



Model Breakthrough Technologies as a Tool to Support Import Substitution in the Pharmaceutical Industry

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ABSTRACT

In this article, the authors posed and solved one of the major issues that dramatically affect the definition of the strategy of advancing development in the industry - are there any in the segment of breakthrough technologies for the production of synthetic active pharmaceutical ingredients (APIs) highly efficient new technologies can on the one hand to provide the lowest operating costs at a stable and safe production of API good quality and in the required amount according to the Russian portfolio of promising drugs and on the other hand, what should be the role of government and development institutions to ensure full and accelerated implementation of these breakthrough technologies in advanced domestic production sites. The authors noted that in the Russian Federation introduced a model of innovative regional clusters (Pilot Innovative Territorial Clusters in Russia, 2013) is the most effective for achieving the scientific and technological cooperation on the development of breakthrough technologies.

Keywords: Active Pharmaceutical Ingredients, Governmental Support, Micro-Reactor Synthesis

JEL Classifications: L69, O10

1. INTRODUCTION

A characteristic feature of the modern Russian pharmaceutical market is total (The Pharmaceutical Market in Russia, 2015), i.e. in all its sectors, import dependence. So the share of domestic drugs in total sales in the pharmaceutical market in value terms in 2014 did not exceed 23% in the commercial retail sector - 25%, in the hospital sector - 25%, in the sector of the beneficiary drug coverage - 13%, in the provision of local drug manufacturing active pharmaceutical ingredients (APIs) - 8%.

By the early 80s, the production of API in the Soviet Union was at a high level. The organizational structure and the level of production, specializing in the production of API, qualified personnel, and close contact with scientists and specialists in

the field of chemical synthesis allows to produce products that meet international standards. The domestic industry is almost completely ensured substances not only their plants for the production of drugs, but also exported ASF. Assortment ASF produced in the USSR, 429 items, including 350 - synthetic drugs 54 - antibiotics and 25 - vitamins. The basic amount of the ASF (380) are available at specialized chemical and pharmaceutical plants. In 1992, Russia produced 272 names API volume of 17.5 thousand (Federal Agency for Technical Regulation and Metrology, 2010). In the following decades, the country has lost the potential for release of AFS, only for the period from 1992 to 2008 API production volumes in Russia declined by more than 20 times. The reasons for this were (Federal Agency for Technical Regulation and Metrology, 2010):

- Reduction in or elimination of various types of raw materials and reagents required for the synthesis of many types of API
- Physical and moral deterioration of the equipment for the production of API
- Imperfection of technological processes and high energy production of API
- Exclusion from the register of ineffective drugs primarily because of their obsolescence or banned
- Non-competitiveness due to the high cost compared with API offered by foreign manufacturers
- Virtual absence of innovative groundwork in the development of the ASF
- Hasty and ill-considered privatization of the pharmaceutical industry.

2. MAIN PART

Intensive dismantling of a large part of production capacity for the ASF has meant that the plants for the production of drugs switched to API offered by foreign suppliers, giving preference to products of China and India as a cheaper and ASF from Europe as a modern and highly effective (Ananikov et al., 2014; Egorov, 2014). Their volume increased in proportion to the issue of drugs. The volume of imports of substances in 2014 amounted to 810 million dollars. In Russia imported about 11 thousand tonnes of API. In value terms, dominated by a substance manufactured in Europe (63%), in real terms a significant proportion of Chinese production of a substance (67%), in second place are the substance of India (11%).

Data on the geographical structure of import of ASF in Russia in 2014 are presented in Table 1.

From the standpoint of national security of the country in solving the problem of drug supply has become dependent on imports of API. In this regard, the import substitution in providing local pharmaceutical industry API is a fundamentally important task, without which it is impossible to overcome import dependence of the domestic pharmaceutical market (The Pharmaceutical Market in Russia, 2015). The international experience of countries that have overcome the dependence of local production by imports of ASF and became their major exporters (China and India), shows that the decisive role in this process was played by government support measures. By the early 90s of the 20th century in India and

Table 1: The proportion of the importing countries in the API Russia 2014

Country of origin	The share in value terms (US. %)	Country of origin	The proportion of in-kind volume (kg), %
Germany	21.3	China	66.7
China	21.2	India	11.0
France	19.1	Germany	9.1
India	10.1	France	3.4
Slovenia	9.4	Austria	1.7
Italy	6.6	United States	1.5
Spain	2.3	Serbia	1.1
Hungary	2.2	Switzerland	0.9
Switzerland	1.3	Spain	0.7
Ukraine	1.2	Italy	0.7

API: Active pharmaceutical ingredients

China formed a policy in the sphere of pharmacy which includes the steps of regulatory, administrative and economic support to local researchers and manufacturers (Federal Agency for Technical Regulation and Metrology, 2010).

