

Dear reader!

Circulation of medical devices and medical equipment has its peculiarities in each country around the globe, and Belarus is no exception.

This review aims at more than depicting a specific regulation pattern applied to medical

goods in Belarus, its goal is to help you to independently assess risks and form a competent and impartial judgement about the business opportunities in Belarus. This review offers a comprehensive presentation of norms that regulate the circulation of medical goods in Belarus.

We believe that this review will be most useful for companies that treat Belarus as their prospective market, either for the production or for the sales of medical goods. This review contains characteristics of regulations applied to all business spheres, from registration and imports to price formation for medical devices and equipment, as of February 1, 2020.

We believe that this review will answer your questions and will be a good guide for your business decisions.

Sincerely,

Dmitry Arkhipenko,
REVERA managing partner

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LIST OF ABBREVIATIONS

BYN Belarusian roubles

USD US dollars

EAEU Eurasian Economic Union

EAEC EAEC

Medical goods/products Medical devices & medical equipment

Ministry of Public Health Ministry of Public Health of the Republic

(MPH) of Belarus

List of administrative Unified List of Administrative Procedures procedures provided by state agencies and other in-

provided by state agencies and other institutions with regard to legal entities and individual entrepreneurs approved by Resolution of the Council of Ministers of the Republic of Belarus dated 17.02.2012

No. 156.

Council of Ministers Council of Ministers of the Republic of

Belarus



State registration of medical products

1.1. GENERAL PROVISIONS

In order to be sold and used in medicine in Belarus, medical goods must undergo the procedure of state registration.

State registration verifies the conformity of medical goods to applicabe requirements for:

- safety
- efficiency
- quality

These requirements are established by the legislation of the Republic of Belarus or by EAEU legislation, as shown in the below table.

The national rules for medical goods registration in Belarus have been established by Resolution No. 1269 of the Council of Ministers dated 02.09.2008.

State registration is mandatory for the following medical goods:

- newly created and offered for medical use in Belarus;
- manufactured in another country and for the first time offered for medical use in Belarus;
- registered earlier and offered for medical use for another medical indication;
- similar to registered medical goods but produced by another manufacturer.

Moreover, medical goods are subject to state registration where a manufacturer or a production site of such goods has been altered and/or added.

State registration is not carried out in respect of:

- previously used and repaired medical goods;
- medical goods manufactured in Belarus under orders and according to documentation of foreign companies, where such medical goods are intended for sale outside Belarus;
 - · component parts of registered medical goods;
- raw stuff, materials and component parts for the production of medical goods in the Republic of Belarus (according to manufacturer's technical standard documentation);
- spare parts for repairs and maintenance of registered medical goods;

Period	Procedure
before December 31, 2021	Applicants may choose registration under national rules or under EAEU rules.
	However, national registration will only be valid within the territory of Belarus and only till December 31, 2021.
after December 31, 2021	Only medical goods registered according to single EAEU rules will be allowed in the EAEU territory ¹

- medical goods subject to a duly MPH permit for realisation and/or medical use of non-registered medical goods;
- medical goods imported in Belarus by a natural person for personal use.

Also, registration is not required for sales and application of medical goods under MPH permits. Those are granted in the following cases²:

- medical goods designed for research activities and international health care programmes;
- medical goods supplied for emergency needs of state agencies, in particular those intended to mitigate effects of natural calamities, catastrophes, epidemic diseases, and medical goods supplied in limited quantities in other exceptional cases;
- medical goods used for treating limited cohorts of patients or patients with rare pathologies;
 - medical goods supplied as foreign gratuitous aid;
- samples of medical goods intended for research activities as part of state registration (re-registration) procedure;
- non-registered medical goods/equipment imported in the territory of Belarus during the validity period of an expired registration certificate.

1.2. STATE REGISTRATION PROCEDURE

State registration procedure involves several stages.

¹ Information of EAEU registration rules is provided in Section 7 hereof.

