

PHARMACEUTICAL CLUSTERS CREATION AND FUNCTIONING

Natalia S. Klunko¹
 Nataliya V. Sirotkina²
 Diana A. Kozachuk³
 Maria A. Liubarskaia⁴
 Victoria V. Vasykivska⁵
 Olena M. Krasnonosova⁶

¹PhD in Economics, Deputy Head of the Department for Postgraduate and Doctoral Studies at the Russian New University, Moscow, Russia. E-mail: nataliya.klunko@gmail.com, <https://orcid.org/0000-0003-0973-4644>

²Doctor in Economics, Professor, Head of the Department for Digital and Industry Economics at the Voronezh State Technical University, Voronezh, Russia. E-mail: docsnat@yandex.ru, <https://orcid.org/0000-0003-0528-106X>

³PhD in Law, Associate Professor, at the Department for Administrative and Financial Law, National University Odessa Law Academy, Odessa, Ukraine. E-mail: kozachukdina@gmail.com, <https://orcid.org/0000-0002-3700-0341>

⁴Doctor in Economics, Professor at the Department for State and Territorial Management at the Saint-Petersburg State University of Economics, Saint-Petersburg, Russia.

E-mail: liubarskaya@mail.ru, <https://orcid.org/0000-0002-5870-6511>

⁵PhD in Law, Docent, Professor at the Department for Administrative and Financial Law, National University Odessa Law Academy, Odessa, Ukraine. E-mail: nata0675@rambler.ru, <https://orcid.org/0000-0001-5290-3963>

⁶PhD in Economics, Associate Professor, Senior Researcher at the Macroeconomic Policy and Regional Development Department at the Research Centre for Industrial Problems of Development, National Academy of sciences of Ukraine, Kharkov, Ukraine. E-mail: krasnonosova@gmail.com, <https://orcid.org/0000-0003-3522-0399>

*corresponding author's email: nataliya.klunko@gmail.com

Abstract: *The experience of using cluster models for regional development in different countries proves the need for an active role in the process of both state and local authorities' economy clustering. Effective practices consist of the fact that the state gives integral and financial support to institutional and cluster formations. The purposeful research of clusters as a subject of public administration either from the side of regional or central government bodies showed the importance for power concentration to create favourable conditions for partnership between enterprises, first of all, in the shape of development assistance to already existing sectors tested by the market. The article deals with the important scientific aspects of both creation and functioning of clusters to secure the pharmaceutical sector competitiveness by means of mobilizing the state strategic resources both at government and sectoral institutes' levels. The methods, which were used to reach the purpose of the research, are as follows: the description method, the table and graphic method, the method of structure and dynamics revelation and methods, which are available for comparison in a certain territory such as: the statistical data and the method of analysis and synthesis. The economy subjects' cluster policy implementation should be carried out by means of forming*

the economic terms movement of a whole production system to a competitive position in terms of cooperation and partnership. It is also important to understand how certain clusters contribute to the economic development of certain regions and to adjust their activity in accordance with that. The new structural element of space progress security in a globalized economy should include clusters as a basis of network territory organization the functioning of which will facilitate both regional and state competitiveness on the whole; as well as contribute to the implementation of investment and innovative development models. The creation of such investment and innovative clusters requires significant boost of relevant theoretical and methodological support because the state should clearly understand where to go and what reforms to carry out. It concerns, first, the administrative and territorial aspects of economic management change namely, the socio-economic specificity of every region.

Keywords: *administrative and territorial management, regional clusters, innovation technologies, institutional instruments, pharmaceutical clusters, pharmaceutical industry.*

INTRODUCTION

The Relevance of the Research

In terms of market globalization concerning the change of role and meaning of main socio-economic development subjects, the sources of competitive regions and sectors are more and more dependent on local factors and features of recourse security (Gafurov, 2012). It is clusters that allow to mobilize a new resource – the network recourse of scientific potential organization on the one hand and productive capacity on the other. The stimulus to the distribution of clusters to industrialized countries within the last 20-25 years has become the potential limitation of large integral enterprises in dynamic global markets. Cluster strategies are widely used in many European countries. In Germany, for example, the program of bio-technological clusters' creation "BioReqio" has been since 1995. The UK government has designated areas around cities like Edinburgh, Oxford and South East England to be the main regions for the location of bio-technological companies. In Norway, the government stimulates the collaboration between enterprises (companies) in a "sea economy" cluster. The close cooperation of enterprises (companies) in timber industry of Finland will provide them with competitive advantages compared to the main trade competitors and ensure them a leading position on both research and technological cooperation level.

Literature Review

The formation of territorial clusters as vertically integrated enterprises and organizations of interrelated sector, which, as a rule, have a common research base and formed elements of management system, is a perspective instrument for the development regional economy with an animation effect. It is clusters that may become the most effective means of economic policy which induces the endogenous development of sectors on the ground of using local terms and resources as well as competitive advantages (Zyablikov, 2017). However, today questions of sectoral cluster creation in Russian Federation haven't been sufficiently elaborated on yet (Abashkin, Boyarov, Kutsenko,

2012); the theoretical and methodological bases are absent now; the sufficient normative-legal bases are not created, which increases the relevance of the research in this direction. Not only should the state contribute to the formation of clusters but also it should become the member of a new network of organizations and enterprises, which haven't had any contact with one another previously.

RESEARCH METHODOLOGY

Theoretical and Empirical Research Methods

Taking into account the classical notion of “clusters”, identified by M. Porter, such structures ought to be positioned as groups of geographically localized interconnected companies as well as suppliers of equipment, components, socialized services, research institutes, IHE (Institutes of Higher Education) and as any other companies collaborating with one another to strengthen the competitive advantages of both separate companies and a cluster on the whole (Islankina & Fiyaksel, 2015). The methodological ground of the cluster theory development is a set of researches, which should be divided into three blocks. The first block deals with the theories, which study the phenomenon such as “clustering” from the point of view of both traditional and regional approach to the scale of production. These theories are defined as the most important factors of cluster creation connected with the scale of production. These theories are as follows: the theory of production location, represented in papers by J.H von Thünen (1826), W. Launhardt (1885), M. Weber(1909), and A. Lösch (1940); the theory of regional specialisation by A. Smith(1776, 1988), D. Ricardo (1817, 2004), E. Hecksher (1919, 1924, 1991) and B. Ohlin(1933, 1952); the industrial theory of the place of location by M. Weber; the concept of polycentrism (geopolitical regions) as well as the balance of geo-strategical powers by S.F. Cohen (1884, 2004); innovation concepts by J. Schumpeter(2008); the concept of growth pole by F. Perroux (2006), which was elaborated on in the works by G. Boudville (2006); and domestic theories of regionalisation developed by representatives of geographic school.

