of over-the-counter (OTC) and prescription only medicines (POM) to the public. While there are applicable laws strictly regulating the OTC and POMs sales, the absence of strict control over drugstores allows pharmacists to make decisions on selling non-
prescribed POMs on the spot. Pharmacies’ objective of making maximum profit prevails over that of providing consumers with drugs under existing intense competition. The practice of uncontrolled drug sales is specifically Russian, as control over the prescription medicine supply is much stricter in European countries.
III. Pharmaceutical Counterfeiting in Russia

Counterfeit pharmaceuticals have clearly reached a serious level in Russia based on recent government statements. According to estimates of the Ministry of Health of the Russian Federation, counterfeit pharmaceuticals worth US$250-US$300 million are being sold in the country every year. The number of counterfeit drugs amounts to 3-4 percent of the Russian drug market, according to Russian Health and Social Protection Minister Mikhail Zurabov in 2006. Counterfeit medicines are a serious and officially acknowledged problem in the Russian Federation.

According to the Russian Ministry of Health, the first confirmed counterfeit pharmaceutical in Russia was found in 1997. That year only one product, involving one batch, was detected on the market. In 1998, six products, involving nine batches, were found. Counterfeit discoveries continued to rise, reaching 101 drugs in 2001.

In 2002, the Russian Ministry of Health stated that more than two thirds (67 percent) of the recorded counterfeit pharmaceutical cases were falsifications of locally produced pharmaceuticals. Counterfeits of foreign drugs constituted 33 percent of recorded cases. This trend has changed. In 2006, the Federal Health and Social Development Agency (Roszdravnadzor), which was founded in 2004 to monitor the drug supply, stated that 73 percent of counterfeit medicines found on the market are of imported drugs. Copies of domestic brands comprised the remaining discoveries. Also, Roszdravnadzor found that the most common type of drugs being found counterfeit were antibiotics.
In September 2003, a PSI member company conducted a randomized purchase and scanning of their products in Russian pharmacies. Over one thousand pharmacy retailers in twenty Russian cities were examined, and over three thousand packs were purchased. Counterfeit products were discovered in 50 percent of the cities and in ten of the twenty regions involved in the market sweep. Of particular concern, in Vladivostok, a city in the Russian Far East, 27 percent of samples purchased of a single product were found to be counterfeit.

In addition to counterfeit medicines, patent infringing products are common on the Russian market. Under current regulations, it is possible to register trademarks very similar to the original. It is sufficient to show any three minor differences to obtain approval for the product. According to a survey of 53 foreign and Russian pharmaceutical companies conducted in April 2002, “look-alike” products ranked second in IP issues concerning industry in Russia, just behind counterfeiting.

In recent years, the number of government drug inspectors and inspections has increased. According to the Roszdravnadzor in 2006, inspections of pharmaceutical distributors and pharmacies have increased two fold since 2004, and the number of government drug inspectors has reached 500.
The Russian inspection of pharmaceuticals on the market, which is carried out by the Roszdravnadzor, appears to be very good. Identification of details and documentation of these details is also very good. Information on counterfeit products identified on the Russian market is available to distributors, pharmacies and the public in the form of an “informing letter”. The following photos typify the quality of documentation contained in Roszdravnadzor’s counterfeit “informing letters”.

However, one negative aspect of Roszdravnadzor’s actions is its slow pace and inefficiency. In particular, even when right holders notify the Federal Service of counterfeit distributions, it often takes over a month to issue an “informing letter” to pharmacies and make seizures, by which time the drugs at issue have all been sold. Also, because Roszdravnadzor generally does not destroy counterfeits, and instead only orders pharmacies to withdraw them, counterfeits frequently reappear in the supply chain.

Despite the absence of having counterfeit trademark specifically defined in Russian law, there are a number of legal actions that can be taken against violators. Criminal and civil cases may be brought against counterfeiters. Also, administrative penalties are possible under Russian law.

