REVIEW ARTICLE

Possibilities of Import Substitution in the Russian Pharmaceutical Market

Olga S. Peskova, Tatyana B. Boriskina, Tatyana D. Ungurayte, Svetlana I. Matyushchenko, Olga V. Urova

Department of Management, Marketing and Production Organization, Faculty of Economics and Management, Volgograd State Technical University 28, Lenin Avenue, Volgograd, 400005, Russia

Abstract

The article investigates the possibilities of import substitution in the Russian pharmaceutical market, the problems of the reaction of the Russian pharmaceutical industry to foreign sanctions foreign pharmaceutical firms. Recently, the Russian government's policy is aimed at the development of its own economy, domestic production that entails new challenges and at the same time, the prospects of development of the domestic pharmaceutical industry.

Key words: Generics, licensing authorities, pharmaceutical cluster, pharmaceutical market, pharmaceutical industry, socioeconomic development

INTRODUCTION

The development of pharmaceutical industry is capable to solve effectively considerable part of needs of the population for provision of medicines. Pharmaceutical branch in social and economic sector of the Russian Federation is the weakest link, and it is several reasons for that. Moreover, the first problem which slows down development of branch is a high dependence on imports. It is obvious that if within toughening of the anti-Russian sanctions the western countries block supply channels of drugs, the Russian pharmaceutical market is threatened if by not a full collapse, then very big problems. To define the reasons of current situation, it is necessary to pay attention on historical heritages of the Russian pharmaceutical industry.

In inheritance from the USSR, we have got strong pharmacological branch with the developed scientific and practical base, but for years of reorganization, it has managed to degrade: Critical wear of fixed assets, their moral obsolescence, and insufficient financing of researches have led to decrease in competitiveness of domestic preparations and have considerably reduced their share in the market.

PHARMACEUTICAL MARKET

Now, the pharmaceutical market of the Russian Federation is included into ten the largest pharmaceutical markets of the world in value terms on absolute measures.[1] The modern pharmaceutical market of Russia is one of the largest markets in the world, taking the 7th place on sales volume in absolute expression, and the considerable part of sales is provided by production of foreign producers.[2,3] According to the licensing bodies, currently in the country 560 producers of the HP having the federal license function, 187 enterprises have regional licenses. According to the international standards, the degree of concentration of pharmaceutical industry in Russia is still exclusively small.

The average profitability of pharmaceutical production is about 17%, degree of wears of fixed assets – 60%, and utilization of capacity – 78%. 65.1 thousand people are engaged at them. The volume of the Russian pharmaceutical market in 2014 is estimated at 919 billion rubles in the final prices (+12% in comparison with 2013, +69% in comparison with 2009); from them 47.3% are the share of the list of vital and essential drugs for 2014 approved by the order of the Government of the Russian Federation of December 7, 2011 No. 2199-r.

Address for correspondence:
Olga S. Peskova, Department of Management, Marketing and Production Organization, Faculty of Economics and Management, Volgograd State Technical University 28, Lenin Avenue, Volgograd, 400005, Russia.
E-mail: peskovaolga81@inbox.ru

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The output of the Russian medicines in 2014 has made 185 billion rubles (+2.4% by 2013, +93% by 2009) in the prices of the corresponding years. Against the growth of the market, the share of domestic medicines in the total amount of the market has grown in 2009 up to 24.3% (132 billion rubles) and in 2014 up to 25.2% (231 billion rubles).

The share of medicines of a domestic production in government procurement in terms of money in 2014 amounts to 23.7%.[4]

THE DEVELOPMENT OF THE DOMESTIC PHARMACEUTICAL MARKET

Recently, the policy of the Russian government was developed facing a domestic production, and it is of great importance. Of course, it is good, but it is unknown, what is the time it is required till that day when our pharmaceutical industry is able independently to close needs for medicines.

In May 2014, the President of Russia, the leader of ONF Vladimir Putin at the St. Petersburg International Economic Forum, has designated need to return domestic market to domestic producer and to liquidate critical dependence on import, the corresponding instructions have been given to the government.

In Russia, for the next decade, a favorable environment for the development of the pharmaceutical market is created. During 2015-2020, according to the existing concept of long-term social and economic development of the Russian Federation, the volume of the public expenditures of branch of healthcare will annually increase. One of the most critical moments in development of the pharmaceutical market is the development of the industry.

