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Update on Russia's Import Substitution Program

(Source: 2015 KIRA EGOROVA, RBTH)

In May, when Prime Minister Dmitry Medvedev tasked the government with creating a program of import substitution in the field of pharmaceutical production, foreign companies were worried. Although Russia's pharmaceutical market — currently worth US$19 billion a year — is a fraction of that of the U.S., which is currently valued at US$377 billion according to Pharmaceutical Commerce, its loss would have been a blow to Western drug companies.

However, the policy may not as provocative as first thought, at least in the short-term. For one thing, the import substitution policies will only affect sales to public health organizations, primarily state run hospitals and pharmacies. Private health clinics and pharmacies are still able to import foreign drugs without restrictions. Nevertheless, there is still cause for concern. Today, 60% of the drugs on the List of Vital and Essential Medicines approved by Russian government bodies for use in public institutions are produced domestically. Under the new policy, this share should increase to 90% by 2018. Nevertheless Import Substitution could actually be beneficial for foreign firms that already have a manufacturing presence in Russia and are working with Russian partners. "For localized foreigners, this is an opportunity to quickly recover the investments that they have made here," said the CEO of the Association of Russian Pharmaceutical Manufacturers (ARPM).

Several international pharmaceutical giants, including AstraZeneca, Sanofi, Novartis and Novo Nordisk, already have production facilities in Russia. Last year, Abbott made one of the largest transactions in the history of Russia's pharmaceutical business by acquiring Russia's second-largest drug manufacturer, Veropharm, for 16.7 billion rubles (US$495 million, at 2014 exchange rates).

Abbott is still optimistic about its prospects in Russia. "We see our investment in Veropharm as an opportunity to participate in the development of the Russian pharmaceutical industry," said the head of Public relations in Russia. The company plans to expand its research capabilities and further develop Veropharm's production base in gynecology, neurology, gastroenterology and oncology, where the demand for innovative products is particularly high. Some international firms that own production facilities in Russia are wary of the government's plans because they may require partially transferring production to a Russian partners' facilities. Others seem to accept this prospect.

The CEO of Sanofi's vaccine division, Sanofi Pasteur, said that the French manufacturer has plans to start production of a popular children's vaccine at Russia's Nanolek factory in St. Petersburg. The plant will produce up to 10 million doses annually, fully satisfying the demand for this vaccine in Russia. "In the strategy of Import Substitution, we see additional opportunities for business

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In Brief . . .

◆ **AmerisourceBergen** launched *CareFront*, a population health management program focused on the needs of patients diagnosed with cancer. Designed to be built into existing employer benefit packages, CareFront connects newly diagnosed cancer patients with resources for their care and explains how to avoid unnecessary medical costs. The program also offers tools to help patients understand their treatment options and financially rewards participants for enhancing the quality of their care. Separately, AmerisourceBergen announced that *Steven Collis*, president and CEO, will also assume the title of chairman following the retirement of chairman *Richard Gozon* at the annual meeting of stockholders in March 2016. *Jane Henney* will also become the board's lead independent director. *(Collis serves as a Director of IFPW and as Chairman of IFPW Foundation.)*

◆ **McKesson** was presented with the *Employer Excellence Award* at the **National Business Coalition on Health's** (NBCH) annual conference, recognizing McKesson's leadership and efforts to improve the health and wellness of employees while creating a health care system focused on lower costs, higher quality, and better health for all.

◆ **Teva Pharmaceutical Industries** and **Takeda Pharmaceutical Co**. are creating a joint venture to boost the supply of generics to the Japanese market. The new business will be 51% owned by Teva and 49% by Takeda and is expected to start operating in the second quarter of 2016. It will operate as an independent company with its own board of directors, chief executive officer, and executive leadership team.

◆ **EBOS Group** was recognized as Company of the Year at the *2015 Deloitte Top 200 Awards*, presented in Auckland. Founded in Christchurch in 1922, EBOS is one of New Zealand's oldest companies and has grown to become the largest and most diversified Australasian marketer, wholesaler and distributor of healthcare, medical and pharmaceutical products.

◆ Japanese companies are focused on expanding their businesses outside of Japan. **Mitsubishi Tanabe Pharma** hopes to generate 40% of its sales overseas in FY2020 (ending March 2021), up from the 25% projected for FY2015, through a possible acquisition in the US. Meanwhile, Japan's **Eisai** is making a foray into the Chinese generic market by acquiring an entire stake in a local generic firm for roughly ¥9.6 billion (US$77 million).

◆ China's Drug regulators will speed up approvals for innovative drugs for major diseases as well as those on the list of the *National Science and Technology Research Program*, according to the *28th China Medicine Industry Development Summit Forum*. In the next few years, the pharmaceutical industry's growth will likely slow to around 10% but demand for drugs won't slow, according to experts. So, faster approvals and pro-industry policies can help make innovative medicine the main investment area in medicine.