The unauthorized use of a trademark is subject to criminal penalties only if such acts are committed repeatedly or have caused substantial damage.\textsuperscript{11} Criminal penalties include fines up to either 200,000 rubles (US$7,100) or 18 months of the infringer’s income, community service in the range of 180 to 240 hours, and a maximum of two years “corrective labor.” Where such violations involve “collusion,” fines can be up to 300,000 rubles (US$10,650), and imprisonment up to a term of five years is also possible. “Repeated” violations generally require proof of usage of a single unauthorized
trademark on two or more lots of goods, or usage of two or more unauthorized trademarks. “Substantial” damage requires evidence of lost profits in excess of 250,000 rubles (US$8,900).

According to the PhRMA Survey of Pharmaceutical Counterfeiting Laws and Remedies, conducted in 2006, Russian police have the authority to initiate criminal cases ex officio, but they are more likely to launch a criminal investigation in cases where the right holder files an “information letter” and provides support and expertise. Also, criminal cases require proof of intent to distribute the counterfeit goods or otherwise enter them into the channels of commerce; finding goods in storage is deemed inadequate to demonstrate such intent.

The counterfeiting of pharmaceutical trademarks is also subject to civil cases, which include actual and pre-established damages. Actual damages are often difficult to prove and thus right holders typically seek pre-established damages under the Trademark Law, which range from 1,000 to 50,000 times the minimum monthly wage.12 The determination of amount is subject to the court’s discretion, but in practice is usually based on the price and quantity of counterfeit goods and the character of the infringer.

In addition to damages under civil law, the trademark owner can seek to have counterfeit labels and packaging removed. If removal is impossible, then the trademark owner can request the destruction of the counterfeit goods and packaging. The Russian trademark law does not expressly provide for injunction relief or provisional measures. However, such remedies are available under the Russian Civil Code.

A third legal avenue against counterfeitors is administrative penalties. Trademark counterfeiting violations are subject to the Code on Administrative Misdemeanors. Police are largely responsible for administrative enforcement. However, the Federal Antimonopoly Service (FAS) also has the ability to undertake administrative investigations, including on an ex officio basis, under the Law “On Competition and Limitation of Monopoly of Markets,” as counterfeiting is viewed as a form of unfair
competition. Since police action on an *ex officio* basis is unusual in Russia, administrative actions are generally initiated on the basis of trademark owner letters.

Under administrative actions, fines range from 15 to 20 times the minimum monthly wage, in the case of individual offenders, 30 to 40 times the minimum monthly wage, in the case of corporate officials, and 300 to 400 times the minimum monthly wage in the case of legal entities.

According to PhRMA’s survey, administrative enforcement can be the most efficient means of combating trademark counterfeiting offenses, if only because authorities tend to have more experience with administrative processes and because the evidentiary burdens are lighter and processes correspondingly quicker. However, the deterrent impact of such actions is limited due to the relatively low penalties.

The Russian Federal Customs Service has authority to act against counterfeit pharmaceuticals. Customs officials may suspend the release of counterfeit goods on their own initiative or on the basis of an application by the right holder. Customs action is generally undertaken on the basis of trademark information recorded in the State Register of Trademarks and Service Marks, which is maintained by the customs service. In such cases, the seized items can be held for 10 days, after which time customs must either release the goods or refer the matter to police to initiate an administrative action. Customs officials are effective in monitoring for goods bearing recorded trademarks and, where evidence of a criminal offense exists, are obligated to provide information to, and coordinate with, appropriate law enforcement authorities, according to PhRMA’s survey.

In addition to these legal options, the Russian State Duma has recently considered a new statute to the legal code that would stiffen penalties for manufacturers and distributors of counterfeit pharmaceuticals. According to the new proposal, the minimum penalty would rise to 500,000 rubles (US$20,000) and the maximum penalty would be a 15-year prison term.
To date, there has been no major anti-counterfeit legal case launched by a research-based company in Russia. This can be attributed to a number of factors including poor cooperation between federal services, inadequacies in Russian law and corruption.

Enforcement against counterfeit medicines is generally weak and the stronger penalties under the law are rarely, if ever, handed down. The Roszdravnadzor can issue warning letters to pharmacies engaged in the distribution of counterfeit medicines and temporarily suspend licenses. However, the permanent suspension or revocation of a license is extremely rare; as it requires proof that the pharmacy or wholesaler knew the product being sold was counterfeit.

