



## **Pharma 2020 The Strategy of Development of the Pharmaceutical Industry of the Russian Federation**

### **Analytical Summary**

The Strategy Pharma 2020 was adopted by the Ministry of Industry and Trade in October 2009. It is targeting the innovative conversion and competitiveness boost of the Russian pharma sector; improvement of its production capacity, stipulating 50% import substitution and further substantial export capacity increase. As a result of the Strategy, the Federal Law “On Turnover Of Medicines” entered into force by September 2010. It introduced, beside other necessary legal amendments, the state regulation of DLO medicines’ prices which did not raise big enthusiasm of the international pharma. The Strategy broadly relies on the international experience and stipulates localisation of full circle production of the international companies in Russia. This level of market exposure is an opportunity as well as a substantial challenge for the international players in connection with the shortcomings of the existing business conditions and legal framework. A number of international Big Pharma companies had to declare their plans to launch production in Russia – total planned additional FDI volume is about USD 1 billion. The Government is expected to keep the Russian pharma market attractive for the international manufactures in order for them to fulfil their localisation plans. The recent intensification of Russia WTO accession process gives additional hope to the international business for the framework guarantees which should fortifying its confidence on the Russian market. Pharma experts generally approve the Strategy Pharma 2020 but express different concerns regarding the feasibility of its goals.

## I. NATIONAL PHARMA

**The Russian pharmaceutical market<sup>1</sup>** represents only 1.5% share of the global pharmaceutical market. In 2009 its volume was around USD 11.6 billion (chart 1.) – about 1% of Russian GDP. It consists of two major segments – commercial (drugstores) - more than 2/3 and additional medicines supply (DLO) public procurement - less than 1/3. DLO public procurement share reached 26% of total medicines sales by 2009 while the share of readymade nationally produced medicines was declining 1-2% per year in DLO portfolio.

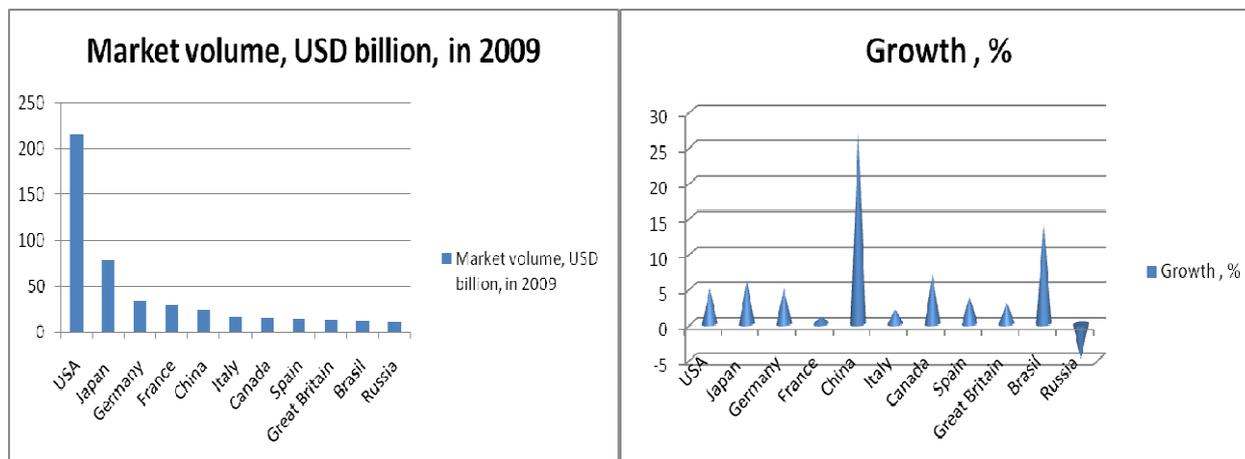


Chart 1.

Chart 2.