Based on the notions formed by these authors, it is possible to separate two central elements. First, the company in a cluster should be somehow connected. These bonds may be both vertical (the set of purchase and selling) and horizontal (additional products or services, the use of special expenses, technologies, institutes and so on.). Moreover, the majority of these bonds “accumulate” social relations and communications, which may be beneficial for the companies. The second fundamental characteristic is as follows: clusters – geographically-close groups of interconnected companies. The common companies' place of location contributes to the formation and boost of advantages, which make the price and which are the result of the interconnection system functioning between enterprises and companies. Thus, the cluster is a geographic concentration of interconnected enterprises as well as suppliers of specialized services (including research, transport, information, marketing, legal, financial and other ones), which either exist or are typical for a certain territory.

Such a notion of clusters has proved itself in practical experience in the USA, European and Post-soviet countries. That's why the model of clusters is not an abstract theoretical idea; it is compliant to institutionalisation and operation; it has a clear “connection” with management practice and is a practical lever of impact; it is important for the creation of innovation-effective and competitive enterprises (Ishenko, 2015). The

economic cluster notion was first used by M. Porter at the end of XX century, who proved that the enterprise competitiveness is defined by the competitiveness of its economic surroundings; the competitive areas do not spread through all the economy equally but are united in so-called clusters.

Territorial clusters as vertically integrated enterprises and interdependent organizations of sectors, which, as a rule, have a common research base and necessary elements of management system, are a perspective instrument for the regional economy development with the animation effect, the achievement of which is contributed by the development of social entrepreneurship, i.e. attraction of both private and contract companies which produce goods and render certain services (including free-of-charge ones) for regions. Territorial clusters, in our opinion, should be ranked on a spatial basis dividing them into some types every of which has specific features and their identification determines the features of functioning forms as well as its activity coordination.

Macroclusters (geo-economic transborder) – are formed by means of distribution of innovative and resource potential of a certain sector in some regions. Meso-clusters (local diversified) – are created by means of companies' density on a territorial basis (within one region) with a simultaneous development of some activity directions. Microclusters (municipal specialized) – are created by means of companies' union, the specialization of which is carried out within the socio-economic area, which is aimed at an ultimate customer with both small- and medium-size companies dominating. In a state government the cluster systems are ranked (Gokhberg, Shadrin, 2013):

- National innovative clusters, which embrace strategic aims of state development with a view to forming national technological platforms;
- Regional production clusters in the interest of which is the development of regions' industrial priorities;
- Local clusters are concentrated on harmonization of regions, cities, separate villages and settlements.

Research Stages

1. The research of both theoretical and methodological bases of clusters and their characteristics in a pharmaceutical sector;
2. The research of foreign experience in cluster creation; and the study of institution prerequisites for their development;
3. The conduct of analysis and assessment of cluster creation and functioning effectiveness in a pharmaceutical cluster;
4. The creation of a standard organization structure (PC = PH/C).

RESULTS

Cluster creation is connected with the necessity to unite business projects of a certain technological area, fundamental developments and modern systems of new products' designing and preproduction of them within one special zone. Taking all these into account and making this question relevant as a functioning element of a social system the superiors and territorial government should understand that the success of cluster unions depends on not only the presence of raw materials or available investments but also they have to understand that it may be secured at the expanse of new management technologies use. One of such technologies is the organization of cluster's development

management by means of specially-created staff – a highly-effective team of top-managers who may run clusters and coordinate the activity of government, science and production (Kutsenko, Islankina & Abashkin, 2017).

In recent years, taking high-tech, economic and social processes' dynamism into account, different forms of team (group) management are considered the subject of close attention by scientists and managements. Cluster creation should be preceded by the cluster analysis, which can be made according to regions' economy groups which are as follows (Kutsenko, E., Islankina, E. & Abashkin, V. (2017):

- Sectors, which bring significant part to GRP (Gross Regional Product) and pay attention to the largest enterprises in a certain territory and to a whole chain of companies connected with the production activity;
- Sectors, which provide the most beneficial opportunities for business development in a certain territory;
- Attendant sectors, which have the best both inner and foreign economic bonds;

In accordance with the cluster analysis results, there are set the main characteristics of clusters existing in a certain territory such as: size, comprehensiveness and the level of development. Clusters, which may be developed in a certain territory as well as resources needed to do it, are defined. Clusters are ranked on a priority level for a certain territory development, which are as follows:

- The highest labour productivity;
- The best opportunities for interrelated business development;
- The great number of employees;
- The significant level of production volume;
- The greatest amount of inner bonds.

Thus, the new structural element of spatial development in a globalized economy have to become clusters as the basis of territorial network organization which functioning will contribute to the increase of both regional and state competitiveness levels on the whole as well as to the implementation of new innovation and investment models. From the theoretical justification point of view, the questions of cluster creation and functioning and their system development are insufficiently studied today. In many countries, however, the national cluster concept and the institutional cluster initiative are absent at all; the participants' rights and functions as well as the rights of local government and local self-government on coordination of actions and the tools of economic and financial clusters are not defined. The role of government, however, is:

- To form cluster initiatives;
- To define the terms of cluster creation, their entities' rights, local self-government functions and local self-government actions on cluster coordination on a legislative level;
- To stimulate cluster structures;
- To develop state-private partnership, companies' network in adjacent sectors, collaborate with the IHE (Institutes of Higher Education) and research institutes and techno-parks;
- To carry out marketing in a certain territory and so on.

The Cluster Approach to the Creation of Innovative Country Infrastructure

Developed innovative infrastructure – is an important part of national economy competitiveness. It is an array of scientific and technical centers and innovative ideas'

developers; an array of financial assets and production capacities as well as the information massive. The scientific and technical centers of innovative ideas include, first, universities, research, scientific and technical institutes as well as developers of new ideas, innovative proposals, inventors and innovators. Financial component is represented by the venture capital and venture banks, which are ready to invest their assets in production of new goods, equipment and other kinds of services. The array of production capacity is comprised of venture companies, experimental workshops, plants and factories, which provide their industrial buildings and equipment, offer services for innovative projects' implementation, produce prototypes and start manufacturing innovative products.

