

## Pharmaceutical industry in the Republic of Belarus 2023



NATIONAL AGENCY OF INVESTMENTAND PRIVATIZATION REPUBLIC OF BELARUS

## Contents

| 1. Current state of the industry  | 3  |
|---|----|
| 1.1. Key industry indicators  |    |
| 1.2. Legal framework  |    |
| 1.3. Scientific and research base   | 6  |
| 1.4. Staffing   |    |
| 1.5. Technologies   |    |
| 1.6. Production and territorial clusters                                  |    |
| 2. Resource and raw material base   | 12 |
| 3. Production infrastructure  | 14 |
| 3.1. Availability of industrial sites, buildings, facilities and offices  | 14 |
| 3.2. Logistics capabilities   | 18 |
| 4. Market Overview  | 19 |
| 4.1. Main Trends  | 20 |
| 4.2. Production and consumption of pharmaceutical products                | 21 |
| 4.3. Foreign trade  | 23 |
| 4.4. Key players  | 27 |
| 5. Investment potential and prospects for the development of the industry | 29 |
| 5.1. Investments and investment attractiveness of the industry            |    |
| 5.2. Export potential and prospects for the development of the industry   |    |
| 6. Investment climate   | 31 |
| 6.1. Macro indicators by country  |    |
| 6.2. Preferential regimes.  |    |
| 7. Investment projects for implementation in the Republic of Belarus      |    |
| 7.1 Investor Roadmap  |    |
| 8. Inforation about NAIP  | 36 |

## 1. Current state of the industry

#### 1.1. Key industry indicators

The pharmaceutical industry in Belarus is one of the actively developing segments attractive to investors due to the steadily growing market for medical services, equipment and medicines in Belarus and other EAEU countries.

To improve the management system of the pharmaceutical industry, the holding company «Belpharmprom» was established in 2017. The management company of the holding is the republican unitary enterprise «Holding Management Company «Belpharmprom». The holding company includes eight organizations, including six manufacturers of medicines, one scientific organization and one organization producing medical products. Cooperation contracts (agreements) have been signed with 20 organizations, including 19 pharmaceutical manufacturers and one manufacturer of medical devices.

The share of Belpharmprom holding member organizations in the total volume of medicine production is 50.1% or \$390.4 million, and in the total volume of export of Belarusian medicines about 80%. The product portfolio of the holding is 745 medicines. The share of organizations members of the holding «Belpharmprom» by the end of 2021 is more than 62% of all exports of domestic medicines. In the retail sector, the holding's share is 65%, and in the hospital sector – 91.5%. The main industry indicators are aggregated within the economic activity «Production of basic pharmaceutical products and pharmaceutical preparations».

The number of organizations operating within the type of economic activity «Manufacture of basic pharmaceutical products and pharmaceutical preparations» is 0.6% of the total number of industrial organizations - 98 organizations (as of 2021). 79.1% are privately owned, 15.1% are foreign-owned, producing 62.4% and 5.4% of the industry's industrial output respectively. The share of micro, small and medium-sized organizations in the volume of production of pharmaceutical products and preparations is 23.6%.

Overall, the pharmaceutical industry produces 1.2% of the total output of the republic, which amounts to \$765.5 million. The pharmaceutical industry produces 1.2% of the country's total output at \$765.5 million, employing 10,300 people (1.2% of the total number of employees). At the same time, the volume of production increased by 53.2% in comparable prices compared to 2015.

From 2017 to 2021, industrial output grew by 29.88%, average monthly wages by 17.11%, and the average number of people employed in the industry by 4.04%. At the same time, capacity utilization decreased by 17.10%, investments in fixed assets - by 20.88%.



| $\bigcirc$ |  |  |
|------------|--|--|
|            |  |  |
|            |  |  |

| Industry  | 2017  | 2018  | 2019  | 2020  | 2021  |
|---|-------|-------|-------|-------|-------|
| Number of organizations, units  | 105.0 | 99.0  | 98.0  | 101.0 | 98.0  |
| Volume of industrial production, USD million                          | 589.4 | 614.2 | 652.8 | 664.0 | 765.5 |
| Specific weight in the total volume of industrial production, %       | 1.2   | 1.1   | 1.2   | 1.4   | 1.2   |
| Capacity utilization rate, %  | 99.3  | 97.1  | 97.3  | 80.0  | 82.2  |
| Average number of employees, thousand people                          | 9.9   | 10.1  | 10.4  | 10.4  | 10.3  |
| to the average number of employees in industry, %                     | 1.1   | 1.1   | 1.2   | 1.2   | 1.2   |
| Nominal average monthly wages and salaries of employees, U.S. dollars | 554.2 | 590.9 | 636.2 | 598.9 | 649.0 |
| Investments in fixed capital, USD million                             | 54.6  | 38.3  | 49.4  | 44.5  | 43.2  |

### Key Indicators of Industry Development

## 1.2. Legal framework

The field of pharmaceuticals and health care is characterized by a large number of industry regulations and procedures, as the industry is focused on human treatment.

One of the most important legal acts is the Decree № 327 of the President of the Republic of Belarus «On the development of pharmaceutical industry» of August 30, 2021 It is aimed at ensuring drug safety of the Republic of Belarus and the further development of the domestic pharmaceutical industry. In particular, we are talking about stimulating pharmaceutical manufacturers in the directions of increasing exports, creating new production facilities for the production of modern high-quality medicines, as well as creating new medicines.

It is planned to provide subsidies to compensate part of the costs associated with the development and registration of new drugs, certification of production facilities for compliance with Good Manufacturing Practice (GMP) requirements. In order to stimulate the production of drugs on a full production cycle, the creation of new effective and high-quality medicines, ensuring their uninterrupted supply to the domestic market, the procurement of such medicines with the use of public procurement procedures from a single source is provided.

In general, the implementation of the proposed measures for the development of the pharmaceutical industry will provide additional growth in the production volume of the industry and increase the volume of exports.

Also among the main normative legal acts are the Law of the Republic of Belarus of June 20, 2006 № 161-Z «On Circulation of Medicines» and Presidential Decree of December 31, 2019 № 499 «On Circulation of Medicines». They are aimed at improving the legal and organizational foundations of state regulation in the field of drug circulation, including state registration of medicines, licensing of pharmaceutical activities, quality control of medicines, their research, pharmacovigilance, industrial production, sales, storage, distribution of medicines, etc.

At the moment, medicines can be produced only by legal entities and individual entrepreneurs. They must have a license for pharmaceutical activities, which is issued by the Ministry of Health. The license allows the production of medicines and their sale. Production must be carried out in accordance with Good Manufacturing Practice (GMP). In order to confirm GMP, you need to obtain the appropriate certificate from the Ministry of Health. If medicines are produced for the purpose of sale within the EAEU, then a certificate is needed to confirm the compliance of medicines with the GMP of the EAEU.

Also, the manufacturer must appoint an authorized person who will be responsible for the quality of the drug produced. The authorized person must be certified and then included in the register. Moreover, the drug produced must be registered in the register of medicines with a registration certificate. Sales of medicinal products are also carried out only under the license. If necessary, a medicinal product can undergo clinical trials according to the Good Clinical Practice Rules of the EAEU (GCP EAEU). Currently, national drug registration procedures have been abolished. Instead of them there are procedures for registration of medicines of the EAEU.



An important document in the industry is the State Pharmacopoeia of the Republic of Belarus. It contains mandatory standards and regulations governing the quality of drugs and substances for pharmaceutical use: general articles on methods of analysis (physical, physical and chemical, biological and pharmacognostic methods, authenticity tests, impurity detection, quantitative tests, pharmaceutical technology tests), containers, reagents, general texts (on microbiology, on biological products, general articles and tables of physical characteristics), extemporaneous drugs, general articles, dosage forms, homeopathic medicines. It should also be noted that in order to create a common pharmaceutical market, the EAEU countries have been working to create a contractual and legal framework, as well as the integration of interagency cooperation. The regulatory framework consists of 74 acts of the Eurasian Economic Commission, which cover all stages of drug circulation, referred to the level of supranational regulation.



#### 1.3. Scientific and research base

Biological, medical, pharmaceutical and chemical technologies and industries are the priority areas of scientific research for 2021–2025 (Presidential Decree No. 156 of May 7, 2020).

