The Innovation Process in the Russian Medical and Pharmaceutical Sector

In Search of Shoots of a New Economy

Based on a series of interviews with managers of medical and pharmaceutical companies and analysis of special literature, the authors try to identify zones in which the full innovation cycle is occurring, from the creation of fundamentally new products to their full commercialization, and to determine the influence of innovation projects on the construction of the strategic process in the firms of the medical and pharmaceutical sector.

The current economic crisis marked the end of the industrial economy’s dominance in developed countries, where it turned out that households were approaching a natural limit of consumption of traditional durable goods: housing, automobiles, household items, and appliances. This has
forced an intensified search for other ways of increasing the quality of life and, consequently, for other bases of economic progress.

**Quality of life**

The number one concern regarding quality of life is maintaining life itself—a full, healthy life that enables people to remain in a condition that causes minimal suffering for themselves or their companions for as long as possible. Ways of accomplishing this include:

- improving the quality of the human environment (environmental living conditions, lowering levels of everyday stress and crime, eliminating harmful habits and inculcating healthy ones);
- improving the quality of health care (methods of diagnosing and treating diseases, conditions for providing medical care).

In talking about health-care quality, two topics are distinguished: making medical services more accessible and changing the methods of diagnosing and treating diseases. It is assumed that fundamental breakthroughs based on a combination of bio- and nanotechnologies can be expected in medical science in the coming years.

At the same time, changes in diagnosis and treatment methods are also extremely interesting from the perspective of management studies. This process has two components. The first is creating and diffusing new diagnosis and treatment methods (the creation of new technologies, their testing, adoption by doctors, and acceptance by patients and society as a whole). All of this relates to the problem of creating and diffusing process innovations and is considered the most attractive direction of management studies.

The second component of the process of changing treatment methods is no less interesting. Diffusing new methods of diagnosis and treatment must be supported by an adequate resource base: design (development) and mastery of the production of new drugs and new equipment (diagnostic and clinical). Another equally serious problem of management studies is study of the processes of creating and adopting product innovations. The study of this problem is even more important because developing the pharmaceutical (creating and producing drugs) and medical industry (creating and producing medical equipment) is a unique example of how production should fit into the context of the new, postindustrial economy.
Statement of the problem

We focus on current characteristics of the way business is conducted in the Russian pharmaceutical and medical industry. Our problem does not include “head-on” study of all possible forms and methods of operation of various types of firms. On the contrary, we tried to determine:

- to what extent do Russian players act as the subject, rather than the object, of a full-cycle innovation process—how much do they participate in all stages of the creation of new product prototypes (drugs or equipment)?
- how do full-cycle innovation projects look in the real world of the Russian medical and pharmaceutical business?
- how are full-cycle innovation projects incorporated into the process of setting and accomplishing firms’ strategic goals?

To answer these questions, in February–April 2009, we conducted a series of interviews with managers of several companies in the medical and pharmaceutical sector. The companies included:

- one of the largest domestic distributors of drugs and medical products;
- a branch office of a large foreign pharmaceutical company;
- branch offices of several large international companies that produce medical equipment;
- a branch office of a diversified global technology corporation that is active in the medical market; and
- several importers and producers of medical laboratory equipment and materials.

All of the interviews were conducted under the condition of anonymity of the respondent and the firm. In the course of analyzing the results of the interviews, supplemented by data from surveys of the sector (including specialized publications of research firms such as Rye, Man and Gore Securities, DSM Group, and Espicom Business Intelligence), we tried to find zones of innovation behavior where the innovation behavior is not forced, but deliberate, frequently going up against unfavorable external circumstances.

In July–August 2009, the interview materials were supplemented by case studies—detailed descriptions of individual aspects of innovation activity prepared by top managers of several medical and pharmaceutical companies.
In search of subjects of the innovation process

The Russian medical and pharmaceutical sector is one of the most globalized in the Russian economy. In 2008, the total estimated size of the market for pharmaceuticals and medical equipment was $21 billion. Of this amount, about $18.4 billion was for drugs and parapharmaceuticals (biologically active additives, cosmetics, etc.) and $2.5 billion for medical equipment. The proportion of Russian-made products in the pharmaceuticals market in the first quarter of 2009 was 65 percent in volume and about 25 percent in value. In the medical equipment market, the share of domestic production was estimated at 20 percent in value.

