# BELARUSIAN PHARMACEUTICAL MARKET

BUSINESS GUIDE

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NATIONAL AGENCY
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REPUBLIC OF BELARUS

# CONTENTS

# BELARUSIAN PHARMACEUTICAL MARKET

In the formation of the EAEU single pharmaceutical market, the investment potential of the Belarusian pharmaceutical market is not fully realized. The production of medicines is mainly represented by the state pharmaceutical companies. They account for 70% -75% of the production of medicines.

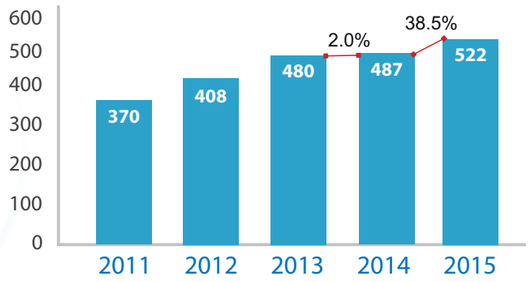
## 1. The Belarusian pharmaceutical market has a positive dynamics of development

The capacity of the Belarusian pharmaceutical market was more than 1 bn US dollars in 2014 (+ 5.6% as compared with 2013).

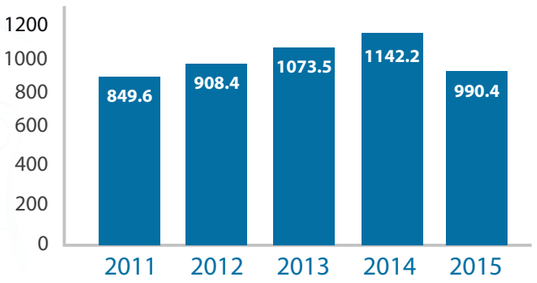
In general, over the last eight years a positive trend in the Belarusian pharmaceutical market can be observed; thus, the market has been growing by 13% annually, significantly outpacing the GDP growth rate (the pharmaceutical market downturn of 2011 in monetary terms happened due to the situation in the country's foreign exchange market).

The production of pharmaceutical products, as well as the pharmaceutical market has a positive dynamics: over the last four years the production has increased by 32% to 487 million US dollars. Positive dynamics in the production was also observed in 2015; the production increased by 38.5% as compared with 2014.

**Production of pharmaceutical products in Belarus, USD mln**

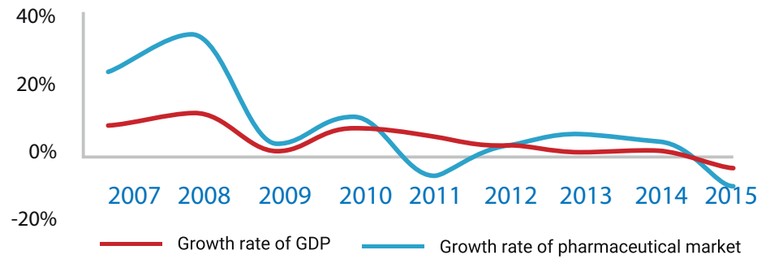



**Capacity of the Belarusian pharmaceutical market, USD mln**





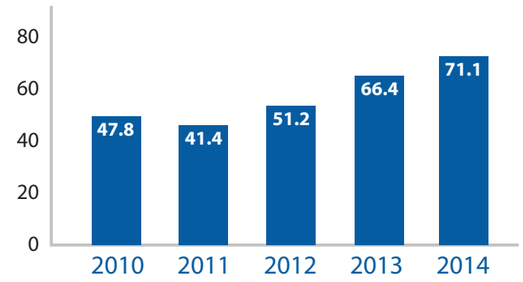

**Pharmaceutical market growth rate**




Currently, the Belarusian pharmaceutical market has registered about five thousand titles of medicines, and the number of medicines produced in Belarus is 1.4 thousand, or 28.5% (in 2008, the amount of medicines produced in Belarus was 550 titles).

