Russia intends to make the drugs that it needs

Russia wants to raise its self-sufficiency in essential drugs, Thomson Reuters' Molly Bowman told Mike Rice.

Prime Minister Vladimir Putin has made the Russian pharmaceutical sector a key government priority, promising nearly US$4 billion in government funding to modernise the local pharma industry. His goal is to have 90% of vital medicines produced domestically by 2020, representing almost half of the Russian pharma market. Domestic firms' share of total drug sales is currently running at about 20%.

"Prime Minister Putin has also announced that there will be restrictions for foreign companies if they do not boost local production and transfer technology to Russia," according to Thomson Reuters' Molly Bowman.

"Packaging is considered to be local production for the moment," she said, "but over time this is expected to change to finished-dose manufacturing." Active pharmaceutical ingredients (APIs), she added, had not been mentioned specifically. "There is no indication that API manufacturing is included," Bowman maintained.

Russia had "very little" local API production, she pointed out, and there were almost no companies with experience in highly-regulated markets. "There are less than 50 Russian-owned groups engaged in API manufacturing and no manufacturing sites have been inspected by the US Food and Drug Administration (FDA)," she said. Little local expertise was available to make active ingredients outside the areas of biotechnology and vaccines, Bowman added.

"Regulated-market players have talked about bringing API production into Russia, but so far we are not aware any have done so," Bowman continued. "Just one Certificate of Suitability (CoS) is held by Biosintez Kombinat for fusidate sodium, while local player ICN-Kursk is owned by Millhouse Capital of the UK."

Compared with other 'BRIC' countries, Russia had just one firm that Thomson Reuters classified as having future potential to supply APIs to regulated markets. This compared with four in Brazil, nearly 100 in India and over 150 in China, she said (see Figures 1 and 2).

Noting some popular API imports into Russia, such as arbidol from Italy, German bicalutamide and Chinese irinotecan, Bowman pointed out that 90% of all substances used by the country to produce drugs were imported from China, Europe or India.

Figure 3 shows the limited number of Russian finished-dose companies compared with other BRIC countries. Bowman noted, however, that there were well under 100 in 1990. "While there are currently few local finished-dose companies with good manufacturing practice (GMP) experience, we expect to see this number rising," Bowman said. Meanwhile, the market would continue to be served by imports "until more of the population has faith in locally-made products".

Foreign pharmaceutical companies would continue to dominate the Russian market, she said (see Figure 4).

Some foreign firms, like Actavis, Polpharma and Stada, had acquired Russian plants in recent years; while others, like Slovenia's Krka, had built their own. Export of finished-dose products was "very limited" – Stada's Nizhpharm was one of the few allowed to make products for the European Union – although companies based in Russia had launched finished-dose products in countries

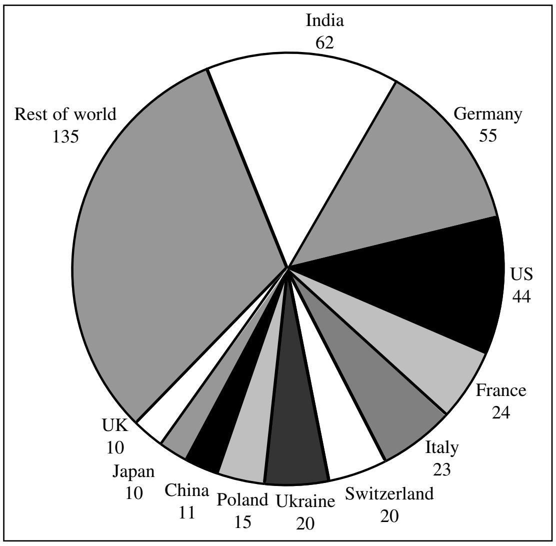
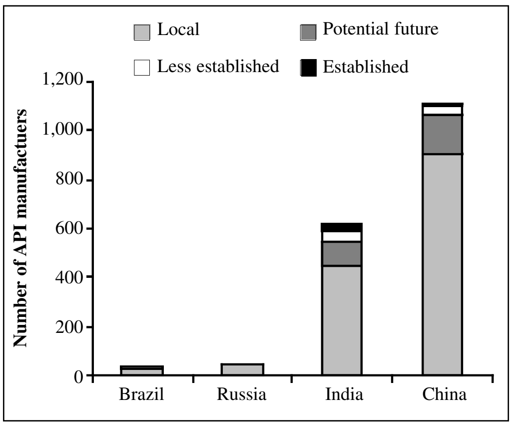


