REVERA

REVIEW OF LEGAL REGULATION OF PHARMACEUTICAL BUSINESS IN THE REPUBLIC OF BELARUS

2019

3RD EDITION

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Good day, dear reader!

Pharmaceutical markets in various countries have their peculiarities in terms of legal regulation, and the Belarusian pharmaceutical market is not an exception. Many pharmaceutical guides would exploit one of the two usual extremities: either provide very generic and loose information, or tend to quote nearly all legal regulations.

Our guide aims at not just reporting the control rules applicable to the Belarusian pharmaceutical market, but at helping you to assess risks all by yourself and to form a competent and unbiased opinion on the opportunities of your business in Belarus. Our guide gives an account of all areas of pharmaceutical business – from registration and imports of pharmaceutical products to price formation – in an integrated and consistent manner. You can get a deeper in- sight into each of the topics by checking the links to applicable legal norms.

This guide will be of great value for companies which look upon Belarus as a prospective market for launching of production or for sales of their pharmaceutical products.

I believe that the Doing Pharmaceutical Business in Belarus guide will provide answers to your questions and will be helpful in making your proper decisions.

Best regards,

Dmitry Arkhipenko,
Managing partner of REVERA

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Belarusian pharmaceutical market performance

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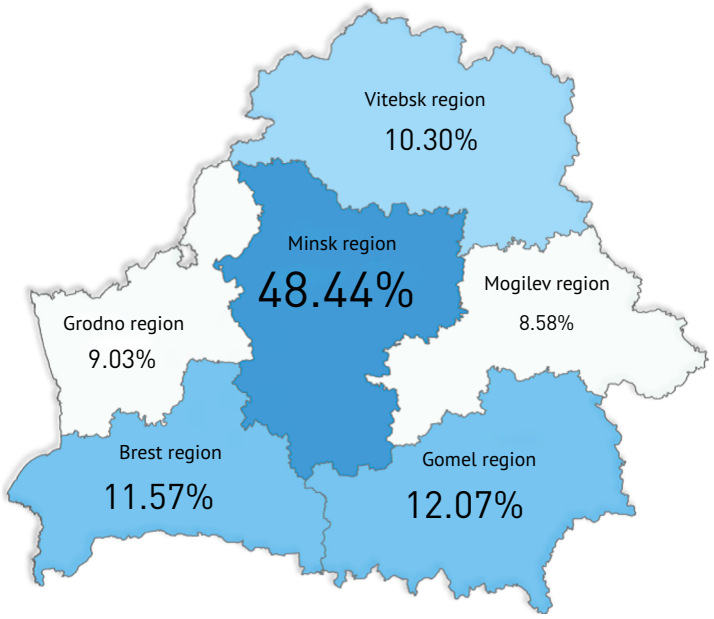
1. Belarusian pharmaceutical market performance

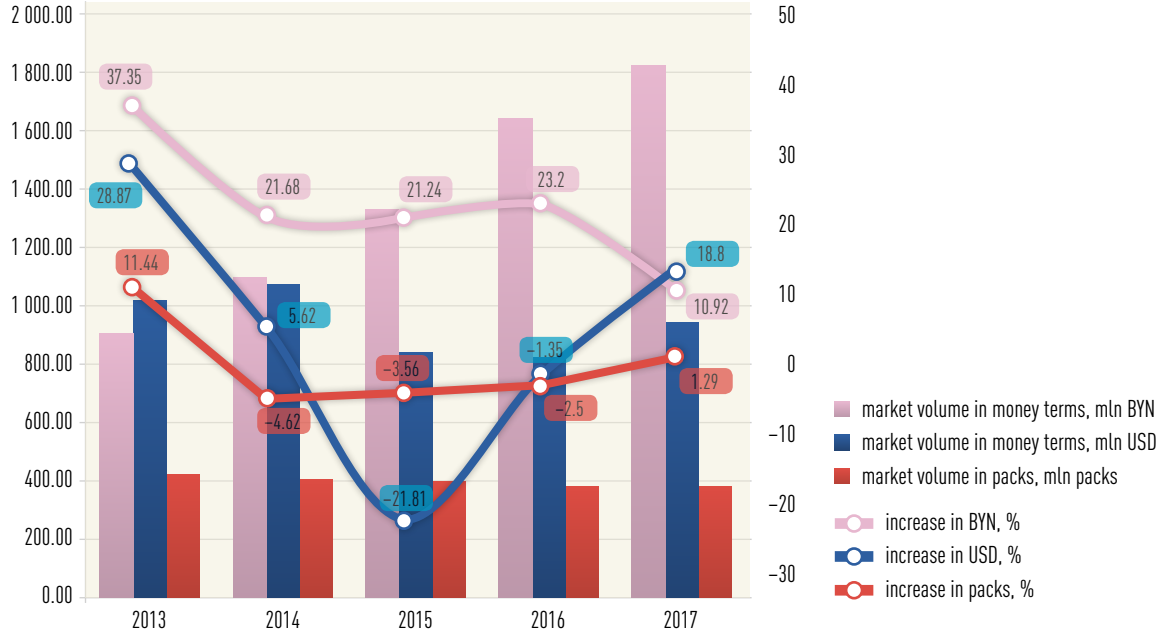
The following table depicts the volumes of the Belarusian pharmaceutical market in 2014 to 2017[1].