Cooperation between federal services is also an obstacle to enforcement. Communication between the Roszdravnadzor and the Ministry of Interior (MVD) appears to be particularly problematic. While the Roszdravnadzor can issue warning letters and order suspension of an infringer’s license to manufacture medicines or engage in pharmaceutical distribution activities, it does not have the authority to initiate administrative or criminal proceedings. These actions must be taken by the MVD, which is charged with fighting economic and organized crimes in Russia.

In addition to the MVD, the police and customs service also have enforcement authority in Russia. However, given the nationwide impact of many pharmaceutical counterfeiting incidents in Russia, the MVD is the main enforcement body.

According to PhRMA’s survey, one common complaint is that the Roszdravnadzor fails to communicate information received from customs or the MVD about counterfeit medicines to downstream distributors and pharmacies. Moreover, because Russian law does not specifically criminalize the production or distribution of counterfeit medicine, enforcement officials require laboratory evidence that the counterfeits are actually harmful to consumers before agreeing to prosecute such
activities as a crime. This indicates that law enforcement is perhaps less inclined to act on information received from the Roszdravnadzor regarding counterfeit medicines due to minimal penalties.

Though concrete examples are difficult to produce, the blurring of the lines between public and private in Russia undoubtedly has a role in explaining the lack of enforcement action against counterfeit medicine manufacturers and traders. Russian businessmen generally have close ties to someone in power or are themselves involved with public governance. These positions allow them to use informal connections to avert enforcement and/or skirt the law.
IV. Counterfeiting Incident System (CIS) Data Analysis

PSI has analyzed data from CIS in order to define the extent of pharmaceutical crime in Russia. The data is assessed in order to identify major trends. Efforts are also made to answer the following questions:

“How often are pharmaceuticals being counterfeited in Russia?”

“What is being counterfeited in Russia?”

“Where are counterfeit pharmaceuticals generally found in Russia?”

PSI’s documentation of incidents in Russia combines reports from three sources: PSI member companies, Roszdravnadzor, and media reports. While PSI member reports are generally specific, including law enforcement seizures or internal sampling discoveries of counterfeit product, reports from Roszdravnadzor and the media contain less detail.

Incidents initiated by Roszdravnadzor generally are in the form of counterfeit “informing letters,” which has been previously discussed. In most instances, the counterfeit informing letters alert the public to counterfeit medicines that have been found in the legitimate supply chain. The location or date of the initial counterfeit discovery is not generally provided by Roszdravnadzor.

The majority of counterfeit “informing letters” involve products produced by non-PSI member companies and details of the specific case are
frequently unavailable to PSI analysts. Therefore, PSI documents these counterfeit incidents by the date Roszdravnadzor issues the counterfeit “informing letter.” In cases where Roszdravnadzor issues multiple counterfeit “informing letters” on the same day regarding the same product but different batch numbers, PSI records this as one incident in CIS. Therefore, the number of counterfeit batches identified in any one year by the Roszdravnadzor will differ from the number of incidents PSI records.

What is the incidence of pharmaceutical crime in Russia?

PSI has recorded three hundred sixty (360) counterfeiting, theft and illegal diversion incidents involving Russia that occurred from January 1, 2004 through December 31, 2006. This incident total represented a 10 percent share of the worldwide total of incidents recorded during the same period of time.

The counterfeiting of pharmaceuticals was the most common type of incident linked to Russia as counterfeiting was involved in 336 incidents or ninety-three percent (93%) of the three year total. There were nineteen incidents involving the illegal diversion of pharmaceuticals from or into Russia. Also identified were five major thefts. The vast majority of counterfeiting incidents over the past three years has been reported via Roszdravnadzor’s informing letters.