² A list of documents required for MPH permit is described in cl. 10.28 of the List of administrative procedures.

Nº	Stage	Description	Time frames
1	Furnishing documents to Expert Centre	This stage involves: 1. Concluding an agreement with national unitary enterprise "Centre for health care expert evaluations and trials" (hereinafter – the Expert Centre, http://www.rceth.by/). 3. Furnish a registration dossier. ³	_
2	Preliminary technical activities ⁴	This stage involves: 1. Primary examination of documents (up to 15 calendar days). 2. Inspection of production facilities. This is done in respect of manufacturers that submit medical goods for registration for the first time, except for medical goods of foreign manufacture (except class 1 (sterile)), provided the application list comprises less than 20 units of medical products and/or less than 5 units of medical equipment ⁵ . 3. Sanitary/hygienic trials. 4. Technical trials. 5. Special documentation expertise by Expert Centre specialists. 6. Clinical trials. Ordered by MPH and carried out in respect of: 1) medical goods of Belarusian manufacture. 2) medical goods of foreign manufacture, where an expert decided to carry out clinical trials based on the results of specialised documentation expertise ⁶ . 7. Other trials (if needed).	150 calendar days
3	Submitting registration dossier to MPH	The Expert Centre will forward the documents to MPH. MPH commission on medical products and medical equipment will render a decision.	From 15 days up to 1 month. The appli- cant will be notified in writing of the decision within 7 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 Expert Centre will enter respective data into the State Register and will issue a registration certificate.	5 business days upon confirmation of pay- ment

Registration certificates are valid during 5 years. Holders must undergo a re-registration procedure (similar to the procedure of state registration):

- upon expiry of validity period of registration certificate,
 - · where medical product name is changed,

- · where manufacturer is reorganised,
- · where manufacturer changes its name,
- · where manufacturer country is changed,
- $\,\cdot\,\,$ where technical regulatory acts applying to medical product are modified/redrafted.

³ A list of documents and relevant requirements are specified in cl. 10.10 to 10.11-1 of the List of administrative procedures, and in MPH Resolution No. 41 dated 15.04.2009.

⁴ The operation procedure has been established by MPH Resolution No. 55 dated 23.04.2015.

⁵ The inspection procedure has been established by MPH Order No. 636 dated 08.06.2017.

⁶ Clinical Trials Guideline as approved by MPH Resolution No. 216 dated 18.12.2008.



Certification and declaration of conformity

In order to be sold and used in Belarus, all medical goods must undergo a procedure confirming their conformity to the applicable requirements of technical regulatory acts¹.

These requirements have been established by the Customs Union technical regulation "Electromagnetic compatibility of technical appliances" (TP TC 020/2011)².

This technical regulation applies to all medical electrotechnical, electronic and radioelectronic products and to all products containing electric/electronic components.

Conformity assessment is carried out in two forms:

1. Obligatory certification – in respect of electrical vibro-massage appliances.

Manufacturer or its authorised representative shall furnish a line of products for certification.

A batch of products (or a single product) manufactured in the EAEU shall be presented for the purpose of certification by manufacturer. A batch of products (or a single product) imported in the EAEU shall be presented for the purpose of certification by importer, manufacturer or manufacturer's authorised representative.

An 'authorised representative' means a person or an entity as stipulated in manufacturer's agreement, that performs actions on manufacturer's behalf for the purpose of conformity assessment within the unified customs territory of the Customs Union and bears responsibility for any non-conformity of products to regulation requirements.

Importer – is an EAEU country resident that concludes a foreign trade contract with a non-resident, sells products and bears responsibility for their conformity to regulation requirements.

Validity period of conformity certificates for batch-produced technical appliances is at most 5 years. No limitation applies to the validity period of conformity certificates for a batch of technical products (a single product).

2. Declaration of conformity.

Declaration of conformity is carried out in respect of medical goods that are classified as technical appliances capable of creating electromagnetic disturbance and/or comprising functions prone to external electromagnetic disturbance.