Scientific support for the development of the pharmaceutical industry is now taking place within the framework of state programs, state scientific and technical programs, innovative projects and initiative search works of individual enterprises, universities and scientific and practical centers.

The main goal of the development of the pharmaceutical industry in the coming years and in the future is to ensure the production and availability of demanded medicines, advanced level of scientific, technical and technological development, as well as strengthening its export potential. In 2016–2020, the state program for the development of the domestic pharmaceutical industry was implemented. The result of the program is 45 registered names of new pharmaceutical products (40 drugs and 5 substances). State scientific and technical program «Development of pharmaceutical substances, medicines and regulatory support of the pharmaceutical industry» was developed for the period 2021–2025. The coordinator of the program is the Ministry of Health of the Republic of Belarus.



Today, a network of state medical and pharmaceutical research organizations of the Ministry of Health system has been formed. It includes 25 organizations. These are 5 universities (Belarusian State Medical University, Vitebsk State Medical University, Gomel State Medical University, Grodno State Medical University, Belarusian Medical Academy of Postgraduate Education), 15 republican scientific and practical centers, 3 scientific and practical centers (Scientific and Practical Center of Hygiene, Minsk Scientific and Practical Center of Surgery, Transplantology and Hematology, National Anti-Doping Laboratory) and 2 enterprises of pharmaceutical industry (Belmedpreparaty and Scientific and Practical Center LOTIOS).

In scientific organizations of the system of the Ministry of Health in 2021 scientific research and development were carried out by 3339 scientific workers, including 2690 persons from the faculty of medical educational institutions. 2016 researchers are highly qualified scientific workers with academic degrees of doctors (365 people) and PhDs (1651 people). In 2021 the Higher Attestation Commission of the Republic of Belarus approved 9 doctoral and 63 candidate dissertations in various specialties of medical and biological sciences.

The total amount of budget financing of scientific and scientific-technical activity

in 2021 in the system of the Ministry of Health was more than 16.7 million dollars. In 2021 scientific research and developments in the field of public health continued within the framework of State Programs «Science-intensive technologies and equipment», «Public health and demographic safety» for 2021–2025; State Program on overcoming the consequences of the Chernobyl nuclear power plant disaster for 2021–2025; State Research Programs «Translational medicine», 2021–2025; «Biotechnology-2», 2021– 2025. In total in 2021 scientific organizations of the Ministry of Health system performed 863 research and development works in full accordance with the schedules and technical tasks.

The most important component of modern scientific work of medical organizations is the scientific-practical and implementation activity, which ensures the fulfillment of the main task of sectoral science - promotion of scientific developments and achievements in the practice of healthcare. In the framework of scientific and scientific-technical activity with participation of organizations of system of the Ministry of Health in 2021188 new methods of medical care (diagnostics, treatment, medical prevention of diseases, medical rehabilitation of patients) are developed, approved for use and introduced in the work of practical health organizations, serial production of 49 medical products is developed and received permission for serial production, serial production of over 100 medicines, diagnosticums, test systems, etc. is arranged.

The implementation of the results of scientific developments in practical health care can significantly improve the quality of medical prevention, diagnosis and treatment of diseases. The «State Program of Social and Economic Development of the Republic of Belarus for 2021-2025» indicates the need to develop a domestic vaccine against COVID-19 and organize its production. In the current five-year period it is planned to increase the volume of production of domestic medicines and expand their nomenclature, ensuring that in 2025 the country produces up to 70% of international nonproprietary names of medicines included in the Republican Drug Formulary, and to increase the export of pharmaceutical products by half.

## 1.4. Staffing

The following universities and colleges train personnel for the pharmaceutical industry (excluding medicine):

• Belarusian State Medical University (Faculty of Pharmacy),

• Vitebsk State Medical University (Faculty of Pharmacy),

• Belarusian State University (Faculty of Chemistry),

 Belarusian State Medical College (specialty «Pharmacy»),

• Vitebsk State Medical College (specialty «Pharmacy»),

 Mogilev State Medical College (specialty «Pharmacy»).

In total, four universities and 16 colleges train personnel in medical specialties.

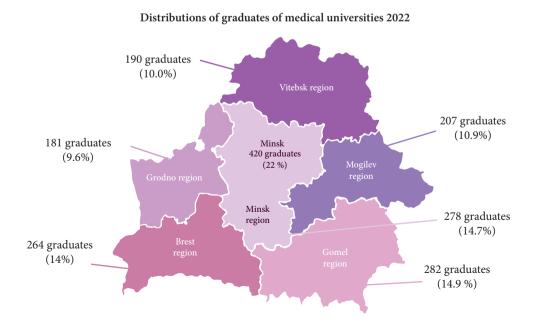


The number of students in higher education institutions in the field of health care, including pharmacy, is 20.6 thousand (with 3.9 thousand admitted and 3.4 thousand graduates in 2021), in specialized secondary schools — 10.8 thousand people (with 4.6 thousand admitted and 4.0 thousand graduates in 2021). The number of students in the master's degree program is 10, 11 people were accepted in 2021 and 13 people graduated. The number of postgraduate students in the pharmaceutical industry — 13, accepted — 3, graduated — 4 people.

The number of medical personnel per 10,000 people will remain at 55.2 in 2021 (EU - 33.4, CIS — 38.1), the number of middle medical personnel at 120.7 per 10,000 people (EU - 86.8, CIS — 62). The indicator of staffing of medical personnel averaged 94.2% in the country, middle medical personnel — 97%.

However, the picture of staffing in the regions is mixed: above the national average is observed in Brest and Grodno regions; below the national average in Vitebsk region and the city of Minsk. In the Gomel region the staffing level remains at the level of the national average. In the Mogilev and Minsk regions it is lower only in doctors, in medium medical personnel it is at the level of the republican average.

Training is also provided as part of the educational programs of individual research and production organizations. For example, the TalenaVita program. Implementation of the program is aimed at solving development of conditions for realization of intellectual and personal potential, professional self-determination and formation of children, development of new forms of inclusion of gifted children in intellectual and cognitive, physical culture and sports and socially useful activities. Scientific change TALENAVITA CAMP lasts 10 days, brings together 30 students from various universities from all regions of Belarus. More than 15 experts in science from more than 10 different organizations, including universities, scientific and medical institutions, work with young scientists. The main topics relate to health and biotechnology.



#### 1.5. Technologies

Biotechnology and microbiology are the near future for domestic pharmaceutical companies. At the moment these directions are being developed at the level of scientific research and implementation of pilot batches. In the long term it is planned to provide production of biological drugs and vaccines. These areas are considered promising, as globally only a few companies are engaged in the production of such products. Moreover, these areas are very knowledge-intensive and require the development of their own scientific schools.

On the basis of the Medicine and Pharmaceutics cluster, cell and molecular genetic technologies, small chemical synthesis technologies, oncology treatment technologies (IHC test system for HER-2 detection, PCR test system for detection of mutations in the EGFR gene, NGS panel for detection of mutations, deletions and translocations) are developed. The first domestic analogues for oncologic therapy have been mastered by a full technological cycle: «Temozolomide, Anastrozole, Vinorelbine, ERESTINIB (the first locally produced targeted drug for the treatment of lung cancer). We have also mastered the technology of producing the following drugs: Epocim or Erythropoietin anti-anemic agent (biosimilar of the original drug Eprex); Leukocim or Filgrastim anti-tumor and immunomodulatory drug (biosimilar of the original drug Neupogen); Eberprot agent for complex therapy of diabetic foot syndrome; Tenecteplase thrombolytic myocardial infarction therapy agent (biosimilar of Metalyze); Glargin, a long-acting human insulin analog used for insulin replacement therapy for diabetes, a biosimilar of the original drug Lantu; Enoxaparin-Belmed, a low molecular weight heparin drug; Mycophenolate mofetil, an immunosuppressant in tablet form, which is used in transplantology to prevent acute transplant rejection.

As part of the «Biotechnologies for Pharmaceuticals» project (commissioned by the Council of Ministers), dry granulation and multilayer tablet production technologies (anticoagulants, antiretroviral drugs and drugs for treatment of the nervous system and musculoskeletal diseases) have also been mastered. Implementation of the project will make a tangible contribution to the innovative



development of the Belarusian pharmaceutical industry and will make treatment of such diseases as HIV, Alzheimer's, gout, epilepsy, rheumatoid arthritis, thromboembolism and others more accessible to the citizens of the country, and will also help reduce mortality in general.

