REVERA

DOING PHARMACEUTICAL BUSINESS IN BELARUS

review of legal regulation of pharmaceutical business in the Republic of Belarus

2020

Dear reader!

Pharmaceutical markets of various countries around the globe have peculiar patterns of legal regulation, and Belarus is no exception. Many pharmaceutical guides of various countries tend to either contain the most general information, or, on the contrary, to set forth an entire text of all legislation.

This guide aims at more than depicting a specific regulation pattern applied to the Belarusian pharmaceutical market, its goal is to help you to independently assess risks and to form a competent and impartial judgement about the business opportunities in Belarus. This guide offers a comprehensive presentation of norms that regulate the pharmaceutical market in Belarus.

We believe that this guide will be most useful for pharmaceutical companies that treat Belarus as their prospective market, either for the production or for the sales of medicines. This guide contains characteristics of regulations applied to all areas of pharmaceutical business, from registration and imports to price formation for medicines.

We believe that this Doing Pharmaceutical Business in Belarus guide will answer your questions and will be a good assistant in making your business decisions.

Sincerely,

Dmitry Arkhipenko,
managing partner, REVERA

REVERA

REVERA

LIST OF ABBREVIATIONS

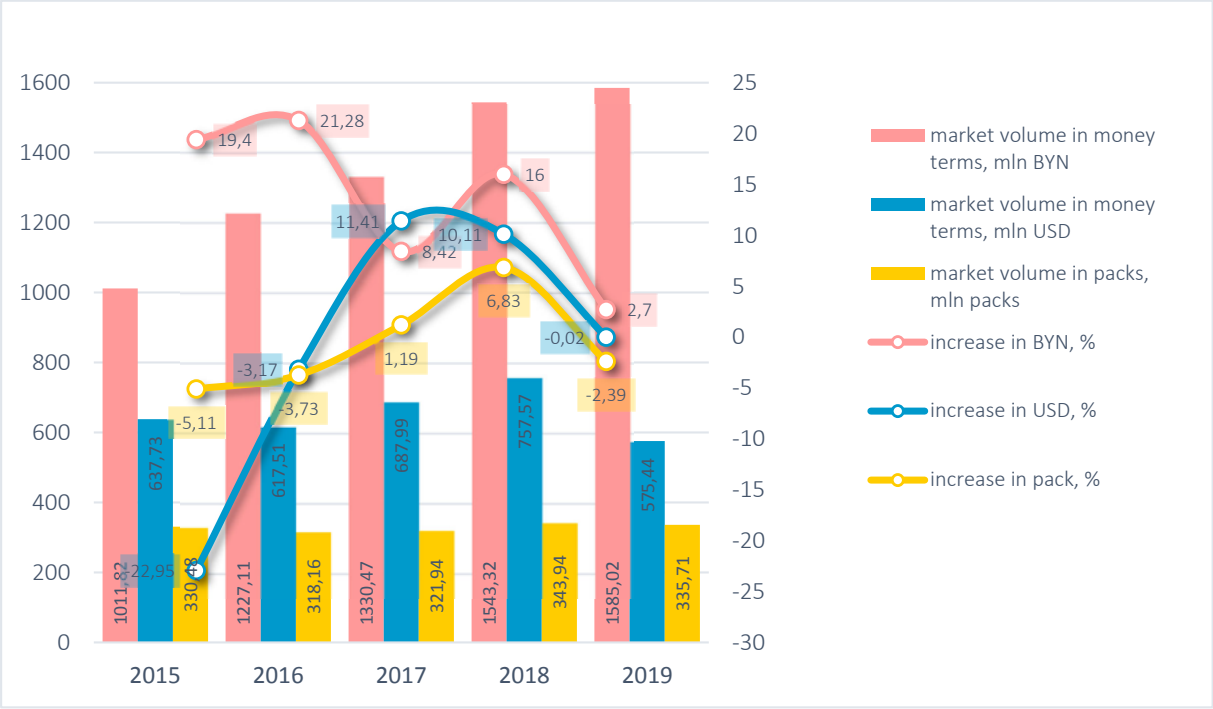
BYN	Belarusian rouble
USD	US dollar
BU	basic unit
EAEC	Eurasian Economic Commission
EAEU	Eurasian Economic Union
IE	individual entrepreneur
Code of Administrative Offences	Code of Administrative Offences of the Republic of Belarus
MPH	Ministry of Public Health of the Republic of Belarus
MART	Ministry of Antimonopoly Regulation and Trade
List of administrative procedures	Uniform list of administrative procedures to be implemented by government authorities and other entities in respect of legal entities and individual entrepreneurs, as approved by Resolution No. 156 of the Council of Ministers of the Republic of Belarus dated 17.02.2012.
Licensing Regulation	Regulation on licensing of particular business activities as approved by Decree of the President of the Republic of Belarus No. 450 dated 01.09.2010
Council of Ministers	Council of Ministers of the Republic of Belarus
Criminal Code	Criminal Code of the Republic of Belarus

1

Belarusian pharmaceutical market performance

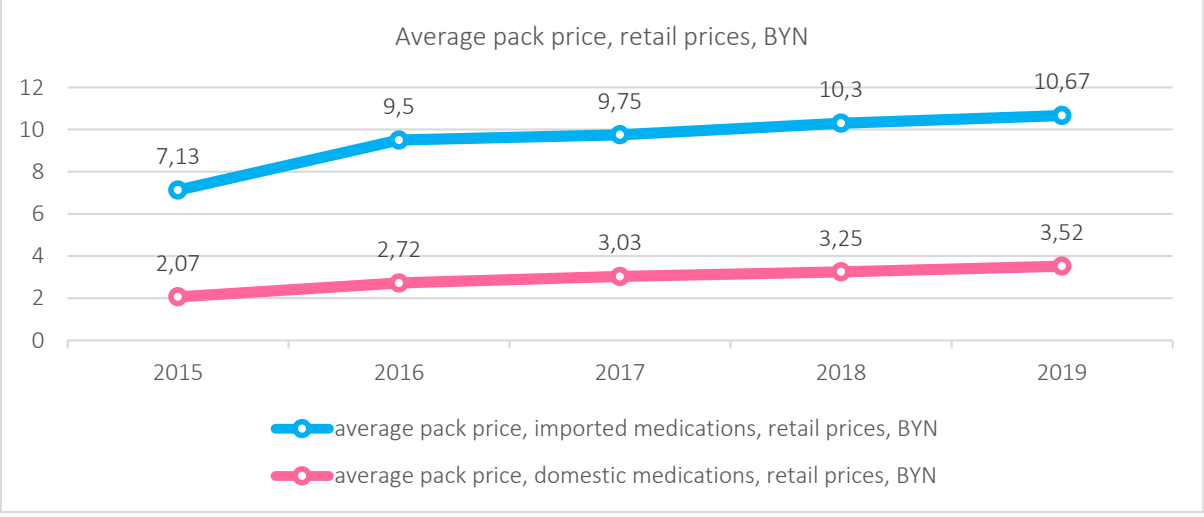
REVERA

The following table depicts the volumes of the Belarusian retail pharmaceutical market in 2015 to 2019[1].



