

# GalbraithWight Horizons<sup>TM</sup> Healthcare System Briefing

## Russian Federation

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## 1 Russia at a Glance

Area: 17 098 242 km<sup>2</sup>

Population: 142,499,000 (2007) The World Health Organisation (2009) "World Health Statistics 2009"

GDP (official exchange rate): \$US 1.232 trillion (2009 est.)

GDP Growth: - 7.9% (2009)

GNP per capita: \$US 15,200 (2009 est.)

Healthcare expenditure as % of GDP: 5,3 (2006, WHO)

## 2 Industry overview

The Russian Pharmaceutical market has been growing rapidly in all segments since the financial crisis in 1998, with an increase of 19% in the CAGR (compound annual growth rate) between 2003 and 2008. The CAGR experienced a slight decline in 2009 due to the global economic crisis but with signs of economic recovery it is estimated to grow approximately 5% over the next 3 years. The Russian Pharmaceutical market is divided into four distinct segments, with the largest being the retail market (approximately 60%) having an annual growth of 15%. The remaining segments of the market are government funded with the state reimbursement system accounting for around 20%, the hospital segment, 14% and national health programmes 4%. The state reimbursement programme started in 2005 and currently includes currently includes drugs for socially dependant citizens, as well as expensive drugs for seven selected diseases. Financing for this programme is expected to increase in 2010 and further into the future. Russia's private sector is limited but developing, largely due to the improved economy and evolving middle class.

## 3 A rapidly changing market: Reform initiatives and political issues

Russia is undergoing significant developments in terms of political reforms and initiatives, many of which will introduce important changes for the pharmaceutical industry. The major trends for Russian healthcare include:

- An increased share of government purchases in the pharmaceutical market
- Government more actively regulating pharmaceutical prices
- The development of foundations for a national drug medical insurance programme which will replace existing preferred population medicine provision programmes

An important development in drug regulation came into effect in 2009 with the acceptance of a new Essential Drug List (EDL), consisting of drugs recommended by WHO (all countries registered in Russia) and an assessment system based on drug inclusion and exclusion criteria. From 2010, drug registration and price declaration are required for drugs to be included on the EDL. In addition, the Ministry of Health and Social Development is currently developing legislature to link EDL with treatment standards, preferential drug provision and pharmaceutical procurement. This new pricing mechanism will come into effect on April 1, 2010 and it is believed that other price-regulating measures will follow. Currently 65 out of 83 Russian regions have price regulation mechanisms with local authorities in some regions lobbying for even stricter controls.

Several major changes will come into force on September 1, 2010 with the new *Medicines Turnover* law. According to the draft law, drug pricing will be more

controlled with price regulation for EDL-listed drugs. Manufacturers will be obliged to perform annual (before December 1) registrations of the maximum factory price calculated according to the Ministry of Health's methodology. This should result in a more efficient and transparent drug registration system with similar conditions for domestic and foreign manufacturers. The review period for generics will be limited to 60 days, and 120 days for new drugs, with applicants being able to track their registration process via the internet. Instead of several specific payments, the registration tax will be fixed at 300,000 rubles (approximately \$10 000). This reform also proposes new safety measures with the implementation of multiple standards to identify sub-quality and imitation pharmaceuticals. With the goal of making production of high-quality pharmaceuticals possible, mandatory GMP standards will be established in Russian factories. Currently there are more than 400 drug manufacturers in Russia with only 30 of them using GMP standards. Local manufacturers will have until January 1, 2014 to switch to GMP production after which date, all non-GMP compliant factories will be closed. It is expected the government will assist domestic producers to modernise their facilities. Although the reform proposes to introduce equal market access for local and foreign manufacturers, in reality more favourable conditions for Russian manufacturers will be created. An Ethics committee will be created to validate clinical trails in certain subject categories. The new law will also address drug supply by allowing drug sales through doctors and outpatient clinics in remote villages without a pharmacy.

As the Ministry of Healthcare and Social Development becomes more influential, most experts believe the government will accept the reforms outlined in the draft *Medicines Turnover* law.

With the *Modernization of ambulance services* reform, the introduction of specialised call centres will help prioritise and optimise the number of incoming emergency calls. It will also upgrade the service to a more Western approach by removing doctors from most paramedic teams (except for psychiatry and intensive care). The reform will be tested simultaneously in three regions (Chuvash, Tatarstan and Rostov) with results expected in 2011.

In line with the government's policy to further develop state reimbursement systems, as from January 1, 2011, several regions (not nominated as yet) will participate in a new pilot project on drug purchase compensation. The project will cover certain vulnerable categories of citizens (same as for the ONLS programme) with payments only being provided for EDL included drugs on the basis of registered prices. If the pilot is successful, the project will be expanded to cover all Russia and all patients, replacing the existing state purchasing scheme.