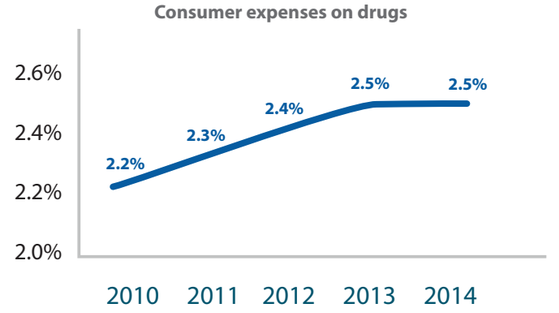
Pharmaceutical expenditure per capita in Belarus grew by 10% annually and amounted to just over 71 US dollars in 2014.

**Pharmaceutical expenditure per capita in Belarus**




Along with pharmaceutical expenditure per capita, general consumer expenses on drugs have been growing as well. Over the last five years it has increased from 2.2% to 2.5%.

**Consumer expenses on drugs**

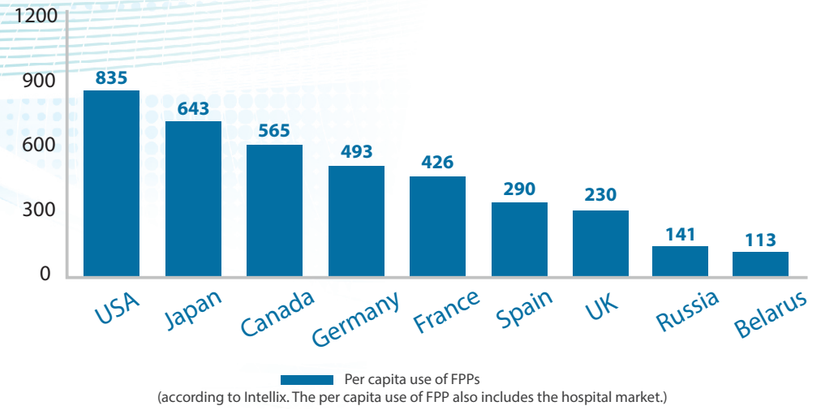


Per capita consumption of medicines has almost doubled in monetary terms over the last five years (average annual growth rate amounted to 12%). However, that figure changed little in 2014 as compared with the previous year and amounted to about 113 US dollars.

**Per capita consumption of medicines in Belarus is about 113 US dollars**

Per capita consumption of medicines in Belarus is rather high in comparison with the CIS countries an is second only to the Russian Federation (the consumption level in Kazakhstan and Azerbaijan is 60-70 US dollars).

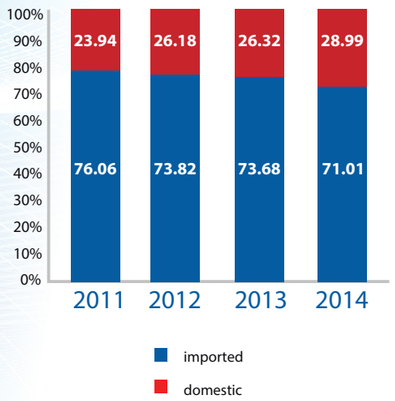
At the same time, the use of medicines in Belarus is significantly inferior to developed European countries and the United States (twice or even more).




## 2. Along with investment in its own production, the state is taking administrative measures against high import

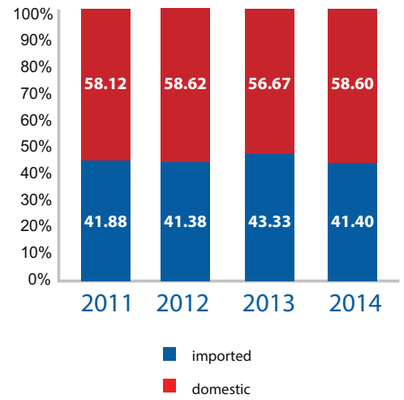
The Belarusian pharmaceutical market (in monetary terms) is always characterized by a high percentage of imported drugs. Thus, according to Intellix, import manufacturers occupied more than 76% of themarket in 2010.