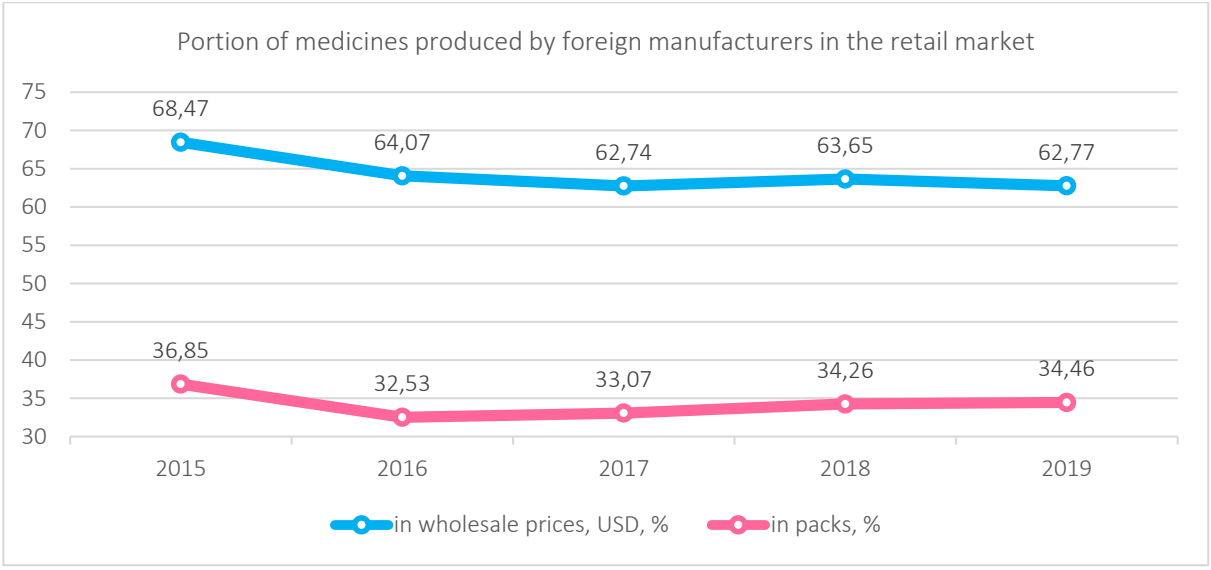
In 2019, the pharmaceutical market saw a decrease of its volumes as measured in natural units by 2.39%, in USD — by 0.02%, while increasing in BYN by 2.7%, as compared to the previous year. Market dynamics measured in BYN has always been positive throughout 2015 to 2019 (unlike in foreign currency).

Average pack price (in BYN) of both domestic and imported medicines has been growing.

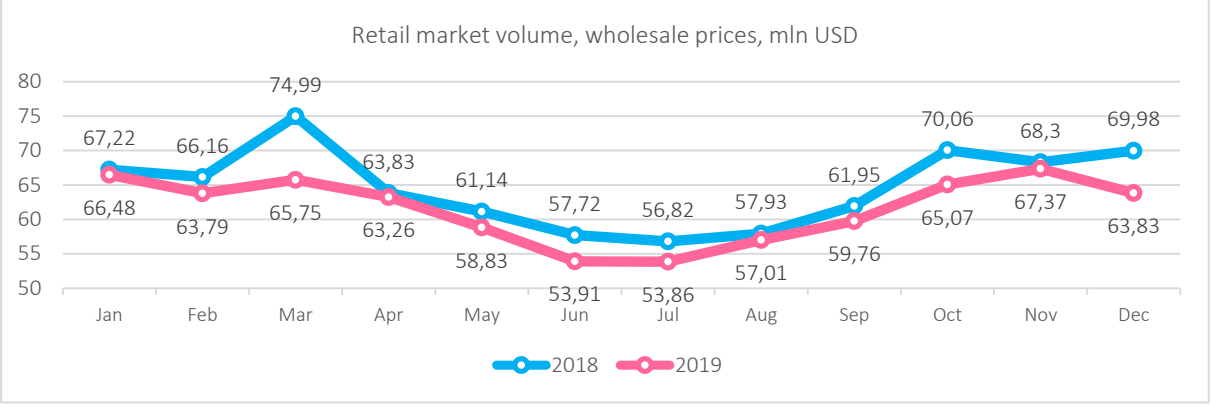


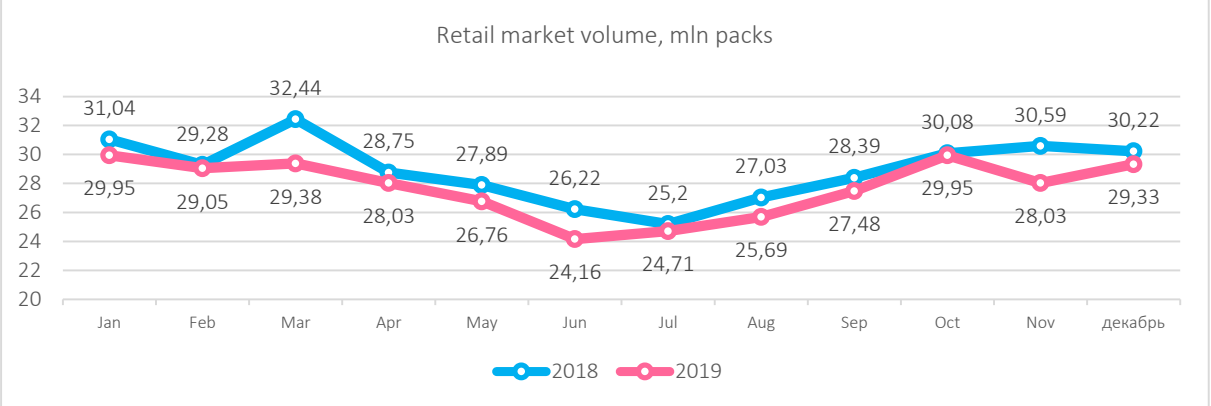
[1] Data in this section have been provided by Intellix-M company. All data, tables and graphic materials are not official statistical data and shall not be deemed to be the sole source of information about the Belarusian market.

In 2017–2019, the portion of medicines produced by foreign manufacturers has been largely levelled off in the retail market.

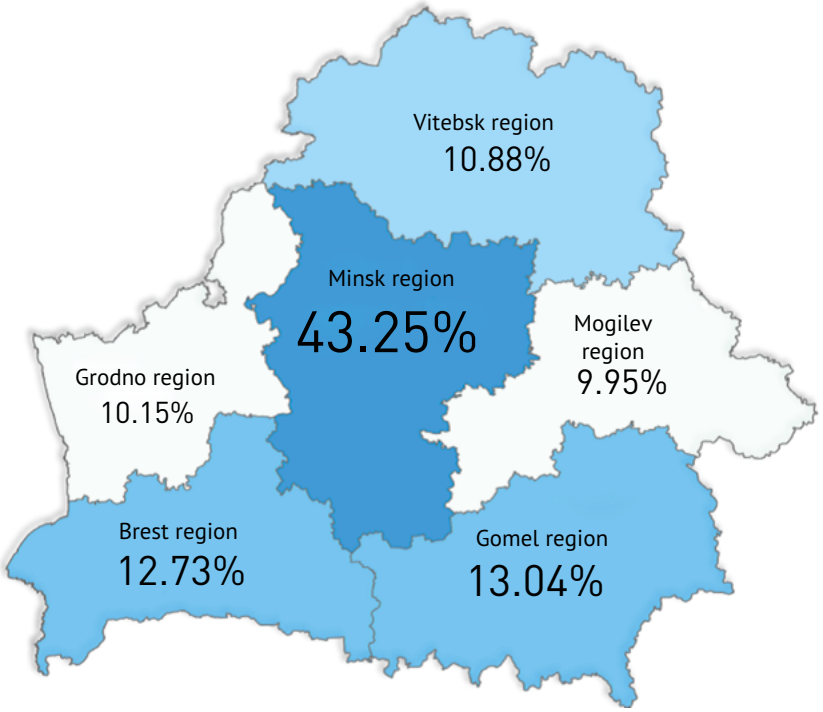


Monthly dynamics of the retail market in 2018–2019 can be depicted as follows.





The regional structure of the Belarusian retail pharmaceutical market in 2019 can be depicted as follows.