The Russian pharmaceutical market is considered to be one of the most dynamic and growing in the world. **It continues to grow in average 10-12% per year since 2003.** Against 8% drop of the country GDP in 2009 the market grew by 22% in RUB and dropped 5% in USD (chart. 2), - which is an excellent performance against e.g. 49% RUB drop of car sales or 16% slow down of construction sector during the same period. In 2010 the sales grew only 6% due to consumer activity slow down and introduction of the DLO state price regulation by the new Federal Law “On Turnover Of Medicines”. The growth may resume to 12% in 2011 provided that the market regulation is not getting tighter. There is a risk that the growth of the market might be hampered (due to its distribution structure) by 50% number decrease of drugstores in 2011 and medicines’ availability decline in remote and rural areas of Russia. This tendency is forecasted in connection with the raised social tax burden for drugstores from previous 14% to 34%.

In the perspective of its sustainable 12% growth, the Russian pharma market volume should reach RUB 400-500 billion (USD 13-16 billion) by 2011 and RUB 1000-1500 billion (USD 30-50 billion)<sup>2</sup> by 2020 in consumer prices, provided that the domestic per capita consumption of medicines rises up to the average European level and the demographic situation improves up to 142-145 million citizens till 2020 according to the strategic social-economic development concept of the Russian Federation. The per capita consumption of medicines in Russia was USD 123 in 2009 and remains the highest on CIS space though 4-5 times lower compared to Europe.

The international companies mainly sell branded generics<sup>3</sup> in Russia which allows the present distribution structure of the Russian pharma market. The main consumer of medicines here is the direct consumer making the choice driven by advertisements and marketing. Thus he/she is ready

<sup>1</sup> Information based on Strategy Pharma 2020 data and Analytical Report “Russian Pharmaceutical Market 2009”, DSM Group, member of ESOMAR, ISO 9001:2000.

<sup>2</sup> 1 USD = RUB 30.

<sup>3</sup> Generic medicine is a drug which is produced and distributed without patent protection

to pay for the brand name being not properly aware of the quality and efficiency of the medicine. International producers continue to profit of this situation. Due to low competitiveness of the nationally produced medicines the imported products dominate on the Russian market allowing the international companies to invest mainly in marketing promotion rather than in R&D.

Out of the DLO list of 2009 containing 463 medicines - 181 names were purely imported drugs - out of it only 70 names were innovative medicines. Only 31 names out of 463 were the medicines produced locally. 251 names of DLO list were both imported and nationally produced – which indicates insufficient production volumes of the national pharma.

**The Russian pharmaceutical industry** supplies both the national health care system and hospital sector with 70% of medicines in physical volume (68 and 72% correspondently) which makes only 19 % in value of the medicines' turnover of the Russian healthcare sector. **The Russian pharmaceutical industry mainly produces low profit generics.** The share of generics registered in Russia is 70-80%. While e.g. in USA it does not exceed 25% or 20% in Japan. The national pharma industry is able to invest only 1-2% of its profit in R&D against the USA and European producers investing in average 10-15% in research as a result half of their production portfolio consists of innovative goods.

**The national production of substances contracted 20 times since 1992.** Today the Russian pharmaceutical industry processes around 8 thousand tonnes of substances per year, most of them are imported and less than 25% are nationally produced. The share of high tech substances processed locally (more than 6 synthesis stages) is 35% in physical volume - out of it 15% produced locally. The share of biotech substances is 39% in value terms - out of it 2% produced in Russia. Other substances are imported from India and China – around 70% and 5% - from industrialised countries. India and China are the major peers of Russia in production of substances, producing with no GMP standard and caring the policy of damping prices.

The Russian pharmaceutical industry is practically not present on the international markets. **In 2007 the export of the nationally produced medicines did not exceed RUB 6 billion which is less than 0.04% of the world medicine sales.** The reason for that is the absence of GMP harmonised standards. In 2009 only around 10% of Russian pharma companies were producing according to GMP standards. The issue of standard harmonisation still remains open and represents a source of regular problems. There are plans to fully convert the national pharma production to GMP standards by 2014.

There are around 600 licensed national pharmaceutical manufactures almost in all subjects of the Russian Federation, most of them are located in Moscow, Nizhniy Novgorod, Kursk, Kurgan Regions, Bashkortostan, Tatarstan, Western Siberia – in Novosibirsk, Tomsk and Omsk. The Russian pharmaceutical industry employs around 65 thousand people - only 10% having sufficient qualification. Around 10 thousand employees should be additionally trained to insure the innovative production launching. The insufficiency of qualified personal is the main reason for licences' purchase on the first two stages foreseen the Strategy. The Russian pharmaceutical industry is strongly concentrated – 10 major companies produce 30% of all national medicines in value terms.