The system of state support included: Subsidizing research programs in the field of pharmacy (up to 70% of their value), preferential loans, tax incentives for pharmaceutical manufacturers, deregulation of prices, to stimulate the search for foreign partners, the reduction of import duties on equipment for the pharmaceutical industry, export subsidies (Romanova et al., 2006). Particular attention was paid to staffing research and production in the field of pharmaceuticals. State support was provided through the system of educational grants for training researchers and managers in the field of pharmaceuticals. As the infrastructure support the development and production of new drugs created science and technology parks, business incubators, pharmaceutical clusters and specialized information systems (Pilot Innovative Territorial Clusters in Russia, 2013). Of particular note is the creation of special government agencies providing assistance to domestic producers for export of medicines, including assistance with the registration in other countries.

As for Russia, the results of the strengths, weaknesses, opportunities and threats - analysis of the key problems of the local production of API presented in Table 2.

Synthesis of API is the most high-tech stage production of drugs. Modern pharmaceuticals in Russia requires new approaches to system development of the industry, including the definition of priorities and directions of scientific and technological development, especially in the formation of the scientific and technological groundwork for the production of API (Ananikov et al., 2014). The current system of state support for the development of the pharmaceutical industry in Russia focused exclusively on products, which was caused by the need to import a wide pool of replacement drugs. At the grocery principle it carried out the first phase of the Federal Program PHARMA 2020, which allowed to achieve the objectives to create a significant number of specific import-substituting products. However, at the present time, the relevance of state support for the creation of pharmaceutical products decreased significantly. Firstly, due to the fact that virtually all promising drugs currently supported within the FTP PHARMA 2020 (Ministry of Industry and Trade of the Russian Federation [RF], 2009; Ministry of Industry and Trade of the RF, 2011; and Federal Agency for Technical Regulation and Metrology, 2010). secondly, because the health system is not stable long-term demand created by the state support of local producers of drugs that often leads to inefficiency of product support, which can then, for various reasons cannot buy the health care system (Evaluate Pharma, 2015).

One of the key problems of the modern pharmaceutical market is the need for long-term development of effective technologies for the synthesis of API (Ananikov et al., 2014; The Pharmaceutical Market in Russia, 2015). Based on the "List of critical technologies," approved by Decree of the President of the RF of July 07, 2011 No. 899, was allocated 21 critical importance of technology of API. At present, local producers have only 9 of them

Table 2: The results of the analysis of the key problems of development of the market of APIs in Russia in the form of a matrix of the SWOT-analysis

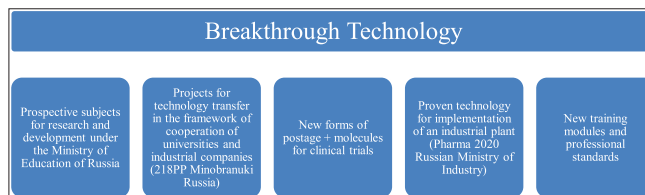
Description	Strengths sides			Weak sides	
	The development of the Russian pharmaceutical market	Macro-economic situation and foreign policy	Implementation of measures to support the pharmaceutical industry	Dependence on imports of substances in key positions	Insufficient base for the development of promising substances
Capabilities					
The development of local manufacturers of pharmaceutical substances	Growth of the market of pharmaceutical products is driving demand for components and substances	Possible restrictions on imports and the weakening of the national currency stimulates the development of local production of substances	Support within the framework of the Federal Program PHARMA 2020 local manufacturers of medicines stimulates demand for local substance (Ministry of Industry and Trade of the Russian Federation, 2009)		
Formation of scientific and technological backlog in the production of substances	Formation of research infrastructure within the federal program allows you to create conditions for the development of local products in the field of substances				
Import substitution	Increased demand for effective economic substance	Growth of the exchange rate increases the opportunities for import substitution, making imports economically viable	Stimulation of import substitution in the framework of public procurement		
Threats					
The complexity of the cost-effective production of substances				Possible competitiveness of domestic products in comparison with cheap Asian counterparts in the current economic model	The lack of effective large-scale production of substances
The complexity of the production of promising substances				The lack of technological capabilities to create high-tech production of substances	Insufficient number of domestic developed breakthrough technologies and research to implementation in production

API: Active pharmaceutical ingredients, SWOT: Strengths, weaknesses, opportunities and threats

are used by only three companies: NTFP Polisan, SC Geropharm, and IBC Generium. At the moment, the system is required to support the transition from creation of products to support the creation of centers of competence for critical technologies that will ensure the strategic development of the industry.