Regional portions of overall sales, wholesale prices, USD, %

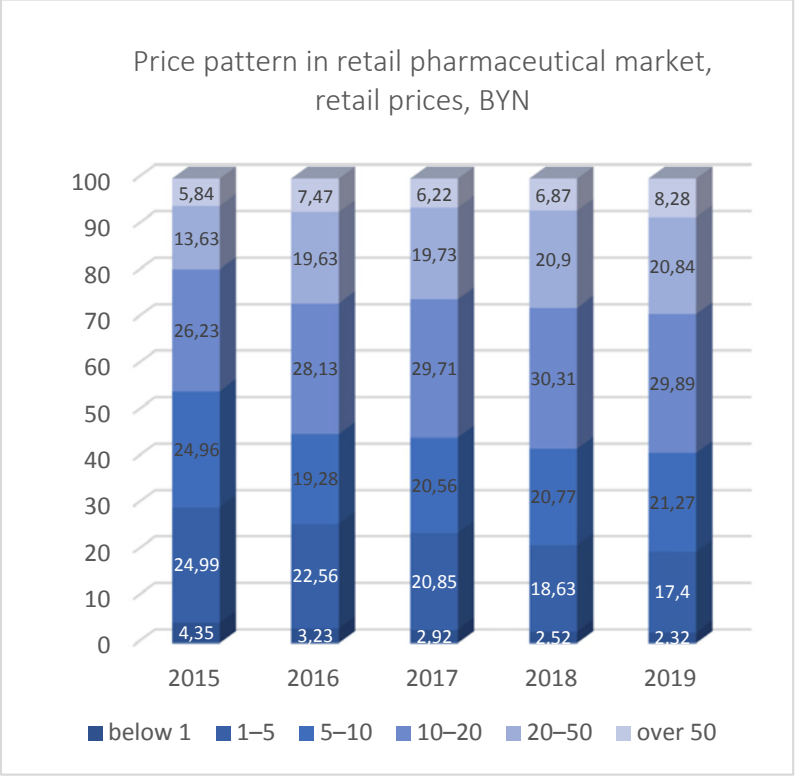
The top 10 manufacturers present in the Belarusian pharmaceutical market in 2019

Corporation	Gross sales in USD, wholesale prices, mln	Q-ty of packs, mln	Sales growth in USD, %	Sales growth in packs, %	Rating dynamics
Borysovsky medicine factory JSC	53.90	69.74	3.04	-5.71	0
BelMedPreparaty RUE	48.80	42.25	-6.20	-5.06	0
LekPharm JLLC	48.13	20.17	3.90	7.62	0
Bayer Healthcare	29.47	2.97	26.77	6.83	3
Sandoz GmbH	25.88	6.21	0.56	7.97	0
PharmLand JV LLC	25.86	16.04	0.43	3.76	-2
Pharmtechnology LLC	23.16	16.94	-6.67	-13.41	-1
MinskInterCaps NUE	21.94	8.59	8.49	-1.78	2
Gedeon Richter	21.10	3.97	-6.23	1.13	-1
KRKA	20.53	4.59	10.83	9.98	3
other	438.67	144.25	-1.67%	-1.43%	

In 2019, the Belarusian retail pharmaceutical market featured the following principal therapeutic groups of medications:

ATS-2	Sales in USD, wholesale prices, mln	Q-ty of packs, mln	Sales growth in USD, %	Sales growth in packs, %
Medications impacting the re-nin-angiotensin system	48.38	16.94	2.31	3.41
Antiphlogistics & antirheumatics	38.87	15.62	0.50	0.59
Antibacterial me dications for regular application	36.37	10.05	-7.52	-4.07
Diabetes medications	26.25	7.43	5.92	6.65
Ophthalmopathy medications	25.85	10.28	1.30	-0.69
Nasal medications	25.65	14.39	-2.91	-7.42
Analgetics	22.93	30.18	-11.86	-8.38
Anticoagulants	21.55	5.84	50.97	1.53
Psychoanaleptic medications	21.54	4.08	3.68	2.60
Cardiac medications	21.29	19.40	0.95	-3.23
Other	468.76	201.47	-0.98%	-2.17%

Dynamics of retail prices in the Belarusian market in 2015–2019 can be depicted as follows.



During recent 3 years, circa 20% of medical products were sold at a price between 5 and 10 BYN, circa 30% at a price between 10 and 20 BYN, and circa 20% at a price between 20 and 50 BYN. In general, there is a tendency of gradual rise of prices in BYN.

2

Licensing of pharmaceutical business

REVERA

In Belarus, a special permit (license) is mandatory in order to carry out pharmaceutical business activities. A license is a document confirming that the license holder (licensee) complies with the prescribed licensing requirements, which are principal rules governing respective sphere of business.

Procedures for issuance and revocation of licenses, requirements to applicants and licensees are established by Regulation on licensing of particular business activities approved by Decree of the President of the Republic of Belarus No. 450 dated 01.09.2010.

Carrying out business activities without a license (where business activity is subject to licensing), or in violation of the established rules and requirements for respective business activity as specified by the license, will entail administrative responsibility (p. 1, art. 12.7 Code of Administrative Offences).

Where revenue from such business activity exceeds 1,000 BU (27,000 BYN or ca. 11,500 USD), such actions will entail criminal responsibility under art. 233 of the Criminal Code.

2.1. GENERAL PROVISIONS

A license is required for the following works/services being part of pharmaceutical activities:

1. Works/services involving commercial manufacture of medicines/ substances and wholesale thereof:

- commercial manufacture of non-sterile medicines and/or pharmaceutical substances and wholesale thereof
- commercial manufacture of sterile medicines and/or pharmaceutical substances and wholesale thereof
- commercial manufacture of gases used for medical purposes and wholesale thereof
- commercial manufacture of radio-pharmaceuticals and wholesale thereof
- commercial manufacture of alcohol-containing medicines and wholesale thereof
- commercial manufacture of medicines in terms of prepackaging and packaging of finished medicines and/or pharmaceutical substances and wholesale thereof
- commercial manufacture of medicines from medicinal plant raw material and wholesale thereof
- commercial manufacture of medicines from donor blood/plasma;
- commercial manufacture of biological (including immunological) medicines and/or pharmaceutical substances and wholesale thereof.

2. Works/services involving sales, pharmacy production and dispensing of medicines:

- pharmacy production of medicines
- supplies of medicines to health care institutions and/or their structural subdivisions
- bulk sales of medicines of domestic and/or foreign manufacture
- bulk sales of medicines to health care institutions
- retail sales of medicines

Licenses are granted by the Ministry of Public Health of the Republic of Belarus (MPH). The MPH is a licensing authority in this sphere and is in charge of decision-making, particularly, in terms of amendments, suspension, resumption, dissolution and revocation of licenses, issues duplicate copies of licenses and monitors compliance with key license requirements and conditions.

Licenses may be issued to Belarusian legal entities and IEs, as well as foreign entities having presence in Belarus.

A license provides a right for respective activities only to its holder (licensee), no assignment of such right to any third parties is possible. A specially established procedure is applicable where the licensee is restructured.

The licensee is obliged to apply for the amendment of its license within one month, if any data specified in the license (for instance, licensee's name, location, etc.) have been changed, or if any provisions of applicable laws have been changed which necessitate such license amendments.

Form of licensee restructuring	License validity
Merger or split-up	The new legal entity must within one month following its state registration apply for a new license
Transformation or spin-off	The newly formed legal entity may operate on the basis of the earlier license, however it must introduce relevant amendments into the license within one month.
Adhesion of the licensee to another legal entity having no license	The legal entity without a license must apply for a new license within one month following the licensee's excluding from the State Register of Legal Entities and Individual Entrepreneurs.
During the specified one month period, it is allowed to operate on the basis of the license granted to the licensee earlier, provided all license requirements are complied with.	

A duplicate copy of a license may be issued, if the license has been lost. The state duty for any amendments into a license and/or issuance of a duplicate copy of a license is 5 BUs (135 BYN or about 60 USD).

2.2. LICENSE ACQUISITION PROCEDURE

The normal license acquisition scheme is as follows:

1. Preparation stage.

This stage is the longest. During this stage an applicant shall prove its compliance with license requirements and conditions. An applicant will need to:

- recruit personnel with requisite education level and qualifications;
- find premises conforming with statutory requirements (supported by a report of a local sanitary authority on such conformity);
- acquire title to, or purchase on another lawful ground, the requisite equipment.

2. Submission of documents to MPH.

In order to obtain a license, an applicant shall submit the following to MPH:

- application;
- an extract from the trade register or a similar document (for foreign entities);
- document confirming payment of state duty (state duty amount is 10 basic units — 270 BYN or circa 115 USD);
- documents confirming compliance with license requirements.

License requirements differ subject to business activity. Accordingly, different supporting documents may be required (for instance, with regard to office premises, employees, equipment, etc.). Documents or data not prescribed by law cannot be required by any authority.

3. Valuation and examination of compliance with license requirements and conditions.

MPH prescribes such an examination or valuation at its own discretion (no prescription criteria established by legislation).

Procedures for valuations and examinations have been established by the Guidelines approved by Resolution No. 145 of the Ministry of Public Health of the Republic of Belarus dated 16 November, 2010.