## **II. PHARMA STRATEGY 2020**

The Strategy of Pharmaceutical Industry Development 2020 (the Strategy) was created jointly by the Government and the private sector. It was adopted by the Ministerial Decree 965 from 23rd

of October 2009, signed by the Minister of Industry and Trade Khristenko. The department of chemical technology complex and bioengineering technologies of Khristenko Ministry was appointed to be in charge of the realisation of the Strategy.

**The governmental bodies responsible for the implementation:** Ministry of industry and trade, Ministry of health and social development, Ministry of economic development, Ministry of education and science, Federal antimonopoly service, Federal service on tariffs, Ministry of internal affairs, Federal security service, Ministry of defence, Ministry of emergency situations, Ministry of foreign affairs, Federal Service on drug control and other interested federal agencies, offices, and executive bodies of the federal subjects.

The Strategy is aimed on complex structural upgrade of the national pharmaceutical industry. The primary objective of the pharma state policy of the Russian Federation was formulated by the Strategy as follows: “**Creation of the necessary conditions for the conversion of the Russian pharma production into the innovative development model**, which should increase the availability of medicines for the Russian population, health care system, defence sector and other federal uniform services and the supply up to the average European level in natural and value terms”.

The document decently reflects the present state of the Russian pharma sector. It stipulates the application of the best international experience and practice, identifies the need of framework improvements of pharma business conditions (legal improvements, export/import conditions, removal of bureaucratic barriers, corruption etc.). The document presents detailed description of measures for localisation of production sites; personal training etc., supported by budgetary calculations’ tables and visual support (charts, diagrams and schemes). It also contains the DLO list purchased within public procurements.

### **The Strategy provisions**

The Strategy identifies the consumption growth potential for locally produced medicines at 10-15% in value and 50-60% in physical terms and clearly draws the conclusion that the international companies would continue to profit of it if the production capacity of the national pharma is not sufficiently improve. **The disability to fully satisfy the internal market and insufficient level of innovations and technology** are identified as key bottlenecks of the Russian pharma.

#### **“Environmental” shortcomings:**

- the registration procedures for the national producers is more complicated and time consuming;
- high inflation, rouble strengthening, high credit rates, high cost of capital construction and constantly rising energy tariffs;
- national producers are entitled to pay higher taxes on sales volumes (12-14%) compared to the foreign companies (0-10% customs duty);
- lack of support of SMS pharma companies by the public procurement system;
- insufficient professional training in pharma R&D and production;
- absence of sustainable R&D investment mechanisms;
- domination of multinational companies on one side and Indian and Chinese damping on the other side;

- shortcomings of Russian patent legislation procedure and non-conformity with the international standards;
- actual absence of the obligatory pharmaceutical production process requirements and control (in spite of the national standard GOST P 52249-2004 is formally identical to GMP, the issue regarding its obligatoriness is still not solved).

### **The Strategy goals:**

1. Improvement of supply of the Russian population, the health care system institutions, defence sector and other federal uniformed services with the nationally produced essential and rare disease treatment medicines;
2. Improvement of competitiveness of the national pharma (by harmonisation with GMP);
3. Fostering of innovative medicines' R&D;
4. Protection of internal market against unfair competition and levelling out market access requirements for national and foreign producers;
5. Technology upgrade of the Russian pharma;
6. Improvement of quality control, removal of excessive bureaucratic registration barriers;
7. Pharma personal professional training according to the international standards.

### **Targeted results by 2020:**

- Increase of the share of locally produced medicines up to 50% (in value terms) on the internal market;
- Increase of the share of innovative medicines up to 60% share (in value terms), change of assortment;
- Increase of pharmaceutical products export by 8 times compared to 2008;
- Insuring of medicinal safety of Russia in compliance with the list of strategic medications and vaccines;
- Establishment of pharmaceutical substances' production sites on the Russian territory for the output of 50 % of finished substances (in value terms), sufficient for production of no less than 85% of the of strategic medications list.