The following chart illustrates the detection of counterfeit, illegally diverted and stolen pharmaceuticals in Russia for CY 2004 through CY 2006:

<table>
<thead>
<tr>
<th>Number of Incidents</th>
<th>CY 2004</th>
<th>CY 2005</th>
<th>CY 2006</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Counterfeit</td>
<td>61</td>
<td>113</td>
<td>162</td>
<td>336</td>
</tr>
<tr>
<td>Diversion</td>
<td>11</td>
<td>5</td>
<td>3</td>
<td>19</td>
</tr>
<tr>
<td>Theft</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Total</td>
<td>74</td>
<td>120</td>
<td>166</td>
<td>360</td>
</tr>
</tbody>
</table>

Russia’s incident totals from CY 2004 through CY 2006 are the second highest among countries. The only country linked to more incidents during the same period of
time is China. Despite China’s overall lead in incident totals, Russia has been the top country for counterfeit seizures/discoveries for CY 2005 and CY 2006.

*What is being counterfeited in Russia?*

The 336 counterfeiting incidents linked to Russia between CY 2004 and CY 2006 involved 114 different pharmaceutical products. Many incidents linked to Russia involve the discovery of a single counterfeit product at a wholesaler or pharmacy. Incidents that involve the seizure of multiple products are rare, as enforcement actions in Russia are nominal.

The counterfeit pharmaceuticals found within Russia range from children’s cold treatments to essential antibiotics, heart medications and blood agents. The medicines targeted by counterfeiters are products with high sales volume as well as expensive imported brands. Both branded and generic pharmaceutical products have been found counterfeit in Russia over the past three years.

When examining the therapeutic categories targeted by counterfeiters in Russia over the past three years, a very different picture emerges in comparison to worldwide trends. Global incident data for CY 2005 and CY 2006 revealed that the top therapeutic categories targeted by counterfeiters were genito-urinary, anti-infectives, and central nervous system. In both years, the genito-urinary category was the most frequent target by a wide margin. In Russia, the top three therapeutic categories involved in incidents between CY 2004 and CY 2006 were – alimentary, anti-infectives, and central nervous system. The genito-urinary category ranked ninth.

The following chart illustrates this finding.
Supplementing the analysis by therapeutic category, the Institute has also examined data related to the formulation of pharmaceuticals counterfeited in Russia. From CY 2004 through CY 2006, there were 438 drugs with a specified type of formulation. This data was compiled in the pie chart below.
The chart disclosed that 69 percent of the 438 counterfeit products were in tablet or capsule form. This is less than the worldwide percent share for the same formulation, which is an 85 percent share, recorded for CY 2006. Of particular interest is the 24 percent share recorded for counterfeit injectables in Russia. This percentage share is double that of the worldwide counterfeit injectables percent share recorded for CY 2006. Also, the percentage share of counterfeit topical medications in Russia is 5 percent greater than the worldwide percentage share recorded for CY 2006. This data indicates that counterfeit injectables and topical medications are more frequently found in Russia when compared to worldwide averages.

*Where are counterfeit pharmaceuticals found in Russia?*

Due to the nature of counterfeit incidents involving Russia, PSI is unable to give an accurate accounting of where counterfeit pharmaceuticals are most frequently found in the country. As previously discussed, Roszdravnadzor’s counterfeit notification letters do not generally indicate the location of the counterfeit discovery. Therefore, PSI must record these as nationwide incidents, void of a specific city or region.

Despite this difficulty, reports from PSI member companies and regional medicine certification centers in Russia have allowed the Institute to compile the geographic locations where counterfeits have been confirmed. PSI has recorded thirty-two of Russia eighty-nine regions, republics, and federal municipalities to have confirmed discoveries of counterfeit pharmaceuticals. The locations within Russia are listed below.

<table>
<thead>
<tr>
<th>Regions Where Counterfeits Have Been Discovered</th>
<th>CY 2004 - CY 2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Altai</td>
<td>Kostroma</td>
</tr>
<tr>
<td>Astrakhan</td>
<td>Kurgan</td>
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<tr>
<td>Bashkortostan</td>
<td>Mordovia</td>
</tr>
<tr>
<td>Chelyabinsk</td>
<td>Moscow City</td>
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<tr>
<td>Dagestan</td>
<td>Moscow Region</td>
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<td>Ivanovo</td>
<td>Murmansk</td>
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<td>Kabardino-Balkariya</td>
<td>Nizhny Novgorod</td>
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<td>Karachaevo-Cherkessy</td>
<td>Novgorod</td>
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<td>Kemerovo</td>
<td>Omsk</td>
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<td>Khanty-Mansiysk</td>
<td>Perm</td>
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<td>Kharbarovsk</td>
<td>Rostov</td>
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<td>Sakha (Yakutiya)</td>
<td>Samara</td>
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<td>Ulyanovsk</td>
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<td>Volgograd</td>
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<td>Voronezh</td>
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</table>
A PSI member company Russian market sampling in 2003 found the highest counterfeit percentages of a specific pharmaceutical product in the cities of Vladivostok (27.2 percent), Rostov-on-Don (23 percent), and Kazan (15 percent). The market sampling also discovered that counterfeits found in Moscow had the same chemical fingerprint of those found in Vladivostok, which is nearly 4,000 miles apart.