Valuation and examination are required in order to validate information integrity in the documents submitted for license acquisition and to check applicant's commitment to its business activities. Based on the results of a valuation or an examination, a conclusion will be prepared stating applicant's compliance (or non-compliance) with license requirements and conditions.

4. Decision on license issuance or refusal.

A decision is normally taken within 15 business days following submission of application. This time frame may be extended by 10 more days, where compliance valuation or examination is performed. The decision will be communicated to the applicant within 3 business days. In case of a positive decision, a license will be granted to the applicant.

Decisions by MPH may be appealed in a court of law within one month following receipt of notification of such decision.

2.3. GENERAL LICENSE REQUIREMENTS

Requirements to applicants differ subject to components of prospective pharmaceutical business activity.

Licensable activities shall be conducted in locations prescribed by the respective license. All licensees shall comply with special legislative requirements (Good Manufacturing Practice[1], Good Distributorship Practice[2] and Good Pharmacy Practice[3], special sanitary regulations, requirements prescribed by acts of the EAEU[4], etc.).

Within 12 months of the decision on license granting being adopted, a licensee shall acquire a certificate confirming compliance of its manufacturing facilities to the requirements of the Good Manufacturing Practice (for corresponding type of activity).All pharmacies regardless of their pattern of ownership shall offer medicines according to the list prescribed by MPH Resolution No. 92 dated 10.12.2018. Also, pharmacies must comply with the requirements in terms of premises and adjacent territories, water supply, water disposal, microclimate, ventilation and room lighting, operation and maintenance of premises, equipment, furniture and fixtures, staff personal hygiene, etc.[5].

[1] Good Manufacturing Practice as established by TCP 030-2017 (33050) approved by MPH Resolution No. 64 dated 19.06.2017. The EAEU Good Manufacturing Practice Rules were approved by EEC Council Resolution No. 77 dated 03.11.2016.

[2] Good Distributorship Practice was approved by EEC Council Resolution No. 80 dated 03.11.2016.

[3] Good Pharmacy Practice was approved by MPH Resolution No. 120 dated 27.12.2006.

[4] http://www.eurasiancommission.org/ru/act/texnreg/deptexreg/LS1/Pages/drug_products.aspx

[5] MPH Resolution No. 154 dated 01.10.2012

Activity	License requirements
Activities/services involving medicine sales, pharmacy production and dispensing	Applicant must validly possess premises, equipment and transport facilities required for the licensed activity.
	Chief executive of a pharmacy storehouse or a pharmacy (or a person in charge of licensed activities in standalone divisions of a business entity, and/or head of the local health agency) must have: – his/her employment in such entity must be primary employment – university degree in pharmaceutics – first or highest qualification category (not required for working in radioactive contamination zones and pharmacies of categories 3 to 5); – certificate of advanced training or professional retraining; – such person must be made responsible (by a written order) for the performance of the licensed activities. All requirements to such chief executives also apply to IEs applying for such licenses.
	At least 2 employees (apart from the chief executive) must have: – higher or vocational secondary pharmaceutical education; – a qualification category (except for employees of pharmacies of categories 3 to 5 and those working in radioactive contamination zones) – certificate of advanced training or professional retraining (in a respective area of expertise).
	Other employees involved in any licensed activity must have: – higher or vocational secondary pharmaceutical education; – certificate of advanced training or professional retraining (in a respective area of expertise).
Activities/services involving commercial production of and wholesale trade in medicines	Applicant must validly possess premises, equipment and transport facilities required for the licensed activity.
	A full-time specialist must have: – university degree in chemical technology, chemical pharmaceutics, chemistry, biology, microbiology, biotechnology, pharmaceutics or medicine; – at least 2 years' work experience in medicine manufacturing enterprises; – such person must be made responsible (by a written order) for the quality and gross sales of medicines manufactured.

3

State registration of medicines

REVERA

3.1. GENERAL PROVISIONS

Pharmaceutical products and medicines (both domestic and foreign) must be registered in Belarus in order to be manufactured, sold and/or used for medical purposes. State registration involves inspection of conformance of a pharmaceutical product to the existing requirements in terms of safety, efficiency and quality. Such requirements have been set out in relevant practices at the national level or at the EAEU level, as shown in the table below.

The following pharmaceutical products are not subject to state registration:

- designed for commercial manufacture for export only
- designed for preclinical studies and/or clinical trials
- produced in pharmacies
- designed for demonstration as exhibition samples

Separate registration of pharmaceutical substances is not required in Belarus. However, registration dossiers for pharmaceutical products containing such substances shall include:

- manufacturer's certificate for such pharmaceutical substance conforming the quality of at least one series of the pharmaceutical substance
- results of stability tests of at least two series of the pharmaceutical substance (plan, report, results tables)

Nevertheless, pharmaceutical substances *may* be registered separately from medicines.

Medicinal plant raw material is subject to state registration as pharmaceutical product following the stage of the production process which gives it a specific pharmaceutical form.

3.2. STATE REGISTRATION PROCEDURE

State registration procedure comprises several stages.

The procedure and terms of state registration of medicines and pharmaceutical substances have been established by Resolution No. 254 of the Council of Ministers of the Republic of Belarus dated 01.04.2015.

A detailed description of the state registration procedure is given on the website of the Centre for Expert Evaluations and Trials in Public Health Service (hereinafter — the Expertise Centre) https://www.rceth.by/Documents/Registration_scheme_LS.pdf.

Also, a streamlined registration procedure has been introduced in 2020[1]. The streamlined procedure implies that:

- deadlines for preliminary work cannot exceed 30 business days from the date of conclusion of agreement with the Expertise Centre
- applicants' expenses for registration cannot exceed 120 BUs (ca. 1,500 USD) net of VAT (the standard procedure has no upper limit of applicants' expenses)

The streamlined registration procedure applies to the following categories of medicines:

- medicines already registered in Australia, Austria, USA, Canada, Switzerland, Japan, Great Britain, Germany, Denmark, Netherlands, Sweden, Spain, Portugal, or registered by an authorised body of the European Union under a centralised procedure to be used in the territory of the above states;
- medicines to cure tuberculosis, hepatitis C, HIV infection, and vaccines endorsed by the requalification programme of the World Health Organisation (under the Joint

Period	Procedure
till 31.12.2020	manufacturers are entitled to choose the type of rules (national or EAEU rules) to be used in the registration of pharmaceutical products
as from 01.01.2021	all pharmaceutical products will be registered only under the EAEU rules[2]
till 31.12.2025	all pharmaceutical products registered under the national rules prior to 31.12.2020 must be re-registered pursuant to the single market rules
as from 01.01.2026	turnover of pharmaceuticals not duly registered or not harmonised in accordance with EAEU requirements will be ceased

[1] Edict of the President of the Republic of Belarus No. 499 "On circulation of pharmaceutical products" dated 31.12.2019

[2] Preliminary work takes 180 calendar days, therefore, in order to be registered under the national procedure, applicants must submit their documents before July 2020. At present, state bodies are negotiating feasibility of filing documents before the end of 2020.

№	Stage	Stage description	Timeframe
1	Primary expert evaluation of documents	This stage involves: 1. Concluding an agreement with the Expertise Centre. 2. Submitting the required documents.[3]	180 calendar days (or 30 business days under a streamlined procedure)
2	Preliminary technical activities[4]	This stage involves: 1. Inspecting manufacturing facilities for compliance with the Good Manufacturing Practice[5] (where no inspection of the production site has been carried out in recent 5 years) 2. Approval of the quality control technique applied to medicines, quality control activities using such technique, and analysis of medicines' quality in clinical trials conducted by public health authorities. 3. Specialised examination of documents for medicines compliance with applicable regulations on safety, efficiency and quality, with due account for their pharmaceutical, clinical and pharmacological peculiarities. 4. Studies of bioavailability (bioequivalence) of generic pharmaceutical products (apart from medicines produced from medicinal plant raw material). 5. Clinical trials. 6. Other studies and trials (as required).	
3	Submitting registration dossier to MPH	1. The Expertise Centre will forward documents to MPH. 2. MPH Commission on medicines and pharmaceutical substances will render a decision.	From 15 days up to 1 month. The applicant will be notified in writing of the decision within 5 business days.
4	Payment of state duty	State registration duty amounts to 10 basic units (270 BYN or ca. 124 USD)	—
5	State registration	The Expertise Centre will enter respective data into the State medicines Register and will issue a registration certificate.	5 business days upon confirmation of payment

procedure between WHO/PQT and HPO evaluation and streamlining of state registration of pharmaceuticals and vaccines requalified by WHO of May 16, 2018)

Registration certificates are valid during 5 years. Upon expiry of this period, holders must undergo a state registration confirmation procedure, which is quite similar to the procedure of state registration. Upon confirmation of state registration, an unlimited registration certificate will be issued. Pharmaceutical substances are granted unlimited registration certificates immediately upon registration.