In 2017, the annual volume of the pharmaceutical market grew by 1.29% in physical terms, and in monetary terms - by more than 10%. The market dynamics measured in BYN has always been positive throughout 2014 to 2017 (unlike in foreign currency). A big increase in USD as compared to a smaller increase in BYN has resulted from the revaluation of the Belarusian rouble in 2017.

The regional pattern of medicines consumption can be depicted as follows.



Regional structure of Belarusian pharmaceutical market in 2017 (sales percentage (in wholesale prices) of the nationwide wholesale volume, in USD)

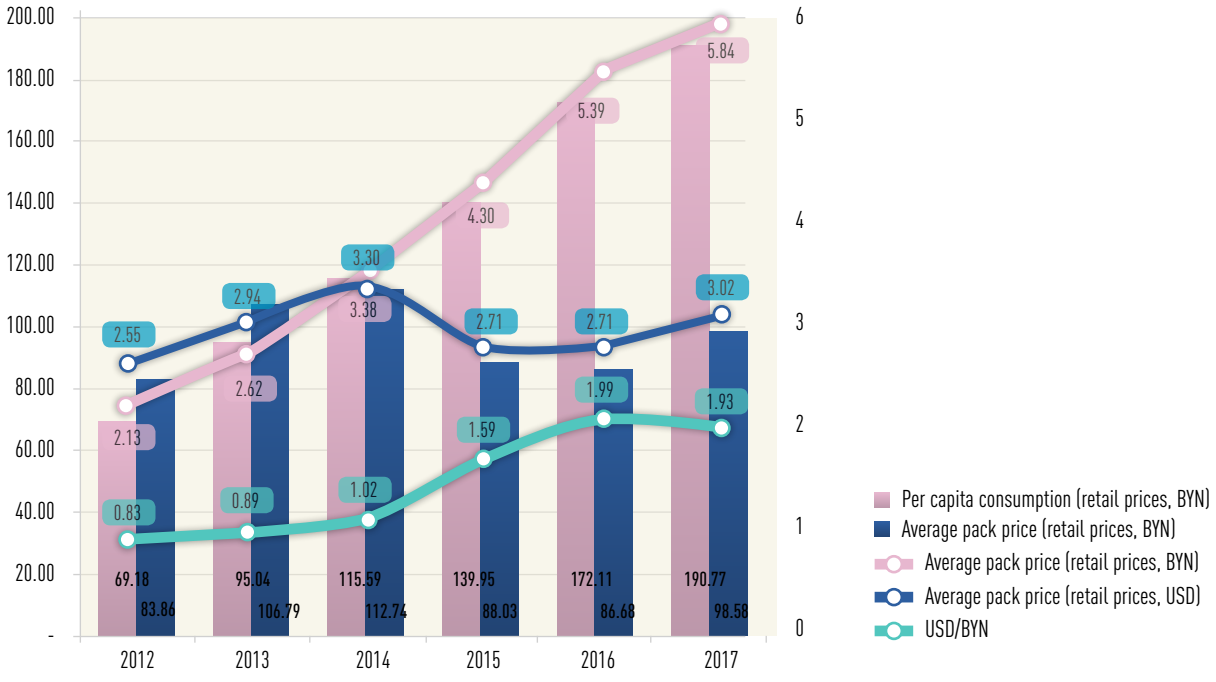


[1] Data in this section have been provided by Intellix-M. All data, tables and graphic materials are not official statistical data and shall not be deemed to be the sole source of information about the Belarusian market.