#### **4 Government healthcare financing**

In 2009 there was relative stability in federal and regional drug reimbursement programmes with total expenditure increasing 33% compared to 2008 and reaching \$US 2.4 billion. Funding for certain costly “nozologies” (diseases), such as schizophrenia was \$US 1.13 billion, a 13% increase compared to the previous year.

Drug registrations increased in 2009; with the Roszdravnadzor (Russian regulatory agency in charge of all drug approvals) registering a total of 1209, of which 675 were local registrations (up 8.6% from 2008) and 534, imported drugs (up 24.2% from 2008).

Additionally, economic aspects of national healthcare are likely to receive more focus in the future. United mandatory standards of healthcare are currently under development and will be used for 90% of all cases (with rare diseases accounting for 10%). These standards will allow for real cost estimation of medical treatment.

#### **5 Pricing and reimbursement**

There is no traditional Western Europe reimbursement system currently in Russia with the existing system guaranteeing free drug provision to certain vulnerable groups of patients. Currently, there are 2 national reimbursement programmes:

- The seven diseases (7N) covering medicines for selected expensive-to-treat diseases, including approximately 66 000 patients. The seven diseases and drugs covered include: Pediatric growth hormone deficiency (somatropin), Cystic fibrosis (dornaza), Multiple myeloma (bortezomib) and Multiple sclerosis (interferons beta, glatiramera acetate)
- The ONLS (a state reimbursement programme) providing necessary medication to socially-vulnerable groups (such as disabled, veterans, liquidators of the Chernobyl accident etc.) with 5.7 million people included in the programme. Examples of large socially vulnerable groups of people:

Together with national funding, all regions have adopted drug reimbursement programmes which are regulated and financed by local authorities. These programmes cover all regionally listed medicines with wealthier regions such as Moscow, Khanty-Mansiysk, S-Petersburg, Samara, Yekaterinburg having a better drug supply service. The main population covered includes children from 0-3 years old and honorary citizens of city.

On January 1, 2010, the Roszdravnadzor started to register the maximum ex-factory price for EDL-listed drugs. As from April 1, 2010, all EDL drugs without this registration will be prohibited from sales in Russia. Russian regions must develop and approve regulations defining maximum wholesale and retail mark-ups by March 1, 2010 as per government decree #1116 dated as of December 30, 2009. The average mark up is 12-15 % for distributors and 15-18 % for pharmacies.

## 6 Generics and innovation

The current Russian president, Mr Medvedev, has declared development of medical equipment, technologies, and domestic pharmaceutical production a top-priority for his government, promising to provide citizens with high quality and affordable medications for prophylaxis and treatment of mortality-inducing diseases.

Associated with the aim to improve Russian drug production, the government has defined a list of strategically-important medications that will be manufactured in Russia, including expensive drugs for treatment of oncology and cardiovascular diseases. Production of flu and cold medicines will also be considerably increased. The goal is for domestically manufactured pharmaceuticals to reach a 50% of market share by 2020 (currently around 20%). This will be stimulated through government purchasing programs.

Brand name products occupy two-thirds of the pharmaceutical market in Russia and their sales were stimulated by the introduction of the DLO Programme in 2006 (divided since 2008 into the ONLS and 7N state reimbursement programmes).

Substitution with a locally produced product is a key goal for the Russian pharmaceutical industry with some lobbyists proposing a ban on exported drugs from federal and local tenders when three or more domestic substitutes are available. State purchasing of Russian-made generics of imported medicines has also been suggested, with the domestic producer Pharm-Sintezn announcing Milanfor, an oncology medicine for treatment of multiple myeloma, and the first generic competitor for Velcade.

As compared to retail, the share of generics is much higher in the underfinanced hospital segment, but the market is fast developing and still remains highly attractive for generic manufacturers.

## 7 Potential market access mechanisms in Russia

Improving market visibility and developing a positive image among Russian authorities are key factors for access to the Russian pharmaceutical market. This usually involves investment in Russian healthcare which many leading global pharmaceutical manufacturers have followed. Some examples include Bayer's construction of a specialised logistics centre intended to function as an integrated pre-wholesale preparation and distribution site for their Russian product portfolio. Several companies, including Sanofi Aventis, GSK, KRKA, Gedeon Richter, Hemopharm and Ferrosan, have also launched proprietary manufacturing facilities opting for either new constructions or renovation of existing obsolete facilities. Many companies prefer new construction - Nycomed recently started construction of a factory in Yaroslavl region and Berlin Chemie recently signed an agreement with the Kaluga region to build its manufacturing facility there. Hoffman La Roche entered a joint scientific agreement with Chemrar, financed by the Russian government, while Hoffman La Roche provides its knowledge and technological expertise. Supporting relevant Russian non-profit organisations, such as patient associations (examples Haemophilia and Oncology associations for example) and industry organizations is another positive approach to improving a company's image.

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