[3] The list of documents is set out in subcl. 10.13-10.18 of the List of administrative procedures. The lists of required documents differ for the registration of pharmaceutical substances and medicines, as well as for Belarusian and foreign manufacturers. The requirements to documents are set out in MPH Resolution No. 52 dated 08.05.2009.

[4] Procedures for work management have been established by MPH Resolution No. 55 dated 23.04.2015.

[5] Inspection procedures have been set out in MPH Resolution No. 72 dated 14.05.2015. At the EAEU level, the Rules of pharmaceutical inspections established by EEU Council Resolution No. 83 dated 03.11.2016 also apply. The EAEU Rules are used during inspections for compliance with the EAEU Good Manufacturing Practice.

3.3. MARKING OF MEDICINES

PP marking rules differ according to the rules used for medicine registration — national rules or EAEU rules.

Packing and labelling of medicines registered pursuant to Belarusian national rules must comply with the requirements set out in Annex 4 to MPH Resolution No. 52 dated 08.05.2009.

Where a medicine is registered pursuant to the EAEU rules, it will be checked for the compliance of its package and marking to the requirements set out in Decision No. 76 of the EEC Council dated 03.11.2016.

Marking requirements comprise requirements to marking content, marking language, application techniques and package design. Mandatory information is different for primary and secondary package.

One of the requirements is that no advertising information or information inconsistent with the patient information leaflet (product insert) may be placed on the package.

Package of a pharmaceutical product	Description
Primary	Package in direct contact with the pharmaceutical product
Secondary	Package enveloping the pharmaceutical product in its primary pack

4

Price formation

REVERA

Price formation for pharmaceutical products in Belarus is regulated by the following means:

1) ex-factory price limits for certain manufacturers;
2) restrictions of wholesale markups;
3) restrictions of retail markups;
4) control of retail prices in pharmacy chains.

Also, as from 2019, prices for a number of medicines are subject to registration.

4.1. EX-FACTORY PRICE LIMITS FOR MANUFACTURERS

Manufacturer's prices for most medicines are free-of-control in Belarus, i.e. they are formed by the supply-and-demand balance[1].

However, controlled prices apply to some medicines. The list of such medicines is exhaustive and includes 35 international nonproprietary names (atropine, metoclopramide, lactulose, etc.[2]), manufactured by a number of Belarusian enterprises (PharmTech, AcademPharm, etc.[3]).

Prices for foreign medicines are not controlled in Belarus. However, a manufacturer must specify a maximum sale price (so called 'posted price') during registration. The posted price must be consistent with prices:

- in the country of manufacture
- - in EAEU countries
- - in other countries neighbouring on Belarus (Ukraine, Poland, Lithuania, Latvia).

An agreement for the supply of medicines in the Republic of Belarus cannot stipulate a price higher than the posted price. Otherwise, registration certificate may be suspended[4], imports of such medicines in Belarus may be banned, and where the importer fails to cure such violation, registration certificate may be repealed.

4.2. MAXIMUM WHOLESALE MARKUPS

Maximum wholesale markups apply to medicines of both Belarusian and foreign manufacture.

Thus, wholesale prices for medicines of Belarusian manufacture are calculated as follows:

Wholesale price = Belarusian manufacturer's price + wholesale markup

Moreover, the rate of the wholesale markup is limited in % to the manufacturer's price. Limits of wholesale markups differ according to manufacturer's prices and comprise markups of all distributors within the medicine distribution chain[5].

The following rules shall also be considered in calculating a wholesale markup.

Costs of ex-factory transportation will increase manufacturer's

Отпускная цена белорусского изготовителя или расчетная отпускная цена за единицу товара, базовых величин[6]	Bulk markup on Belarusian manufacturer's price or calculated ex-factory price, %	Resale markup on Belarusian manufacturer's price or calculated ex-factory price, %
below 0.5	9	30
0,5–1	8	25
1–1,5	7	14
1,5–3	7	12
3–5	6	10
5–10	4	5
over 10	2	1

[1] Law № 255-Z dated 10.05.1999.

[2] List of medicines subject to maximum manufacturer's prices is set out in Resolution of the Council of Ministers No. 56 dated 19.01.2012.

[3] List of enterprises subject to maximum manufacturer's prices is set out in MPH Resolution No. 137 dated 07.09.2012.

[4] Par. 4, p. 16, art. 8 of Law No. 161-Z dated 20.07.2006.

[5] Decree No. 366 dated 11.08.2005.

[6] As of March 1, 2020, one basic unit makes 27 BYN or ca. 12 USD.

price and, consequently, the eventual markup and the wholesale price, regardless of the fact who will perform transportation of goods under the agreement — manufacturer or wholesale buyer.

Where manufacturer grants a monetary discount, it will not affect the eventual markup and the wholesale price — they will be calculated net of such discount. This discount (i.e. available benefit) may be only used for procurements of Belarusian pharmaceutical products, development of pharmacy chains in rural areas and for compensation of losses on internal drug production of pharmacies.

Manufacturer's commodity discount (products supplied for free) will not impact the wholesale markup as well — because the bulk price will be formed on the basis of the contract price net of discount.

Wholesalers may sell medicines at a lesser price than the ex-factory price (for instance, during marketing actions).

Wholesale prices for foreign medicines are calculated according to the formula:

Wholesale price for foreign medicines = calculated ex-factory price + wholesale markup

Therewith, calculated ex-factory price shall be determined as follows:

Calculated ex-factory price = contract price + customs charges + import VAT + carriage costs

'Contract price' is the price under an agreement with a foreign manufacturer/supplier. Contract price shall not exceed the price declared for the purposes of registration in Belarus.

In order to calculate the wholesale price, a seller may realign the contract price each month subject to currency rate fluctuations, if:

- medicines have been placed under a customs procedure of clearance for domestic consumption, and
- the wholesale buyer has accounts payable to the foreign supplier with respect to such medicines.

As in the case of Belarusian drugs, monetary discounts of foreign manufacturers/suppliers will not affect the calculation of the wholesale price. However, benefits of such discounts may be used without any restrictions.

4.3. MAXIMUM RETAIL MARKUPS

Retail prices for medicines of both Belarusian and foreign manufacture are calculated as follows:

Retail price = wholesale price + retail markup

Retail markups are also calculated as per cent rates of Belarusian manufacturer's (ex-factory) price or of calculated ex-factory price (in case of medicines of foreign manufacture).

Maximum retail markups differ from wholesale markups. Retailers may also sell medicines at a price lower than the wholesale price or the ex-factory price.

4.4. REGISTRATION OF PRICES

As from January 1, 2019, only those medicines are allowed in Belarus for which a maximum manufacturer's price has been registered. This rule applies to an exhaustive list of medicines for oncological and cardiovascular diseases (altogether 37 international non-proprietary names including melphalan, medroxyprogesterone, pegaspargase, etc.[7]).

Furthermore, 2020 saw an introduction of mandatory registration of limit ex-factory prices on medicines intended for extracorporal fertilisation and medicines included in the MPH list of main pharmaceuticals[8].

The procedure for price registration have been established by Resolution of the Council of Ministers No. 776 dated 31.10.2018.

MPH is the registering body. Documents shall be submitted to the Centre of expert evaluations and trials in public health service. All formalities will take 18 to 42 calendar days (where submitted data must be redefined).

For a price to be registered, an applicant shall furnish information on ex-factory prices in reference countries, namely: in Armenia, Bulgaria, Hungary, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Moldova, Poland, Russia, Romania, Czech Republic, Estonia and the production country.

This information will be used to determine the maximum sales price. The Instruction on maximum sales price calculation techniques was approved by Resolution No. 83 of the Ministry of Antimonopoly Regulation and Trade (hereinafter — the MART) dated 19.11.2018.