In addition, test systems for detection of SARS-CoV-2 strain coronavirus RNA were developed; technology for production of immunoglobulin against SARS-CoV-2 virus from anti-COVID-19 immune plasma; methods for production of purified and inactivated preparation of SARS-CoV-2 virus as a candidate for vaccine creation. Production of Gam-CovID-Vac, a combined vector vaccine for the prevention of SARS-CoV-2induced coronavirus infection was organized.



### 1.6. Production and territorial clusters

There are two pharmaceutical clusters in Belarus.

#### 1. Medical-pharmaceutical cluster in Vitebsk - Union of legal entities «Medicine and Pharmaceutics - innovation projects».

It includes Vitebsk State Medical University, Nativita JLLC, BelVitunifarm OJSC, VitVar LLC, AconitPharma JLLC, Medelcombel JLLC, Pharmmarketing Group LLC, CCUE «Vitebsk Regional Marketing Center», NP «Union of pharmaceutical and biomedical clusters» (Russia), RPE «Akadempharm», LLC «SIVital», P. Masherov Vitebsk State University. Masherov Vitebsk State University.

The research core of the cluster is the Center of Transfer of Medical and Pharmaceutical Technologies, which was created on the basis of Vitebsk State Medical University. Currently, the Technology Transfer Center covers most of the stages of drug development: conducting preclinical, bioequivalent and clinical trials. The main goal is the full cycle of development of innovative drugs and synthesis of pharmaceutical substances.

At the moment the Union unites about 15% of Belarusian pharmaceutical companies. And despite the fact that clusters tend to be territorial in nature, the non-profit Partnership «Union of Pharmaceutical and Biomedical Clusters of Russia» is part of the first medical-pharmaceutical Union in Belarus.

## 2. Cluster of high technologies in the field of complex medical equipment / instrumentation.

Base organization: CJSC «LINEV-ADANI»; participants: 6 organizations from Belarus, Russia, China, Great Britain, USA. It is more oriented towards the development of medical instrumentation.

## 2. Resource and raw material base

The basis for the manufacture of drugs are pharmaceutical substances - active chemical substances with which the therapeutic properties of the drug are associated. About 40% of the used drugs are of plant origin, the rest are created by chemical synthesis.

Belarusian medicines also contain mostly imported substances, there are few entirely Belarusian medicines. Belarus produces only 100 pharmaceutical substances and imports 1395. As a result, there are 93.31% of imported pharmaceutical substances.

The main supplier of substances to Belarus is China (more than 70% of the items), the second is India. Saline solutions, absorbent cotton, bandages, and other dressings are produced by Belarusian companies.

For this reason, the search for new types of medicinal plant raw materials, study of the resource potential and conditions of cultivation of specific plant species in certain climatic conditions, study of the component composition of medicinal plant raw materials is relevant. Cultivation of medicinal plants is also relevant due to their safe effect, insignificant number of side effects, possibility of rational combination of medicinal plants among themselves and synthetic drugs.

In addition, the cultivation of medicinal plants on plantations makes it possible to preserve areas that are the habitat of some valuable representatives of medicinal raw materials. In Belarus, the farm «Bolshoye Mozheikovo» in Shchuchinsky district specializes in the cultivation of medicinal herbs (chamomile, marigold and valerian). JSC «Belaseptica» in Myadel district - 25 kinds of herbs useful for health (echinacea, white clover, sage, bison, yarrow, mint, hyssop, motherwort, valerian, etc.) LLC «Kalina» in Orsha district is engaged in growing, collection, preparation of medicinal plant raw materials (48 names), their processing and production of finished herbal medicines, collections, and production of plant products. At present more than 35 names of medicinal mono herbs and gatherings are registered and produced.



The second direction of drug production is the production of tinctures. Production of tinctures is based on the use of percolation technology, which allows to get the maximum active substances from herbal medicinal raw materials. 7 herbal tinctures are currently registered and produced in total.

Also a project (BelAseptica CJSC) on the production of pharmaceutical substances from domestic endocrine-enzyme and special raw materials of animal origin obtained from the slaughter of cattle and pigs is being implemented. Thus, dried bovine bile is used in production of the following ready-made medicines: Allochol (53,3%), Cholensim (33,3%), medical canned bile (100%), Festal (9,36%), Enzystal (9,36%).



Pancreatin - produced from the pancreas and used in the production of finished drugs: cholensim (33.3%), festal (35%), mesim (38%), Creon (48%), wobenzyme (42%), pancreatin (39%). Dry plant extracts: garlic, St. John's wort. Pepsin - produced from the pancreas of pigs and is used as a pharmaceutical substance and as an enzyme for the production of cheese. Organization of production of enzyme preparations from animal raw materials will allow to set up production: from pancreas - deoxyribonuclease, ribonuclease, trypsin, chymotrypsin; from lungs - aprotinin, heparin; from testes - ronidase, lidase; from brain - cerebrolysin; from blood - hematogen, fibrin, solkoseryl; from thyroid - calcitonin, thyroidin.

## 3. Production infrastructure

#### 3.1. Availability of industrial sites, buildings, facilities and offices

One of the most promising sites for the implementation of pharmaceutical production is the Chinese-Belarusian Industrial Park «Great Stone». One of the main activities of the park is the development of manufactures in the field of pharmaceuticals, biopharmaceuticals and medical devices.

Also the development of pharmaceutical production can be carried out within the clusters — it is the Union of legal entities «Medicine and Pharmaceuticals — Innovation Projects» and the cluster of high technology in the field of complex medical equipment / instrumentation.

Production of pharmaceutical products and medical devices is also carried out within the framework of science and technology parks.

The Scientific and Technological Park of BNTU «Polytechnic» has established production and sale of more than 12 types of medical products for cardiology, oncology, dentistry (for example, intraoral dental device designed to prevent snoring and sleep apnea (breath-holding); stent-graft for thoracic aorta designed for treatment of aneurism and splitting aneurism in the descending aorta, etc.).

The scientific and technological park «Unitechprom BSU» produces import-substituting drugs for the treatment of oncological diseases of the head, neck, abdomen (for example, pharmaceutical substances temozolomide, cisplacel, prospidia chloride). In 2020, the first full-cycle series of the original drug Temodex for local chemotherapy of malignant brain tumors was produced. Patents of the United States, India, and the European Union were obtained for this drug.



Assistance in the implementation of projects is provided by:

The Association of International Pharmaceutical Manufacturers (AIPM)

It is a non-profit organization representing the professional and business interests of international pharmaceutical manufacturing companies. AIPM was established in June 2005 and today its members are 28 leading pharmaceutical companies of the world.

The main mission of AIPM is to promote economic and legal policy of Association members, which leads to the growth of an organized and open ethical market of pharmaceuticals in the Republic of Belarus.

Companies that are members of the Association:

Association of pharmaceutical manufacturers of the Eurasian Economic Union

The purpose of the Association is to coordinate the business activities of the members of the Association - pharmaceutical manufacturers of the Eurasian Economic Union engaged in the production of medicines, as well as to protect and represent the common interests of the members of the Association, including assistance in achieving compliance with the rules of good manufacturing practice (GMP) by the members of the Association; promotion of drug supply to the population and medical institutions, development of the pharmaceutical market of the EAEU member countries; promotion of scientific research in the field of drug circulation.

The Association includes leading full-cycle pharmaceutical manufacturing companies:



| Indicator                               | 2020    | 2021    | 2022              |
|---|---------|---------|-------------------|
| Total supply, thousand sq. m.           | 1 254   | 1 404   | 1 513             |
| Input, thousand sq. m                   | 87      | 150     | 109               |
| Vacancy rate, %                         | 4,0     | 3,8     | 4,0               |
| Range of rental rates, 1 sq.m./ month*. |         |         |                   |
| - Class A, €/BYN                        | 4.2-7.0 | 4.2-7.0 | 4.2-7.0/11.6-19.3 |
| - Class B, €/BYN                        | 2.4-5.0 | 2.4-5.0 | 2.4-5.0/6.6-13.8  |

## The main indicators of the development of the market of production and warehouse real estate

\*excluding operating costs and VAT

The supply of space has increased. Especially in the Minsk region. At the beginning of 2022 in Minsk region there were more than 70 large-format (5 thousand sq. m. and more) modern objects of commercial production and warehouse real estate, the runoff of which amounted to 1 404 thousand sq. m. The second stage of the third complex of objects of the Minsk city technopark with the area of 16,1 thousand sq. m was put into service. The reconstruction of the complex continued since 2013 and it allowed to increase the area of the technopark up to 36,9 thousand sq. m. Minsk Technopark accommodates 45 resident companies with the staff of over 1 thousand people, implementing projects in various fields (from electric drive production to microelectronics and pharmacology).