The transition to state support of advanced technologies allows you to create technology platforms, on the basis of which you can create entire classes of new products. Under a breakthrough technology meant new high-technology manufacturing pharmaceutical products with a valid patent protection in the synthesis method, the method of manufacture or hardware solution, introduced into production in the last 5 years or are in 2014 in a pilot stage of industrial production, combining high efficiency methods for the synthesis of energy efficiency, environmental safety and low operating costs. Model breakthrough technology is shown in Figure 1.

Figure 1: Model breakthrough technology



Breakthrough technologies, developed and implemented in the framework of clusters forming the cluster complex investment project in accordance with the requirements of the Ministry of Economic Development of Russia, and is also the subject for effective technology transfer within the core program of the Russian Ministry (Pilot Innovative Territorial Clusters in Russia, 2013). From this perspective, breakthrough technology is a tool

for innovation management, scientific and technical activities of the cluster. This technology should allow to increase the yield of the final product, increase the efficiency of synthesis and reaction under milder conditions to increase the selectivity of the synthesis and to minimize the number and quantity of side products that enable the regenerated catalyst and/or reagents for reuse and minimize the quantity and types of solvents used. Among the pharmaceutical products of breakthrough production technology will be present pharmaceutical substances from the list of strategically important drugs, the production of which must be provided on the territory of the RF (The Federal Government on July 6, 2010 N. p. 1141). Support breakthrough technology will allow system development in the section of scientific groundwork, relevant educational programs and industry support.

Data on consumption in Russia in 2014 for the production of API the most popular in the world of drugs are shown in Table 3.

The analysis shows that for the local market a substance best-selling drugs in monetary terms must be in sufficiently small quantities, so the data in Table 3 that the need for API for the production of 18 of the 28 most sought-after drugs does not exceed 1000 kg and for 16-100 kg. Pharmaceutical production in small volumes of highly efficient process requires the organization in terms of yield of the final product, its economy and the guarantee of good quality with a minimum volume of the party.

Thus, the most urgent problem of long-term development of the domestic pharmaceuticals is the creation of technologies for highly

technological and economic point of view, the synthesis of API in a small volume. It is crucial to the creation of a technological platform for the further development of a wide range of high-performance technologies.

In summary, you can highlight the key factors that determine the need for a new approach to the organization and support system development:

- According to the results of the first etapaFTsP PHARMA 2020 - acquisition of domestic manufacturers of available foreign technology production of pharmaceuticals and API (with the support of Industry and Trade of Russia).
- Identify the segment demanded technologies (high performance synthesis) that cannot be purchased by Russian producers in modern conditions because of the magnitude of investments required in the presence of technological risks and the inadequate level of competence.
- Increased activity of foreign players on the protection of intellectual property in the field of advanced technologies and molecules leads to a reduction of the field of a patent for the use of technology by domestic players.
- Rapid development of nano-medicine and new forms of delivery of drugs into the human body has led to the formation of a new dynamic market modern formulations targeted delivery of already known substances or combinations thereof (as projected consulting company Frost and Sullivan global market nano medicine in the period from 2012 to 2019 (Egorov, 2014; Kondratjev, 2011) should increase by more than two-fold). The absence of technologies for the manufacture of new dosage forms of the drug substance to the conveying direction of local manufacturers leads to a weakening of their position in the market. Thus, there is a need to support research aimed at accelerating the introduction of technologies drugs with new forms of delivery, given the rapid scaling technology and conduct of clinical and pre-clinical trials for new drugs.
- Determine the range of breakthrough technologies that have the possibility of accelerating the scaling and guaranteed implantation Russia provided their state support.
- There is a need in the local development of technological groundwork and educational programs, forming a set of competencies to ensure staffing introduction of breakthrough technologies API.