The innovative infrastructure information massive is comprised of a set of consulting companies, patent offices, information agencies and so on. It is impossible, however, to say the opposite that the creation of such a hub as the center of competitive goods production will serve the basis for creating the zone of serving companies around it and their further integration into a cluster. The hub is a key unit securing combination and interconnection of all the innovative infrastructure entities and without which it cannot function well or its capacities will be significantly limited. The hub can be the beginning, the starting point of a future cluster network system origin and the onset of new collaboration between the economic entities. The most innovation-active company, research institute or the IHE (Institute of Higher Education) may become the initial centers, i.e. the hub, which is united with certain amount of thoroughly selected, interdependent on a technological chain and interested in the economic symbiosis business-partners.

Among the terms securing the state economic development in the era of market globalization the important role is played by the innovative enterprises' activity, the innovative infrastructure common development, the connection with both scientific and institutes of higher education and constant increase of a staff skill level. Innovative activity – is a distinctive feature of many existing clusters as well as their infrastructure environment. Innovative structure as any other large network creations (e.g. the Internet, network economic and social union and others.) has a complex inner organization and under certain circumstances it may become a self-organized system on the basis of both collaboration and widespread interaction of hubs, clusters and economic development centers. According to the theory of self-organized systems, which the innovative structure is attributed to, the amount of such development centers, hubs and clusters may be insignificant. If to increase both psychical and psychological potential, they may effectively grow in accordance with current economic terms and normative-legal acts. It allows to form massive cluster groups as innovative development cells, i.e. the innovative structure subjects, which are self-organized in different regions of the country (Islankina, 2015).

The cluster accumulates certain amount of commercial structures around itself, which offer their own services, important while implementing their innovation projects in different levels, not only to cluster's enterprises but also to other nearest innovation-active companies. That means that the innovative infrastructure of clusters is gradually changing into a state innovative one (Kutsenko, 2012a,b). Cluster is a contractual union of both legal and individual person without creation a new legal entity. Pharma clusters on the map of Russian Federation are showed in the Figure 1.



Figure 1. Pharma clusters on the map of Russian Federation

It is important to pay attention to the voluntary nature of cluster unions' creation without any external compulsion from the site of the state administrative government. Entrepreneurs, based upon a commercial reason, come to a conclusion that it is important and mutually beneficial to create such a union. Only in this case does psychical splash happen and what's more important is that the splash of psychological activity happens on the ground of both personal and commercial interest and enthusiasm necessary for hub's creation, which spreads the circle of its influence on other companies and may turn into a cluster. The cluster's hub may become either one or any other potentially innovative enterprises able to produce qualitative and competitive products and who are one of the market leaders. The use of cluster approach is one of the most effective mechanisms of structural economy development. According to the innovative activity, the network systems may be of some types: with the center (hub) or, seldom, without distinct center. The positive side of cluster activity is that its members do not compete with one another but serve different segments of the market.

The most successful innovative clusters are created where they make the innovative breakthrough in a field of production, technologies or services. The specific innovative direction of clusters' activity requires the need for including the companies' cluster into a common network, which create additional infrastructure covering around the production center (Zemtsov S.P., Barinova V.A., Bukov D.V., Eremkin V.A., 2015). In comparison with other types of entrepreneurial networks, the clusters unite a broader circle of innovative activity members. The innovative cluster infrastructure can be attributed to the following items: research and design institutes, universities, IHE (Institutes of Higher Education), information agencies, standardization centers, trade associations and agencies, which secure the education, special education and staff retraining (Gokhberg, L. M., & Shadrin, A. E. (Eds.),2013). The infrastructure cluster covering provides the selection, development and implementation of innovative projects.

Clusters unite both independent and informal companies connected with one another, which may collaborate with other companies out of this cluster. This is the concentration of both industrial and other subjects, which have economic benefits due to close location from one another. But all the subjects of one cluster may actively broaden their activity field as well as offer their services on commercial basis both for a range of neighboring clusters and for other separate enterprises carrying out innovative projects. The neighboring clusters' innovative infrastructure impact may spread (by means of constant development of human services) for a whole region or, in case of further clustering, for a whole country (Gokhberg & Shadrin, 2013). Thus, the region's clustering may secure the innovative infrastructure common development without any additional investments from the state.

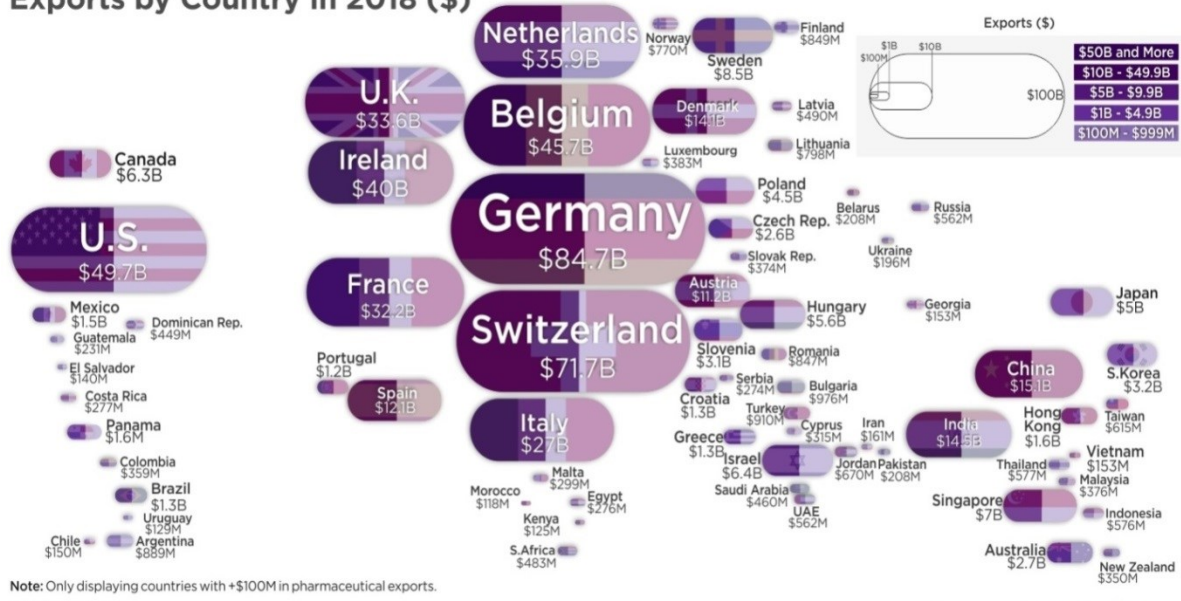
Clusters as well as the innovation structure, which is formed around them, make the attractive basis for the implementation of innovations, influx of investments and the small- and middle-size entrepreneurship development (Azoev, 2012). This diversity of large innovation-business networks is especially effective in terms of crisis. The use of cluster approach and the spread of economy clustering processes are one of the most effective mechanisms of national innovation system development. Gradual increase in the amount of cluster structures and their concentration in different countries will lead to the creation of new entrepreneurial subjects around them, which are self-organized on a commercial basis and which specialize in rendering services on innovative projects' implementation for a wide range of innovation-active enterprises. Hence, the spread of such structure networks, which specialize in innovation services, will serve the basis for the self-organization of the system of actively working innovation structure.