Russia is a vast country spanning eleven time zones. The map below illustrates the geographic location of where counterfeits have been seized or discovered in Russia. The areas in red are those regions or republics where PSI has documented the seizure or discovery of counterfeit pharmaceuticals.

From CY 2004 through CY 2006, 330 incidents involved the seizure or discovery of counterfeit pharmaceuticals in Russia. Of these 330 incidents, 320 involved
counterfeit product discovered in the legitimate supply chain. This means that counterfeit medicine was found in licensed pharmacies and/or wholesale distributors. Based on this data, Russia has recorded the most incidents of counterfeit pharmaceuticals within the legitimate supply chain worldwide.

How are counterfeits introduced into the legitimate supply chain in Russia? Evidence suggests that this may occur in two ways. First, if the counterfeit manufacturer also operates as a legitimate pharmaceutical manufacturer, they may also own a licensed wholesale company. This allows the enterprise to produce counterfeits, mix them with legitimate products at the licensed wholesale business and sell the product to pharmacies and other distributors. Second, the counterfeit products may enter the legitimate supply chain through forged certificates of analysis. The extent to which large licensed distributors, such as CIA International, are liable in purchasing from questionable sources is unknown. However, it is likely that pressure to procure products at the lowest possible price frequently lead to the disregard of inaccuracies and transactions with unknown businesses.

Along with the frequent penetration of Russia’s official pharmaceutical distribution channels, a number of incidents indicate that counterfeits are also available through unregulated outlets. A number of counterfeit medicine seizures have been made against individuals selling products from personal residences and unlicensed businesses. Also, the largest unregulated market place, the Internet, is becoming an outlet for the sale of counterfeits and unapproved medicines.

The number of counterfeiting incidents linked to Russia certainly places it among countries most cited as counterfeiting havens, China and India. Despite this commonality, Russia’s counterfeiting problems differ significantly from the two countries.

Both China and India are linked to a considerable number of incidents as a manufacturing source or transit country for counterfeit medicines found in other
countries. During CY 2006, 41 percent of the counterfeiting incidents linked to China involved counterfeit product found outside of China, but China was identified as the country of origin. The percentage was even higher for India at 75 percent.

Conversely, Russia was documented as the source or transit point for counterfeit in only 2 percent of incidents recorded between CY 2004 and CY 2006. CIS indicates that Russia was a transit point for counterfeit pharmaceutical products moving from China to North America in one incident in 2005. This one incident was significant as it involved hundreds of thousands of counterfeit tablets being smuggled by a Russian airline pilot. This method indicates a counterfeit smuggling group that is well entrenched and connected. Despite this one incident, PSI has no further evidence indicating that Russia is a major exporter of counterfeit pharmaceuticals or APIs beyond the former Soviet republics.
IV. Enforcement

In February 2006, Russian President Vladimir Putin visited the Prosecutor-General’s Office of the Russian Federation. Putin was reportedly dissatisfied with the lack of progress in fighting crime and asked for better protection of intellectual property rights in the country. “The turnover in counterfeit medicines is beginning to pose a real threat to the health of the nation and the widespread presence of counterfeit goods undoubtedly discredits Russia as a reliable business partner,” stated Putin.

Despite this call for a crackdown on counterfeiters and those who peddle fake medicines, PSI has documented very little Russian law enforcement action. This is troubling given the rate at which counterfeit pharmaceuticals are being discovered in the country.