In accordance with the problem we posed, we tried to understand the extent to which Russian players act as the subject, rather than the object, of a full-cycle innovation process (the creation of new product prototypes). In analyzing the interviews and collecting additional information, we concluded fairly quickly that none of the Russian players in the pharmaceutical sector are creators of fundamentally new product prototypes.

Russian branch offices of foreign pharmaceutical companies (which are set up if an international company prefers not to work exclusively through a Russian distributor) are mostly sales subsidiaries, with a minimal level of value added. In cases where a foreign company nevertheless sets up production in Russia (e.g., the Gedeon Richter firm), developing drugs remains the prerogative of the parent company’s research divisions.

National pharmaceutical companies have been placed in situations that allow them to utilize and market only generic drugs and branded generics (i.e., drugs with patents that have already expired). This is because of several circumstances: the lack of long-term lending and venture capital (the full cycle of synthesis, testing, and marketing of a new drug takes ten to sixteen years), and narrowness of the domestic market, which does not allow firms to make economically justified expenditures for creating fundamentally new drugs using exclusively their own resources.

Although in the first quarter of 2009 the volume of the commercial segment of drugs increased by 31 percent in comparison with the first quarter of 2008 (because of a 30 percent increase in the average cost of a package of drugs during the same period), the absolute sales of the most popular drugs are still not very high. In March 2009, the most popular drug in Russia, Arbidol, accounted for 2 percent of the market.
($150 million per year), and the annual sales volume of the remaining twenty most popular drugs was estimated at $40–60 million. The cost of development and full-scale clinical testing of a fundamentally new drug averages $750 million (not counting $140 million after a permit has been issued).

Consumer attitudes toward Russian-made pharmaceutical products is a significant factor. Foreign drugs can be sold at prices two times or more higher than those of equivalent Russian ones (drugs containing the same active ingredients).

National research centers specializing in development of drugs: because of institutional restrictions, the State Scientific Center for Antibiotics, the State Scientific Center for Applied Microbiology and Biotechnology, and the Vektor State Scientific Center for Virology and Biotechnology could not raise enough money to develop fundamentally new drugs and they mostly provide scientific services for domestic pharmaceutical producers. State scientific centers that specialize in clinical medicine (coloproctology, laser medicine, etc.) were transformed into specialized diagnostic and treatment centers in the 1990s.

Nevertheless, new drugs have been created in Russia. Russian producers are learning to produce an increasingly large number of drugs by putting finished substances into tablet form, as well as synthesizing new types of active ingredients; widespread screening and preclinical testing of new molecular compounds (testing conducted prior to trying the drugs on people) are under way; and Western corporations, including those with a large share of the Russian drug market, use Russia extensively as a base for clinical tests. In particular, because of the mass transfer of clinical tests to Russia, drugs that have been put on the European and American markets recently are ideally suited precisely for Russians. True, they are tested mainly on poor citizens and will be sold mostly to wealthy ones, and the degree of genetic and physiological differences between the rich and the poor has not been adequately studied.

In other words, the Russian pharmaceutical sector is mainly as the object, not the subject, of the international innovation process.

According to the current situation, the understanding by Russian players in the pharmaceutical market of their own actions as a process of creating the foundations of an “economy of life” is minimal. During the interviews, we were repeatedly able to affirm that the general rules of doing business in the sphere of consumer goods apply in the pharmaceutical sector. These are optimization of the product and sales line in order
to maximize gross sales and net profit, and the use of the inelasticity of
demand and imperfection of the market to keep prices high, among oth-
ers. A healthy cynicism is manifested particularly in the optimization of
foreign companies’ product lines. If a new product that is launched does
not reach the planned level of sales, it is quickly taken off the market,
despite all its wonderful curative properties. That is why the order of
the Ministry of Health no. 277, of May 27, 2009, “On Organizing and
Conducting the Monitoring of Drug Prices and Assortment at Inpatient
Medical and Preventive Treatment Facilities and Pharmacies in the
Russian Federation,” set the objective of monitoring not only prices but
also the assortment of drugs in pharmacies, primarily cheap, low-profit
drugs, trying to maintain pharmacies’ basic assortment in the situation
of declining household incomes.