Self-organization – is a synergetic process of system's elements chaotic activity ordering and their transition to a completely new level at the expanse of inner factors without external influence. This, however, does not mean that these structures are unmanageable. They handle not commands but limit parameters (Kutsenko, 2012). The state regulates the boundary conditions of activity both for innovation infrastructure subjects and clusters, which, based on commercial reasons, are self-organized under the pressure of market mechanisms; hence, they spread the area of their services to all regions making an integral innovation infrastructure of the country.

Modern State of Pharmaceutical Clusters' Creation

The overall performance of the situation in a world economic market allows to define the main tendencies, which, in any case, have an impact upon the development of pharmaceutical cluster sectors. First, there is a real investment boom in the world. Secondly, analysts give a stable forecast of the market's growth and the change of drivers; it is innovative drugs but not generics as it was not long ago. The average growth is 6.5%. Thirdly, the main directions for sales increase are the drugs for curing cancer, AIDS, diabetes, rheumatism and sterility. The pharmaceutical sector is extremely precious, and it continues to rise as far as there is nothing more precious than health. The import and export of pharmaceutical products according to countries in 2018 is showed in the Figure 3.

Pharmaceutical Trade Around the World Exports by Country in 2018 (\$)



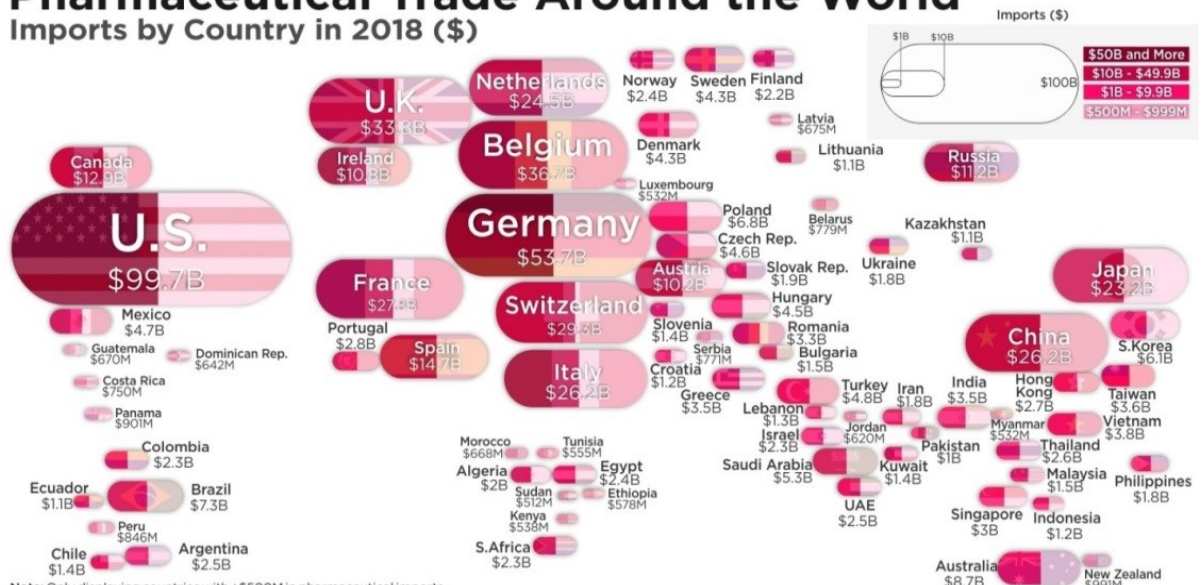
Note: Only displaying countries with +\$100M in pharmaceutical exports.
 Article & Sources:
<https://howmuch.net/articles/pharmaceutical-trade-around-the-world>
 World Trade Organization - <http://wto.org/>

howmuch.net

Figure 2. The export of pharmaceutical products by countries in 2018

The USA, of course, is one of the largest importers of pharmaceutical products in the world at the amount of \$99,7 bn. As the opium crisis continues in the USA, the pharmaceutical companies are subjected to be thorough tested, which was showed in Johnson & Johnson agreement. Despite close attention, the pharmaceutical sector continues to rise fast. The pharmaceutical companies have to pay huge fines for its role in opium epidemics.

Pharmaceutical Trade Around the World Imports by Country in 2018 (\$)



Note: Only displaying countries with +\$500M in pharmaceutical imports.
 Article & Sources:
<https://howmuch.net/articles/pharmaceutical-trade-around-the-world>
 World Trade Organization - <http://wto.org/>

howmuch.net

Figure 3. The import of the pharmaceutical products by countries in 2018

The largest world exporters of pharmaceutical products:

1. Germany: \$84,7 bn.
2. Switzerland: \$71,7 bn.
3. The USA: \$49,7 bn.
4. Belgium: \$45,7 bn.
5. Ireland: \$40 bn.

The largest world importers of pharmaceutical products:

1. The USA: \$99,7 bn.
2. Germany: \$53,7 bn.
3. Belgium: \$36,7 bn.
4. The UK: \$33,8 bn.
5. Switzerland: \$29,3 bn.

The pharmaceutical sector deals with tens of thousands of dollars every year, the greatest amount of which comes from Europe and the USA. As far as the opium crisis in the USA continues to rage, it is not surprisingly that the USA is the leader on the import of pharmaceutical products. While the local government of the USA tries to put the responsibility for the opium crisis on large pharmaceutical companies, they are not worried about the American law on drugs. The Big Pharma is a large industry and it is planning to grow more aiming at developing markets in such countries as India. Despite people all over the world are worried about the growing increase in pharmaceutical products, this increase facilitates the growth of such large companies. Thus, the sector will continue to play the main role in a world market within the next few years. But at the same time, according to NAVADHI¹ market research the pharmaceutical industry turnover will reach US\$1,57 bn., to 2023. The growth of this market is forecast on the ground of different factors such as market drivers, current and forthcoming tendencies and current growth model and market challenges.