Per capita consumption of medicines (as measured in BYN) is growing annually: the last two years have seen a double increase, while the currency rate of the Belarusian rouble has doubled as well. Consumption of medicines as measured in USD has decreased. Actually, people do not consume more nowadays, the expenditures have grown only due to the price increase directly resulting from the devaluation of the Belarusian rouble. This trend applies both to foreign and Belarusian medicine.

Consumption in USD and in packs per 100,000 people

Region	Consumption in USD per 100,000 people	Consumption in packs per 100,000 people
Minsk region	13 358 321	4 658 462
Vitebsk region	8 121 670	4 033 667
Gomel region	8 081 464	3 977 007
Grodno region	7 959 054	3 689 162
Brest region	7 820 259	3 749 149
Mogilev region	7 557 118	3 738 448



Per capita consumption of medicines in 2012-2017

Top 10 manufacturers
in the Belarusian pharmaceutical market in 2017

Corporation	Wholesale sales in USD, mln	Q-ty of packs, mln	Increase in whole sales in USD, %	Increase in whole sales in packs, %
БЕЛМЕДПРЕПАРАТЫ РУП	98.18	54 85	9.19	-1.64
БОРИСОВСКИЙ ЗМП РУП	62.97	83 11	10.42	0.71
ЛЕКФАРМ СООО	49.76	17.90	18.48	3.66
НОВАРТИС	41.86	6.74	22.09	14.99
ФАРЛМЭНД СП ООО	28.30	17.77	1655	7.74
САНОФИ-АВЕНТИС	24.81	4.06	4.13	1.25
ФАРМТЕХНОЛОГИЯ ООО	24.36	20.62	16.24	0.47
ТАКЕДА	21.61	2.46	0.23	2.29
ГЕДЕОН РИХТЕР	21.43	3.44	8.98	14.74
БАЙЕР ХЭЛСКЭР	21.42	285	7.31	3.45
Прочие	542 25	168.05	15.41%	1.00%

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Licensing of pharmaceutical business

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2. Licensing of pharmaceutical business

In Belarus, a license is mandatory for the production, packaging, retail and wholesale, pharmacy production and dispensing of medicines. Also, licenses are required for the processing and packaging of medicinal plant raw material, production and sales of herbal teas .

Procedures for obtaining and revocation of licenses, requirements to applicants and licensees have been 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.

Licenses are normally granted by the Ministry of Public Health of the Republic of Belarus (hereinafter – MPH). Licenses may be issued to Belarusian legal entities and individual entrepreneurs, as well as to foreign entities having representative offices in Belarus.

Requirements to applicants for licenses will differ depending on a particular type of business activity.

Activity	License requirements
Activities/services involving sales, pharmacy production and dispensing of medicine	Applicant must validly possess premises, equipment and transport facilities required for the licensed activity.
	Chief executive of a pharmacy storehouse or a pharmacy (or the person responsible for licensed activities in separate divisions of the organization, and (or) the head of the healthcare organization) must have: ▸ primary employment in the organization. ▸ 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 secondary pharmaceutical education; ▸ a qualification category (apart from 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 and wholesale trade of medicine	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, biotechnology, pharmaceutics or medicine; ▸ at least 2 years' work experience in medicines manufacturing enterprises; ▸ such person must be made responsible (by a written order) for the quality manufactured medicines and its wholesale trade.

Licensed activities are carried out only in the location specified in the license and in compliance with special legislation (requirements of Good Manufacturing Practice[2], Good Distributorship Practice[3] and Good Pharmacy Practice[4], special sanitary regulations, requirements established by acts of the Eurasian Economic Union[5] (hereinafter – the EAEU), etc.).

Particularly, all pharmacies regardless of their form of ownership shall have available madicine according to the list prescribed by MPH Resolution No. 92 dated 10.12.2018. Also, pharmacies must comply with the requirements for premises, water supply, water disposal, microclimate, ventilation and room lighting, operation and maintenance of premises, equipment, furniture and fixtures, to staff personal hygiene, etc[6].

[2] 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.

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

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

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

[6] MPH Resolution No. 154 dated 01.10.2012

3

State registration of medicines

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3. State registration of medicines

3.1. General provisions

Domestic and foreign medicines must be registered in Belarus in order to be manufactured, sold and/or used for medical purposes. State registration involves inspection of compliance of medicines with safety, efficiency and quality requirements. Such requirements have been set out in relevant practices at the national level or at the EAEU level, as shown in the table below.