**Share of imported and domestic drugs (in value terms, %)**



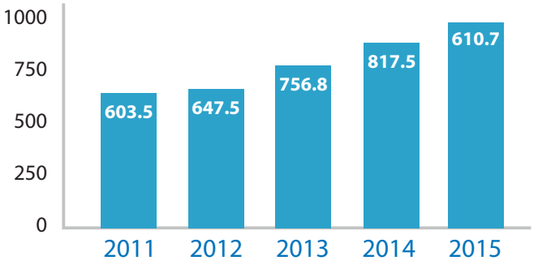



**Share of imported and domestic drugs (in physical terms, %)**




Belarus imported pharmaceutical products worth 610.7 million US dollars in 2015, including medicines worth 405.1 million US dollars. The average annual growth rate of imports in 2004-2014 amounted to 14%, but it dropped by 25.3 % in 2015.

**Imports of pharmaceutical products to Belarus, USD mln**




The geographical structure of imports is quite diversified. Thus, the following countries occupy the largest shares: Germany (11.8%), Russia (11.3%), India (6.6%), USA (6.5%), France (6.2%), Hungary (5.5%), Italy (4.5%) and Austria (4.2%). In order to reduce dependence on import and increase domestic production, the Republic of Belarus adopted the “State Program on development of import-substituting production of pharmaceutical substances, finished drugs and diagnostic tools for 2010 2014 and for the period until 2020”. According to this program, the share of domestic drugs in the Belarusian pharmaceutical market should have reached 50% in value terms by the end of 2015. It should be noted that the domestic drugs captured 52.6 % of the market in physical terms in 2015.

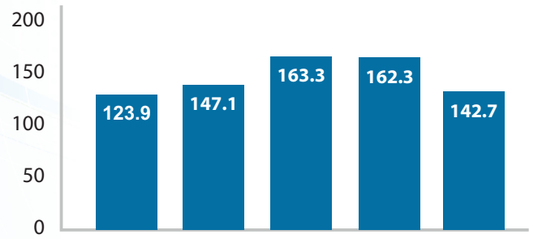
Implementation of the program for import substitution of the pharmaceutical industry depends largely on the raw materials and active pharmaceutical ingredients that are needed for medicine production, but that are not produced in Belarus. Thus, about 60 substances are synthesized in the country for medicine production and more than 800 substances are imported (2012 data). Generally, substances are bought in countries with a significant competitive advantage of the production costs, namely India, Pakistan and China.

Since the production of substances is very expensive and based on the scale effect, and also has a low marginality, it is more appropriate to produce finished pharmaceutical products (FPPs) in Belarus.

## 3. Export potential

Exports of pharmaceutical products amounted to more than 142.7 million US dollars in 2015, decreased by 12.1% in relation to 2014.

**Exports of pharmaceutical products from Belarus, USD mln**




According to the data of 2015, the decline was observed in both exports and imports of pharmaceutical products. Thus, exports decreased by 12.1%, imports decreased by 25.3%. The geographical structure of exports reflects the impact of the EAEU countries (85.8% of the products are exported to the EAEU countries). More than 90% of export products are accounted for the CIS countries.

The mass segment and low prices are the main competitive advantages of Belarusian medicines producers.

The main share of Belarusian exports goes to state-owned companies (90%). Exports account for 48% of total sales at Republican Unitary Enterprise Belmedpreparaty, and 53% of total sales at OJSC Borimed.

Absence of the GMP international standard certificate in the majority of Belarusian enterprises does not allow them to deliver their products to regulated markets (including the EU, USA). Currently, only a few shops of Belmedpreparaty, as well as a number of private companies have these certificates.

Compulsory licensing of any imported medicine was introduced in Ukraine on March 1, 2013. One of the licensing demands is conformity of production with the GMP requirements. As a result, export of drugs from Belarus to Ukraine almost stopped in 2014. However, when some shops of Belmedpreparaty RUE got the GMP international standard certificates at the end of 2014, the deliveries to Ukraine were resumed but in much smaller volumes.



## 4. Competitive environment

The industrial manufacturing of medicinal products is carried out by nearly three dozen companies, among them – two state owned companies and three companies with the state share over 50%. Private businesses are usually either small or mediumsized companies and occupy a small share in the market.

Currently, 70% -75% of the total industrial production of medicines is provided by state-owned enterprises, 25% to 30% is provided by non-state ones. The largest of the Belarusian State Medicines manufacturers are Belmedpreparaty RUE and Borimed OJSC. Also, there are some other major Belarusianproducers with foreign capital – Lekpharm JLLC ( Bulgaria), JV Pharmland LLC (the Netherlands)).