Within the scope of the procedure, the maximum sales price will be agreed upon with MART. All prices will be registered in Belarusian roubles. Registration is free of charge.

[7] The full list is set out in Decree No. 345 dated August 22, 2018

[8] Edict of the President of the Republic of Belarus No. 499 "On circulation of pharmaceutical products" dated 31.12.2019

4.5. RETAIL PRICE CONTROL

Annually, the Ministry of Health of the one part and pharmacy chains/ distributors of the other part, sign a memorandum on medicines price control.

According to memorandum terms, business entities undertake to buy more medicinal products of domestic manufacture and to sell medicinal products at prices not higher than the recommended limit retail prices as defined by the MPH and published on the BelPharmacia website[9].

The Price Control Memorandum is not a legally binding document. Nevertheless, business entities would normally comply with its provisions in order to avoid potential problems with the regulator[10].

[9] https://pharma.by/news/1458.html

[10] http://www.belta.by/society/view/minzdrav-budet-prinimat-k-aptekam-bolee-strogie-mery-za-nesobljudenie-predelnyh-rekomenduemyh-tsen-269918-2017/?utm_source=belta&utm_medium=news&utm_campaign=accent

5

Centralised purchases of medicines

REVERA

A large portion of pharmaceutical products is consumed by public health centres, hospitals and other facilities of the state health care system. This may make supplies of medicines to public health institutions a priority for many pharmaceutical companies. In this regard, suppliers have to understand fine points of public purchases in order to be successful in their business.

5.1. GENERAL PROVISIONS

All procurements of pharmaceutical products for the public sector in the Republic of Belarus are always centralised purchases. This allows reducing delivery costs, as centralised purchases for the entire public health system are much more cost-efficient than purchases by separate health care facilities. 'Centralised purchases' imply arrangement of purchases by an organiser on behalf of one or more customers.

Public health care facilities are funded from the state budget: they purchase medicines by means of budget funds within the public purchasing procedures.

Peculiarities of centralised public purchases of medicines till December 31, 2020 have been defined by Edict of the President of the Republic of Belarus No. 40 dated 07.02.2019, and by MPH Resolution No. 161 dated 11.02.2019.

Centralised purchases of medicines in Belarus are carried out under the following scheme:

1. Competent public authorities and institutions (Presidential Property Management Department, regional executive committees, etc.) determine the lists of medicines to be purchased.

2. BelPharmacia RUE and regional Pharmacia enterprises act as organisers of state purchases.

3. Organisers conclude agreements with suppliers of medicines.

4. Customers (health centres, hospitals, pharmacies) buy medicines from organisers without participating in any procurement procedures.

BelPharmacia carries out procedures of centralised state purchases according to a specific stock list, within the scope of nation-wide needs. The purchased medicines will then be transferred to regional Pharmacia enterprises, which thereafter conclude contracts with winners for further sales of pharmaceutical products to health care institutions.

Regional Pharmacia enterprises also carry out procedures of state purchases, however according to different stock lists of medical supplies pursuant to the local needs, and thereafter conclude contracts with winners for further sales of pharmaceutical products to health care institutions.

An annual plan of centralised procurements is formed on the basis of application requests submitted by health care institutions and is subject to MPH approval. Medicines not included in the annual plan may be purchased at the expense of own floating assets (for instance, domestic medicines required for fee-based medical services), or at the expense of extra-budgetary resources (foreign medicines).

5.2. PECULIARITIES OF PURCHASES OF MEDICINES

Organisers normally arrange the following procurement procedures:

- electronic auction
- open competitive tender
- bidding procedure
- single-source buying procedure

These procurement schemes are organised according to the standard procedure pursuant to Law No. 419-Z dated 13.07.2012.

Website http://goszakupki.by/tenders/posted is the official Internet platform containing information on state purchases, in particular on centralised purchases of medical goods. This official website contains such information as:

- annual centralised purchases plans, invitations to purchases procedures, in particular state purchases procedures, reports on results of such procedures, documents pertaining to purchases procedures, and relevant amendments;
- information on agreements/contracts and relevant amendments;
- register of unfair suppliers;
- register of persons accredited at the official website;
- hyperlinks to texts of regulatory acts pertaining to purchases, in particular centralised purchases.

Purchases of medical goods via electronic auctions are carried out on the electronic trading platform zakupki.butb.by, operated by the Belarusian Universal Commodity Exchange.

You can find more detailed information about participating in procurement procedures, in particular centralised purchases of medicines, carried out via the electronic trading platform on the following websites:

- for residents of the Republic of Belarus:
  http://zakupki.butb.by/auctions/template_docs/download/user_memo_rb.pdf
- for residents of the Russian Federation:
  http://zakupki.butb.by/auctions/template_docs/download/user_memo_notresident.pdf
- for other non-residents:
  http://zakupki.butb.by/auctions/template_docs/download/user_memo_world.pdf.

Also, all information on public purchases in Belarus is available in the State Information and Analytics System for public purchases (SIAS) at https://gias.by/gias/#/contract.

5.3. PREFERENTIAL CORRECTION

Preferential correction may be applied to bid prices offered by participants of public procurement procedures. 'Preferential correction factor' means an advantage granted to participant's goods/works/services as compared to other bids.

During a purchases procedure, a bid price offered by a participant entitled to preferential correction will be compared to other participants' bids with the deduction of preferential correction.

Preferential compensation factor	Application terms
15 %	Participant offers goods/works/services originating from the Republic of Belarus and/or another country to which the Republic of Belarus has granted 'national regime of treatment' pursuant to international treaties of the Republic of Belarus.[1]
25 %	Participant offers in-house production (goods/works/services) of an entity having at least 50% of disabled persons on its staff schedule.

[1] Countries enjoying the 'national regime of treatment' today are: Russian Federation, Republic of Armenia, Republic of Kazakhstan, Kyrgyz Republic.

6

Advertising and promotion

REVERA

Belarus has special requirements to the advertising of medical goods that must be observed along with general advertising requirements[1].

'Advertisement' means any information about advertised item disseminated in any form and by any means as long as it is intended to attract attention to advertised item, create or keep up interest to it, or promote it in the market.

Violation of applicable advertising requirements will entail administrative liability in the form of fine:

- for natural persons: 5 to 30 basic units (circa 60 to 360 USD)
- for individual entrepreneurs: 10 to 40 basic units (circa 120 to 480 USD);
- for corporate entities: 20 to 50 basic units (240 to 600 USD)[2].

6.1. PECULIARITIES OF MEDICINES ADVERTISING

Special rules	Description
Advertisements must be approved by MPH	All advertisements of medicines in Belarus must be approved by the MPH[3]. Pendency time is 15 to 30 calendar days. The effective duration of such approval is 1 year. No approval for adverts are required in the following cases: – in venues of medical or pharmaceutical exhibitions, workshops, conferences, and similar events, where advert information is furnished only to medical and pharmaceutical specialists; – in specialised print publications, as set out in MPH Resolution No. 63 dated 23.07.2013 ("Health Care" journal, "Medical Bulletin" newspaper, etc.).
Prohibition of medicine advertising in a number of cases	Advertising is prohibited for the following medicines: – non-registered medicines. The only exception is advertising of non-registered medicines during clinical trials, and only for the purpose of engaging volunteers (patients) to participate in such trials. – medicines sold only on prescription. Exceptions: advertising is allowed only in specialised print publications and venues of medical or pharmaceutical exhibitions, workshops, conferences, and similar events.
Content of adverts	The list of requirements to the content of medicines adverts (and respective prohibitions) is very broad. For instance, adverts must indicate that the information is of an advertising nature, that the advertised product is a medicine, that the package insert shall be carefully read, etc.

6.2. PROMOTION OF MEDICINES

Promotion of medicines in Belarus is regulated in several areas.

Firstly, there are Rules for informing medical and pharmaceutical employees of registered medicines[4].

Thus, manufacturers' representatives promoting medicines must have a university degree in medicine or pharmaceutics and be competent in medicines marketing. Such representatives are prohibited to:

- be present and/or to speak at any events not approved by respective healthcare institution;
- place (distribute) information materials in any places not specified by respective healthcare institution;
- enter offices or other working spaces of healthcare institutions or otherwise draw workers' attention away from their job duties;
- distribute (furnish) any samples of medicines, either for a compensation or free of charge;
- carry out activities/actions aiming at arousing workers' interest in ordering or selling medicines.