Conditions are somewhat different in the sphere of production of
medical equipment. The public is dominant in the pharmaceutical market
(only about 30 percent of drug volumes are purchased at the expense of
the federal budget). Thus, producers clearly dominate the drug market
in Russia. The public has a scant presence in the medical equipment
market (devices for measuring blood pressure, blood sugar levels, etc.).
More than 90 percent of the equipment is purchased by government treat-
ment institutions, and the remaining 10 percent by private clinics. This
means that producers have to deal with a skilled buyer that dominates
market power.

We tried to find traces of a full-cycle innovation process in the sphere
of production of medical equipment (diagnostic equipment and consum-
able, equipment for dental practice, orthopedics, and implants, syringes,
etc.). The first interviews conducted at Russian companies working in
this sector already gave us some hope. We saw a business attitude that
can best be defined by the word “luck”:

- setting of business goals in terms of the level of the product’s
technology and how much it increases the diagnostic or clinical
effect;
- perception of the business’s quantitative parameters (level of
sales, necessary amount of current assets, accumulated credits,
and net profit) as conditions that make it possible to develop
new product prototype.

In a number of cases, we could observe examples of an unselfish
overstepping of legal limits that is unique for Russian business. The
example of A. Koretskii, manager of the innovation division of the largest higher educational institution in the south of Russia, is revealing. The office of the public prosecutor of Rostov oblast took legal action against him because the research group that he is in charge of developed and turned over to the emergency medical service in Taganrog a “computer cardioanalyzer.” The team of emergency medical technicians transmits cardiac performance readings over the Internet to the dispatch center at the hospital, where leading diagnosticians interpret them. Fortunately, the court did not see turning over a unique scientific development accomplished in response to an individual technical assignment as a crime of “illegal business activity” (as reported on Rossiia television channel’s 11 o’clock News, January 27, 2009).

We should immediately point out that the absolute scale of such business is very small. We mentioned that imported equipment accounts for 80 percent (in value) of the medical equipment market in Russia. Nevertheless, gaps remain open for domestic production in almost all spheres of medical equipment and materials. This is indicated by little-known facts about exports of Russian equipment to developed countries. For instance, in 2006 Germany imported $4.9 million worth of Russian electronic diagnostic equipment, and another $1.1 million was received from exports of such equipment to the United States. Russian orthopedic products are exported to European Union countries (more than $2 million in 2006).12

The structure of the market itself fosters the appearance and continued existence of such gaps. The $600 million annual output of Russian companies is provided by 660 manufacturers, with 250 “major” ones accounting for 90 percent of the sales. The mix of medical equipment manufacturers is quite diverse:

- several large, specialized medical equipment manufacturers (created in the Soviet era, these companies were privatized in the 1990s and now exist in the form of open joint-stock companies);
- medical equipment plants (departments, units) set up in various defense firms in the 1980s as part of the conversion of the defense industry. These firms have various legal forms (state unitary enterprise, closed joint-stock company, open joint-stock company); and
- newly created private companies, almost all of which spun off in the early 1990s from various specialized scientific and design institutes.13
At the latter, small and very small private medical equipment manufacturers were able to see the beginnings of understanding by businessmen of their role in creating an economy of life. And a combination of the following diverse factors explains this.

- Existence as a closed joint-stock company or a limited liability company enables these companies to conduct a more flexible financial policy and earmark funds for research and development even when the firm’s core operations are losing money.
- The lack of liquid assets and the desire to minimize management expenses force some of the firms to bring the younger generation into the business—the sons and daughters of the “founding fathers.” This, in turn, significantly lengthens the time horizon of the firms’ strategic plans, frequently to the time when the grandchildren have grown up.
- The innovation cycle for the development of new equipment itself can be significantly cheaper and, most important, shorter. The cycle for registering a new prototype of a medical product takes from six to eighteen months, while the product itself can be custom-made, if necessary, in a few days or hours.
- Most of the firms that produce medical equipment are forced (in order to maintain the business’s total sales volume) to act as dealers (distributors) of related imported equipment. This opens up broad opportunities for direct copying of the latest equipment, imitation, and creative development of advanced technological principles and techniques for implementing them.
- Finally, the very nature of the buyer of the finished product (we remind readers that government procurement of medical equipment accounts for 90 percent of the market) forces the manufacturer to conduct in-depth training of both the client (managers of government institutions) and the end user (the personnel of medical institutions)—hence, the very high requirements for qualifications of the manufacturer’s personnel.