In 2014, according to the Intellix preliminary data, the share of supply of Belmedpreparaty RUE in the retail and hospital markets was 8.3%, the share of Borimed OJSC was 4.5%, the share of JV Pharmland LLC was about 3%, and the share of Lekpharm JLLC was 3.3%.

However, the downward trends have been observed over the last two years in the share of public enterprises in the total volume of medicine production by 1-3% annually.

In 2014, the combined supply share of five leading foreign brands in the Belarusian market was over 16%, while in physical terms their share amounted to only about 5%.

The Belarusian pharmaceutical market has a strict medicine cost differentiation: domestic producersare low and middle-low segments, f oreign ones belong to an expensive segment. In this regard, the difference in prices is extremely noticeable. If the volume-weighted average price for medicines made by Belarusian producers is 1.36 US dollars (in whole-sale prices), then the average price for medicine of foreign producers is 4.42 US dollars (in wholesale prices). The price difference is more than twice.

Thus, the production of drugs in Belarus is concentrated primarily in public companies. Private business is widely represented in retail and wholesale trade. According to expert estimates, about 75% of medicine imports are controlled by 10 private wholesalers.

State-owned enterprises provide 70% - 75% of the total industrial production of medicines

Currently, international pharmaceutical companies do not have their own production in Belarus.

**The main players of the Belarusian pharmaceutical market**

| Company | Type of ownership | Wholesale in dollars, 2014 (±by 2013)* | Wholesale in USD,%* | Production |
|---|---|---|---|---|
| Belmedpreparaty | State (100%) | 88.25 (+16.3%) | 8.27 | Belmedpreparaty RUE has a number of unique productions and it is a single producer in Belarus of insulin preparations; enzymatic and biogenic preparations; preparations for treatment of oncological diseases and tuberculosis; narcotic and psychotropic preparations. The nomenclatureof produced products is represented by more than 300 names of medicinal products: dextran-based blood substitutes; infusion solutions in flasks; syrups; tinctures and alcoholbased preparations; substances, etc. |
| Borisov PMP | State (99.97%) | 48.48 (+10.4%) | 4.54 | The main specialization of the enterprise is generic production. Borisov Plant of Medical Preparations has injectionsolutions in ampoules and sterilepowder forms, antibiotics, tablet drugs, liquid phytochemical preparations and soft dosage forms, preparations of hard gelatin capsules. |
| Sanofi Aventis | Foreign (France) | 38.33 (+8.4%) | 3.59 | The extensive portfolio of original medicinal products, generics and overthe-counter drugs in the key therapeutic areas (diabetes, oncology, cardiovascular diseases, diseases of central nervous system, internal diseases, thromboses, veterinary medicine, rare diseases) and also vaccines (by Sanofi Pasteur department of vaccines). |
| Novartis | Foreign (Switzerland) | 35.01 (-1.8%) | 3.28 | Over-the-counter drugs (OTC), enteral medical nutrition, baby food andaccessories, energy and youth drinks, pharmaceutical products and substances which are no longer covered by patent protection, goods and services to correct and protect eyesight, goods to protect health of domestic animals and also preserve health and increase productivity of farm livestock. |
| Bayer HelthCare | Foreign (Germany) | 34.16 (+9.53%) | 3.2 | The company unites the global activity of Pharmaceuticals depar tments (pharmaceutical prescription drugs), Consumer Care (over-the-counter drugs), Medical Care (treatment and express diagnostics of diabetes along with injection systems) and Animal Health (animal health). |

* according to Intellix data

## 5. Investment activity

Investment activity in the pharmaceutical industry of Belarus is characterized by the follo-wing features:
- funding for state-owned companies and soft loans for the construction of new plants;
- implementation of individual projects by private investors;
- absence of major international players;
- mainly small and medium investment projects worth up to 50 million US dollars are implemented.

In accordance with the Decree of the President of the Republic of Belarus No.174 as of April 16, 2012 "On Some Measures to Develop the Pharmaceutical Industry", the state support will be provided in the form of concessional financing of five projects of state pharmaceutical com-panies totaling 157 million US dollars, 27 investment projects have been included in the list for exemption from import duties and VAT on imported equipment. In addition, about 40 million US dollars is allocated to state enterprises to acquire intellectual property rights, licenses and register new drugs.