According to data from the Counterfeiting Incident System, the number of arrests related to pharmaceutical crime from CY 2004 through CY 2006 totaled twenty-four (24). Nine of the twenty-four arrests related to the diversion of pharmaceutical products.

The chart below indicates the number of arrests by year and activity.

<table>
<thead>
<tr>
<th>Year</th>
<th>Point of Sale</th>
<th>Transporting</th>
<th>Manufacturing</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004</td>
<td>3</td>
<td>3</td>
<td>0</td>
<td>6</td>
</tr>
<tr>
<td>2005</td>
<td>8</td>
<td>0</td>
<td>0</td>
<td>8</td>
</tr>
<tr>
<td>2006</td>
<td>0</td>
<td>6</td>
<td>4</td>
<td>10</td>
</tr>
</tbody>
</table>

From CY 2004 through CY 2006, PSI has documented nine incidents that involved Russian law enforcement action. These nine incidents, involving enforcement actions, represent fewer than 3 percent of the incidents reported for Russia over this period of time. Four of the nine actions were against manufacturers of counterfeits. Three were against counterfeit medicine sellers, and one action was against a Russian pharmaceutical distributor.
When Russia’s arrest totals are compared to China, which recorded the second highest number of seizures/discoveries of counterfeit pharmaceuticals in CY 2006, the totals are disproportionate. In 142 incidents in 2006, Chinese law enforcement made 183 arrests. Of the 183 arrests, 119 were against counterfeit manufacturers. This demonstrates that Chinese law enforcement is significantly more active against counterfeiting syndicates than are their Russian counterparts.

PSI has been unable to confirm the widely reported statistic that approximately 70 percent of all forged drugs sold in Russia are produced domestically. Law enforcement raids against manufacturers of counterfeit medicines in Russia have been very few. Three of the four raids against manufacturers, which PSI has documented, were conducted in and around Moscow. One raid was also reported in the southern Russian city of Nalchik, near the Georgian border.

The relatively small number of raids in Russia against manufacturers of counterfeit pharmaceuticals makes it difficult to gauge the amount produced domestically. Though the industrial scale production of counterfeits by domestic companies has been confirmed by PSI members, there have been a number of incidents involving counterfeits manufactured in Asia. In CY 2006 and CY 2007, a number of counterfeit medicine seizures have been made by Finnish Customs in Helsinki. These seizures included thousands of loose tablets and capsules en route from India and China to Russia. In one case, the products were concealed in vacuum cleaners to avoid detection. Additionally, the Institute has documented a small number of raids against manufacturing operations in China where counterfeit Russian packaging was seized.

While the public has knowledge of the prevalence of counterfeit medicines in Russia, there is a lack of investigative reporting on incidents by Russian media. The media generally reports basic counterfeit statistics issued by Roszdravnadzor and sporadic raids on manufacturing operations. However, an examination of the number of counterfeit medicines found in Russia compared to the level of law enforcement action
has not been done. This may be attributable to the lack of an independent press and an inability or unwillingness to be critical of government practices.

Based on CIS data, member information and open sources, the risk to pharmaceutical products in the Russian Federation is substantial. The relatively large amount of counterfeits found in the legitimate supply chain and dearth of law enforcement action is an alarming concern. Greater cooperation and communication is needed between the Russian agencies and centers that monitor the drug supply and law enforcement. Also, industry must become more engaged with Russian authorities on the counterfeiting issue.
V. Reported Developments

Public Sector Reports

Russia ranks second in the spread of counterfeit medicine
According to Aleksandr Chekalin, the deputy minister of the Ministry of Internal Affairs of the Russian Federation, Russia occupies second place worldwide in the prevalence of counterfeit medicines. Chekalin noted the results from a 2006 nationwide ten-day operation named “Pharmakolog”. The operation revealed over 26 thousand instances of substandard medicines, around two thousand instances of counterfeit medicine sales and 1,500 instances of expired medicine sales.\(^\text{17}\)