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 medicine.
till 31.12.2025	all medicines registered under the national rules before 31.12.2020 must be re-registered according to the single market rules
as from 01.01.2026	turnover of pharmaceuticals not duly registered or not conforming to the EAEU requirements will be ceased

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

The following medicines 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 medicines 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)

Pharmaceutical substances may be registered apart from medicine.

Medicinal plant raw material is subject to state registration as medicines after passing through the production process stage of giving it a specific pharmaceutical form.

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.

3.2. State registration procedure

State registration procedure comprises several stages.

№	Stage	Stage description	Timeframe
1	Submitting documents to the Expertise Centre	This stage involves: 1. Concluding an agreement with the Centre of expert evaluations and trials in public health service (hereinafter – the Expertise Centre, http://www.rceth.by/). 2. Submitting the required documents.[7]	—
2	Preliminary technical activities[8]	This stage involves: 1. Primary examination of documents. 2. Inspecting manufacturing facilities for compliance with the Good Manufacturing Practice[9] (where no inspection of the production site has been carried out in recent 5 years) 3. Approval of the quality control technique applied to medicine, quality control activities using such technique, and analysis of quality of medicines in clinical trials conducted by public health authorities. 4. Specialised examination of documents for medicines compliance with applicable regulations on safety, efficiency and quality, with due consideration of their pharmaceutical, clinical and pharmacological peculiarities. 5. Studies of bioavailability (bioequivalence) of generic medicines (apart from medicines produced from medicinal plant raw material). 6. Clinical trials. 7. Other studies and trials (where necessary).	180 calendar days
3	Submitting registration dossier to MPH	1. The Expertise Centre forwards 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 working days.
4	Payment of state duty	State registration duty amounts to 10 basic units (255 Belarusian roubles or ca. 124 US dollars)	—
5	State registration	The Expertise Centre will enter respective data into the State Medicines Register and will issue a registration certificate .	5 working days upon confirmation of payment

[7] The list of documents is set out subcl. 10.13-10.18 of the Joint list of administrative procedures conducted by public authorities and other institutions with respect to legal entities and individual entrepreneurs (hereinafter – the List of administrative procedures) as approved by Resolution of the Council of Ministers No. 156 dated 17.02.2012. The lists of required documents differ for the registration of pharmaceutical substances and PPs, as well as for Belarusian and foreign manufacturers. The requirements to documents are set out in MPH Resolution No. 52 dated 08.05.2009.

[8] The procedures for works management have been established by MPH Resolution No. 55 dated 23.04.2015.

[9] The 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.

Registration certificates are valid during 5 years. Upon expiration of this period, it is necessary to go through the procedure of confirming the state registration (similar to the registration procedure), after which an unlimited registration certificate is issued. Pharmaceutical substances are granted unlimited registration certificates immediately upon registration..

3.3. Marking of medicines

Medicines marking rules differ according to the rules used for medicines registration – national rules or EAEU rules.

If medicine is registered in Belarus pursuant to Belarusian national rules, it will be checked for the compliance of its package and marking with the requirements set out in Annex 4 to MPH Resolution No. 52 dated 08.05.2009.

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

If medicine is registered pursuant to the EAEU rules, it will be checked for the compliance of its package and marking with the requirements set out in Decision No. 76 of the Council of Eurasian Economic Commission (hereinafter – the EEC) 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 that does not comply with the instructions for medical use (leaflet) may be placed on the package.

4

Price formation

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4. Price formation

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

1) ex-factory price limits for certain manufacturers;

2) restrictions of bulk markups

3) restrictions of retail markups

4) control of retail prices in pharmacy networks

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. the supply-and-demand balance forms them[10].

However, controlled prices apply to some medicines. The list of such medicines is exhaustive and includes 35 international generic names (atropine, metoclopramide, lactulose, etc.[11]), manufactured by a number of Belarusian enterprises (PharmTech, AcademPharm, etc.[12]).

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 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[13], imports of such medicines in Belarus may be banned, and where the importer fails to eliminate such violation, registration certificate may be annulled.

4.2. Maximum bulk markups

Maximum bulk markups are established for both Belarusian and foreign medicines.

Belarusian manufacturer's price or calculated ex-factory price per unit, in basic units*	Bulk markup on Belarusian manufacturer's price or calculated ex-factory price, %	Retail 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 basic unit is 23 Belarusian roubles or ca. 12 US dollars

[10] Law № 255-3 dated 10.05.1999.