That's why clusters – with the view to creating new structural elements of spatial development security in a globalized market – should be the basis of the network territorial organisation which functioning will facilitate the increase of both regional and state competitiveness as well as the implementation of investment and innovation development model. The pharmaceutical cluster (FC) – is a sectoral and territorial voluntary union of scientific structures (producers of remedies), manufacturing companies (pharmaceutical enterprises (FE)), factories and plants), distributors, chemist's shops, equipment suppliers as well as suppliers of parts and special services, medical bases for the assessment and implementation of their developments, infrastructure subjects (research institutes, IHE and other facilities), which supplement one another; they closely work with other sectors of scientific facilities as well as public organisations and local governments with a view to increase the competitiveness of pharmaceutical cluster (PC) and to consolidate the social provision of people with pharmaceutical products and to assist both regional and state economic development.

The scientific centers, however, remain the main basis for the innovative cluster. Thus, the PC – is the union of production, distribution and remedy selling; the union of science and education, which secures and carries out purposeful activities on production, development and advancement of competitive products both to inner and foreign markets by means of using private and state mechanisms. The aim of PC creation – is to increase the competitiveness level of PC and the pharmaceutical sector overall. The distinctive feature of the cluster approach in pharmacy is the development of innovative

remedies and their implementation into production, which, on the other hand, is a global aim of domestic pharmaceutical industry. As far as the pharmaceutical clusters have to be the growing points of inner markets in a regional and national scale at all the levels of pharmaceutical products life circle and to be the basis for the improvement of external economic activity. Moreover, the important thing for pharmacy is the provision of people with the effective remedies at a reasonable price, which is made due to the optimization of resources use in terms of a certain region, i.e. sectoral cooperation and expenditure economy.

Among the potential PC segments, it is possible to highlight the following: RI ((Research Institutes) the development of innovative remedies, the creation and production of pharmaceutical substances and generic remedies and so on.); pre-clinical bases; clinical bases in all the spheres of modern medicine; sectoral IHE (research developments on new remedies' creation, qualified staff training system: pharmacists, pharmaceutical production processing engineers, medical representatives of pharmaceutical companies, managers and so on.); pharmaceutical distributors; producers; chemist's shops. The cluster-creation element should be the IHE of the international level, around which are created small innovative enterprises cooperating between the applied science and pharmaceutical industry. The cluster-creation factor is the presence of both the international airport and the ramified transport network.

The potential PC partners have to become companies rendering freight services; companies rendering warehouse services; local governments (local administration, city council, local self-government bodies); companies performing recycling of waste; infrastructural sectors (financial institutions: banks, credit communities and so on.); insurance companies; information services (marketing, information and advertising agencies); economic and legal (auditing services and legal advises); leasing facilities; outsourcing agencies and consulting companies; pharmaceutical associations; dedicated plants (medioprohylactic institutions (MPI), veterinary clinics and veterinary chemist's stores); medical equipment producers and pharmaceutical equipment producers.

The structure of PC is showed in the Figure 8. Thus, the PC will unite both the competence and experience of leading pharmaceutical producers, distributors, project companies in the sphere of contemporary production creation, medical equipment producers, sectoral higher and middle professional colleges, sectoral RI and government bodies as a pharmaceutical cluster development process coordinator.

The cluster management and the cooperation of its participants should be based upon single approaches and requirements to the quality of remedies and upon the provision of PC members with benefits and information security. The choice of cluster members has to be made on the ground of nomenclature significance and the volume of pharmaceutical products' production and on their development perspectives taking into account the scientific researches.

Pharmaceutical cluster	Pharmaceutical manufacture	Enterprises, plants, factories	
	Medicine sale	Pharmacies, pharmamarkets, whole trade	
	Scientific educational infrastructure	}	Industrial research institutes
			Industrial higher educational institutes
	Scientific analytical infrastructure	}	Venture companies
			Investigational sites
	Additional manufacture	}	Analytical labs
			Medicine devices
			Medicine equipment
	Logistic infrastructure	}	Material and substances
			Warehouses
	Special medical facilities	}	Transport companies
			Medical and preventive treatment facilities
	Financial and information infrastructure	}	Vet pharmacies and clinics
			Financial institutions
			Insurance companies
			Information providers
			Leasing companies
	Pharmaceutical association	}	Autosource companies
			Consulting companies
Legal companies			
Manufacturers			
Innovative medication manufacturers			
		Distributors	

Figure 4. The standard organizational structure of the pharmaceutical cluster (PC = PH/C) (developed by the authors)

The PC authority (cluster council) has to be responsible for due informing of cluster members about the perspective directions of its development; about the effective implementation of remedies into medical practice; and about the increase of potential as well as RI's and higher education facilities' material and technical resources' provision. In order to meet all the interests of PC members and to provide them with certain security, the cluster authority must secure a single approach while making contractual relationships and implementing common projects in the sphere of development, production and pharmaceutical products' selling. The cluster policy of the pharmaceutical sector development means the coordination of aims and tasks for achieving the synergetic effect while producing and advancing clusters' products in the pharmaceutical market of Russian Federation and abroad.

The state efforts, however, concerning the cluster development and support may be directed at the security of certain benefits, the creation of favourable conditions for lending the pharmaceutical cluster members; the security of tax concessions as well as at

the consecutive increase in the pharmaceutical companies investment attractiveness as far as the innovative pharmaceutical products have the significant export potential and long-term selling perspectives for the provision of secured investment return. The main factors, which secure the state participation in the creation of PC and the provision of its activity, are the state demand for pharmaceutical products, its large volume and social importance, national security provision, guarantees of the pharmaceutical sector's activity dependence absence on external factors if the situation changes in a world market.

The financing of events concerning the development and perfection of PC is made at the expense of both budgetary and off-budget sources:

- Budgetary expenses can be attributed to: the expenditure of both regional and state budgets aimed at the security of PC infrastructure, the State budget expenditures on research and experimental-design works and on the capital investments of state facilities (FE, IHE and so on);

- Off-budget expenditures can be attributed to: investments in the creation PC as well as in the implementation of research projects; at the same time, the common (so-called project) financing on the ground of both state and business cooperation can also be taken into account.