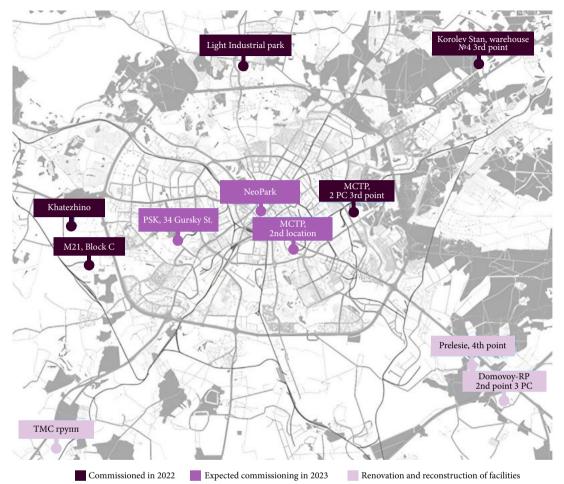
A multifunctional complex «Khatezhino» of class «A» with a total area of 38 thousand square meters, built in accordance with the requirements of the tenant - Internet retailer «Triovist» (21vek. by), was commissioned in the village of Tabory. In the transport and logistics complex «Korolev Stan» a new phase of the warehouse building number 4 of class «A» with a total area of 16.1 thousand square meters. m, which allows you to assign the complex to the largest in Belarus - the total area of TLC «Korolev Stan» is 62.4 thousand square meters.

In the industrial-warehouse complex «M21» of the company BFB in the v. Antonishki the «C» block of 22.7 thousand square meters was commissioned, increasing the total area of the complex to 40.3 thousand square meters.

The largest production and warehouse facility in the Minsk region is Velikiy Kamen industrial park, which has a total area of 140 thousand square meters of industrial and warehouse premises.



### Location of new warehouse facilities in the Minsk region



"Belpromstroi" company commissioned the Light Industrial Park manufacturing and warehouse complex with a total area of 16.1 thousand sq. m. in the village Tnyanka, 2 km from the Minsk Ring Road.

Total for 2022 in Minsk region is put into operation five industrial-warehouse facilities with a total area of 108,8 thousand square meters, and the total runoff in the region is 1 513 thousand square meters. In 2023 about 60,5 thousand sq. m are expected to be commissioned.

Low vacancy rate is characteristic of production real estate objects, it is zero in Minsk Technopark, about 15% in «Great Stone».



#### 3.2. Logistics capabilities

As of 2021, there are 58 logistics centers in Belarus. Eleven logistics centers provide primarily transport and logistics services, 17 perform wholesale and logistics (distribution, distribution) functions, while the rest have concentrated their efforts on the provision of warehousing and cargo handling services.

There are 21 logistics centers with temporary storage warehouses and customs warehouses on their territory: Brestvneshtrans, Transit, Brest-Beltamozhservice, Brest-Beltamozhservice-2, Beltamozhservice-Mogilev, Beltamozhservice-2, Beltamozhservice-Mogilev, Beltamozhservice-Gomel, Beltamozhservice-Kamenny Loh, Beltamozhservis-Bobruisk, Belmagistralavtotrans, TLC Kolyadichy, Bremino-Bruzgi, Dominik, Khatezhinsky Cold Storage Plant, Ozertso-Logistic, Belsotra, Velikiy Kamen, Bremino-Orsha, Bremino-Berestovitsa, Bremino-Bruzgi. Business entities also have 13 container terminals for handling containers of different types.

Out of 58 logistics centers, 17 are state-owned or have more than 50% of the state's stake (shares) in the authorized fund of a business company. The remaining logistics centers were created with the participation of national (Evrotorg, A-100, Tabak-Invest, Belinterproduct, Darida, Alidi West, ALMI, Vitalur, Electrosila, Millennium Group, BelVillesden, Romaks, Astomstroy, Libretik, BIGZZ, OMA) and foreign investors (Azerbaijan, Belgium, Germany, Iran, China, Lithuania, Poland, Russia, Ukraine, Serbia, Turkey and Czechia).

There are 18 logistics centers that are multimodal: Brest-Beltamozhservice, Brest-Beltamozhservice-2, Beltamozhservice (Minsk), Beltamozhservice-2, Beltamozhservice-Mogilev, Beltamozhservice-Gomel, Beltamozhservice-Bobruisk, TLC «Kolyadichi, Khatezhinskiy Cold Storage Plant, Ozertso-Logistic, Velikiy Kamen, Bremino-Orsha, Bremino-Berestovitsa, Mihanovichi Logistics Center, Eurosklad, Eurasia, Dobrada, National Airport «Minsk».

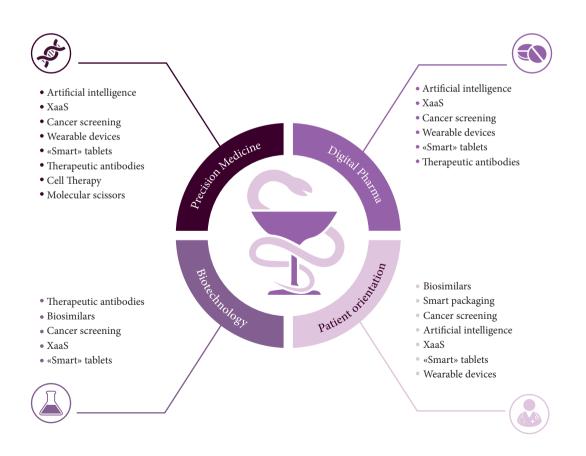
A number of logistics centers in Belarus either rent warehouse space (fully or partially without identifying an «anchor» tenant) to third parties without providing them any services, or have organized economic activities of an industrial or service nature on this space.



## 4. Market Overview

Current trends in the global pharmaceutical market are based on breakthrough technologies such as genome editing, personalization of drug therapy, investments in niche areas of drug research and development (orphan drugs), increase in the biotechnology sector, use of big data system, etc. The trends are presented in more detail in the figure below.

The volume of the global pharmaceutical market has reached \$900 billion, and by 2026 will reach \$1.4 trillion. This means that Belarus is moving in the right direction, developing pharmaceutical production. According to IQVIA analytical data, the Belarusian market has been growing steadily over the past few years, and in the last 2 years it has noticeably accelerated. In 2021, the drug market of the republic showed positive growth rates of 19% and amounted to \$1.51 billion, with the retail market share reaching 71.6%, the hospital market share reaching 27.8%, and the non-medical segment share reaching 0.6%. The growth driver is the hospital segment, which grew by 53% last year.



### 4.1. Main Trends

One of the most important trends in the Belarusian pharmaceutical market is the development of the biotechnological sector. First of all, it is vaccine production, production of drugs based on monoclonal antibodies. In the nearest future considerable efforts will be made to develop raw material base, i.e. production of pharmaceutical substances. The main task is to create importsubstituting production of basic pharmaceuticals.

In order to saturate the domestic market with import-substituting drugs in demand by domestic manufacturers, more than 60 new drugs are registered and placed on the market annually.

In the COVID-19 pandemic, 156 names of Belarusian medicines were used as basic drugs for therapy of patients with coronavirus infection. These were mostly antibiotics, drugs for treatment of pneumonia and other respiratory diseases, and cardiovascular diseases. In 2021 we promptly organized production and supply of Sputnik V vaccine to domestic health care from a semiproduct of a Russian company. In 2022 together with the Russian partner at the production facilities of Belpharmprom Holding full production cycle production of Sputnik group vaccines was organized.