**The federal budget is the main financing source of the measures foreseen by the Strategy.** The government plans to spend till 2020 RUB 177 620 million (USD 6 billion, in prices of February 2009) distributed as follows: Education and infrastructure – RUB 35 220 million; Transfer to GMP – 36 000 million; R&D – RUB 106 400 million. Other sources of financing: the federal subjects' budgets, funds of commercial and social organisations, etc. Academic institutions, venture foundations (OAO RBK) and seed financing foundations – State corporation “Rosnanotech”, federal purpose-oriented programs (State Corporation “Rostekhnologii” and the banking credit (with the assistance of State Corporation VEB) should be other important financing mechanisms of R&D, preclinical, first and second phase clinical tests. **The return of investments should start in 2017** through the lower prices of locally produced generics and innovative medicines purchased in the framework of DLO public procurement as well income tax revenues increase.

The Strategy foresees 2 alternative development scenarios – inertial – preservation of the status quo of the sector and **innovative scenario** comprising investment and innovative phases and planned to be realised in 3 stages.

**I stage – 2009 – 2012 – construction of new production sites and R&D** – Measures: GMP harmonisation, improvement of quality control, educational and professional training programs, adoption of the necessary legislation changes, anti-corruption measure. Among additional specific measures the government considers **the possibility of customs fees' increase for imported medicines and substances**, those with expired patent if 'the national market is fully supplied with the locally produced analogues of the equal quality'.

**II stage – 2013 – 2017 – home production of national generics, creation of import substitution market mechanisms, focusing on internal market, realisation of medicines independence of the Russian Federation.** In this period the national pharmaceutical industry should be able to produce up to 50% of medicines - more than 200 names - from the DLO list. Here the measures are focused on the support of the national/local producers and localisation of full cycle production of international companies and can be classified as follows:

Protectionist measures:

- public procurement priority for national/local producers;
- 3 years advanced public procurements' planning for local producers;
- levelling out of the requirements for the national and foreign producers regarding the substances quality control procedure (introduction of auditing of foreign producers of substances by the state expert organisations);
- accreditation of all foreign producers of pharmaceutical substances and official medicines entering the Russia market by the regulation bodies of the Russian Federation in order to strengthen quality control for official medicines.

Technology acquisition and transfer measures:

- encouragement of joint clinical tests and licence transfer to the Russian partners;
- establishment of joint structures of researchers and manufactures for licences' acquisition and establishment of production sites on the territory of Russia;
- home production of high tech and biotech substances;
- establishment of technology transfer centres abroad;
- import of R&D experienced foreign specialists to Russia (primarily those of Russian origin).

Domestic localisation of international production:

- a foreign companies' licensed production should be located on the territory of the Russian Federation if the home production of the innovative medicines is missing;
- support of preclinical studies carried out by the foreign companies producing in Russia;
- revision of the list of strategic medicines and organisation of their full cycle production on the territory of Russia, improvement of the state procurement system;
- introduction of the necessary changes to the government decree from 16<sup>th</sup> of July 2005 №438 in order to allow the company-producer the import of registered substances for production purposes in Russia.

Liberalisation measure:

- cancellation of registration of medicines produced only for export purposes;
- cancellation of registration of substances.

**III stage – 2018 – 2020 - Export orientation, expansion to the global markets** Here the measures should foster R&D to improve the national export competitiveness and efficiency:

- grants and tenders for SMS scientific companies;
- application of modern R&D technologies;
- patent research;
- monitoring of the international markets;

- improvement of preclinical and clinical procedures;
- nano-biotechnology R&D;
- upgrade of professional training.

### **Cluster-based development concept**

The Strategy presents a detailed consideration of the territorial dimension for the development of the national pharmaceutical industry and suggests a cluster system which has been “already successfully implemented abroad”. The idea is to locate on one territory (federal district) a chain of companies active with full pharma cycle - R&D, production, professional training, distribution - logistics and sales. The cluster should be concentrated towards a major (federal) university. Ural, Privolzhskiy, Siberia and Central Federal Districts are considered to be the most appropriate for the development of the pharma clusters. *Indeed, e.g., the investment proposal paper sent to the Swiss side by the Presidential Envoy in the Ural Federal District Vinnichenko (on the result of the official visit of the Ambassador to Yekaterinburg in May 2010) contains a pharmaceutical cluster investment project.*