The PC classification was offered on the ground of literature sources' research (table 1).

Table 1. The classification of types of the pharmaceutical cluster creation

Nº	Sign	Cluster type	Characteristics
1	According to the type of partner relations	Formal	Cluster relations are obligatory contractual with the creation of higher non-governmental public agency (cluster council), which takes all the necessary strategic decisions
		Informal	Cluster relations are not legalized by contracts
2	According to the direction of integration relations	Vertical	Relations with individual customers and suppliers, which are based on personal contracts
		Horizontal	Relations with other management entities
		Mixed	The most widely spread form of subjects' union
3	According to the specific activity	Processing	Enterprise unions, which are characterized by processing activity (pharmaceutical cluster)
		Innovative	Great amount of new companies emerging during the process of commercialization of technologies and research activity results (biotechnology and so on.)
4	According to the economic-organizing signs	Italian	The union of great amount of small enterprises for competitiveness increase
		Japanese	The union of enterprises around the leader
		Finnish	High innovation level among members
		American	High competitiveness, which does not stipulate any relations improvement
		Indo-Chinese	The key role belongs to the state and the main attention is paid to foreign investments
5	According to the	Origin	Some participants start cooperating with one another with a view to implementing new opportunities

development level	Development	Emergence of new cluster participants and formation of both formal and informal relations
	Maturity	Ramified cluster relations and establishment cooperation with other ones
	Transformation	The change of technologies and processes and the transformation in some new clusters' signs

Form the point of view of pharmaceutical business organisation features, there are three main clusters. They include production, normative-legal and marketing clusters (Ashton, 2008). All these clusters contribute to any pharmaceutical clusters' growth and development. The production cluster is more bound to the research and developments, clinical trials and mass production of new remedies. The normative-legal, on the other hand, take care of legal matters and companies' activity aspects. Finally, the marketing cluster is directly connected with the increase in sales and income.

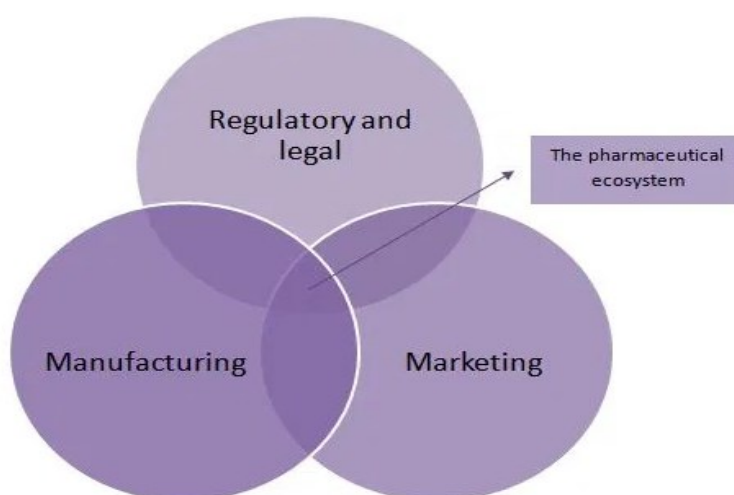


Figure 5. Three main cluster types of pharmaceutical business

The production cluster is the important art of pharmaceutical business. The first and foremost component is the raw materials (in the shape of substances) procurement in pharmacy. It is accomplished by means of many methods such as tenders, contests, competitive negotiations and even direct purchase. The production level aim is the provision of qualitative remedies at a low price as the customers want (WHO, 2002). The chemical composition creation includes the production of remedies, which are stable and reasonable.

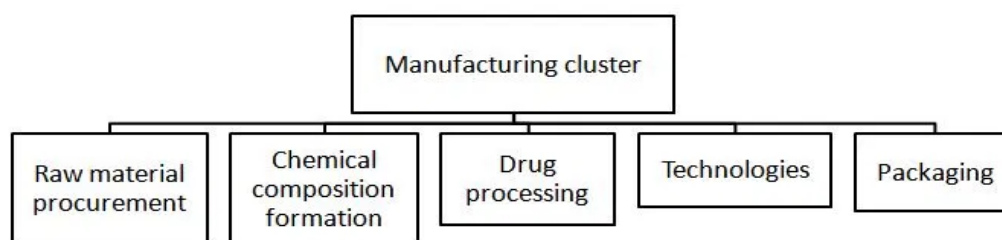


Figure 6. The pharmaceutical business production cluster

Moreover, the processing of remedies or their synthesis is the industrial production of remedies. The process of remedies' synthesis includes:

- Powder mixing;
- Grinding and granulation;
- Covering;
- Extrusion of melt and remedies' pressing and others (Gibson, 2016).

The normative-legal cluster is the one created by means of normative and legal aspects.

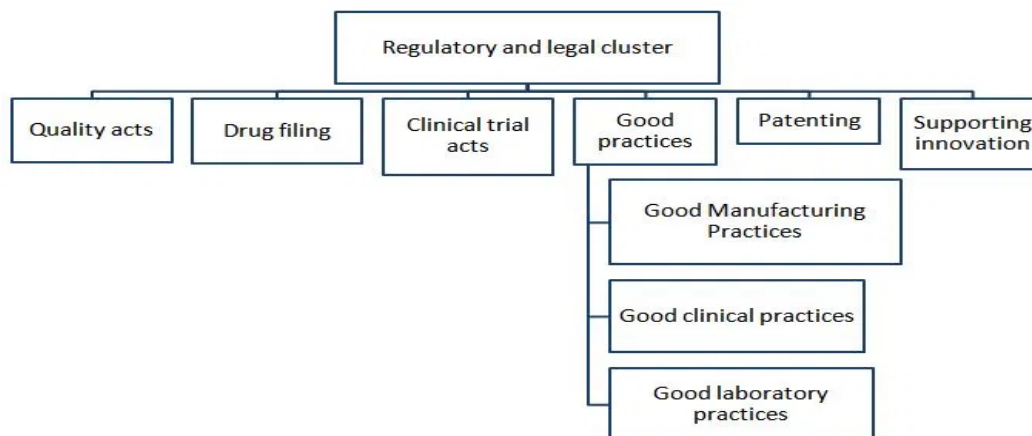


Figure 7. The normative-legal cluster of pharmaceutical business

This cluster secures that the company observes the law and rights of remedies' development. The check of remedies' quality and efficiency is the main step in the production of medicines. The registration of medicines is another normative requirement as well as the main legal cluster component. It includes applications for regulating authorities' approval such as the national (the central organisation on medical standards' control) and the international ones (FDA) (Feldman & Frondorf, 2016). The normative-legal cluster is also responsible for the control of clinical trials' acts made for any other company developing new remedies. The good manufacturing practice is under the normative-legal cluster's control as well (Lee et al., 2015). The good manufacturing practice (GMP), good clinical practice (GCP) and good laboratory practice (GLP) is the responsibility of the regulation cluster. This cluster accounts for patenting of new remedies as well as for that the pharmaceutical compounds will meet the regulations and be protected by the law. The marketing cluster plays an important role in pharmaceutical business operations. It bears responsibility for selling, marketing of pharmaceutical compounds and rivalry strategies.