We pay special attention to bringing new drugs demanded for COVID-19 prophylaxis to the market. For example, there are already 3 domestic analogues of imported Xarelto (Xariva, Rivaksan and Rivaroxaban-LF), Devit 50000 analogue (D3-CAPS), pediatric doses of Oseltamivir (Flucaps) and domestic low molecular weight heparin Enoxaparin-Belmed. Negotiations are underway to organize production at the facilities of Belpharmprom Holding of drugs used to treat COVID-19 (analogues of Molnupinavir and Paxlovid) as well.

Among the new drugs are the local drug Ambrocar for chronic respiratory diseases therapy in the form of an inhalation solution, the first Belarusian generics: Glinor for treatment of diabetes, Flualor for treatment of throat and laryngeal diseases, as well as demanded on the market woundhealing agent Panthenol-Belmed in the form of cream for external use, eye drops Tropicamide used in ophthalmology for vision diagnosis, Citicoline, a drug for treatment of neurological and cognitive disorders, Acezon 600, powder for treatment of respiratory diseases accompanied by formation of difficult to release phlegm, etc.

The quality of produced medicines and compliance of production with the most stringent international standards has become a business card of domestic manufacturers. All production sites are certified for compliance with Good Manufacturing Practices (GMP), and some sites with exportoriented products are certified for compliance with GMP of the EAEC and PIC/S countries.

Another promising area of development is the production of pharmaceutical substances necessary for the reproduction of highly effective modern generics. The Institute of Bioorganic Chemistry of the National Academy of Sciences of Belarus has developed technologies for synthesis of drug substances, including those with high antitumor and antiviral activity (leucladin, zamitsit, fludarabel, alamine, cytarabine, thioguanine, cyclocytidine, phosphaden, sodium levothyroxine) and hemosorbents (ovosorb, antiglobulin E, liposorb, nucleosorb), BAA phytonol.





#### 4.2. Production and consumption of pharmaceutical products

The industrial production of drugs is currently carried out by about 40 organizations. As of 2022, 4304 drugs have been registered. The volume of the pharmaceutical market is estimated at about 760.7 million U.S. dollars. The volume of industrial production of pharmaceutical products in 2021 is 765.5 million dollars.

A total of 5.6 thousand names of medicines and pharmaceutical substances are registered in the country, of which 1686 are of domestic production: 1578 names — generic, 86 — original and 22 — innovative. Organizations-participants of Belpharmprom Holding have registered 745 medicines: generic — 692, original — 45, innovative — 6, biosimilars — 2. They belong to different pharmacotherapeutic groups: anticancer drugs, drugs for treatment of cardiovascular diseases, antifungal, antiviral and antibacterial, as well as for treatment of diseases of the musculoskeletal system, digestive tract and metabolism. Most of the companies have certificates for compliance with GMP-EAEC regulations, work is underway to obtain certificates for GMP of the European Union, and innovative drugs are actively being developed. The volume of innovative products shipped in 2021 was \$174.2 million, which is 24% higher than in 2020 and 57% higher than in 2019. At the same time, the share of shipped innovative products in the total volume of shipped products increased from 19.6% in 2019 to 25.4% in 2021.

Currently, over 50% of drugs in our country are domestically produced, 73% are imported raw materials, and 27% are domestically produced raw materials.

If we consider the production of individual pharmaceuticals, the picture is as follows.

| Indicator   | 2017   | 2018   | 2019   | 2020   | 2021   |
|---|--------|--------|--------|--------|--------|
| Drugs containing penicillin or other antibiotics  | 131.13 | 125.93 | 143.44 | 150.96 | 151.95 |
| Drugs containing hormones but not antibiotics   | 18.42  | 15.90  | 12.53  | 16.52  | 17.14  |
| Drugs containing alkaloids or their derivatives,<br>vitamins, other drugs containing mixed and<br>unmixed products, but not containing hormones<br>or antibiotics | 415.60 | 445.70 | 469.16 | 469.25 | 524.11 |

Production of specific types of pharmaceutical products, mln USD

The largest volume of production falls on Drugs containing alkaloids or their derivatives, vitamins, pharmaceuticals other containing mixed and unmixed products, but not containing hormones or antibiotics - \$524.11 million. They occupy 68.47% of the total production of pharmaceutical products in the country.

In 2021, consumption (sales) of pharmaceutical products was \$862.6 million, of which \$810.4 million were drugs (93.94%) and the rest were veterinary drugs. In 2020, pharmaceutical sales were \$745.1 million and drug sales were \$693.1 million (93.02%). Annual sales growth for pharmaceutical products was 15.78% and for drugs was 16.92%. Stocks of pharmaceutical products and drugs were \$80.44 million in 2020 and \$90.05 million in 2021 (11.95% growth). The share of health care spending from 2020 to 2022 averages 6-6.5%.

The leading drugs in the consumption structure in Belarus, as in the world practice, are cardiovascular drugs, antibiotics, chemotherapeutic drugs and a number of others. Per capita consumption of medicines in Belarus is the highest compared to CIS countries and is second only to Russia.

# Top 10 most demanded drugs produced by Belpharmprom companies:

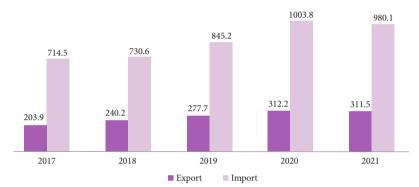
- 1. Analgesics;
- 2. Anti-inflammatory and anti-rheumatic drugs;
- 3. Drugs to treat anemia;
- 4. Plasma exchange and perfusion solutions;
- 5. Psycholeptics;
- 6. Antimicrobials for systemic use;
- 7. Psychostimulants;
- 8. Antiseptics and disinfectants;

9. Other drugs for the treatment of diseases of the nervous system;

10. Antidiarrheals, intestinal anti-inflammatory and antimicrobial drugs.

## 4.3. Foreign trade

Foreign trade in pharmaceutical products is reflected in Group 30 of the Commodity Nomenclature of Foreign Economic Activities. These are codes 3002 Vaccines, blood serums, blood; 3003 Drugs of two or more components, not packaged for retail sale; 3004 Drugs packaged for retail sale. Exports and imports of pharmaceutical products for the period 2017-2021 are as follows.



#### Foreign trade of pharmaceutical products, mln USD

Thus, in the pharmaceutical industry, imports exceed exports by an average of 3 times.

Let's consider import and export by HS codes (all values of import and export in thousand USD).

#### Export of pharmaceutical products according to HS codes, thousand USD

|      | HS Code 3002: Human blood;<br>animal blood prepared for<br>therapeutic, prophylactic or<br>diagnostic uses. | HS Code 3003: Medicaments<br>consisting of two or more<br>constituents mixed together for<br>therapeutic or prophylactic uses,<br>not in measured doses or put up for<br>retail sale | HS Code 3004:<br>Medicaments consisting<br>of mixed or unmixed<br>products for therapeutic or<br>prophylactic uses, put up in<br>measured doses or in forms<br>or packings for retail sale. |
|------|---|--|---|
| 2017 | 6 255.8   | 379.5  | 188 597.0   |
| 2018 | 15 929.9  | 168.6  | 213 960.7   |
| 2019 | 13 252.7  | 196.3  | 255 459.0   |
| 2020 | 20 105.3  | 151.2  | 283 981.7   |
| 2021 | 25 081.3  | 326.3  | 278 203.3   |

Thus, the main export position of the domestic pharmaceutical industry is medicines packaged for retail sale. For the period from 2017 to 2021, products worth \$1,302 million were exported, of which medicines packaged for retail sale accounted for 93.71%. In 2021, their share was 91.63%.

HS Code 3004: HS Code 3003: Medicaments Medicaments consisting HS Code 3002: Human blood; consisting of two or more of mixed or unmixed animal blood prepared for constituents mixed together for products for therapeutic or therapeutic, prophylactic or therapeutic or prophylactic uses, prophylactic uses, put up in not in measured doses or put up for diagnostic uses measured doses or in forms retail sale or packings for retail sale 29 068.2 2017 161 846.0 473 443.4 2018 175 469.3 27 137.6 472 685.4 2019 189 198.2 32 237.3 563 873.5 2020 341 995.5 34 112.1 571 021.0 2021 328 312.3 15 318.3 569 103.1

Import of pharmaceutical products by HS codes, thousand USD

Thus, the main import item is also medicines packaged for retail sale. For the period from 2017 to 2021, products worth about

\$3,985 million were imported, of which medicines packaged for retail sale accounted for 66.51%. In 2021, their share was 62.35%.