**The strategy identifies the following international and internal risks relevant for its implementation period.**

- *Infrastructure risks* - insufficient number of modern facilities, production sites and science research centres, as well as weak coordination system for research and business.
- *Anthropogenic and ecological risks* - 60% wear of fixed assets and possible damage for the environment.
- *Insufficient financing* may retain the R&D of new medicines and substances.
- *Legislative risks* - the shortcomings of the legislation aggravate companies’ prompt reaction to the changing market situation.
- *Personnel risk* – lack of qualified specialists and educational programs.
- *Macroeconomic risks* – possible economy slowdown, investment slowdown, high inflation, strengthening of rouble and other.
- *Global risks* – the downturn of the global economy.

### **III. ANALYSIS.**

**The Strategy received an overall positive feedback of the national pharma circles.** It is considered to be timely and necessary. Though the document could not avoid the ideological superstructure expressed through the medicines’ security priority, it is justly based on the universal principles of the industry development – from production localisation on the territory of the country and satisfaction of internal demand to the industry export capacity building-up.

The Strategy proclaims **modernisation of pharma, which should contribute to ‘the innovative image’ of Russia** and goes in line with the Russian economy modernisation plan stipulated by the Strategy of the Economic Development 2020 of the Russian Federation (which is currently in the process of reconsideration in order to make it more business oriented). The science-intensive industries should be given the priority and contribute to the innovative development of the Russian economy. Pharma was acknowledged to be number 2 worldwide for investments volume in R&D, placed between the automobile industry and technology hardware<sup>4</sup>. The Russian leaders

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<sup>4</sup> UK Department for business innovations and skills BIS R&D Scoreboard 2010  
[http://innovation.gov.uk/rd\\_scoreboard/downloads/2010\\_RD\\_Scoreboard\\_data.pdf](http://innovation.gov.uk/rd_scoreboard/downloads/2010_RD_Scoreboard_data.pdf)

for R&D investments are Gazprom, Avtovaz and Lukoil - which so far does not testify the implementation of a very active phase of diversification-modernisation.

### Implementation

In accordance with the provisions and goals of the Strategy the **Federal Law 1815 from 12.04.2010 N 61-FZ “On Turnover Of Medicines”** came into force as of 01.09.2010. The Law contains detailed provisions for all stages of medicines’ turnover: R&D, preclinical and clinical tests, expertise, state registration, import, export and realization of medicines. The Ministry of health care and social development considers it to be “a breakthrough” towards the transparency of expertise, regulation and registration procedures. On the opposite during its approval process the project of the Law and particularly its core provision on *state regulation of prices of medicines from DLO list* was actively criticized by the Russian medicine science academy, Federal antimonopoly service, Association of clinical research, Independent psychiatric association and other institutions and experts. **Professional pharma circles consider the new law to be even more corruption receptive and anti-social.** The law stipulates the increase of medicines’ registration fees which should complicate the market entry for smaller and medium size national pharma companies. In spite of its doubtful quality the law was finally adopted under a strong pressure of Prime Minister Putin and the Ministry of health care and social development. The Law comprises a number of facilitations for the local producers foreseen by the Strategy – like *leveling out of market access requirements for foreign and local players, cancellation of registration of substances* which should simplify the registration of home-produced medicines, etc. It *foresees suspension of some provisions* for the national producers in connection with GMP transitional period.

The Strategy provisions converted the notion of “**a national producer**” into “**a local producer**” – a Russian or international company, of any capital origin, producing on the territory of Russia. On the adoption of the Strategy a number of Big Pharma international companies already declared their readiness to invest in local production facilities - all together around USD 1 billion - in the nearest future. It is clear that localisation of production would be a political decision for those pharma companies who are planning to stay in the long term on the Russian market and maintain their share in DLO public procurements. The degree of their localisation should influence the government decision to favour them respect. So far many companies tend to move to Russia only the final stages of production (packaging) and clinical tests of new medicines which is not enough for going local.