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

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

[13] Par. 4 p. 16 art. 8 of Law No. 161-3 dated 20.07.2006.

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

Wholesale price for Belarusian medicine = Belarusian manufacturer's price + bulk markup

Moreover, the rate of the bulk markup is limited in % to the manufacturer's price. Limits of bulk markups differ according to manufacturer's prices and comprise markups of all distributors within the medicines distribution chain[14]

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

Costs of ex-factory transportation will increase manufacturer's 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.

The manufacturer's financial discount does not affect the eventual markup and the wholesale price – they will be calculated net of discount. This discount (i.e. available benefit) may be only used for procurements of Belarusian medicines, development of pharmacy networks in rural areas and for compensation of losses from the intra-pharmacy production of medicines

Manufacturer's commodity discount (products supplied for free) will not impact the bulk 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 foreign medicine = calculated ex-factory price + bulk markup

Therewith, calculated ex-factory price is 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:

- Mediciness 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 medicines, 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 can also be 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 bulk markups. Retailers may also sell medicines at a price lower than the wholesale price or the ex-factory price.

4.4. Registration of prices of medicines

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 (37 international generic names including melphalan, medroxyprogesterone, pegaspargase, etc.[15]).

[14] Decree No. 366 dated 11.08.2005.

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

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 dated 19.11.2018. Within the frameworks of the procedure, the maximum sales price will be agreed upon with the Ministry of Antimonopoly Regulation and Trade of the Republic of Belarus (hereinafter – the MART).

All prices will be registered in Belarusian roubles. Registration is free of charge.

4.5. Retail price control

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

According to memorandum terms, business entities undertake to buy more medicines of domestic manufacture and to sell medicines at prices not higher than the recommended limit retail prices as defined by the MPH and published on the BelPharmacia website[16].

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[17].

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

[17] 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

Centralized purchasing of medicines

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5. Centralized purchasing of medicines

Purchasing of medicines for the public sector in the Republic of Belarus are centralized. This allows reducing delivery costs, as centralized purchasing for the entire public health system are much more cost-efficient than purchasing by separate health care facilities[18].

Centralized purchasing of medicines in Belarus are implemented 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 NUE 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 state purchases procedures.

BelPharmacia carries out procedures of centralized state purchasing 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 medicines 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 medicines to health care institutions.

An annual plan of centralized purchasing is formed based on 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).

[18] Decree of the President of the Republic of Belarus of 07.02.2019 N 40.

6

Advertising and promotion of medicines

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6. Advertising and promotion of medicines

6.1. Peculiarities of medicines advertising

Special requirements to the advertising of medicines in Belarus have been established by Law No. 225-З dated 10.05.2007 and by MPH Resolution No. 63 dated 23.07.2013.

6.2. Promotion of medicines

Medicines are promoted in Belarus by various means:

The Rules for informing medical and pharmaceutical workers of registered medicines have been established[19].

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

- be present and/or to speak at any events not approved by respective health agency;
- place (distribute) information materials in any places not specified by respective health agency;
- enter offices or other working spaces of health agencies 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 and activities/actions aiming at arousing workers' interest in ordering or selling medicines.

Special rules	Description
Advertisements must be approved by MPH	All advertisements of medicines in Belarus must be approved by the MPH*. 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 medicines advertising in a number of cases	Advertising is prohibited for the following medicines: 1) 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. 2) prescription medicines. 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, there should be an indication of the advertising nature of the information , the fact that the advertised object is a medicine, a recommendation to read the instruction, etc.

* cl. 10.19 of the List of administrative procedures.

[19] MPH Resolution No. 44 dated 17.04.2015.

Also promotion activities are restricted by anti-monopoly regulations[20].

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)

[20] Prohibitions and restrictions for officials have been established by Law No. 305-3 dated 15.07.2015.

7

Procedures for importation (exportation) of medicines

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7. Procedures for importation (exportation) of medicines

7.1. General rules

Only the following medicines may be imported in Belarus:

- registered in the Republic of Belarus
- with effective period of validity;
- of good quality and not forged.

Medicines 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 group 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[21].