**Construction of a full-cycle innovation project at a medical equipment manufacturer**

We look at an example of a full-cycle innovation project carried out in the Unimed group of companies, an importer, supplier, and producer of products for clinical laboratories.
The structure of the innovation process itself is entirely standard in this group of companies.

1. An application for development, which describes the basic characteristics of the product qualitatively and quantitatively, and general characteristics of the market (limiting capacity, anticipated growth, proposed price level for the product), is submitted directly to the general director, sometimes as a simple internal e-mail message.

2. The application is considered at a meeting in which the marketing department, the research and development (R&D) department, and the company’s managers take part. Specialists assess the fundamental feasibility of the application, both technically and economically.

3. If as a result of the meeting the participants conclude that the idea may be useful, in principle, then the next stage will be to conduct research. In this stage, the basic principles of creating the product are tried out, and the most efficient technical solutions are sought.

4. In the stage of development and study of a model (prototype), the products being developed are turned over to a laboratory for testing and modeling of the product’s use by the end users, taking into account the established practice, the culture of laboratory work, and the skills of laboratory technicians.

5. The research culminates in drawing up a design specification for development. The design specification contains all of the technical parameters for the future product and the most important design solutions, definitively formulated. The design specification contains a section on economic parameters, including limits for development funding and production costs. Development culminates in drawings and diagrams of the product to be produced, documentation of how the product is produced, and a set of prototypes as well as a set of documents for registration and certification.

6. A work specification for preparing a product promotion program is drawn up at the same time.

7. Then the procedure for registering the product with Roszdravnadzor has to be carried out. Clinical and technical tests of the product are part of the registration process.

8. In the stage of putting the product into production, a program
for promoting it in the market is developed and approved. In this stage, several lots of the product are produced according to the technical documentation, and individual production techniques are frequently changed in the course of working out the production technology. All of the changes are immediately added to the production documentation. In the course of setting up production, possibilities of lowering the cost of production are studied, for example, using special technological equipment or alternate production methods.

9. After several pilot lots have been produced, when the company is sure that the production process is stable and meets the assigned requirements, the tests are repeated, and all of the necessary changes are made in the documentation.

10. Finally, the design and technological documentation is approved for series production. Promotion methods are worked out while the pilot lots are being produced.

11. In the course of series production, when experience in using the new product has been accumulated, the new product often has to be improved. If the product requires changes that the company cannot carry out, in principle, then the product is taken out of production. But the firm tries to foresee this point and develop a replacement product that is based on new technical solutions.

The development of Univet 2 microtest tubes is given as an example of a full-cycle innovation project at Unimed.

Thanks to deliveries under the national project “Health,” the number of hematological analyzers in Russia’s laboratories doubled in two years, which led to increased needs for test tubes for taking blood. At that time, the need was met only by expensive imports. Someone had the idea that the company itself could produce test tubes with anticoagulant (a substance that prevents clotting of the blood) at a lower price to meet the need for them at medical institutions that could not afford the imported ones. Because of the lack of funds for purchasing expensive test tubes, the laboratories of such medical institutions were trying to make test tubes with anticoagulant on their own, which the company’s employees had noticed.

The company set the objective of developing a technical process that would make it possible to apply finely dispersed powder to the bottom of test tubes. The R&D department researched deposition of the pow-
der, selected technical requirements for the spray-coating process, and succeeded in creating a unit that spray-coated purchased test tubes with sufficient accuracy. A technology was worked out accordingly, tests were conducted, the product was registered with Roszdravnadzor, and production began.

In the course of using these test tubes, Unimed employees noticed that the laboratory technicians did not always properly perform the process of mixing the blood. It was proposed that the design of the test tube be changed so that it would be easy for the laboratory technician to mix its contents. At the plant they devised a simple but reliable design of the test tube’s cap that solved this problem. This design was patented and molds were developed to produce the test tubes and caps.

