

An infusion of foreign pharmaceuticals into the Russian market is helping to meet consumer demand for high quality, low cost medicine. Imports of pharmaceutical products into this vast consumer base grew to US\$1.23 billion in 2000, a 48% rise in one year. All vital signs indicate that the upward trend is continuing.

Rx for Russia's ailing pharmaceutical sector

Market overview

First quarter results for 2001 showed the pharmaceutical import market was worth US\$560 million, up 19% from Q1 last year. With 62% of total sales, foreign firms, mostly North American and Western European, dominate the market. Half of all Russian consumers must pay for their medicine directly, but this costs only a small portion of the average annual household budget — between US\$5 and \$10.

The domestic pharmaceutical sector is weak, comprising 700 small firms that use outmoded equipment and have little funding for research and development. Most (80%) of domestic products must be made from imported chemicals, making them more expensive, in many cases, than foreign brands. Between 80% and 90% of domestic output is generic, principally low-margin drugs such as painkillers that require less advanced production methods.

Opportunities

Russia is enduring a critical shortage of essential medication. With 10 million Russians afflicted with diabetes, and cases of TB, hepatitis B, hepatitis C, and HIV on the rise, Canadian firms producing good quality, competitively priced treatments will find a receptive market. Domestic producers simply cannot meet the demand for cardiovascular drugs, analgesics,

antiseptics, anti-inflammatories, antibiotics, anaesthetics, tranquillizers, psychotherapeutics, central nervous stimulants and anti-viral treatments.

Market access considerations

The Russian Ministry of Health imposes several requirements before foreign pharmaceuticals can be sold in Russia:

- Registration, the responsibility of the Department for State Control of Quality, Effectiveness and Safety of Medicines and Medical Equipment, involves clinical testing assessments



for all drugs. The 1995 Memorandum of Understanding between Health Canada and the Russian Ministry of Health may facilitate the process, although its dispositions were not introduced into the Russian regulatory system.

- Certification, a week-long process; requires submission of test results conducted during registration before a Certification of Conformity can be granted by Russian health authorities.
- Application for an import permit is made only after a drug has been registered and certified. The permit is granted to either the manufacturer or to the Russian counterpart.

Although Russian authorities thoroughly check documentation and certification, they often fail to examine the medicine itself. This has resulted in an influx of counterfeit drugs, estimated to comprise at least 3.7% of the total market, an increase from 0.05% in 1999. Lack of enforcement will likely cause the problem to

grow worse, despite the fact that Russia's intellectual property legislation is approaching international standards. A new VAT tax on drugs slated for 2002 will undoubtedly worsen the situation by encouraging consumers to turn to counterfeit medication, which is often less expensive.

Russia's poor distribution network also poses serious constraints. Unlike more developed countries that use a small number of large distributors, there are more than 2,000 Russian companies acting as intermediaries, which makes it almost impossible to supervise and track the flow of medicines. Only a select number of distributors, such as Protek and SIA International, provide nation-wide coverage through regional distribution networks.

Major competition

Foreign pharmaceuticals are popular in Russia and global giants such as Novo Nordisk, Aventis Pharma and Novartis are already well established in the Russian market. Eastern European companies such as Hungary's Gedeon Richter and Slovenia's Krka are also considered major exporters. ICN Pharmaceuticals, AKO Sintez, Erka F, Akrikhin and Moskhimpharmpreparaty dominate local production.

Useful Web sites

- AIPM — The Association of International Pharmaceutical Manufacturers, Web site: www.aipm.org
- BISNIS — The Business Information Service for Newly Independent States, Web site: www.bisnis.doc.gov
- Coalition for the Protection of International Property Rights, Web site: www.cipr.org
- Health Canada, International Policy Division, Web site: www.hc-sc.gc.ca/hpb-dgpps/therapeut

For more information, contact Patrick Boulanger, Trade Commissioner, Canadian Embassy, Moscow, tel.: (011-7-095) 956-6666, fax: (011-7-095) 232-9949, e-mail: patrick.boulanger@dfalt-maeci.gc.ca