Two large investment projects in the health sector were implemented in Belarus in 2013; in 2014 six investment projects were implemented. In 2013-2014, economic benefits from the implementation of these projects were estimated at 50-70 million US dollars.

Nine investment projects are to be implemented outside Decree No.174 from 2014 to 2017

The following major investment events in the private pharmaceutical sector should be mentioned:
- In May 2014, JV Lekpharm was sold to Rompharm Company (Bulgaria), one of the founders of the company (a 40% stake). The amount of the transaction (transfer of 51% of the shares) was not disclosed.
- In January 2016, in the town Beshenkovichi, Vitebsk region, JV Nativita (Russia, India, Lithuania) is planning to launch the production of the first biotechnology generics (medicine for treatment of cancer, autoimmune diseases and severe infectious diseases). The volume of invest-ment at the first stage amounted to at least 10 million US dollars.

**Key investment projects implemented in Belarus in the pharmaceutical industry in 2015-2017**

| Project description | Implementation Project description stage | Volume of investment |
|---|---|---|
| Establishment of a new production of hard gelatin capsules at Minskintercaps UE USD 6.2 mln (2015) with Baltijos prekybos regionas UAB (Lithuania). | Completion stage | USD 6.2 mln |
| Establishment of sterile antibiotic powder production at Borisov Plant of Medi-cal USD 25 mln Preparations OJSC (2015). | Completion stage | USD 6.2 mln |
| Creation of facilities compliant with GMP international standards for medicines produced at Belmedpreparaty RUE in Lida (2015). | Completion stage | No information |
| Establishment of a plant that produces pharmaceuticals from human blood plasma USD 23 mln (immunoglobulin,albumin, coagulation factors VIII and IX) with a 100 000 processing volume of plasma per year at Pharmland JLLC (2015). | Completion stage | USD 23 mln |
| Establishment of pharmaceutical production in accordance with GMP standards, a USD 15 mln complete cycle. A modern production of the first generic drugs for treatment of diseases, including cancer is to be organized at NATIVITA JLLC in Beshenkovichi. | Completed | USD 23 mln |
| Creation of a pilot plant for production of medicines in the form of transdermal patches at Belmedpreparaty RUE. At the first stage it is planned to develop transdermal patches with narcotic analgesic fentanyl for treatment of oncology patients. | No information | No information |

## 6. Manufacturing pharmaceuticals

Guidelines for manufacturing pharmaceuticals in Belarus are established by the Good Manufacturing Practise (**GMP**) adopted by the Ministry of Healthcare of the Republic of Belarus (**Ministry of Healthcare**).

Pharmaceuticals can be manufactured by legal entities and individual entrepreneurs that hold a pharmaceutical licence issued by the Ministry of Healthcare. The licence issued is perpetual and allows manufacturing and wholesale trade in pharmaceuticals in accordance with GMP and Good Wholesale Practice.

GMP and Good Wholesale Practice are the main cornerstones of manufacturing and wholesale trade in pharmaceuticals in Belarus.

The licence requirements for legal entities cover in particular:

- employing a person responsible for licenced activity, who meets certain requirements, for example, has higher pharmaceutical education and primary employment with the applicant for licence;
- having sufficient and appropriate premises and technical equipment for manufacturing;
- having a nomenclature of pharmaceuticals to be manufactured adjusted with the Ministry of Healthcare.

## 7. Entering the market

Pharmaceuticals can be manufactured, sold and consumed in Belarus after they received a marketing authorisation from the Ministry of Healthcare.

Marketing authorisation is not required in some instances, such as:

- pharmaceuticals manufactured in pharmacies;
- pharmaceuticals intended for use as exhibition samples;
- pharmaceuticals intended for pre-clinical and clinical trials;
- pharmaceuticals imported to Belarus by individuals intended for personal use.

Retail trade in pharmaceuticals can be performed exclusively through pharmacies

The marketing authorisation is issued initially for the term of five years, and then a pharmaceutical may pass confirmation procedure and receive a perpetual marketing authorisation. Before receiving marketing authorisation an applicant shall pass a complex of preliminary technical works, including initial expertise of documents, inspection of the industrial manufacturing for GMP compliance carried out by the Centre for Expertise and Testing in Healthcare (**CETH**) and submit to CETH a registration dossier – a set of documents required for receiving marketing authorisation.