In addition, information was received from the marketing offices that the presence of a capillary in the test tube for taking blood is a necessity, and that laboratories are willing to pay extra for this. So, the R&D department was given the assignment of developing capillaries and a technological process for applying EDTA\textsuperscript{15} in them. Here the company encountered major technical problems, but they were solved within six months. Several technological processes had to be tested before the company managed to develop its own spray-coating technology, which required the development of special production equipment.

At present, the new product has been registered and prototypes have been manufactured. The equipment for producing the new product is being manufactured. A pilot lot is expected to be produced by the end of 2009.

What did we see that was unusual in the organization of the innovation process at Unimed (and at a number of other companies involved in the sales and development of medical equipment)? First of all, there is the potential involvement of sales personnel: any of them, who, being in contact with the market, see demand that is not being satisfied or are capable of foreseeing a future change in clients’ needs can approach the marketing department with a suggestion to consider an application for development and thereby initiate the innovation process.

A second important feature of the way the innovation process is organized is the construction of innovation projects based on the needs of the market. This is fairly uncommon in the Russian conditions.

Finally, the third feature is the nature of the “innovation meeting.” The decision to start a project is made if none of the participants in the collegial coordination still has an objection to the fundamental usefulness of the
proposed project. At first glance, this decision-making principle creates a serious filter for innovation ideas, but it actually lessens resistance in subsequent stages of the project’s implementation.

The process of carrying out full-cycle innovation projects in producing medical equipment is complicated by problems that innovative Russian firms have in common.

1. A shortage of financial resources. No bank in Russia is willing to finance projects to develop complex new medical equipment products. Companies are forced to finance all developments with their own funds.
2. Weakness (immaturity) of the industrial services market. Outsourcing of individual technological processes is either completely impossible or prohibitively expensive.
3. The inertia of customers—medical institutions and government agencies—who prefer to purchase (imported) products that have been shown to be reliable.
4. Inability of the end users to clearly articulate and protect their interests.
5. Because of the latter circumstance, Russian companies that create innovative products are forced to set up systems for noncommercial promotion:
   - they organize free professional development courses for end users, at which most of the time is spent on introducing work methods, rather than on advertising specific solutions that the company offers;
   - they endeavor to participate in creating a regulatory framework for the sector;
   - they publish training manuals and write instructive articles in professional journals;
   - they train sales agents to conduct lessons with end users, which raises their overall professional level.

The place of innovation projects in the strategic process of firms

How does adopting the practice of full-cycle innovation projects, as described above, affect the way that such companies construct their strategic process? A moderate decrease in Russian production of drugs
(by 5 percent in relation to April 2009) and a sharp drop in production of medical equipment (by 42.9 percent) were already seen in May 2009.16

Talking with the managers of companies that have undertaken major innovation projects, we saw significant distinctive characteristics in how they set their strategic goals.

The most important objective is to preserve the company’s strategic core. This core consists of two approximately equal parts: (1) key personnel within the company who are capable of carrying out innovations as well as specialists from allied companies and occasional subcontractors (highly skilled lathe and press operators, designers of industrial equipment, electronics engineers) who are worth their weight in gold; and (2) key “agents of influence” in government agencies (purchasers) who can ensure that the firm maintains its presence in the government procurement market.

Sales volume has a subordinate place in the system of strategic indicators. At the beginning of 2009, companies developed “forks” in the level of current sales in relation to the same periods of the previous year.17 The accuracy of the forecast made at the beginning of the year is steadily declining, and the only goal that is still significant is to keep the firm on the list of qualified suppliers.

Besides the negative quantitative goals, the presence of positive “goals/dreams” is noticeable: many companies (including some of the smallest ones) are sincerely striving for the standards of their products (techniques for using them) to become the standards in their segment or in the whole sector.

Distinctive characteristics of the process of setting goals force companies to adjust their overall system of strategic actions. It mostly consists of many “do nots”:

- they do not get involved in detailed positioning of the business or in-depth comparison of the firm in relation to its closest competitors;
- they do not construct elaborate strategic plans;
- they do not conduct a comprehensive audit of assets, especially intangible ones; and
- they do not have a corporate policy system (plans in relation to acquiring new assets or getting rid of existing ones).