In order to import any unregistered medicines on the above grounds, an importer has to obtain an MPH opinion letter. The relevant procedures are set out in cl. 10.5 of the Catalogue 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 opinion letter, 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 medicines 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 medicinal narcotic drugs

In order to import medicinal narcotic drugs in the Republic of Belarus (or export such drugs outside its territory) a special MPH permit is required. Such permits are issued in respect of medicines that are included in the National List of medicinal narcotic drugs, psychotropic substances and their precursors subject to government control in the Republic of Belarus.[22]

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 Catalogue 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 medicinal narcotic drugs in the EAEU customs territory (or export such drugs outside its customs territory), an importer in addition has to obtain a special single-use import license. Such rules apply to the medicines listed in cl. 2.12. Annex 2 to EEC Board Decision No. 30 dated 21.04.2015.

Such licenses are granted by MART, in presence of opinion letter of 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.[23]

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[24]:

- medicinal narcotic drugs by natural persons to a limit-

[21] Similar cases of importation of unregistered PPs 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 PPs according to the list set out in cl. 2.14 Annex 2 to the above Decision.

[22] MPH Resolution No. 19 dated 11.02.2015.

[23] Cl. 9.2.1. of the Catalogue of administrative procedures.

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

ed extent (narcotic 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);

- medicinal narcotic drugs, intended for emergency actions in emergency situations;
- medicinal narcotic drugs 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

Regulation of medicines turnover at the EAEU level

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8. Regulation of medicines turnover at the EAEU level

At the moment, the single EAEU market of medicines is legislated and is rapidly growing.

The 'single market' of medicines implies that all medicines 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.

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 medicines	▸ granting permits on preclinical and/or clinical studies of medicines ▸ price formation ▸ retail trade ▸ state purchases of medicines and other procedures related to cost recovery in the sphere of pharmaceuticals trade ▸ advertising

The single EAEU market of medicines is regulated by the Agreement on uniform principles and rules of medicines turnover within EAEU of 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 medicines.

8.1. Harmonisation of pharmacopeias

Standardisation of requirements to medicines is a prerequisite for the proper functioning of the single market. To this end, the EAEU Pharmacopeia has been created – that is, a uniform code of requirements to medicines 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 medicines 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.

As of today, an outline of section 1 of volume 1 of the EAEU pharmacopeia has been published. Harmonised specific pharmacopeia articles (monographs) about pharmaceutical substances and medicinal raw material of natural origin (both vegetable and animal) will be included in the following volumes.

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[25].

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)[26], Good Clinical Practice (GCP)[27] and the

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

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

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

current requirements to studies (tests) of medicines. Also, the EAEU rules for studying biological medicines[28] and the EAEU rules for studying the bioequivalence of medicines[29].

8.3. Registration and expert appraisal of medicines

For the purpose of free 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[30]. The unified rules stipulate two procedures for the registration of medicines:

- mutual recognition procedure
- decentralised procedure

Under the mutual recognition procedure, medicines will first be registered in an EAEU country (a 'reference state') and obtain a registration certificate there. Thereupon, such medicines 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 simultaneously evaluated both in the reference state, and in the recognition states. This allows reducing the overall pendency time.

Within the mutual recognition procedure, 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[31].

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 medicines. However, medicines registered in accordance with the national legislation of a member country will only be allowed in the market of such member country.
till 31.12.2025	All medicines registered under the national rules before 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 conforming to the EAEU requirements will be ceased.

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 medicines 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.

In order to harmonise the pharmaceutical markets of EAEU member countries, a transition period has been established that will ensure 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

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

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

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

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

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 whith 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[32].

8.5. Wholesale trade, transportation 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 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 drugs and their precursors, highly toxic medicinal agents and ionizing radiation emitting agents.

8.6. Harmonisation of pharmaceutical inspection procedures

The EEC Council has established the harmonised requirements for non-recurrent pharmaceutical quality system inspections. The results of such inspections will be recognised in all EAEU member states. Such inspections will reveal whether the 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 medicines 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[33].

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. Setting 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 their own pharmacovigilance systems to secure proper safety of medicines. 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.

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

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

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Information in this review is presented in concise form.The authors are not liable for any damages inflicted to any persons because of any action or refusal to act based on any information from this review. You should always consult a specialist in a relevant field for any concrete questions.

For the purposes of this review, all money measures have been recalculated according to BYN/USD official exchange rate as of 1 February, 2019.

Some figures were indicated using "base units" – an all-purpose economic indicator applied in Belarus in calculations of duties, taxes and other payments. As of 1 February, 2019, one basic unit equals to 25,5 BYN (about 12 USD).

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