To production of pharmaceutical production, it has shown special requirements which number has included scientific and technical base and level of scientific developments in pharmacy and medical equipment. In 2009, we have decided to review a situation and developments of pharmaceutical industry of the Russian Federation till 2020. Nearly 178 million rubles and as envisioned by authors are allocated for the program, in 5 years the share of production of a domestic production on the Russian pharmaceutical market has to grow to 50% (in value terms). For 2015, the government refers the following to the main objectives of development of pharmaceutical industry:

- Increase in a share of medicines of a domestic production according to the nomenclature of the list of VED to 67% and strategically significant medicines and the list of vital and essential drugs.
- Ensuring purchase of medicines according to the list of VED of mainly Russian production by adoption of the draft of the resolution of the government of the Russian Federation "About establishment of restrictions for the admission of the medicines coming from the foreign states at implementation of purchases for ensuring the state and municipal needs."
- Implementation of the resolution of the government of the Russian Federation of February 5, 2015 No. 102 "About establishment of restriction of the admission of separate types of the medical products coming from the foreign states for implementation of purchases for ensuring the state and municipal needs."
- Development of an order of definition of a stage of technological process of production of medicines and also an order of issue of the conclusions about extent of localization (The Federal law of December 22, 2014 No. 429-FZ "about modification of the Federal law 'about the address of medicines)' for the purpose of granting to producers with different degree of depth of technological process of the differentiated scale."

There is a wish to allocate the main directions of implementation of the tasks especially as they form the factors defining on the development of a pharmaceutical industry:

1. High scientifically – technical base and level of own developments in the field of pharmacy and medical equipment and also existence of innovative production and hi-tech production equipment in branch.

After the adoption of strategy of development of pharmaceutical industry of the Russian Federation for the period till 2020 in various subjects of the Russian Federation pharmaceutical clusters which represent "group of companies of developers, producers, and suppliers of the equipment, the research centers, higher educational institutions, science and technology parks, business incubators, and other companies which work in adjacent fields of activity began to be formed actively and are capable to increase competitive advantages of a cluster in general."[4] In 2010, in the pharmaceutical market of Russia, the new concept "pharmaceutical cluster" has appeared. According to strategy "FARMA-2020," a pharmaceutical cluster – group of geographically localized interconnected innovative firms – developers of drugs, production companies, suppliers of the equipment, accessories, specialized services, and infrastructure facilities: The research institutes, higher education institutions, science and technology parks, business incubators, and other organizations supplementing each other and increasing competitive advantages of the separate companies and a cluster in general. A distinctive sign of effectively operating clusters is an exit of innovative production. The creation of pharmaceutical clusters – one of tasks for achievement of the objectives of "FARMA-2020," especially as the format of clusters has been approved by the president. Moreover, local authorities have hurried to report on formation of similar conglomerates and officially announced such plans in Volgograd, Moscow, Rostov, Novosibirsk, Samara, Sverdlovsk, Tomsk and also in Stavropol Krai, St. Petersburg, in the Urals and in Altai Krai, the Republic of Tatarstan.[5]

Among leaders, there are also pharmaceutical clusters in the Yaroslavl and Kaluga areas and in Moscow area. For the past several years, the Russian and foreign companies have invested in creation of the latest productions in the territory of the country more than 100 billion rubles. The plants in Russia were constructed by such world giants as "Bayer," "Takeda," "Novartis," "Berlin-Chemie," "Nycomed," "AstraZeneca," and "Teva." As a result Russia has received all key production technologies of medicines of both the synthetic and biotechnological nature. One more pharmaceutical cluster (Novouralsk) specializes in biopharmaceutics. It is scientific and technological park of a full cycle of production – from idea to a proprietary medicine. Exactly here synthesize insulin which is cheaper than import analogs. The first Russian analog of insulin can be available for sale in 2016. In April of this year, the preparation has arrived on registration of the Ministry of Health for obtaining permission to clinical tests.