Foreign trade of pharmaceutical products by HS codes, 2017-2021

| HS code | Description   | Export, thousand US<br>dollars | Import, thousand US<br>dollars | Excess of imports<br>over exports |
|---------|---|--------------------------------|--------------------------------|-----------------------------------|
| 3002    | Human blood; animal blood<br>prepared for therapeutic,<br>prophylactic or diagnostic<br>uses  | 80 625.0                       | 1 196 821.3                    | 14.84                             |
| 3003    | Medicaments consisting of<br>two or more constituents<br>mixed together for<br>therapeutic or prophylactic<br>uses, not in measured doses<br>or put up for retail sale    | 1 221.9                        | 137 873.5                      | 112.84                            |
| 3004    | Medicaments consisting<br>of mixed or unmixed<br>products for therapeutic or<br>prophylactic uses, put up in<br>measured doses or in forms<br>or packings for retail sale | 1 220 201.7                    | 2 650 126.4                    | 2.17                              |



During the period from 2017 to 2021, pharmaceutical products were exported to 67 countries. The following countries are in the top 10 countries in terms of exports. For the period from 2017 to 2021, pharmaceutical products were imported from 87 countries. The following countries are in the top 10 countries in terms of imports.

| Country      | Export,<br>thousand US<br>dollars | Share,% |
|--------------|-----------------------------------|---------|
| Russia       | 240 059.9                         | 79.1    |
| Kazakhstan   | 15 605.0                          | 5.1     |
| Uzbekistan   | 10 534.9                          | 3.47    |
| Azerbaijan   | 6 219.4                           | 2.0     |
| Moldova      | 5 185.4                           | 1.7     |
| Ukraine      | 5 004.3                           | 1.6     |
| Kyrgyzstan   | 4 416.8                           | 1.5     |
| Georgia      | 3 836.0                           | 1.3     |
| Armenia      | 2 321.1                           | 0.8     |
| Turkmenistan | 1 614.6                           | 0.5     |

Top 10 countries for the export of pharmaceutical products in 2021

#### Top 10 countries for exports by code 3002

| Country        | Export,<br>thousand US<br>dollars | Share,% |
|----------------|-----------------------------------|---------|
| Russia         | 62 446.4                          | 77.5    |
| Uzbekistan     | 13 026.8                          | 16.2    |
| Kazakhstan     | 2 147.8                           | 2.7     |
| Ukraine        | 1 000.3                           | 1.2     |
| Netherlands    | 577.2                             | 0.7     |
| United Kingdom | 344.7                             | 0.4     |
| Lithuania      | 240.1                             | 0.3     |
| Czech Republic | 203.7                             | 0.3     |
| Kyrgyzstan     | 149.8                             | 0.2     |
| Georgia        | 147.1                             | 0.2     |

| Country  | Импорт, тыс.<br>долл. США | Share,% |
|----------|---------------------------|---------|
| Russia   | 159 248.3                 | 17.5    |
| Germany  | 144 436.9                 | 15.8    |
| France   | 60 713.9                  | 6.7     |
| India    | 51 353.6                  | 5.6     |
| Slovenia | 42 497.5                  | 4.7     |
| Italy    | 41 985.9                  | 4.6     |
| USA      | 33 273.9                  | 3.6     |
| China    | 32 050.9                  | 3.5     |
| Hungary  | 30 089.1                  | 3.3     |
| Poland   | 25 045.9                  | 2.7     |

## Top 10 countries for the import of pharmaceutical products in 2021

#### Top 10 countries for imports by code 3002

| Country     | Import,<br>thousand US<br>dollars | Share,% |
|-------------|-----------------------------------|---------|
| Russia      | 242 774.0                         | 20.3    |
| Germany     | 128 703.4                         | 10.8    |
| USA         | 122 694.9                         | 10.3    |
| Poland      | 90 960.1                          | 7.6     |
| Netherlands | 75 401.8                          | 6.3     |
| Italy       | 64 425.3                          | 5.4     |
| France      | 58 952.2                          | 4.9     |
| Estonia     | 43 912.9                          | 3.7     |
| Austria     | 43 794.2                          | 3.7     |
| Denmark     | 42 976.6                          | 3.6     |

## Top 10 countries for exports by code 3003

| Country     | Export,<br>thousand US<br>dollars | Share,% |
|-------------|-----------------------------------|---------|
| Russia      | 1 169.6                           | 95.7    |
| Kazakhstan  | 39.1                              | 3.2     |
| Switzerland | 13.2                              | 1.1     |



## Top 10 countries for exports by code 3004

| Country           | Export,<br>thousand US<br>dollars | Share,% |
|-------------------|-----------------------------------|---------|
| Russia            | 946 172.2                         | 77.5    |
| Kazakhstan        | 82 750.0                          | 6.8     |
| Azerbaijan        | 28 485.0                          | 2.3     |
| Uzbekistan        | 24 911.4                          | 2.0     |
| Ukraine           | 19 767.0                          | 1.6     |
| Kyrgyzstan        | 16 889.1                          | 1.4     |
| Moldova, Republic | 15 677.8                          | 1.3     |
| Georgia           | 15 016.5                          | 1.2     |
| Romania           | 13 413.0                          | 1.1     |
| Turkmenistan      | 10 183.2                          | 0.8     |

## Top 10 countries for imports by code 3003

| Country         | Import,<br>thousand US<br>dollars | Share,% |
|-----------------|-----------------------------------|---------|
| Russia          | 63 420.8                          | 46.0    |
| India           | 62 761.2                          | 45.5    |
| China           | 6 667.3                           | 4.8     |
| Mexico          | 1 747.7                           | 1.3     |
| Algeria         | 1 619.1                           | 1.2     |
| Ukraine         | 663.5                             | 0.5     |
| Korea, Republic | 584.4                             | 0.4     |
| Belgium         | 201.3                             | 0.1     |
| Slovenia        | 78.0                              | 0.06    |
| Germany         | 54.4                              | 0.04    |

## Top 10 countries for imports by code 3004

| Country  | Import,<br>thousand US<br>dollars | Share,% |
|----------|-----------------------------------|---------|
| Germany  | 412 756.0                         | 15.6    |
| Russia   | 293 250.7                         | 11.1    |
| France   | 198 696.5                         | 7.5     |
| India    | 163 803.6                         | 6.2     |
| Slovenia | 154 327.7                         | 5.8     |
| Hungary  | 133 658.3                         | 5.0     |
| Poland   | 131 003.2                         | 4.9     |
| Italy    | 109 603.0                         | 4.1     |
| Ukraine  | 97 788.1                          | 3.7     |
| Latvia   | 77 783.4                          | 2.9     |

#### 4.4. Key players

Belmedpreparaty RUE is the largest pharmaceutical company in the country. Belmedpreparaty RUE has a number of unique productions and is the only Belarusian manufacturer of insulin, enzyme and biogenic drugs, drugs for treatment of oncological diseases and tuberculosis, narcotic and psychotropic drugs. In general, the company is a multi-stage production based on knowledge-intensive technologies, producing more than 350 types of medicines.

OJSC Borisov Medical Preparations Plant (BZMP, Borimed) is the largest manufacturer and exporter of broad-spectrum pharmaceuticals in the Republic of Belarus. BZMP produces more than 250 items of medicines of 12 pharmacotherapeutic groups. The annual output is over 5 billion tablets, over 200 million capsules, over 15 million packages of ointments, over 15 million vials of tinctures and solutions, 300 million ampoules of injectable solutions, 50.0 million vials of antibiotics. More than 50% of production is exported annually

Minskinterkaps UE is a leader in the domestic pharmaceutical industry in the production of pharmaceuticals in hard and soft gelatin capsules. The assortment of the company is annually replenished with new drugs, about 95% of which are produced under the import substitution programme and are generics of original brands. In 2021, Minskinterkaps UE was registered as a resident of the Minsk Free Economic Zone. Belarusian-Bulgarian "Lekfarm" JLLC is a modern enterprise in the development, production and sale of pharmaceuticals. The main focus of development and production are drugs affecting the cardiovascular system. The company also produces drugs for the treatment of musculoskeletal system, nervous system, general pain relief, treatment of the gastrointestinal tract, anti-cold and vitamin-mineral complexes. The company has 150 national registration certificates. Given all the dosages produced, the company produces 197 medicinal products.