### Pros and cons

Some experts consider the Strategy’s assessment of growth potential of the Russian pharma market at 10-12% till 2020 too optimistic. The historical data (reflected in roubles) indeed showed the robust nominal growth originated in principle by the rouble depreciation - 3 fold in 1998 and 30% in 2008 as well as robust inflation at average 12% during the mentioned period. The negative tendencies like forecasted 50% number decrease of drugstores in 2011 and state price regulation bring down the growth expectations and make the Russian pharmaceutical market less attractive. The experts claim that **the future growth potential of the Russian pharma consumption should be based on DLO public procurement share’s increase and introduction of medicine reimbursement insurance system** – while these two opportunities are not considered by the present Strategy.

**The import fees on medicines are unlikely to be raised during the pre-election period till spring 2012** as it should lower availability of the quality imported generics on the Russian market due to their prices increase. This will definitely negatively impact the election spirit. Russians historically trust more the quality of imported medicines. It is well known that some

nationally produced analogue medicines are of worse quality than the imported ones, though according to the documentation they are identical. This situation is gradually improving but is far from being perfect. If the quality of the nationally produced medicines will be improved only on paper and in parallel the duties will be finally raised it will diminish the availability of the quality medicines on the Russian market.

The Russian IPR protection legislation in principle corresponds to the international standards. It was harmonised in connection with the WTO accession requirements. In spite of it the practical application of the legal provisions needs further improvement. IPR disputes and court cases stumble in Russia on a number of remaining legal contradictions and procedural inefficiency. **The Strategy does not suggest any concrete improvements in terms of law implementation efficiency or other facilitations in the IPR sphere.** Though it could better consider its practical dimension and e.g. promote the idea of the introduction of the IPR courts (which was actively discussed during 2010 and is planned to be implemented by 2012); suggest protection mechanisms of private partners participating in public-private R&D projects, etc.

The international business should take as a positive message the reference of the Strategy to the international experience for the structural upgrade of the national pharmaceutical industry. It means that **the Russian government would have to provide favourable market treatment to the international business encouraging it to bring its technologies and move their production activities to Russia.** The international companies are expected to get more exposure on the Russian market which, in principle, is acceptable in a transparent and efficient legal environment. So far the ability of the Russian government to insure it remains a major concern. Therefore in order to stay on Russian market the international business should constantly reassess its risks and adapt the business strategy according to the volatile Russian political and business environment. Most of the international pharma companies are members of professional unions and lobby organisations (ARPP, SPFO, AEB, AmCham<sup>5</sup> etc.) in order to stay timely updated on the legal changes and lobby their interests.

The increase of the Russian pharma export capacity is the crowning and the most ambitious goal of the Strategy. The successful creation and production of innovative medicines would, increase the export chances of the national pharma industry. In this connection the experts consider the **R&D budget of the Strategy insufficient for the innovative breakthrough.** The R&D of a single innovative medicine costs from USD 500 million to 1 billion and takes 5 to 15 years till its production phase. Some representatives of the Russian pharma think these costs to be overstated and consider a budget of USD 60-70 million to be sufficient for creation of a new medicine. Currently the size and terms of the Russian pharma private capital is not sufficient for R&D purposes taking into account the risks and return of investments period. The financing R&D infrastructure is presently rather weak and underdeveloped in Russia. The insufficient financing might as well aggravate the establishing of Russian technology transfer centres abroad. The export increase of the national pharma looks to be relatively feasible through localization of international pharma production and transition of national pharma companies to GMP standards. It is not specified by the Strategy to where exactly the country is going to export but the CIS space is the most obvious export destination for the Russian pharma industry.

The cluster approach for Russian pharma development was criticized by some experts though the idea to locate the full circle pharma production on one space was assumed as a relevant one.

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<sup>5</sup> ARPM – Association of Russian Pharma Manufactures <http://www.arfp.ru/> , SPFO – Union of professional Pharmaceutical Organizations <http://www.spfo.ru/en> , AEB - Association of European Businesses <http://www.aebus.ru/> , AmCham – American Chamber of commerce <http://www.amcham.ru/>

**The facilities of techno park size are hardly needed for implementation of innovative projects.** They look to be suitable for pharma “consumer goods” production but would not necessarily provide the right conditions for innovative R&D which is often performed in small-size specifically equipped laboratories which are seen to be the future of innovative global pharma.