Retail or wholesale trading (without manufacturing) requires a pharmaceutical licence covering trade services. This licence may cover one or several of the following activities:

- preparation of pharmaceuticals in pharmacies;
- pharmaceuticals retail trade;
- pharmaceuticals wholesale trade.

Within Belarus retail trade can be performed exclusively through pharmacies. Requirements for obtaining this licence are similar to those for a manufacturing licence; particular requirements vary depending on the type of the activity planned.



## 8. Clinical trials

Clinical trials are conducted according to Belarusian Good Clinical Practice. It was drafted based on Guideline for Good Clinical Practice of International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use and reflects international standards of conducting clinical trials.

Clinical trials are conducted in state healthcare organisations defined by the Ministry of Healthcare and per latter's authorisation. Trials can be commenced only if pre-trial research has shown that the pharmaceutical is safe and effective and if the risk of side effects is reasonable in the light of the expected positive effects.

The rights of individuals participating in the trial must be protected according to the law. Trial subject shall be informed on various issues of clinical trial, such as its purpose, estimated risks and expected benefits. Trial subject may refuse from participation at any stage. Participation of some individuals is prohibited or subject to limitations (pregnant women, minors, etc).

Agreement on conducting clinical trials is concluded between the sponsor and medical institution. There is a template form of a clinical trials agreement adopted by Belarusian law, which is used as a guidance by Belarusian healthcare organisations. Conclusion of an agreement directly with investigator is not allowed.

Clinical trials involve various participants:

- independent ethics committee (**IEC**) is created to protect rights, safety and well-being of involved individuals by reviewing all aspects of the trial and approving its startup. IEC reviews trial-related materials before and during the trial;
- monitor is appointed by the sponsor and acts as an intermediary between the sponsor and medical institution, overseeing the progress of a clinical trial and ensuring that it is conducted, recorded and reported in appropriate manner;
- investigator may delegate all or some of its duties to a contract research organisation (**CRO**). Quality and completeness of data collected during a trial remains responsibility of an investigator, while CRO ensures and control quality of the trial.

Clinical trials agreement cannot be concluded whith investigator directly

Clinical trials are formalised by a number of documents:

- protocol of clinical trial describes purposes, design, methodology and organisation of the trial and is approved by IEC and the Ministry of Healthcare;
- informed consent testifies that the subject was duly informed on the main aspects of the trial and is signed by the trial subject;
- investigator's brochure is a compilation of the clinical and nonclinical data on the investigational pharmaceutical and is provided to the investigator.

## 9. Marketing pharmaceuticals

Advertising pharmaceuticals and activities of medical representatives are the main ways pharmaceuticals are marketed in Belarus.

Advertising of pharmaceuticals is subject to general and pharma-specific regulations on advertising in Belarus.

General requirements to any advertisement cover, in particular, its form, language, contents and advertiser details. For example, any advertisement shall not contain propaganda of violence and cruelty, guarantee of future effectiveness or income from the activity advertised, shall not use pseudonyms, images or statements of Belarusian citizens without their consent, etc.

Marketing authorisation and Ministry of Healthcare approval are critical for advertising of certain pharmaceuticals

Pharma-specific rules provide that pharmaceuticals advertisements shall indicate that checking PIL/consulting a doctor is required. They also shall be in plain language, avoid scientific definitions and confusing or misleading phrases and shall not guarantee medical effect, contain recommendations of state bodies or provide material benefits for using a pharmaceutical.
As a general rule, a pharmaceutical can be advertised only after approval of the Ministry of Healthcare is obtained and provided there is a respective marketing authorisation. Certain exceptions apply to pharmaceutical advertisements made during clinical trials when the registration is still pending. Advertising of pharmaceuticals released only under prescription (for example, heavy pharmaceuticals) is allowed only in specialised mass media and in places where medical/pharmacist events are held.

The approval for carrying out advertising is obtained via CETH and is valid for one year. There are two main exceptions when the approval is not required:

- target audience is medical stuff/pharmacists and advertising is performed in the places where medical/pharmacist events are held (seminars, exhibitions, conferences);
- advertising is performed in specialised mass media listed by the Ministry of Healthcare (currently, 42 magazines and newspapers).