Secondly, promotion activities are restricted by anti-corruption regulations[5].

[1] Peculiarities of medical goods advertising have been established by Law No. 225-Z dated 10.05.2007 and by MPH Resolution No. 63 dated 23.07.2013.

[2] P. 1 art. 12.15 of Administrative Code of the Republic of Belarus.

[3] cl. 10.19 of the List of administrative procedures.

[4] MPH Resolution No. 44 dated 17.04.2015.

[5] Law No. 305-Z dated 15.07.2015.

Such rules apply to officials such as:

- chief executives of health care / pharmaceutical facilities and their deputies (for instance, chief medical officer)
- chief executives of structural subdivisions of health care / pharmaceutical facilities and their deputies (for instance, chiefs of departments, accountant general)
- doctors (as persons authorised to carry out legally significant actions, for instance, to write out prescriptions, sick notes)
- chief executives and officials of local health care departments

Prohibitions for officials	Exceptions from the prohibition
Taking presents	Only souvenirs during protocol events and official events are allowed
Making trips at the expense of another person relationship to whom are connected with official activities	Allowed where it is: – an official business trip; – financed by a close relative; – made in accordance with an international treaty or an arrangement between state authorities of different states; – made upon senior officer's consent and at the expense of a non-government association (fund)

7

Procedures for importation/ exportation of medicines

REVERA

7.1. GENERAL RULES

Generally, only the following medicines are allowed to be imported in Belarus:

- registered in the Republic of Belarus
- with effective period of validity
- of good quality, not forged

Pharmaceutical products cannot be imported in Belarus without state registration, unless they are intended for:

- pre-clinical trials
- state registration
- using as exhibition samples
- clinical trials
- curing restricted cohorts of patients with uncommon pathologies
- mitigating effects of emergency conditions or epidemic diseases
- imported as foreign gratis aid
- imported by natural persons for individual use
- imported pursuant to the requirements of customs laws of the Eurasian Economic Union[1].

In order to import any unregistered medicines on the above grounds, an importer has to obtain an MPH resolution. The relevant procedures are set out in cl. 10.5 of the List of administrative procedures and Resolution of the Council of Ministers No. 1397 dated 23.09.2008.

Documents required for such opinion letter shall be submitted to the Expertise Centre. An opinion letter will be issued within 20 calendar days. Such opinion letters are valid within 6 months.

Also, unregistered medicines may be imported without an MPH resolution, if they are placed under a customs procedure of processing within the customs territory, customs warehouse, free customs zone, free warehouse, destruction, or customs transit.

Exportation of pharmaceutical products has only one peculiarity: if medicines are intended exclusively for commercial production for export, they need not be registered in Belarus.

7.2. PECULIARITIES OF IMPORTATION/ EXPORTATION OF MEDICINES CONTAINING NARCOTIC/PSYCHOTROPIC SUBSTANCES AND PRECURSORS

Medicinal agents containing narcotic/psychotropic substances and precursors are subject to the same state regulation policies that apply to narcotic/psychotropic substances and precursors.

Requirements to narcotic/psychotropic substances and precursors are defined by article 15 of the Law of the Republic of Belarus No. 408-Z dated July 13, 2012 "On narcotic/psychotropic substances, precursors and analogues".

In order to import narcotic/psychotropic substances and precursors in the Republic of Belarus (or export such substances outside its territory), a special MPH permit is required. Such permits are issued in respect of medicines which are included in the National List of narcotic drugs, psychotropic substances and precursors subject to government control in the Republic of Belarus.[2]

Procedures for issuing such permits have been established by Resolution of the Council of Ministers No. 1397 dated 23.09.2008 and cl. 10.27.1 of the List of administrative procedures. Documents shall be submitted to the Expertise Centre. Pendency time is 15 calendar days. Such opinion letters are valid for 1 year, or for the duration of the import contract.

In order to import narcotic/psychotropic substances and precursors in the EAEU customs territory (or export such drugs outside its customs territory), an importer has to obtain a special single-use import license. Such rules apply to the substances listed in cl. 2.12. Annex 2 to EEC Board Decision No. 30 dated 21.04.2015.

Such licenses are granted by MART, provided an authorisation document has been granted by MPH. Pendency time is 15 calendar days. Such licenses are valid for 1 year (unless another duration is set out in the supply contract). The fee is 5 basic units.[3]

Upon expiry of a license, an importer is obliged to furnish a statement of license fulfillment to MART within 15 calendar days.

Acquisition of a license is not required for the importation of[4]:

- substances by natural persons to a limited extent (narcotic

[1] Similar cases of importation of unregistered medicines in the EAEU territory have been approved by cl. 11 Annex 21 to EEC Board Decision No. 30 dated 21.04.2015. These cases pertain to the medicines according to the list set out in cl. 2.14 Annex 2 to the above Decision.

[2] MPH Resolution No. 19 dated 11.02.2015.

[3] П. 9.2.1. Перечня административных процедур.

[4] Cl. 6 Annex 10 as approved by EEC Board Decision No. 30 dated 21.04.2015.

drugs — not more than the rate of weekly need; psychotropic substances and precursors — not more than 90 single doses, upon availability of supporting medical documents or copies thereof duly certified by a notary or by the issuing health care institution);

- substances intended for emergency actions in emergency situations;
- substances in first-aid kits in vehicles, in limited quantities specified by the legislation of the state of registration of such vehicles (however, narcotic drugs cannot be kept in railway or motor vehicles in any circumstances).

8

Rules of medicines turnover at EAEU level

REVERA

At the present day, the single EAEU market of pharmaceutical products has been legislated and is rapidly growing.

The 'single market' of medicines implies that all pharmaceutical products conforming to the standards of good pharmaceutical practices (laboratory, production, clinical, pharmacovigilance practices, etc.) and duly registered pursuant to the unified rules of registration and expert evaluation will be freely traded within the EAEU.

The single EAEU market of pharmaceutical products is regulated by the Agreement on uniform principles and rules of pharmaceutical products turnover within EAEU dated 23.12.2014.

All issues unified and harmonised at the EAEU level are key issues intended for the creation and proper operation of the single market of pharmaceutical products.

Issues regulated at the supranational level	Issues regulated at the national level of EAEU member states
– development – preclinical and/or clinical studies – quality control – registration – manufacturing – distribution of pharmaceutical products	– granting permits on preclinical and/or clinical studies of medicines – price setting – retail trade – state purchases of medicines and other procedures related to cost recovery in the sphere of pharmaceuticals trade – advertising

8.1. HARMONISATION OF PHARMACOPEIAE

Standardisation of requirements to pharmaceutical products is a prerequisite for the proper functioning of the single market. To this end, the EAEU Pharmacopeia has been created — a uniform code of requirements to pharmaceutical products applying to all EAEU member states.

Activities aiming at creating a uniform EAEU Pharmacopeia have been implemented since 2016. Harmonised uniform pharmacopeia articles (monographs) will be included into volume 1 of the EAEU Pharmacopeia and will set requirements to the quality control methods pertaining to pharmaceutical products and equipment used in quality testing, packing materials, chemical agents, drug formulations, pharmaceutical substances, standard samples and additive agents used in the production of medicines intended for the EAEU market.

At present, the EAEU Pharmacopeia Committee has approved a number of draft pharmacopeia articles, such as "Equipment", "Physical and physico-chemical methods", "Tests for limit impurity content" and "Methods of quantitative measurement". Other pharmacopeia articles are at present under discussion. The list of approved pharmacopeia articles and the list of those under discussion are available at the Eurasian Economic Commission website[1].

It is worth noting that the EAEU pharmacopeia requirements will be mandatory for all medicines circulating in the EAEU. It is anticipated that the EAEU pharmacopeia will be updated at least once each 5 years.

8.2. PRECLINICAL AND CLINICAL STUDIES

Within the single market, preclinical and clinical studies (tests) of medicines in EAEU member states are conducted pursuant to the unified rules of Good Laboratory Practice (GLP)[2], Good Clinical Practice (GCP)[3] and the current requirements to studies (tests) of medicines. Also, the EAEU rules for studying biological medicines[4] and the EAEU rules for studying the bioequivalence of medicines[5] have been approved.