Belarusian-Dutch Farmland JLLC. Currently, the company is one of the leaders in the Belarusian pharmaceutical market in terms of production and sales of pharmaceuticals, solutions and medical devices. It conducts the full cycle of drug development: from molecule search to mass production and marketing. The company focuses on drugs for the treatment of cardiac, neurological and infectious diseases, and conducts research in the field of oncological, immunocompetent and other socially relevant diseases. The company has 130 national registration certificates and 20 foreign registration certificates.

Nesvizh Medical Preparations Plant is the largest producer of infusion drugs in Belarus. The plant is the main supplier of infusion and injection drugs.



Ekzon RUE. Exon produces pharmaceuticals in tablets, powders, granules, capsules, syrups and haematogen. The plant is active in packaging products of foreign manufacturers for the Belarusian market.

JLLC "Nativita" currently ranks among the top 3 companies on the hospital market in Belarus and is the No. 1 company in the oncology segment. The company's portfolio includes more than 20 registered medicines for the treatment of oncological, autoimmune and other diseases.. NatiVita initiated the creation of the first pharmaceutical cluster in the Republic of Belarus: the Medicine and Pharmaceuticals - Innovative Projects Union.

**Rubicon Ltd.** The priority area of soft dosage forms production is the development and production of suppositories. The main area of development of solid dosage forms production is tablet production. More than 20 names of generic and original medicinal products are in development. Currently, more than 80 different names and forms of pharmaceuticals and medical devices are being produced.

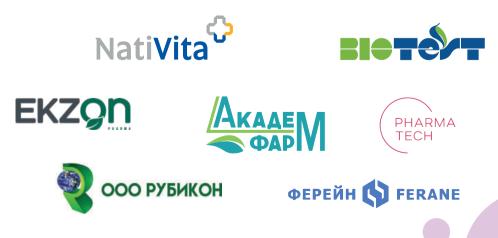
**Biotest RPC**. One of the first private pharmaceutical companies in the Republic of Belarus. The main activity of the company is production of medicines and biologically active supplements. It also produces tea drinks (phyto teas, herbal teas). The assortment list of products contains

over 65 medicines, 24 kinds of biologically active additives and 30 names of tea drinks.

ACADEMPHARM RPUE is a dynamically developing knowledge-intensive state pharmaceutical enterprise. The main activities are: laboratory pharmaceutical research; industrial production of pharmaceuticals and other pharmaceutical products, vitamin, vitamin-mineral and metabolic complexes, nutraceuticals; contract pharmaceutical production. The company's assortment of mastered medicines consists of more than 40 products of various pharmacotherapeutic groups.

Ferane Joint Stock Company. Ha The company produces about 50 types of medicines and dietary supplements used for treatment and prevention of cardiovascular, infectious, gastrointestinal and other diseases. Increased capacity for the production of medicines included in the clinical protocols for the treatment of COVID-19 coronavirus infection.

**Pharmatech Joint Stock Company** is a modern pharmaceutical company, whose main focus is the production of pharmaceuticals, dietary supplements, specialised products, and the provision of contract manufacturing services. In 2013, the company was the first in the Republic of Belarus to start production of antiretroviral medicines for HIV therapy.



## 5. Investment potential and prospects for the development of the industry

#### 5.1. Investments and investment attractiveness of the industry

On August 30, the President of the Republic of Belarus signed Decree No. 327 aimed at further development of the pharmaceutical industry; creation of new pharmaceutical production facilities; increasing the output of pharmaceuticals and increasing their export. More than 20 investment projects are planned to be implemented at pharmaceutical companies until 2030, about 300 names of medicines will be developed.

In accordance with the Decree, pharmaceutical organizations may receive subsidies for:

• reimbursement in 2022–2030 of part of the interest for using loans received under the guarantees of the Government of the Republic of Belarus for the implementation of investment projects for the creation, technical re-equipment and reconstruction of production facilities aimed at creating new production facilities and (or) expanding the range of medicines;

• compensation in 2022-2025 of part of the costs related to:

— the conduct of preclinical (non-clinical) studies and clinical studies (trials), as well as the performance of work on the examination and registration (confirmation of registration) of medicines, bringing registration dossiers in line with the requirements of the EAEU;

 obtaining certificates of conformity with the requirements of the Rules of Good Manufacturing Practice of the EAEU; - the inspection and certification of the production of medicines for compliance with international requirements of good manufacturing practice.

The procedure and conditions for the provision of these subsidies are determined by the Council of Ministers.

In addition, the Decree provides for the exemption of manufacturers of pharmaceutical products from paying VAT and customs duties in relation to technological equipment, components and spare parts for it, raw materials and materials imported into the territory of Belarus for exclusive use in the country, in order to implement certain investment projects.

The following investment projects received subsidies under Decree No. 327:

 creation of a modern automated production of anticancer drugs in the form of freeze-dried powders, concentrates and solutions for injections;

 construction of a building to accommodate storage facilities and production of nonsterile medicines at a production site in Lida;

 creation of production of medicines in the form of eye drops using BFS technology;

- creation of pilot production of solid dosage forms using innovative technologies.

## 5.2. Export potential and prospects for the development of the industry

The pharmaceutical industry of Belarus has a serious scientific and, along with this, export potential. Export deliveries were made to 67 countries of the world, the holding's participants exported to 34 countries. The structure of exports is dominated by the Russian Federation, Azerbaijan, Ukraine and Uzbekistan.

The program of socio-economic development of the Republic of Belarus for 2021-2025 (approved by Decree of the President of the Republic of Belarus dated July 29, 2021 No. 292) predicts a 2-fold increase in exports of pharmaceutical products over a five-year period.

The driving forces behind this development are industrial parks, mainly Great Stone and Bremino-Orsha, attracting investments for the development of traditional and innovative Chinese medicine and pharmaceuticals (in particular Great Stone), as well as for the production of pharmaceutical products and preparations. In 2022, Great Stone and Bremino-Orsha received 53 new residents, some of whom will implement projects in the pharmaceutical sector. Most pharmaceutical products are innovative. In 2021, compared to 2020, the volume of innovative pharmaceutical products increased by 29%, while the export of pharmaceutical products increased by 4.5%. The share of exports in the volume of production amounted to 28.3%.

Certification of industrial production of drugs and pharmaceutical substances for compliance with good manufacturing practices (GMP) of the Republic of Belarus, the European Union (EU), PIC/S, FDA (USA) is being carried out. About 90% of all production sites of the organizations have already been certified. Certificates of compliance with GMP-PIC/S of Ukraine and GMP-EU of Romania were obtained to develop the export potential. The export strategy of Belarusian pharmaceutical organizations provides access to the markets of South-East Asia, Latin America, the Persian Gulf and developing countries of Africa, which are comparable with the EAEU requirements in terms of regulatory requirements. These regions are among the markets with the most positive dynamics of annual growth in consumption of medicines and increase in public spending on health care. This direction will be facilitated by obtaining new registration certificates for Belarusian medicines in foreign authorized bodies.

The main focus in 2021-2025 will be on the countries of Southeast Asia: Vietnam, Cambodia, Laos, Myanmar, and the Philippines. Work on registration of Belarusian medicinal products continues in these countries.

In 2021-2025 it is planned to increase the production of domestic medicines and expand their nomenclature, providing up to 70% of international nonproprietary names of medicines included in the Republican Drug Formulary, and to increase the export of pharmaceutical products by half mainly due to organizations of private ownership. This is the aim of the Comprehensive Program of pharmaceutical industry development for 2021-2025.



Concrete steps have already been taken in this direction. The Belarusian Ministry of Health has signed a cooperation agreement with the Chinese pharmaceutical company North China Pharmaceutical Company Limited (NCPC), which will supply substances and raw materials for the production of drugs to the organizations of Belpharmprom Holding. Now the Chinese company cooperates with Belmedpreparaty and Ferane companies. The Chinese corporation Sinopharm was also invited to discuss projects for localization of drug production in Belarus and the creation of a joint venture.

A significant moment in the development of the domestic pharmaceutical industry is the formation of a common market of pharmaceutical products of the EAEU. This will increase the competitive advantages of pharmaceutical products manufactured in the Union and strengthen the export potential of domestic companies.