Prosecutor calls for intensified fight against counterfeit drugs
The Office of the General Prosecutor of the Russian Federation called on the Roszdravnadzor and MVD to take measures to stop the import and trade of counterfeit drugs. According to statistics from the General Prosecutor, 12 percent of medicines in the Russian pharmaceutical market are counterfeit and the problem is continuing to grow. Counterfeits pharmaceuticals have been frequently found in the following regions: Tatarstan, Perm, Volgograd, Ivanovo, Kirov, Lipetsk, Novgorod, Pskov, Rostov and Tver.\(^\text{18}\)

Ministry of Health discloses counterfeit pharmaceutical statistics
Russia’s health ministry estimates that counterfeit pharmaceuticals worth US$250-US$300 million are being sold in the country every year. The deputy head of the parliamentary committee on economic policy, entrepreneurship and tourism, Elena Panina, told the lower chamber of the parliament, the Duma, that almost 70 percent of them – including antibiotics, cardiovasculars and gastrointestinals – are being made in Russia. Last year state control organizations withdrew from pharmacies 182 batches of medicines under 48 brands, of which more than 70 percent imitated products from non-Russian manufacturers.\(^\text{19}\)
Counterfeit medicine discovered in Samara

According to Aleksey Spektor, the head of the Samara’s Ministry of Health Regional Pharmaceutical Control Service, counterfeits discovered in the region appear to have stabilized. In 2003, 94 batches of counterfeit medicine were discovered in the market. That number has dropped to 38 batches in 2005 and 6 batches in 2006. Two counterfeit batches have been found in Samara through the first quarter of 2007.20

Center for Quality Control in Astrakhan finds fakes

Through the first ten months of 2006 the Astrakhan Regional Center for Certification and Quality Control discovered six different counterfeit pharmaceutical brands. In all, eight batches were confirmed counterfeit from the six brands. Also, six batches from six different pharmaceutical brands were found to have questionable authenticity.21

Operation Pharmkolog nets suspect counterfeits in Novgorod

The head of the Roszdravnadzor service in Novgorod, Lyudmila Nikiforova, stated that a nationwide operation at the end of 2006 turned up two pharmacies in Novgorod selling pharmaceuticals of questionable authenticity. Materials have been prepared to have the pharmacies’ licenses suspended, but this action has been put on hold. Roszdravnadzor is still awaiting confirmation from laboratory analysis of the products.22

Inspections find fake medicine in Bashkortostan

During operation “Pharmakolog”, authorities in Bashkortostan discovered 459 violations in the pharmaceutical market. Of these violations, sixteen were for improper storage and sale of medicine. The sale of expired medicine was found in 54 cases, and 45 cases related to the sale of counterfeit pharmaceuticals.23

Counterfeits found in the Republic of Sakha

According to the MVD in the Republic of Sakha (Yakutiya) a number of pharmacies were found to be selling counterfeit pharmaceuticals in 2006. During checks of the pharmacies Fragonar and Zdorove in Yakutsk, the capital city of the Republic of Sakha,
inspectors uncovered at least four different counterfeit medicines. The counterfeits were of popular imported brands and were in the formulation of oral and injectables.\textsuperscript{24}

\textit{Counterfeit identified in Tomsk Region}
During the first ten months of 2006, six incidents of counterfeit medicine were uncovered in the Tomsk Region, according to the Tomsk Center for Certification and Quality Control of Medicines. The Center carried out 54 inspections of pharmacies in the region and discovered the fake medicines. In 2005, the Center discovered 17 incidents of counterfeiting.\textsuperscript{25}

\textit{Anti-counterfeit operation in Ivanovo Region uncovers fakes}
The Ministry of Internal Affairs in the Ivanovo Region conducted an operation called “Pharmakolog.” The operation, which lasted from October 23 until November 1, was intended to uncover counterfeit medicines and other criminal activity surrounding the pharmaceutical sector in the region. The operation discovered 209 instances of illegal sale of medicines. Among the 209 instances, five incidents of counterfeiting were confirmed.\textsuperscript{26}

\textit{Fake medicines found in Vologda Region}
According to the director of the Vologda Center for Certification and Quality Control of Medicines, Yuriy Gammermayster, two incidents of fake medicines were discovered in the region during the first six months of 2006. The counterfeits were found during pharmacy inspections in the region.\textsuperscript{27}

\textbf{Private Sector Reports}

\textit{30\% of drugs are counterfeit in Russia}
According to the Director General of the Consumer Rights Protection National Foundation, Alexander Kalinin, about 27 percent of the drugs sold in Russia are counterfeit. The proportion is 20 percent in Moscow. “And these are medicines, and not sausages or a belt that I can throw away if I don’t like it. State-regulated forms and
methods should be used here,” stress Kalinin. Kalinin said his foundation would soon begin testing the drugs sold in Russia, because the watchdog is receiving numerous complaints from Russians and resident foreigners.  