8.3. REGISTRATION AND EXPERT EVALUATION OF MEDICINES

For the purpose of unhindered circulation of medicines within the EAEU, the Rules for registration and expert appraisal of medicines have been prepared and put into effect as from 06.05.2017[6]. The unified rules stipulate two procedures for the registration of medicines:

[1] http://www.eurasiancommission.org/ru/act/texnreg/deptexreg/LS1/Pages/pharmacopoeia_PO.aspx

[2] Approved by EEC Council Decision No. 81 dated 03.11.2016.

[3] Approved by EEC Council Decision No. 79 dated 03.11.2016.

[4] Approved by EEC Council Decision No. 89 dated 03.11.2016.

[5] Approved by EEC Council Decision No. 85 dated 03.11.2016.

[6] Approved by EEC Council Decision No. 78 dated 03.11.2016.

- mutual recognition procedure
- decentralised procedure

Under the mutual recognition procedure, a medicine is first registered in an EAEU country (a 'reference state') and obtain a registration certificate there. Thereupon, such pharmaceutical product will be registered in other EAEU member states (so called 'recognition states'), under an abridged procedure, and will be granted a registration certificate in each recognition state.

The decentralised procedure differs in that the registration dossier will be concurrently evaluated both in the reference state, and in the recognition states. This allows reducing the overall pendency time.

The mutual recognition procedure has already been implemented. EAEU member states have undertaken to mutually recognise the results of pre-clinical, clinical and other studies of medicines, results of production inspections, trials inspections, and pharmacovigilance inspections for the compliance with good pharmaceutical practices, and the requirements approved by the Eurasian Economic Commission[7].

For the purposes of registration and expert evaluation of medicines under the Eurasian Economic Commission Rules, the unified Nomenclature of pharmaceutical forms approved by EEC Board Decision No. 172 dated 22.12.2015 shall be used.

All pharmaceutical products duly registered according to the unified rules and marketed within the EAEU must have marking in accordance with the uniform Requirements to medicines and veterinary drugs marking as approved by EEC Board Decision No. 76 dated 03.11.2016. Such medicines shall be accompanied with a core data sheet conforming to the uniform requirements as approved by EEC Board Decision No. 88 dated 03.11.2016.

Period	Procedure
till 31.12.2020	Applicants are entitled to choose the type of rules (national or unified) to be used for the registration of pharmaceutical products. However, pharmaceutical products registered in accordance with the national legislation of a member country will only be allowed in the market of such member country.
as from 01.01.2021	All medicines are to be registered only under the EAEU rules[8]
till 31.12.2025	All pharmaceutical products registered under the national rules before 31.12.2020 must be re-registered pursuant to the EAEU single market rules.
as from 01.01.2026	All marketing authorisations issued under the national rules will be invalidated. Accordingly, turnover of pharmaceuticals not duly registered or not harmonised in accordance with EAEU requirements will be ceased.

In order to harmonise the pharmaceutical markets of EAEU member countries, a transition period has been established to secure a smooth transition from the national regulation to the unified regulation.

8.4. MANUFACTURING OF MEDICINES

The EAEU Good Manufacturing Practice (GMP) Rules were approved by EEC Council Decision No. 77 dated 03.11.2016. These rules are mandatory for all manufacturers within the EAEU territory and are applied for the issuance of production licenses and manufacturer inspections.

The status of manufacturer's Qualified Person has been established in order to secure proper compliance with these rules. A Qualified Person is appointed by a manufacturer and certified in accordance with the procedure and requirements set out in EEC Council Decision No. 73 dated 03.11.2016. Duly certified Qualified Persons will be put on the relevant register available at the EAEU web-portal[9].

8.5. WHOLESALE TRADE, SHIPPING AND STORAGE OF MEDICINES

Good Distribution Practice (GDP) Rules approved by EEC Council Decision No. 80 dated 10.11.2017 are used within the EAEU framework. These rules set out uniform requirements to the procedures of purchasing, storing, importing, exporting, trading (except retail sales to end consumers) without limitations of sales volumes, and transportation of

[7] Cl. 7 art. 7 Agreement on uniform principles and rules of pharmaceutical products turnover within EAEU.

[8] Preliminary work takes 180 calendar days, therefore, in order to be registered under the national procedure, applicants must submit their documents before July 2020. At present, state bodies are negotiating feasibility of filing documents before the end of 2020.

[9] https://portal.eaeunion.org/sites/odata/_layouts/15/Registry/PMM02/TableView.aspx?ItemId=371&ListId=0e3ead06-5475-466a-a340-6f69c01b5687.

medicines marketed within the EAEU.

EAEU member states still may regulate specific stages of medicines distribution at the national level, as long as such regulation complies with the EAEU GDP.

For instance, this applies to particular stages of distribution of narcotic/psychotropic agents and precursors, highly toxic medicinal agents and ionizing radiation emitting agents.

8.6. HARMONISATION OF PHARMACEUTICAL INSPECTION PROCEDURES

The EEC Council has established harmonised requirements for non-recurrent pharmaceutical quality system inspections. Results of such inspections will be recognised in all EAEU member states. Such inspections will reveal whether the applied production schemes conform to the requirements of the EAEU Good Manufacturing Practice.

General requirements to pharmaceutical inspections are set out in art. 10 of the Agreement on uniform principles and rules of pharmaceutical products turnover within EAEU and the Rules of pharmaceutical inspections as approved by EEC Council Decision No. 83 dated 03.11.2016.

Pharmaceutical inspections are carried out by pharmaceutical inspectorates of EAEU member states. The inspectorates are guided by the General requirements to pharmaceutical inspectorates quality system as approved by EEC Council Decision No. 82 dated 03.11.2016. The register of EAEU pharmaceutical inspectors is available at: portal.eaeunion.org[10].

Timeframes of routine pharmaceutical inspections, decision making procedures and lists of entities that have passed inspection checks and have been granted respective certificates will be established by respective pharmaceutical inspectorates.

8.7. GENERAL PHARMACOVIGILANCE REQUIREMENTS

The requirements to the pharmacovigilance system have been determined by EAEU Good Pharmacovigilance Practice (GVP) as approved by EEC Council Decision No. 87 dated 03.11.2016.

All entities must elaborate and implement own pharmacovigilance systems to secure proper safety of pharmaceutical products. All pharmacovigilance specialists within each entity shall be responsible for the proper functioning of the pharmacovigilance quality system.

Authorised government bodies will conduct inspections of pharmacovigilance systems. Such inspections may be abrupt, therefore entities must always make sure they are ready for them.

[10] https://portal.eaeunion.org/sites/odata/_layouts/15/Registry/PMM09/TableView.aspx

This material has been prepared by REVERA specialists in partnership with specialists from the Ministry of Public Health of the Republic of Belarus, on the basis of legislation of the Republic of Belarus as of March 1, 2020 (unless the text indicates otherwise), for information purposes only.

Information in this guide has been presented in concise form. The authors are not liable for any damage inflicted to any person due to any action or inaction based on any information from this guide. You should always consult a specialist in a relevant field for any concrete question.

For the purposes of this guide, all money measures have been recalculated according to BYN/USD official exchange rate as of March 1, 2020.

Some figures are indicated using the 'basic unit' — an all-purpose economic indicator applied in Belarus in calculations of duties, taxes and other payments. As of March 1, 2020, one basic unit equals to 27 BYN (about 12 USD).

Cover photo by — Joshua Coleman, unsplash.com

REVERA

REVERA

ranked among the leaders in the Belarussian market of legal services according to Chambers Global and Legal 500

20

years of experience at the Belarussian market of legal services

>40

lawyers in our team — the biggest number for Belarus

>3000

clients have worked with us

№1

in most nominations of The Legal 500 international guide

REVERA is a member of TerraLex network that unites 155 independent law firms from 100 countries of the world

BEST

the best law firm in 2011 and 2013 according to the Ministry of Justice of the Republic of Belarus

>500

foreign investors have received our consultation

Regarding the regulation of the pharmaceutical market in Belarus, please contact:

Dmitry Arkhipenko, managing partner of REVERA

+375 29 665 54 43 | da@revera.by

Valentin Anikin, associate of the Pharmaceuticals and healthcare specialization of REVERA

+375 29 641 52 66 | va@revera.by