Figure 4: The origins of finished-dose companies on the Russian market (Source – Thomson Reuters Newport Premium)

	Brazil	Russia	India	China
Established	0	0	22	12
Less established	1	0	44	36
Potential future	4	1	97	158
Local	31	43	452	906
Total	**36**	**44**	**615**	**1,112**



Figures 1 and 2: Numbers of API makers in BRIC countries; established firms have years of experience in regulated markets, less established have only some experience (Source – Thomson Reuters Newport Premium)

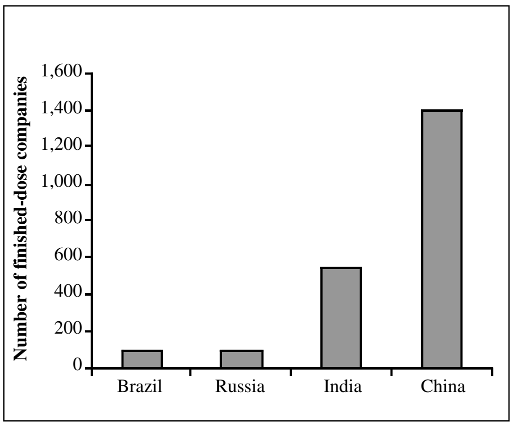


Figure 3: Numbers of finished-dose companies in BRIC countries (Source – Thomson Reuters Newport Premium)

as diverse as Argentina, Bangladesh and Jordan, as well as Russia's neighbours.

"Russian companies are also looking at markets overseas," noted Bowman. "Pharmsynthez wants to purchase pharma producers in Europe as well as in the US and Israel. We have also heard of Russian firms looking beyond eastern Europe at Asian markets."

Among the foreign firms investing in Russia, Teva was planning a US$100 million investment in a drug production plant, noted Bowman, and Actavis had sunk US$30 million into Zio Zdorovie's facilities. "India's Lupin is considering whether to build a US$50 million plant plus research and development centre, and Dr Reddy's is looking at doing something similar," Bowman said. "Global drug makers are expected to pour over US$1 billion into setting up local production in Russia."

Meanwhile, the deadline to improve GMP compliance had been moved several times, with the latest date set at 2014, observed Bowman, who pointed out that new legislation was intended to improve the transparency of the drug-registration process, to provide defined timelines for application reviews and to introduce price regulations for 'essential medicines'. "Time periods for reviewing applications should now be about 10 months, when they were previously 1.5 years or longer," she said, although she admitted "it is still unclear what changes will come into effect".

"Major problems with corruption still exist and data confidentiality is poor," Bowman said. "Counterfeiting continues to be an issue, and while the authorities are taking steps to combat the problem, most counterfeiters are unlikely to face meaningful sanctions."

The rules governing drug imports had also been overhauled, she said, with declarations of conformity replacing mandatory certification. But while the new rules were intended to make preparing and submitting declarations more transparent and with distinct timelines "implementation has yet to be determined".

One of world's fastest-growing markets

Nevertheless, the Russian pharma market was one of the fastest-growing in the world, she noted. The market's compound annual growth rate was expected to be around 13% over the next three years. "Forecasts put the market at over US$60 billion by 2020," she said, adding that with the uptake of private medical insurance "that figure could be closer to US$80-90 billion".

Noting that the average *per capita* consumption of medicines was expected to quadruple over the next decade, Bowman pointed out that the market was dominated by branded generics. "Most patients pay out of their own pockets and request a low-cost option. They also perceive branded generics to have greater quality," she said, noting that OTC products were purchased much more frequently than prescription drugs.