What remains in the “dry residue” of the system of strategic actions? It is made up of two different parts. The open part is a system of projects on various scales and of varying duration. There is usually no hierarchy
of projects, and the amount of resources needed to carry out all of the projects that are contemplated and already being implemented greatly exceeds all of the firm’s conceivable and inconceivable available resources. nevertheless, the projects are initiated and, what is interesting, carried out.

One of the conditions for success of this chaotic system of work on projects is the principle of collegial coordination that was already mentioned: all key participants must openly and consciously agree to the extent of their participation in the proposed work.

The closed part of the system of corporate actions is the corporate policy system. Only a small part of the corporate policies (usually sales policy) is spelled out in written form. The larger part of the policies is the founding fathers’ injunctions: “We will do this, but no way will we do that.” As long as this system is in place, the firm’s pretensions to continue its mutually beneficial relations with key employees and outside agents of influence will be preserved.

Conclusion

Upon analysis, in the Russian medical and pharmaceutical sector we found full-cycle innovation projects oriented toward creating an economy of life in private manufacturers of medical equipment. We remind readers that these firms have only a small share in what is itself a tiny part of the Russian economy (0.06 percent of GDP). We tried to show that, even under these conditions, there are real prerequisites for operating a third-millennium business (when profit is perceived as a byproduct of satisfying socially justified curiosity). Note that, with respect to the actual operating conditions (a combination of in-house production and importing), this business serves as an integral part of the global economy.

Making such a segment something more than a statistical observation error of the national economy does not depend heavily on the government’s protectionist efforts or on the appearance of “business angels” (who try to launder money through venture funds). In our opinion, growth can occur only from within, by including strategic management of assets, primarily intangible ones, in the system of such firms’ strategic actions. This requires the rejection of several of the founding fathers’ injunctions, as well as the retraining of the worthiest representatives of investment companies’ “office plankton” for work
on transforming drawings, formulas, and notes written on napkins into financial resources for the qualitative and quantitative development of a high-tech business.

Notes

1. This is the intention of the American administration’s new initiatives in the field of health care.


3. For more on the basic elements of the process of developing and implementing a strategy, see I.B. Gurkov, “Strategicheskii protsess rossiiskikh kompanii,” Ekonomicheskaia nauka sovremennoi Rossii, 2009, no. 2.

4. It is not completely clear whether this includes the amounts of counterfeit drugs that are sold. The World Health Organization estimated that in the decade beginning in 2000, counterfeit drugs (both Russian-made and imported from China, India, Pakistan, the Czech Republic, and Poland) accounted for at least 10–12 percent of the Russian drug market (see A. Rogachev, “Risks of the Russian Pharmaceutical Market,” Journal of Medical Marketing, vol. 8, no. 3, p. 202).

5. According to data from DSM Group and Espicom Business Intelligence for 2008 and the first quarter of 2009.


10. In particular, this is why prices for imported drugs were indexed in proportion to the increase in the dollar/euro exchange rate in Russia. The average price of a package of drugs increased 30 percent from March 2008 through March 2009. However, at the end of 2009, when the dollar exchange rate fell, a corresponding decline in drug prices was not seen.

11. The best description of a state of luck was given by V.V. Maliavin: “Unrestrained joy, completely unclouded ecstasy with the pure game of being, where there are no rules, only chance, and where nothing can be changed” (V.V. Maliavin, Sumerki Dao [Moscow, 2001] pp. 356–57).


13. The pioneers of this business were able to take advantage of their status as “scientific and technical cooperatives” at the end of the 1980s.

14. In marginal cases, firms are set up as “microcorporations” constructed around an unincorporated businessman.
15. In the laboratory, EDTA (ethylenediaminetetraacetic acid) is used to counteract the coagulation of blood in a test tube, which is necessary for conducting certain analyses.


17. “Forks” usually consist of 3–4 “prongs,” for example, 10 percent decrease—“very bad,” steady volume—“satisfactory,” 25 percent growth—“good,” and more than 25 percent growth—“excellent.”