In Novouralsk, the production of antibiotics on the German technologies is also localized, and the production of domestic antiviral preparations is arranged. The regional authorities assure that the areas of scientific and technological park will be completely occupied soon by new residents who will sate the market with new qualitative domestic drugs. In May 2014, opening of new production of influenza vaccines of a full cycle on the basis of the St. Petersburg scientific research institute of vaccines and serums of FMBA of Russia in St. Petersburg has taken place. The project has been realized at strategic cooperation with Federal State Unitary Enterprise NPO Microgen. In April 2014, in the Russian Federation, the preparation of rituximab in domestic production developed with the assistance of Minpromtorg of Russia in 2010-2012 is registered within action "Organization of trial production of substances and medicines on the basis of the monoclonal antibodies necessary for release of expensive import-substituting preparations of JSC BIOCAD of the State program." ".... important it is not simple to develop domestic generics and hi-tech bio-analogs, but, first of all, to create innovative preparations that the Russian patients first-ever got access to drugs of new generation for reasonable price," according to Dmitry Morozov, the CEO of biotechnological corporation BIOCAD.[6]

The state investments into the development of technology and the organization of production with were put by 285 million rubles. In total from the moment of the state registration of a preparation about 130 thousand packing's of the developed preparation for the total amount of 5.5 billion rubles, the main part is associated with government procurement, the economy of budgetary funds from purchase of a domestic preparation only in 2014 has exceeded the volume of the state investments into the development of a preparation.

In October, 2014 medicine nonacog alfa (a recombinant factor of fibrillation of IX) developed within action "Creation of the modern biotechnological center 'Generium' of the State program is registered." Following the results of realization of action of CJSC Generium became the producer of a full cycle of three main medicines for the treatment of various forms of hemophilia: Recombina nt factors of fibrillation of VII, VIII, and IX.

The state program "Development of the pharmaceutical and medical industry" for 2013-2020 has allowed creating competitive and more available analogs of foreign preparations in such areas as oncology, immunology and neurology. There were new production and technological competences: Monoclonal antibodies (JSC BIOCAD), insulin and their analogs (LLC Gerofarm-bio), cytokine and factors of growth (JSC BIOCAD), recombinant factors of fibrillation (CJSC Generium), recombinant enzymes (CJSC Generium), recombinant vaccines (Federal State Unitary Enterprise NPO Microgen, Federal State Unitary Enterprise St. Petersburg Research Institute of Vaccines and Serums and Enterprise for Production of Bacterial Drugs of FMBA of Russia, Federal State Unitary Enterprise the Enterprise for Production the Bakteriynykh and Virus Preparations of Institute of Poliomyelitis and Viral Encephalitis of M.P. Chumakov of the Russian Academy of Medical Science), the recombinant proteins received in Escherichia coli (competence from Soviet period — JSC BIOCAD, CJSC Generium, and other companies).

According to analytical agencies, the total amount of private investments into pharmaceutical branch during the implementation of the program has exceeded 120 billion rubles. For comparison, the volume of the state investments has made 39 billion rubles. During implementation of the state program, more than 30 domestic companies have been modernized; more than 50 billion rubles in the creation of new productions are attracted.

For example, the LLC Geropharm-bio Company has realized the project on construction of plant on production of insulin on a full cycle in the Moscow region. In the Ryazan region, the biopharmaceutical plant of the LLC Fort company is open (500 new workplaces are created, 4.5 billion rubles are attracted).

In the Kirov region, at the end of 2014, opening of innovative industrial complex of the LLC Nanolec Company has taken place. CJSC R-Farm has realized the project on construction of pharmaceutical industrial complex in Yaroslavl. LLC Infamed (The Kaliningrad Region) has invested more than 1 billion rubles in the production of antiseptic tanks, including the unique domestic preparation "Miramistin."

In June 2014, opening of the new production case of the St. Petersburg scientific research institute of vaccines and serums of the Russian Ministry of Health in the Leningrad region has taken place. The LLC NTFF Polisang Company invested 2.5 billion rubles in construction and start of the

second turn of producing infusion in St. Petersburg. The Medsintez plant has opened a site on the production of preparations of insulin. JSC Rafarma (Lipetsk Region) has finished construction of the industrial complex including several lines of production of different dosage forms with a total cost of the project over 3 billion rubles of JSC Biosintez (Penza) finishes reconstruction of the case with several ampoule and infusion lines. Construction in the Kaluga region of pharmaceutical plant in the territory of scientific and technological park of "Grabtsevo" of LLC NovaMedica is carried out. The program promoted increase in investments into branch both from domestic producers and from the foreign companies.

Now such companies as Merck Serono, Johnson&Johnson, Boehringer Ingelheim, Pfizer, Abbvie, Amgen, have reported about cooperation with the Russian companies in the sphere of localization of own production on the platform of the domestic companies. Novartis, Teva, Novo Nordisk, Sanofi, Nycomed, LLC KRKA RUS, Gedeon Richter, Servier, STADA CIS, CJSC Berlin-Farma (Menarini Group subsidiary), and Ferring Pharmaceuticals invested in creation of own productions in the territory of the Russian Federation. The Abbott Company has acquired 100% of shares of the Russian company JSC Verofarm and realizes the project on construction of a new production site covering Vladimir region.