**Enforcement Actions**

*Moscow police bust clandestine manufacturing operation*

Moscow police busted a clandestine counterfeit manufacturing facility in April 2006. Five products were identified as being counterfeit. The main ingredient used in the fake products was starch. Four individuals were taken into custody (3 from Tajikistan and one from the Republic of Georgia), according to media reports.

*Bryntsalov fined for violations*

In November 2006, a Moscow court ruled that pharmaceuticals firm Bryntsalov-A must pay a 40,000 ruble (US$1,500) fine for improper storage of drugs at its facilities, among other violations. The decision has been viewed as very weak given the evidence that the company and its founder, Vladimir Bryntsalov, have engaged in mass production of counterfeit medicines. The Bryntsalov-A case had been of concern to U.S. trade negotiators involved in Russia’s bid to join the World Trade Organization. The time of the ruling came just an hour after U.S. President George W. Bush departed Moscow completing a bilateral agreement facilitating Russia’s WTO application.

**Legislative Developments**

*Duma reviews plans to toughen penalties against counterfeiters*

The State Duma examined plans to stiffen penalties for manufacturers and distributors of counterfeit pharmaceuticals in April 2007. This was the first reading of a bill to create a new statute in the legal code covering the manufacture, intent to supply, supply, storage, transportation and importation of counterfeit pharmaceuticals. According to the new proposals, the minimum penalty would rise to 500,000 rubles (US$20,000) and the
maximum penalty would be a 15-year prison term. The maximum penalty would be applicable if a counterfeit led to the deaths of two or more people.\textsuperscript{31}

\textit{Roszdravnadzor preparing amendments to the criminal code}
Russia’s federal service for surveillance in healthcare and social development, Roszdravnadzor, has proposed to introduce criminal and administrative penalties for those dealing in counterfeit medicines. A deputy head of one of Roszdravnadzor’s departments, Aleksander Toporkov, told a press conference in Moscow that amendments to the criminal code have been drafted. They include the introduction of fines of up to 500,000 rubles or four-year imprisonment for individuals and fines of up to 1 million rubles or eight years for groups of people involved in manufacturing, purchasing, storing, transporting, or selling counterfeit medicines when they harm a patient.\textsuperscript{32}

\textit{Duma approves provisions to tighten sanctions against counterfeiters}
Russia’s lower house of parliament, the Duma, has approved revisions to the Civil Code that target intellectual property rights, although more corrections are foreseen prior to its second reading. The amendments do not specifically target the pharmaceutical industry, but will have important consequences for drug-makers both foreign and domestic operating within Russia. Specifically, intellectual property rights are now applicable to products commercial names and know-how, and patent ownership can now be extended to industrial inventors and designers of industrial samples. Crucially for the Russian pharma market, provisions are made for tightening the sanctions against counterfeit drug manufacturers and wholesalers. Under the new rules, the authorities have the right to seize production equipment and even liquidate a company if its owners are found guilty of participating in the counterfeit drugs trade.\textsuperscript{33}

\textit{Russian Senate calls for stronger punishment for medicine counterfeiting}
Russian senators urged the Justice Ministry to examine all regulatory acts developed by the Health and Social Development Ministry, the Federal Supervision Service for Public Health and Social Affairs, and the Federal Mandatory Medical Insurance Fund. During a hearing held by the Federation Council, the upper house of the Russian parliament,
senators called for an amendment to the Criminal Code that would inflict stronger punishment on those found guilty of counterfeiting medicines. “The effect of counterfeit medicines can be likened to that of a terrorist act,” a member of the Federation Council Health Committee, Khusein Chechenov, said.34
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