## **Conclusion**

The Pharma Strategy 2020 is in process of implementation. The adoption of the Law “On Turnover of Medicines” is the major step on this way. It brings additional challenges and opportunities through setting the new rules of the game on the Russian pharma market. The international companies should weight all pros and cons for its business development in Russia. Finally they should take an individual decision depending on their position on the Russian market regarding their anchoring here.

Attachments:

1. Expert opinions
2. Top 20 pharma companies on sales volumes on the Russian Market in 2009 + their market expose information.

Tatiana Malysheva

Moscow, 25.03.2011

## **Legal Disclaimer**

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## ANNEX 1. EXPERTS' OPINIONS<sup>6</sup>

**Mr. Mladentsev, independent expert, member of the committee on entrepreneurship in healthcare and pharmacy, Trade Industrial Chamber of Commerce of the Russian Federation.**

“There can be any strategy. It is being criticised and further reconsidered, some say it needs more detailed revision. But it is not the strategy, but the mechanism for its realisation which is important... They should create a national coordination committee in charge of the strategy by the President of the Russian Federation.” *The expert means that without direct president supervision the Strategy will not be realised.*

**Mr. Miroshnikov, Academician of the Russian Academy of Science, Deputy Director of Shemiakin and Ovchinnikov Institute of bio-organic chemistry.** “We are moving in this direction but there is still a long way towards 50% of import substitution.”

**Mr. Bachurin, Director, Institute of physiologically active substances by the Russian Academy of Science (Chernogolovka), member-correspondent RAS, member of the expert board of NP “Orchimed”.** “First of all the issue of IPR should be solved. As far as this issue is not solved many project remain only good intentions. Companies are very reluctant to contract with the state organisations, particularly if the Russian Federation is registered as the owner.”

**Mr. A. Ivanova, Director, National Distributor Company.** “50% share of nationally produced medicines is targeted in value terms - this goal may finally be reached due to simple cost increase and inflation... It is a question if the Ministry of Industry and Trade will receive the whole financing (USD 6 billion for 11 years which is USD 550 million per year)... 11 year-period is too short for creation of original Russian medicines”.

**Mr. Danilov, Editor, pharma portal Pharm-MedExpert.Ru** “The average cost of R&D of one medicine is USD 800 million and soon the costs may rise up to USD 1 billion, while the Strategy foresees only USD 3.5 million for R&D.”

**Mr. Shirshov Gennadiy P. Executive Director, Union of Professional Pharma Organizations SPFO<sup>7</sup>.** “The document is not of the governmental but of ministerial level – it is not enabled with the sufficient power for other ministries and committees. The Strategy it is not enough demand oriented. The demand should be mainly embedded in the public procurement (presently having insufficient 26% share) supported by medicinal reimbursement insurance (which presently does not exist in Russia). Localization of production of international companies on the territory of Russia is not profitable - to settle a production costs USD 100 million while in average the return is only 5 million per year on the Russian market - to operate under these conditions does not make sense... The growth potential of the pharma consumption in Russia is exaggerated, if not to say, exhausted within the present distribution system. No population growth or European level of per capita consumption is feasible. The growth of Russian pharma did not exceed 7% per year since 2002. The willingness of international business to invest might be further aggravated by the state regulation of prices. The raise of duties on imported medicines is excluded in the forthcoming State Duma and President election period. Big Swiss pharma companies have nothing to be afraid of as they are well settled in Russia and could adjust their market strategy accordingly (also thanks to SPFO effort)”.

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<sup>6</sup> Professional opinion poll issue: “PHARMA-2020, Problems and perspectives “.

<sup>7</sup> Telephone conversation.