Transition to the GMP standards

The main problem in pharmaceutical industry connected with restructuring by modernization of pharmaceutical industry according to the international standards. One of key problems of branch in the context of import substitution remains also transition to the GMP standards which became obligatory since January 1, 2014. However, still pharmaceutical enterprises have an opportunity to ignore this requirement. As the statistics shows, only 10% of the domestic enterprises have completely passed to the GMP standards, 40% of the enterprises are affected by system of ensuring quality, separate production sites work on GMP. In 2014, only 28 companies have obtained licenses, having confirmed compliance of the production GMP. Thus, now only 80% of production in terms of money and 67% in natural conform to the standard. However, rate of checks of the enterprises is inadequate to objectives on import substitution and in the present mode can drag on for several years. Today production of the enterprises which have not confirmed compliance of GMP competes in the market with the preparations made on GMP. In prime cost of the last huge financial, means are put. However, as a result of GMP, being the rule "not for all," gives to the enterprise only PR effect. The unfair producer remains in the market, is unprofitable to make investments in modernization, and the patient has no the guaranteed choice from drugs of appropriate quality.

Production of own substances

Since 1996 when in the pharmaceutical market of the Russian Federation, there was a tendency to increase in a share of OTC medicines and reduction of a share of prescription medicines. At that time, this ratio made 50:50. In such situation for many enterprises, there was only exit to cease to operate own capacities for production of substances and to replace them with production of the finished pharmaceutical products. According to some information, today to 3/4 Russian productions of generalized least squares uses the substances made abroad in the production. The Russian enterprises are practically in complete raw dependence from import. Full import substitution of drugs is impossible without development of production of pharmaceutical substances. Most less currency jumps have affected the plants working at the Russian raw materials; it was simplest to them to keep the pre-crisis prices. But needs of a pharmaceutical market of Russia for substances only for 15-20% are provided with internal raw materials. It is caused by high costs of their production and low competitiveness in comparison with the main suppliers of pharmaceutical products - India and China. Nevertheless, a number of the Russian producers have already arranged production of substances; however, it closes requirements only of the separate enterprises and for very limited number of names. About production of substances in full for needs of branch as it was in the Soviet years, the speech does not go yet. By 2020, when the pharmaceutical industry will begin to work in large quantities at domestic raw materials, definition of criteria of domestic producer will become inevitable. In Strategy of development of pharmaceutical industry of the Russian Federation till 2020 to this date in Russia is planned production of such volume of pharmaceutical substances which will be able to provide release of a half of ready dosage forms (besides in terms of money) will be arranged, including it is not < 85% of drugs from the list vital.[5]

Optimization of a government procurement system of medicines

According to new conditions since the beginning of 2016, foreign suppliers will not be able to participate in purchasing auctions for the provision of medicines of exempts and medical institutions if two and more suppliers of the drugs made in the territory of EEU apply for the tender. At the same time, those who only pack proprietary medicines on the Russian productions (namely, in such form in Russia the majority of plants of foreign pharmaceutical companies works) will be expelled from system of state procurements and will be able to sell the products only in retail networks. Producers of a full cycle will receive price preferences. Moreover, of course, these restrictions will not concern the patented preparations which analogs in Russia are not present. So far, the import share in the total amount of medicinal state procurements makes about 85%. It is worth expecting that to

some extent it, of course, will be reduced; however, there is one essential nuance: According to new rules any productions of a full cycle located in our territory fall under definition "domestic producer." The largest foreign companies working in Russia already have managed to be prepared for the future changes, having adjusted full cycles of production of drugs at the plants. Moreover, it will grant him full authority to be considered "domestic" at tender auctions and, respectively, to receive all those preferences which rely completely our productions.

CONCLUSIONS

All these problems are only insignificant part of tasks which the state should solve if it is interested in the creation of a full-fledged pharmaceutical industry and ensuring medicinal safety of the country. Despite numerous difficulties, in general for four with small years of action of this program, the output of medicines in Russia has increased twice.

Today will precipitately speak about full import substitution in pharmaceutics. Certainly, it is necessary to accelerate all processes, to realize this idea, but time, when we can refuse preparations of import production completely has not come yet. It needs to be accepted as a reality. The past years at us in the country have appeared a pharmaceutical industry, making competitive production.

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