Figure 8. The pharmaceutical business marketing cluster

The cluster is aimed at different customers on the ground of pharmaceutical classification (Torjesen, 2015). They account for the assessment of expenditures and

prices for the prescription drugs and monitor that the demands of customers are duly met. This cluster is liable for the impact of advertisements, doctors, hospital administration and community (Bhutada, Rollins & Perry, 2017). The world pharmaceutical cluster is expected to grow within the next few years despite the recent growth retardation in key markets all over the world. The reasons for that are simple: the growth and aging of population, the income level increase and the origin of new diseases. The volume of world pharmaceutical market is expected to be \$1,57 tr., by 2023. The North America is thought to be among the leading markets with the share of 45,33% by 2023; having increased its share according to 2017. The EU, instead, is thought to face the decrease in its market share; it will amount to 20,24% of a world pharmaceutical market by 2023 according to 2017. It is expected that the Asian-Pacific pharmaceutical market will keep a runner-up position with its share of 24,07% in 2023. Latin America, the Middle East and Africa (IEA) will keep their 7,53% and 2,96% of their world pharmaceutical market in 2023.



Global Pharmaceuticals Market 2023

Geography-wise Market Share of Global Pharmaceuticals Market in 2023

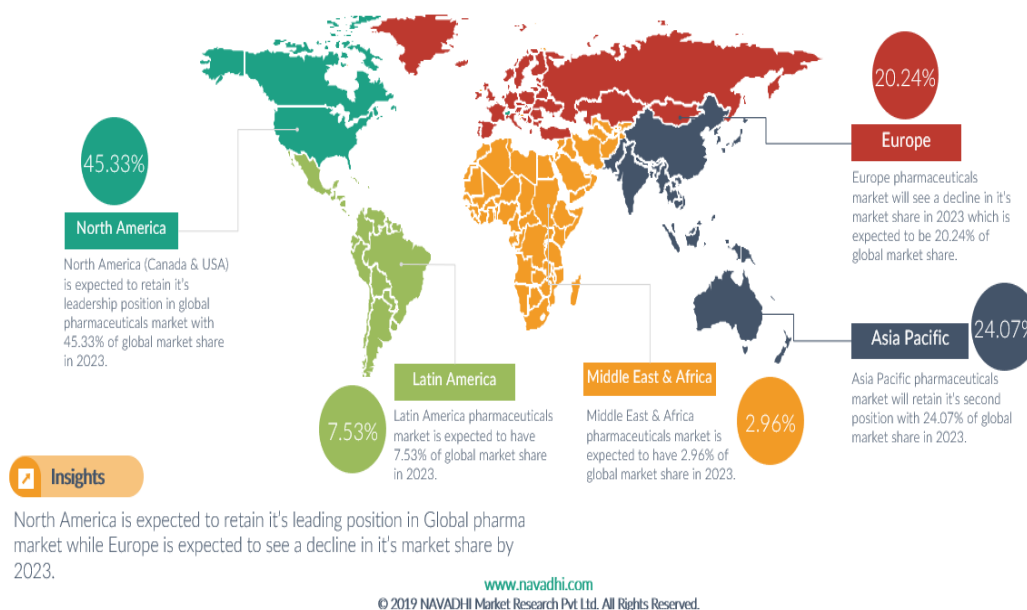


Figure 9. The estimated global pharmaceutical market by 2023.

This increase is conditioned by the growth and aging of population in key markets. According to the UN, the planet population will highly likely exceed the amount of 9,3 billion people by 2050; around 21% of this population is expected to be older than 60. Besides the growth and aging of population, the purchasing power increase and the access to qualified medical care and remedies both for low- and medium-income families all over the world is also a momentum for the pharmaceutical industry growth. Another aspect, which drives this rise, is the increasing amount of pharmaceutical companies in the market of rare and specialized illnesses. The innovations in the sphere of advanced biological remedies, nucleic acid therapy and cellular therapy as well as in the sphere of bionics and implants did attract investments even to non-pharmaceutical companies such

as Facebook, Qualcomm and others; which is a momentum of the pharmaceutical industry as well.

On the other hand, the adoption of control policy over the expenses together with toughening the government rules in key markets is thought to have an impact upon the pharmaceutical industry growth. Pharmaceutical companies have to cut down on their expenses for research and development (R&D) due to the growth impairment within the last few years; which is also expected to hamper the growth of pharmaceutical market as far as the income from new remedies' selling makes up a significant revenue share of pharmaceutical companies due to the remedy exclusiveness. Moreover, the market of generics faces with the decrease in the investments profitability because of the drop in prices in key markets, which forces many companies to find other ways and markets to support the growth.



Growth Drivers & Inhibitors

What are the growth drivers and inhibitors for global pharmaceuticals industry?