The requirements towards activities of medical representatives are established by the Instruction on the Order and Terms of Informing Medical and Pharmaceutical Specialists, which entered into force in May 2015.

Informing medical and pharmaceutical specialists can be performed by representatives of pharmaceuticals' manufacturers, who have higher medical or pharmaceutical education and possess knowledge in the sphere of pharmaceuticals' circulation.

Oral presentation and placing information materials are the main forms of informing specialists

Informing can be carried out in two forms. Firstly, in the form of an oral presentation with or without demonstration of informational and other materials regarding a pharmaceutical when holding meetings, conferences, seminars, symposiums and other events defined by the director of the healthcare organisation. Secondly, in the form of placing information materials in the places defined by the director of the healthcare organisation. Healthcare organisations adopt action plans which indicate such events and places.



There are certain restrictions for representatives. In particular, they are prohibited to:

- enter into offices and staff areas of the organisation, except for the offices of the individuals responsible for organisation of informing of doctors;
- attend and/or make presentations on the events that were not defined for informing by the organisation;
- place information materials in the places which were not defined for informing by the organisation;
- provide false or partial information on pharmaceuticals;
- provide pharmaceuticals specimens, prescriptions, advertisement materials;
- run campaigns aimed at boosting interest of doctors/pharmacists to sell or prescribe particular pharmaceuticals.

Information provided by medical representatives shall comply with certain requirements. For example, such information shall indicate the trade name of the pharmaceutical, caution measures, realisation terms, etc.

## 10. Intellectual property

Belarusian law distinguishes between original and generic pharmaceuticals:

- original pharmaceutical differs from previously registered pharmaceuticals with its pharmacologically active substance(s), and its safety and efficacy shall be proven by preclinical and clinical trials;
- generic pharmaceutical contains the same pharmacologically active substance(s) in the same pharmaceutical form as an original pharmaceutical, is equivalent to and therapeutically interchangeable with an original pharmaceutical.

The general term of patent protection under Belarusian law is 20 years. For pharmaceuticals this term may be extended if from the date of applying for patent until the date of obtaining the marketing authorisation more than five years have passed. The extension term is calculated from the date of applying for patent until the date of obtaining marketing authorisation, minus five years.

Original pharmaceuticals are patented for 20 years, as a general rule

If the patent owner is either not using a patent or is using it insufficiently within five years after the patent grant and refuses granting a licence, the interested party may claim issuance of a compulsory licence – essentially, the right to use the patent without the consent of the patent owner. Such claim is reviewed by the Intellectual Property Board of the Supreme Court of Belarus. In case of a positive ruling, the court grants licence and defines the scope of licence, royalty and other relevant terms.

Belarusian law differentiates between international non-proprietary name (INN) and trade name of pharmaceutical. It is not allowed to register a pharmaceutical with the trade name equal to the name of already registered pharmaceutical.

Belarusian law currently does not provide for a specific regulatory data protection establishing a period of exclusivity.[1] Original clinical trials data can rather be protected under general trade secret regulations and confidentiality provisions, which oblige experts examining the registration dossier to keep it confidential.

Experts examining the registration dossier are obliged to keep it confidential

1 Data exclusivity refers to a period of protection of original clinical trials data, which was submitted to prove the efficacy and safety of a brand-name pharmaceutical. During this term generic manufacturers cannot reference such data in their own applications.

## 11. Localisation

Belarusian law does not define "localisation". In practice the process of localisation implies placing in some or another form of manufacturing in Belarus by a company, which previously was solely an importer or did not perform activities in Belarus at all.

Regulation on Classifying the Products as Products of Own Manufacturing sets criteria for recognition of a company as a "manufacturer". Generally, a manufacturer is an entity which performs a number of manufacturing and technological operations, while such operations are executed by its employees, with its materials, at its premises, etc. Currently in bulk packaging of pharmaceuticals is considered to be manufacturing.