Decisions on state support breakthrough technology should be taken with the following characteristics thereof, formalized in the full dossier of technology:

- Scientific and technical level of technology
- The level of maturity of the technology as of 2014 and the forecast level of maturity in 2020
- Basic pharmaceutical products derived using the technology
- Manufacturing operations, analyzed duplicated in other technologies
- Experience in the implementation of technology, particularly scaling and commercial introduction
- The current patent situation and prospects of patenting
- Analysis of the current in the Russian Scientific and Technological Reserve

Table 3: Volumes of consumption of ASF in Russia for the production of the most popular drugs in value terms in 2014

Medicament	API mass, kg
Fluticasone	16.0
Salmeterol	16.0
Sitagliptin	243.2
Rosuvastatin	1238.0
Pregabalin	12,507.0
Lenalidomide	1.3
Imatinib	1062.6
Aripiprazole	14.3
Esomeprazole	384.6
Tiotropium bromide	0.3
Glatiramer acetate	91.6
Budesonide	10.3
Formoterol	10.2
Emtricitabine	63.5
Tenofovir disoproxil	62
Rivaroxaban	186.2
Celecoxib	1523.7
Bortezomib	0.5
Pemetrexed	4.4
Ezetimibe	14.0
Telmisartan	573.2
Clopidogrel	7435.9
Fingolimod	0.1
Atorvastatin	6212.2
Valsartan	12,740.9
Tadalafil	50.7
Simeprevir	1.0
Abiraterone	69.0

API: Active pharmaceutical ingredients

- The status of the level of maturity of technologies as of 2014 in Russia
- Scenario level of maturity status of technologies in Russia in 2020 (Ministry of Industry and Trade of the RF, 2009; Ministry of Industry and Trade of the RF, 2011)
- Analysis of possible ways to introduce breakthrough technologies for the production of ASF in Russia, including analysis of existing technological platforms for the introduction of advanced technologies of production
- Information on possible ways of using the centers of collective use of scientific equipment in the design and implementation.

Determination of the list of advanced technologies allows you to create a program of support and development that, in turn, creates a platform for further development of a pool of new drugs. It is obvious that the development and implementation of advanced technologies is only possible with the effective cooperation of many subjects of the pharmaceutical market, assuming an accurate understanding of the competence of each of the participants for the intensive development of research and development work to establish effective technology to local manufacturers (The Pharmaceutical Market in Russia, 2015).

In terms of organizational development model is innovative pharmaceutical cluster is the most effective for achieving the scientific and technological cooperation on the development of breakthrough technologies. This cluster is the most effective in terms of ensuring the competitiveness of its member companies by the synergistic effect. In 2012, as a result of competition of Russian Ministry of Economic Development was generally agreed a draft list of innovative clusters, which included a pilot program of 25 regional clusters. Of the 25 selected clusters 7 (“Pharmaceuticals, medical technology and information technology Tomsk region,” “Innovation cluster of information and biopharmaceutical technologies of the Novosibirsk Region,” “Altai biopharmaceutical cluster,” “cluster” Fiztech XXI) (“Dolgoprudny, Khimki.” “The cluster of medical, pharmaceutical, radiation technology of St. Petersburg,” “Cluster pharmaceutical, biotechnology and biomedicine (Obninsk),” “Biotechnology innovation regional clusters ‘Pushchino’)” relate to the pharmaceutical industry that characterizes the high level of clustering the most effective modern pharmaceutical production. As part of the support programs it is expedient to concentrate resources in the direction of increasing the efficiency of production of API within regional clusters of innovation by forming a cluster and inter-cluster-building programs and the introduction of advanced technologies (Egorov, 2014; Frost and Sullivan, 2014; Pilot Innovative Territorial Clusters in Russia, 2013).

In the framework we have set ourselves a priority determination of high-performance new technology production of synthetic ASF capable of providing low operating costs at a stable and safe production of API of good quality and in the required RF amount according to the portfolio of promising drugs, and defining the role of the state and its development institutions to ensure full and accelerated implementation of these breakthrough technologies in advanced domestic production

sites has been compiled dossiers on technological “technology intensive micro-reactor synthesis of API (organic synthesis) and key intermediates.” If this we did a comprehensive inspection technology based on a critical analysis of the novelty of the method, the results of the introduction of advanced technology overseas production sites, the level of maturity of the technology, its ability to foster scaling and definition of the required level of scientific and technical training for its development and implementation. It should be noted that the accelerated development of innovative methods and technologies for the continuous micro reactor synthesis allows today successfully design and implement production facilities and technologies to dramatically reduce operational cost of production due to the intensification of organic synthesis, the availability of opportunities for synthesis at a “soft conditions.” High-yield, safe realization of previously impossible syntheses and complete process automation. This contributes to an increased mass and heat transfer rate, isothermal holding all classes of exothermic and endothermic reactions, increased product yield through improved regio- and stereo selectivity and intensification of the synthesis reaction leading to the reduction in the number and quantity of side products. Found technological solutions represent a safe, fully controlled use of operations with higher system pressure and high temperatures to achieve maximum reaction rate and higher productivity. The consistent quality of the target product provides increased reliability, consistency, controllability and stability inherent in the steady technological regime in a continuous process and provides accurate residence time of the reaction mixture in the reactor, its controlled distribution, the ability to accurately reproduce all the conditions for all processes in all coordinates, guaranteeing consistent quality the desired product without the accumulation of toxic and reactive intermediates (Baxendale et al., 2015).