On top of the privately-paid pharmacy segment and hospitals, the Russian pharma market also contained the publicly-subsidised DLO programme, explained Bowman, which had been started in 2005.

Intended to provide free drugs to veterans, pensioners and the disabled, the DLO programme initially suffered from payment delays and supply issues. Now the programme purchased therapies through a tendering system rather than at prices set by the government. These tenders were for drugs aimed at 'expensive' chronic diseases – as well as drugs for acute needs such as transplant surgery – which were then distributed to health providers. "The programme is advantageous for foreign producers of innovative drugs," said Bowman, "because it has increased demand from potentially heavy consumers who previously had no means of purchasing them."

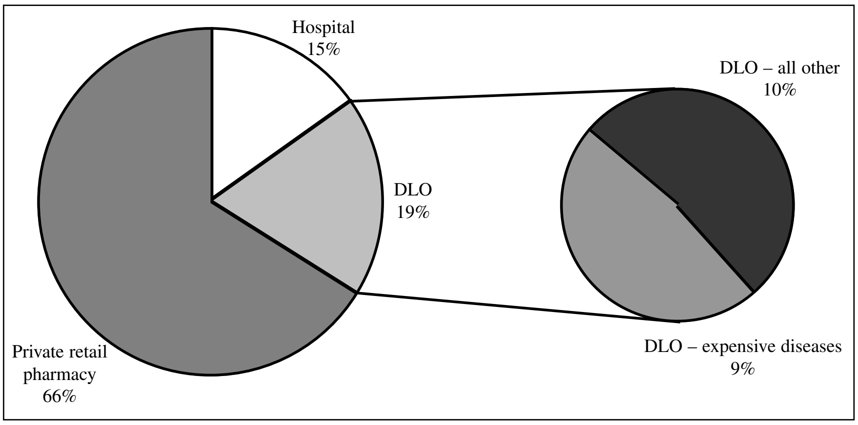


Figure 5: Segments of the Russian pharmaceutical market; private retail is the fastest-growing and imports account for 47% of DLO volume (Source – VOI Pharma Handbook 6th Edition)

According to VOI Consulting, DLO sales account for about a fifth of the market (see Figure 5).

Many foreign firms were partnering with Russian companies, Bowman commented. Lilly, she noted, was spending US$1.27 billion to become a founding partner in a new US-Russia research partnership.

India's Jubilant, meanwhile, had reached an agreement with Russia's Kraspharma on producing and purchasing raw materials, and Jubilant's compatriot Dr Reddy's had done a deal with the local player R-Pharm (**Generics *bulletin***, 14 January 2011, page 10). This allowed the Russian company to manufacture and distribute some of Dr Reddy's products in Russia. "Dr Reddy's will import and market certain R-Pharm products in India, as well as co-develop some 'high-technology' products with the Russia firm," she said.

Ranbaxy had signed a memorandum of understanding with the government of the Yaroslavl region, she added, which included collaborating with academic and research centres on clinical trials (**Generics *bulletin***, 11 February 2011, page 3). "Although the majority of clinical work in Russia continues to be sponsored by foreign companies, the number initiated by domestic companies grew from 33% in 2009 to 43% last year," commented Bowman, who added that most studies were focused on oncology, as well as neurology and infectious diseases.

"As the Russian middle class grows and demand for treatments rises, the market will continue to expand," maintained Bowman. However, the size of the country and its poor infrastructure would continue to hamper distribution beyond the big cities. "There is a large and willing clinical-trial base," she added, "but trials in Russia can require significantly more oversight than in the west, even though they cost much less."

"Russia continues to offer a low-cost production base and a good platform to get into other regional markets," she added, "as government incentives are aimed at pushing exports as well as providing local investment."

Poor enforcement of intellectual-property rights and counterfeiting would continue, however, despite government promises. Nevertheless, its emphasis on foreign investment and partnerships as well as on modernising facilities offers numerous opportunities. G

"As the Russian middle class grows and demand for treatments rises, the market will continue to expand"