## 6. Investment climate

#### 6.1. Macro indicators by country

In general, the main macroeconomic indicators have a positive trend.

Thus, GDP for 2021 at current prices amounted to 68.23 billion dollars. In comparable prices, GDP grew bv 2.3% compared to 2020 and 6.1% compared to 2015.

Labor productivity, respectively, amounted to 3.2% compared to 2020 and increased by 11.5% since 2015.

The growth of industrial output in 2021 compared to 2020 amounted to 6.5%, compared to 2015 - 19.3%.

The growth of real wages in 2021 compared to 2020 amounted to 4.4%, compared to 2015 - 40.8%.

The growth in exports of goods in 2021 compared to 2020 amounted to 32.5%, compared to 2015-49.9%.

In 2021, the inflow of foreign investments into the economy of the Republic of Belarus amounted to 8.7 billion USD, of which 75.39% are direct, 0.05% are portfolio, 24.56% are other foreign investments. Foreign direct investment on a net basis (excluding debt to a direct investor for goods, works, services) amounted to 15.26%.



#### 6.2. Preferential regimes

#### General guarantees

Belarusian legislation provides the following basic guarantees to investors:

- the right of private property and its protection without discrimination
- protection against illegal actions of state bodies, which violate rights of investors and/or cause losses
- equality of rights for national and foreign investors
- free repatriation of profits
- protection of investments against nationalization and requisitioning

By law, nationalization can only be carried out on the basis of public necessity and subject to appropriate compensation. Compensation for nationalized property must be paid in a timely manner and include the value of the nationalized property and other losses caused by nationalization. The legislation also establishes a number of circumstances under which requisitioning is possible. These are mainly emergencies such as natural disasters, accidents, epidemics and epizootics, as well as when the public interest requires these measures.

#### Investment agreement

- VAT deduction in full amount
- exemption from import duties and taxes on import of technological equipment, raw materials and materials into the territory of the Republic of Belarus
- exemption from reimbursement of losses in forestry and agricultural production

# Small and medium-size cities, rural territories

- exemption from income tax for 7 years
- exemption from real estate tax for 7 years
- exemption from import customs duties on imported (imported) goods contributed to the statutory fund, from the date of manufacture of which not more than 5 years have passed for some commodity items
- exemption from profit tax in the part of profit received from sale of goods of own production; exemption from income tax for 7 years

#### Bremino-Orsha

- 0% VAT and duty on customs
- 0% corporate tax for 9 years
- 0% property tax for 20 years
- 0% VAT for 15 years at realization, rent (leasing) to residents of real estate objects till 1 January 2033
- 0% income tax, tax on dividends and similar income for 5 years from the announcement of profits (for the founders of resident companies and joint ventures)
- 0% tax on dividends and similar income from the date of declaration of profits up to 1 January 2033 (for joint ventures if accrued from a management company)
- 5% on royalties until January 1, 2028

#### Industrial park «Great Stone»

- exemption from income tax on revenue from the sale of goods (works, services) of own production within ten years from the date of registration as residents
- exemption from property tax on properties
- exemption from tax on land plots
- until 1 January 2027, the income tax rate is 9%
- full deduction of VAT amounts charged for imported goods (works, services) as well as property rights used in designing, construction and equipping of buildings and structures in the Industrial Park
- exemption from customs duties and VAT on goods (production equipment, components and spare parts, materials and raw materials) imported to Belarus for the implementation of investment projects

#### Free economic zones (FEZ)

- exemption from profit tax when selling products for export and to other FEZ residents
- exemption from real estate tax on properties in FEZ within three years of registration
- exemption from land tax and land lease for the period of design and construction, but for no longer than 5 years from the date of registration. Exemption irrespective of the direction of their use (if sold for export or to other FEZ residents)

 exemption from payment for the right to conclude a land plot lease agreement The choice of preferential treatment will depend on a number of factors and components of the investment project, such as the need to create infrastructure facilities, export orientation of the project, implementation of innovative technologies and many others.

More detailed information about the business environment, investment opportunities in the Republic of Belarus can be found on the website of the National Agency of Investment and Privatization of the Republic of Belarus at www.investinbelarus. by/en/business-environment, as well as to get necessary advice and assistance in implementation of the investment project in Belarus by contacting representatives of the Agency at the contacts specified on the website www.investinbelarus.by/en/contacts.

## 7. Investment projects for implementation in the Republic of Belarus

#### "CREATION OF A NEW PRODUCTION OF SOLID DOSAGE FORMS"

Implementation place: Minsk region, Borisov The current stage of the project: development of project documentation Years of project implementation: 2021 – 2029 Total investment: \$49.7 million Expected investor contribution: \$20 million

**Project Description:** within the framework of the project, it is planned to build a new workshop for the production of solid dosage forms with a capacity of 1,336 million tablets per year in accordance with GMP requirements. The created capacities will allow expanding the range of produced import-substituting drugs for the domestic market and for the markets of foreign countries.

#### "DEVELOPMENT OF PRODUCTION OF DRUGS", UE "MINSKINTERKAPS"

#### Implementation place: Minsk

The current stage of the project: pre-investment stage has been completed, design and estimate documentation and a business plan for project implementation have been developed Years of project implementation: 2021 – 2025 Total investment: \$8.2 million Expected investor contribution: \$5.1 million

**Project Description:** within the framework of the project, it is planned to organize an additional site for the production of drugs in soft gelatin capsules of small batches with a design capacity of 120 million capsules per year, which will increase production volumes both according to the current nomenclature and the development of a new one.

#### "CREATION OF DRUG PRODUCTION USING BLOW-FILL-SEAL TECHNOLOGY", BELMEDPREPARATY RPC

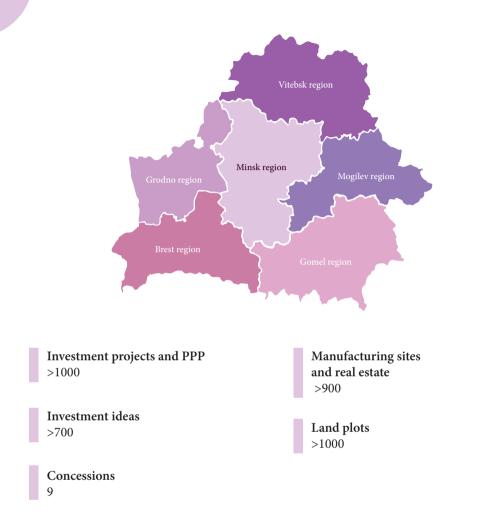
Implementation place: Minsk The current stage of the project: the investment idea was developed Years of project implementation: 2023 – 2027 Total investment: \$19.8 million Expected investor contribution: \$19 million

**Project Description:** the project provides for the creation of the production of medicines in the form of eye drops in polymeric primary packaging, produced using the blow-fill-seal technology. The implementation of the project will increase production volumes and expand the range of eye drops produced.

"CREATION OF PRODUCTION OF MEDICINAL PRODUCTS", JSC "BZMP" Implementation place: Minsk region, Borisov The current stage of the project: the investment idea was developed Years of project implementation: 2026 – 2030 Total investment: \$80 million Expected investor contribution: \$60 million

**Project Description:** the project involves the construction of a new production building for the production of drugs based on monoclonal antibodies that meet GMP requirements. There is a land plot with an area of 8.3819 hectares for the implementation of the project.

## 7.1. Investor Roadmap





More investment projects and ideas, as well as land plots and real estate objects for the implementation of investment projects can be found on the interactive portal «Investor's Roadmap»

## National Agency of Investment and Privatization

The Agency is a state institution that provides assistance at no cost or foreign investors interested in launching a business in Belarus:

- provision of information about investment opportunities, preferential regimes and benefits granted, economic sectors and legislation
- provision of up-to-date information about investment projects
- assistance in selection of sites and premises
- search for prospective partners for investment projects, arranging meetings and negotiations for establishing cooperation

- providing a platform for negotiations and support during negotiations
- organization of visits to the Republic of Belarus (schedule development, visa support)
- representation of investor's interests during negotiations with governmental representatives concerning implementation of investment projects, as well as improvement of investment climate in the Republic of Belarus
- aftercare

#### Follow us: /investinbelarus



mail@investinbelarus.by www.investinbelarus.by +375 17 200 81 75 +375 17 226 41 66



36