Additional factors that influenced the choice of this technology in the first leading sites in the European Union, was the decrease in capital expenditures producer API due to the possibility to reduce the size of the required space, and reducing the time of introduction of technology in their scaling up to an industrial level. For local domestic manufacturer important factors will be simpler, well-defined way of scaling from laboratory to production facilities and production capacity API for its own product portfolio based on the needs of the domestic market coverage and share of PL products in this market.

The main production facilities, has successfully implemented industrial or semi-industrial production of API for this technology are:

1. LonzaAG, the company’s plant in the city of Visp, Switzerland
2. DSM, the company’s plant in the city of DSM Fine Chemicals Austria NfG GmbH Linz, Austria
3. Sigma-Aldrich, the company’s plant in the town of Buchs, Switzerland.

Core competencies of advanced innovative platform companies are manufacturing LonzaAG ASF and their intermediates, the development of methods and technologies for the synthesis and development of the ASF and the industrial mass production of

their own micro-reactor equipment. Competence areas of DSM and Sigma-Aldrich more modest - they are concentrated in the production of API and their intermediates, and the development of methods and technologies for the synthesis of API. These sites buy serial (typical) equipment or order the individual types of micro-reactor systems at their core developers.

Based on the critical analysis and execution of the dossier, we have systemized the main conclusions regarding the applicability of this breakthrough technology for highly efficient local production of ASF in Russia and noted the main trends in this technology market in the next 5 years.

3. CONCLUSIONS

Intensive micro-reactor synthesis of API and key intermediates is a breakthrough multi-disciplinary area, and requires a systematic approach on the part of the company's management to coordinate the chemists, engineers, designers benchmarking of production processes, equipment manufacturers and engineering companies, regulators and inspectors of appropriate practices by state of control over production. Technological difficulties of transition to a micro reactor technology and continuous synthesis were successfully overcome in the advanced markets in the last 4 years on a semi-industrial pilot and the level of performance, and are being introduced today in the semi-industrial/commercial production of API (Baxendale et al., 2015). When you create a synthesis scheme API opened new possibilities for a combination of modern scientific approaches to the synthesis of enantiomerically pure compounds with the micro reactor technology in the context of full and safe methods of controlling the stereochemistry of reactions in the industrial production of API (Egorov, 2014). There is every reason to believe that an intensive micro-reactor synthesis of API is a "platform" technology, allowing innovative approach to take advantage of the existing backlog in Russia and quickly put into production the new AFS portfolio as cost-effectively at local production. At the same time we will be able to rely on highly qualified specialists, determine the development of the national scientific school of organic synthesis, and working in Russia on the development of methods of "realization of reactions with atomic precision."

The main expected technological trend in this market in the next 5 years is a more profound market diversification:

- For the production of micro reactor equipment for the API
- For services in the field of technology transfer and the intensification of the synthesis of the continuous synthesis of new methods of continuous micro reactor synthesis of API and key intermediates, asymmetric catalysis mikror eaktornomu (Baxendale et al., 2015)
- Engineering analytical equipment, validation of methods and rules of industrial complexes.

In these new market segments is forecasted substantial volume of orders from the pharmaceutical companies planning to invest in micro-reactor methods of synthesis of API. On the appeal of these niches much of the activity of companies actively positioning themselves on the latest exhibitions and conferences,

among which there are young companies that stand out from the research laboratories of Western technological universities (Basel, Kaiserslautern, Karlsruhe, Zurich, Eindhoven).