Localisation of manufacturing gives a range of advantages, for example:

- possibility to obtain state subsidies aimed at local manufacturers;
- customs advantages (no need to perform customs clearance in case of selling products in Belarus or within the EEU);
- potential access to tax benefits in case of placing manufacturing under special legal regimes (for example, as a resident of free economic zone or under an investment treaty);
- no need to register pharmaceuticals intended solely for export.
- Possible localisation models include:
- brownfield – acquisition of a local manufacturer (share in such manufacturer), establishing a joint venture with a local manufacturer, purchase/rent by a newly established entity of existing site for placing new manufacturing;
- greenfield – creation of manufacturing "from scratch";
- contract manufacturing – conclusion of an agreement with a local manufacturer;
- out-licensing – transfer of licence and know-how to a local manufacturer.

Each localisation model has its pros and cons. For example, brownfield localisation, on the one side, implies risks of investing into an existing company and may entail significant costs for due diligence. On the other side, the local partner has knowledge of local market and its peculiarities, which may be a significant advantage. Contract manufacturing allows relatively prompt launch of manufacturing and relatively easy exit from localisation. At the same time, the foreign investor cannot influence the decision making by the local partner, which may cause inconveniences or even trigger risks in some circumstances.

## 12. Expected launch of EEU single market of pharmaceuticals

2017 is expected to see full-scale launch of a single market of pharmaceuticals in the framework of the EEU, which may be a game changer in the industry. Currently over 30 draft acts have been adopted, establishing EEU rules and principles for movement of pharmaceuticals and covering such issues as registration, clinical trials, inspections, pharmacovigilance, and information exchange.

One of the key features of the single market will be EEU registration procedure, envisaging validity of marketing authorization throughout the EEU. Creation of a supranational registration authority like the FDA or EC is not expected. Registration will remain the domain of the national registration authorities.



Upon launch of single market the applicant will be able to choose between two EEU registration procedures – the consecutive procedure and the simultaneous procedure. Under both procedures the applicant chooses a reference state, where registration activities will mostly be performed, and a recognition state(s), where registration activities will be rather limited.

Under the consecutive procedure, registration is performed in a reference state and then recognition of registration is performed in other member-state(s). Under the simultaneous procedure, registration in a reference state and recognition in other member-state(s) are performed simultaneously.

Registration in a reference state will involve filing the registration dossier and samples of pharmaceutical, examination of documents, laboratory trials and, if necessary, inspection of manufacturing, pharmacovigilance, pre-clinical and clinical trials. Recognition in a recognition state will involve filing the registration dossier and studying the examination report prepared by the reference state.

Marketing authorisation will initially be issued for five years and then, after successful re-registration, for an indefinite period. The five-year term starts from registration in the reference state.

Before expiry of the five-year registration term, the authorisation holder applies for re-registration in all member states where the pharmaceutical is registered. Re-registration is based on risk-benefit assessment of the pharmaceutical by the reference state. If the outcome is positive, an indefinite marketing authorisation is issued.

It is expected that certain transition period will be envisaged, when old registration procedures will still apply. The applicant may choose which procedure to apply – EEU or national – within the next five years (until 31 December 2020). If the national procedure is chosen, the applicant must nevertheless ensure compliance of the pharmaceutical with EEU requirements within the next ten years (until 31 December 2025).

Within next ten years (until 31 December 2025) the authorisation holder should adjust the registration dossier of pharmaceuticals already registered. The adjustment procedure does not involve risk-benefit assessment unless the holder wishes to extend registration to member-state(s) where the pharmaceutical was not registered. Before the registration dossier is adjusted, re-registration is performed under the national procedure.

Single EEU market is expected to increase the number of joint cross-border projects and facilitate participation in government tenders by the foreign companies.

**Cooperative projects across the EEU involving Belarusian pharmaceutical companies**

On May 25, 2013 SKY LTD and Belmedpreparaty RUE (Belarus) concluded a contract to register the Proendoferin substance and original pharmaceutical product Endoferin developed by SKY LTD (the Russian Federation), but not registered in Russia.

Borisov Plant of Medical Preparations OJSC concluded distribution contracts with Borifarm LLC (Russia) and Borisov KZ LLC (Kazakhstan).

In 2010, the research and production company Katren CJSC (Russia) acquired shares of the pharmaceutical distributor Dominantapharm ALC (Belarus). A year earlier it had acquired shares of Amity International LLC, the pharmaceutical distributor operating in Kazakhstan.