## ANNEX 2.

**TOP 20 PHARMA COMPANIES ON SALES VOLUME  
ON THE RUSSIAN MARKET IN 2009<sup>8</sup>**

Rating in 2009	Change of position	Company name	Sales volume million RUB	Increase %	Market share %	Web site, projects in Russia beginning 2011 <sup>9</sup>
1	1	SANOFI-AVENTIS	18 373	24.3	4.2	<a href="http://www.sanofi-aventis.ru">http://www.sanofi-aventis.ru</a> representative office, distribution of medicines, joint clinical tests, <b>declarations of intentions to produce locally</b>
2	-1	NOVARTIS (Swiss based)	16 637	11.3	3.8	<a href="http://www.novartis.ru">www.novartis.ru</a> Representative office, distribution of medicines, <b>R&amp;D partnership with Shemiakin and Ovchinnikov Institute of bio-organic chemistry</b>
3	3	FARMSTANDART (Russian)	15 470	38.3	3.5	<a href="http://www.pharmstd.ru">http://www.pharmstd.ru</a>
4	0	F. HOFFMANN-LA ROCHE LTD (Swiss based)	14 853	18.0	3.4	<a href="http://roche.ru">roche.ru</a> representative office, distribution of medicines
5	-2	BAYER SCHERING PHARMA AG	13 609	3.1	3.1	<a href="http://bayerscheringpharma.ru">bayerscheringpharma.ru</a> representative office, distribution of medicines
6	1	BERLIN-CHEMIE /A. MENARINI/	12 285	12.8	2.8	<a href="http://berlin-chemie.ru">berlin-chemie.ru</a> Representative office, distribution of medicines
7	3	GEDEON RICHTER	11 916	34.9	2.7	<a href="http://g-richter.ru">g-richter.ru</a> 8 regional representative offices, distribution, <b>local production</b>
8	-3	JANSSEN PHARMACEUTICA N.V.	11 095	-7.3	2.5	<a href="http://janssenpharmaceutica.be">janssenpharmaceutica.be</a> (no Russian site) Representative office, distribution
9	-1	NYCOMED	10 731	14.8	2.5	<a href="http://www.nycomed.ru">www.nycomed.ru</a>

<sup>8</sup> Source: Analytical Report "Russian Pharmaceutical Market 2009", DSM Group, member of ESOMAR, ISO 9001:2000.

<sup>9</sup> Own study

						Representative office, distribution, <b>scholarships for students, plans to produce in Jaroslavl Region</b>
10	-1	TEVA PHARMACEUTICAL	10 493	14.4	2.4	<a href="http://www.tevapharm.com">http://www.tevapharm.com</a> Representative office, distribution of medicines (no Russian site)
11	2	SERVIER	8 780	19.2	2.0	<a href="http://www.servier.com">www.servier.com</a> 1. representative office, distribution, R&D, <b>production since 2007 in Moscow Region</b>
12	3	SCHERING-PLOUGH	8 270	19.3	1.9	<a href="http://www.schering-plough.ru/">http://www.schering-plough.ru/</a> representative office MSD pharmaceuticals
13	-2	PFIZER	8 041	4.5	1.8	<a href="http://www.pfizer.ru">http://www.pfizer.ru</a> <b>Cooperation with NPO Petrovaks Pharm Moscow Region (production of vaccine)</b>
14	-2	LEK D.D. (Sandoz Group)	7 909	3.1	1.8	<a href="http://lekpharma.ru">http://lekpharma.ru</a> Representative office, distribution
15	-1	GLAXOSMITHKLINE	7 671	6.6	1.8	<a href="http://www.glaxosmithkline.ru/">http://www.glaxosmithkline.ru/</a> representative office, distribution, clinical tests
16	0	KRKA	7 189	16.3	1.6	<a href="http://www.krka.ru">http://www.krka.ru</a> representative office, distribution, <b>production since 2003 in Istra Moscow Region</b>
17	0	NOVO NORDISK	7 108	20.3	1.6	<a href="http://novonordisk.ru">novonordisk.ru</a> Representative office, distribution, clinical tests since 1997, <b>plans to produce insulin in Tver, Kaluga, Jaroslavl Regions</b>
18	0	BOEHRINGER INGELHEIM	6 807	19.5	1.6	<a href="http://www.boehringer-ingelheim.ru">http://www.boehringer-ingelheim.ru</a> Representative office, distribution
19	0	OCTAPHARMA AG (Swiss based)	6 139	10.4	1.4	<a href="http://www.octapharma.com">http://www.octapharma.com</a> representative office, distribution
20	0	ASTRAZENECA	5 993	10.7	1.4	<a href="http://www.astrazeneca.ru/">http://www.astrazeneca.ru/</a> representative office, distribution, <b>plans to invest in Kaluga</b>