(Sources: BioCentury, China Daily USA, Drug Store News, IFPMA, Pharma Japan, PRNewswire and Scrip)

Rx Trends

(Sources: IMS Institute for Healthcare Informatics and an article prepared by Michael Johnsen and published by Drug Store News)

In the U.S., pharmaceutical spending on an invoice price basis will reach as high as US$590 billion by 2020, the IMS Institute for Healthcare Informatics reported, representing a 34% increase over the 2015 level of spending. The dispensing rate of generic medicines will increase from 88% to as high as 92% by 2020. And as many as 225 new molecules will be brought to market, with one in three focused on treating cancer. "This is further evidence of the strength of the pipeline with respect to bringing clinically differentiated and new medicines to market, not only in cancer, but also in hepatitis-C, auto-immune disorders, heart disease and a wide array of rare diseases as well," commented Murray Aitken, IMS Health senior vice president and executive director of the IMS Institute for Healthcare Informatics. "We're expecting, indeed, 75 new orphan drugs will come through by 2020."

Worldwide, IMS is projecting that total drug spend will increase 30% from 2015 through 2020 and will reach US$1.4 trillion in 2020. "Much of this growth is due to greater access to medicines, particularly in lower- to middle-income countries," Aitken said. "We're projecting that the total volume of medicines consumed in 2020 will be 4.5 trillion doses that is up 24% from the level of 2015, mostly driven by increased access in the large pharmerging markets." More than half of the world's population will live in countries where medicine use will exceed one dose per person per day by 2020, up from 31% in 2005, as the "medicine use gap" between developed and pharmerging markets narrows. Global spending is forecast to grow at a 4%-7% compound annual rate over the next five years. "During the next five years, we expect to see a surge of innovative medicines emerging from R&D pipelines, as well as technology-enabled advances that will deliver measurable improvements to health outcomes," Aitken stated. "With unprecedented treatment options, greater availability of low cost drugs and better use of evidence to inform decision making, stakeholders around the world can expect to get more 'bang for their medicine buck' in 2020 than ever before."

Russia (cont.) . . .

expansion," he said. Sanofi Pasteur plans to start the localization process of its vaccine production next year with the transfer of know-how for production technology and quality control systems. The whole process should be complete by 2019.

Germany's Bayer is also moving forward on working with local partners. "Bayer is pursuing its localization strategy through selective partnerships with Russian producers focused on full-cycle production," said Bayer's CEO in Russia. In 2012, Bayer entered into a partnership with Russian manufacturer Medsintez. In 2015, the first commercial batch of the antibiotic *Avelox* was produced at Medsintez laboratories.

Russia's pharmaceutical market is divided into two segments: the private sector (commercial companies and individuals) — worth US$11.2 billion — and the public sector (state hospitals, clinics) — worth US$4.9 billion, according to calculations by DSM Group. The state budget is used to purchase drugs for state-owned clinics and pharmacies where low-income citizens with chronic diseases receive medicines for free or at discounted prices. Drugs for these clinics must be purchased from the state-approved List of Vital and Essential Medicines.

McKesson's Investment in Home Healthcare

(Source: An article prepared by Brian Gormley and published by the Wall Street Journal)

Since launching last year, the capital investment arm of McKesson, McKesson Ventures, has focused on startups that play into large shifts the team sees coming in health care, a hunt that led recently to ClearCare Inc.

Consumers' increased role in their care, new modes of medical reimbursement and other changes prompted by the federal health-care law are encouraging investment in software and other tools to help companies, caregivers and patients adjust to the new landscape. Through the third quarter of this year, venture funding in digital health reached US$3.3 billion, according to Rock Health leading to the possibility that 2015 could overtake last year's record total of just more than US$4 billion. The surge is leading to high valuations for some private companies, but the fundamentals driving the investment are strong, says Tom Rodgers, who leads the venture arm of McKesson Corp. His group, revealed in December 2014, is investing US$250 million in themes such as consumerism in health care and new models for delivering medical services.

ClearCare, which provides software to homecare services companies, covers these and other trends the group is watching. As reimbursement shifts to reward healthcare providers for keeping people healthy, instead of volume of services provided, more attention is being paid to the time patients spend outside the hospital or the doctor's office, Mr. Rodgers said. This includes care delivered in the patient's home.

Homecare providers help senior citizens receive care and support at home instead of the nursing home or doctor office. The spread of smartphones, improved technology to monitor patients remotely, and new telemedicine services are making it easier to provide home care. ClearCare's cloud based technology helps homecare providers run their operations.

Other venture investors are thinking along the same lines. In July Hometeam Inc., which uses software to match caregivers to senior citizens looking for in-home care, said it had raised US$11 million from Lux Capital and others. Another startup, HomeHero Inc., which helps families find and hire in-home care through an online marketplace, disclosed a US$23 million financing led by Graham Holdings Co. in June.

McKesson Ventures has invested an undisclosed amount in San Francisco based ClearCare, whose other backers include Bessemer Venture Partners. It has also funded companies like telemedicine startup Carena Inc. and Kyruus Inc., which helps healthcare providers match patients with the right doctor.

Mr. Rogers believes that healthcare IT was once a backwater market in venture capital, but no more. He indicated that there are important problems that need to be solved and it is rewarding to see significant investments being dedicated to the resolution of these problems.