Figure 10. The global analysis of the pharmaceutical industry and tendencies of 2023. The report deals with the growth forecasts for 39 countries together with 5 main geographical regions



Global Pharmaceuticals Market Forecast 2023

Geography-wise Forecast Coverage of Global Pharmaceuticals Market

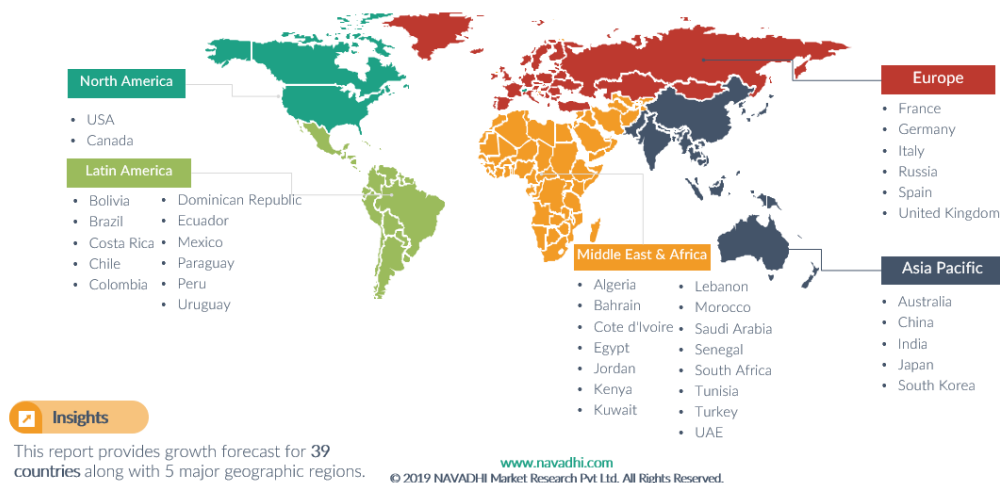


Figure 11. The global analysis of pharmaceutical market and tendencies of 2023

The world pharmaceutical market has reached an unprecedented level in 2018 and is estimated at \$1,11 tr. This figure should be \$1,43 tr., by 2020. In terms of growing pressure on the development of remedies for meeting the constantly growing demand, the pharmaceutical companies continue to diligently work to offer the most innovative and advanced treatment modes to patients. Pharmaceutical companies spend around 150 billion dollars for research and development activities annually. Only a small percentage out of thousands of compounds is approved by regulating authorities for further use by patients for curing the disease and improving the quality of life. In 2018, however, the record number of new remedies developed by pharmaceutical companies all over the world was approved by different regulating authorities. The large amount was approved by the USA regulating authority, FDA, which approved 55 new remedies and broke its own record on generics' approval (781 compared to 763 in 2017).

DISCUSSIONS

As the pharmaceutical cluster creation experience indicates if one wants to develop the PC, it is important to have the following conditions:

- The presence of both scientific bases and abilities to perform pharmaceutical developments taking good laboratory practice (GLP) into account;
- The presence of modern enterprises, which meet all the good manufacturing practice (GMP) requirements, able to produce different pharmaceutical products (domestic and contract production both from the side of cluster members and large foreign pharmaceutical companies);
- The presence of a ramified distribution system of remedies meeting all the good distribution practice (GDP) requirements;
- The presence of certified centers of both pre-clinical and clinical trials;
- The presence of modern warehouses, transport and refrigeratory chains, which meet all the good storage practice (GSP) requirements;

- The presence of modern retail companies certified to meet all the good participatory practice (GPP) requirements;
- Attraction of foreign companies for the transfer of technology and specialists into the sphere of distribution and production of remedies;
- Creation of scientific centers on the ground of RI and IHE;
- Innovative pharmaceutical products' implementation;
- The use of outsourcing;
- The presence of staff;
- The presence of substances' producers;
- The presence of main, additional and packaging materials' producers;
- The presence of pharmaceutical equipment producers;
- The presence of venture companies and the use of its funds and transferring technologies;
- The implementation of investment projects in the sphere of pharmaceutical industry, which are connected with modern productive capacities creation (carrying out the engineering training on the territories allocated for the placement of objects and putting both regional and budgetary investments into such spheres as transport availability, power supply, heat supply, water supply, water disposal and gas supply).

Thus, the advantages of cluster approach implementation into the activity of pharmaceutical industry are as follows: the acceleration of investment projects' implementation date; the cluster members' expenditure economy; the decrease in the level of risk for cluster members; highly-trained staff rotation; ability to get the integrated solution of such issues as training, re-training and staff involvement; the increase in the scale of production; the organisation of the pharmaceutical industry scientific maintenance; the increase in the level of investment attractiveness; the boost in the pharmaceutical sector export potential; and the tax revenue increase. Moreover, the implementation of PC contributes to jobs creation and localization of the pharmaceutical sector on a certain territory.

CONCLUSION

The development of clusters is a perspective managerial form of socio-economic processes in regions. They will facilitate the security of fast economic growth, the revival of domestic industry, the development of industrial collaboration on the ground of cooperation and specialisation, the increase in the level of regions innovation development efficiency, which is an effective means of attraction of the direct foreign investments. Finally, this will contribute to achieving a high economic development and competitiveness levels of Russian regions and their deserved place in a global system of economic relations. The creation of cluster networks allows to increase the competitiveness level of regions and to provide the population including a highly trained staff with jobs and to boost the tax revenue.

The innovation and technological clusters consist of research facilities, small- and middle-size companies and centers for the transfer of technologies' transfer. The centers of technologies' transfer are made for providing a broader access to industrial innovations such as entities, which can approve their approbation as well as their perfection and the spread of the data collected. Cluster functioning is impossible without scientific facilities carrying out the innovation development. Research facilities play almost the main role in

a cluster network because it is they who are responsible for the development and creation of the main innovative product. It is innovation trend that is the feature, which distinguishes the cluster from other economic facilities.

The cluster creation allows to achieve the maximum level of function efficiency of all its subjects because they are united by the only aim; they have common relations and the access to material, labour, financial resources and information channels. Neither creation nor effective cluster networks functioning are possible without the state participation or support both on state and regional levels. This intervention, however, should not be excessive. The main reasons why the level of clusters' initiatives is so low are small and insufficient cluster budgets (as the study shows that clusters mostly depend on the financing of projects and on minor income from a membership fee); the experience and development level absence (the study also showed that in highly-developed countries clusters are ranked as ones having a quality mark and a different system of aims assessment and a different level of cluster initiatives implemented); the low level of participation in the activity sphere from a wide circle of interested sides / cluster members (companies, service providers, non-governmental organisations, universities and research institutes); hostile environment, where clusters emerge and develop; the national policy in the sphere of clusters' creation.

These are the main problems in a cluster creation potential, which contribute to the increase in competitiveness, innovation and economic development levels of the pharmaceutical cluster. The implementation of management cluster models (particularly pharmaceutical ones) in the state will allow to increase the volume of production and the amount of jobs for service rendering in a certain territory; it will lead to the revenue coming to local budgets; to provide new jobs; to increase the standard of well-being; to diminish social tension in cities and to meet the needs of territorial communities and others.

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