Thus, systematizing the main conclusions drawn from the done research and arguments in response to our question, we would like to emphasize - for highly efficient local production of synthetic API is necessary to introduce the technology of intensive continuous micro-reactor manufacturing API and key intermediates, as today in Russia for their effective and rapid development of all the prerequisites. The main reserve - National school of modern organic synthesis and high schools, have good connections with the domestic pharmaceutical industry. This is a reserve in the event of a real basis for the effective promotion of continuous laboratory scale synthesis for the industrial production level. For our domestic pharmaceutical science great opportunities, allowing 100% use a school of modern organic synthesis represented by the advanced RAS institutes and universities (Egorov, 2014). In Russia, where the competent positioning of competence centers for highly efficient local production AFSmy be able to develop their own methods of synthesis marketable ASF, as well as within the projected staffing requirements ahead to organize the training of young specialists at the centers and training of production personnel at industrial sites customer technologies (Baxendale et al., 2015).

The development of breakthrough technologies API creates new challenges for the development of the education system since the introduction and use of these technologies requires appropriate competence. In addition, the steady production standards in many cases, becomes an additional barrier, which is quite difficult to overcome. The key question becomes how can people with the skills they possess, and the culture of production to which they are accustomed, to turn cutting-edge technology of synthesis of innovative scientific and technical projects in the established method for the production of high-quality API. Today, at this stage of understanding the problem, specialized education must actively engage in the process of implementing an innovative and breakthrough technologies must be prepared targeted interdisciplinary educational programs and modules aimed at improving the skills of staff. This approach is advisable to implement within the framework of cluster cooperation of educational centers and industrial enterprises. As for higher education, the modern educational standards allow them to enter the variable part special subjects and educational modules for breakthrough technologies API forming competence, self-defined educational institutions. Definition of a set of competencies of graduates formed, focused on work in the field of advanced technologies API should be discussed and agreed with the representatives of industry self-regulatory organizations of pharmaceutical clusters and the Association of Russian Pharmaceutical Manufacturers. In this context, it may be proposed to discuss the following set of competencies that need to be created for the accelerated introduction of advanced technologies API involving acquiring knowledge and skills to:

- Effective scaling of laboratory and pilot methods for continuous synthesis and design of equipment under the order

- Optimal micro reactor design synthesis routes and reliable transfer of manufacturing processes
- Understanding of the extent of time and distance by which supported a more fundamental understanding of the scale and sensitivity of equipment used
- Support the implementation of continuous production, requiring effective work in multi-disciplinary and multi-functional development teams intensive and continuous process (Baxendale et al., 2015)
- Developing methods of analysis and analytical techniques that are required for the design and control of micro reactor process.

To generate it, is not an exhaustive set of competencies necessary to strengthen the engineering training and knowledge on basic and applied chemistry to ensure the quality and reliability of API production.

At the second level of higher education, a master's degree, industry universities should provide specialized training in master's programs directly aimed at the development of breakthrough technologies API, and adjust the subject of dissertations and doctoral graduate, focused its research on fundamental problems of development of breakthrough technologies API.

Given that the process of preparing the relevant staff through postgraduate, master's, and especially the baccalaureate, long-term process, the most expeditious way is the implementation of the system of additional vocational training programs and retraining of specialists for the transition to breakthrough manufacturing technology ASF, allowing to undertake professional activities immediately after graduating with a relatively short duration of between 3 months and 1 year.

To stimulate demand for the development of educational programs on innovative methods of development and production of API should be linked to provide state support to domestic producers of API with the following obligations of recipients:

- Direction applicants for special admission to specialized educational institutions, implementing educational programs towards the preparation related to the development and production of API
- Providing opportunities for practical training of students enrolled in these areas
- The direction of specialists for training and retraining oriented production technology breakthrough API, the system of additional vocational training of specialized universities.

The real innovation will only take place when the projects implementation of advanced technologies, the effort required on the part of education, research, development and production of pharmaceutical companies will together aim to develop new methods for the production of API. With the implementation of the cluster approach and educational center of the cluster ensures the development and launch of individual educational

programs designed for implementation of the specific objectives of the cluster project. In the cluster, in this case generated program on the development of advanced educational modules aimed at training a sufficient number of experts on the subject. It is necessary to expect that in the format of the activities of scientific and technical council of the "Pharmacy of the Future" in the framework of the technological platform "Medicine of the Future" in the light of the implementation of the program of development of pharmaceutical science and pharmaceutical education, including support for their educational programs and initiatives, both from the Ministry of Education of Russia, and from side leading pharmaceutical companies, we will see in the near future development of breakthrough technologies, including operating mechanism as a public and private funding of training programs, which in turn will lead to the creation and implementation of their own development in accordance with the road map measures necessary for the introduction of advanced technologies of local production of API in Russia.

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