Declaration of conformity for line-produced technical appliances shall be done by manufacturer (or manufacturer's authorised representative).

Declaration of conformity for a batch of products or a single product shall be done by manufacturer, manufacturer's authorised representative or importer.

Validity period for declarations of conformity for line-produced goods is at most 5 years. Validity period for declarations of conformity in respect of a batch of products or a single product is not limited.

In order to certify or register a declaration of conformity, applicants shall address a certification agency, one of them being national unitary enterprise "Belarusian State Metrology Institute" http://www.belgim.by/.

¹ P. 4 art. 39-1 of Law No. 2435-XII dated 18.06.1993.

² Decision of Customs Union Commission No. 879 dated 09.12.2011.



Pricing

In Belarus, price formation in respect of medical goods is regulated by the following means:

- 1) restrictions of wholesale markups
- 2) restrictions of retail markups

Rules of price formation with regard to medical products have been established by Edict of the President of the Republic of Belarus No. 366 dated 11.08.2005.

3.1. MAXIMUM WHOLESALE MARKUPS

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

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

Wholesale price = Belarusian manufacturer's ex-factory price + wholesale markup

Therewith, bulk markup rate is limited in % to manufacturer's price. Limits of wholesale markups differ according to manufacturer's prices and comprise markups

of all distributors within the PP distribution chain.

Maximum wholesale markup rates differ for medical products and medical equipment.

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

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 medical goods, development of pharmacy networks 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 wholesale price will be formed on the basis of the contract price net of discount.

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

Table 1. Maximum wholesale markups and retail markups (medical products)

Belarusian manufacturer's price or calculated ex-factory price per unit, in basic units	Wholesale 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	11	30
0.5–1	8	25
1–1,5	8	21
1.5-5	8	17
over 5	4	6

Table 2. Maximum wholesale markups and retail markups (medical equipment)

Belarusian manufacturer's price or calculated ex-factory price per unit, in basic units	Wholesale markup on Belarusian manufacturer's price or calculated ex- factory price, %	Retail markup on Belarusian manufacturer's price or calculated ex- factory price, %
below 1 ths.	20	20
1 ths. to 5 ths.	10	0
5 ths. to 50 ths.	8	0
50 ths. to 100 ths.	5	0
over 100 ths.	3	0

Wholesale prices for foreign medical goods are calculated according to the formula:

Wholesale price = calculated ex-factory price + wholesale 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 adjust the contract price each month subject to currency rate fluctuations, if:

- medical goods 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 medical goods.

As in the case of Belarusian medical products, 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.

3.2. MAXIMUM RETAIL MARKUPS

Retail prices for medical products of both Belarusian and foreign manufacture are calculated according to the formula:

Retail price = wholesale price + retail markup

Retail markup is also calucated as percentage from ex-factory price of a Belarusian manufacturer or from calculated ex-factory price (for medical products of foreign manufacture).

Maximum rates of retail markups are different from those of wholesale markups. Retail traders may as well sell medical products at a price below wholesale price or manufacturer's ex-factory price.



Centralised purchases of medical goods

4.1. GENERAL PROVISIONS

All procurements of medical goods for the public sector are always centralised purchases. This allows reducing prices for medical goods supplied for state health care facilities and cut delivery costs. Thus, centralised purchases are cost-efficient for the state budget. 'Centralised purchases' mean purchases of goods carried out by a single 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 procurement procedures.

The peculiarities of centralised purchases of medical goods have been determined by Edict of the President of the Republic of Belarus No. 40 dated 07.02.2019, and by MPH Decree No. 162 dated 11.02.2019.

Thus, the following peculiarities apply to centralised purchases of medical goods:

- MPH determines the lists of medical goods subject to centralised purchases;
- RUE BelMedTechnika and its subsidiaries are organisers of centralised purchases of medical goods.
- organisers in their own name conclude agreements with suppliers of medical goods;
- customers (public health centres, hospitals) purchase medical goods from organisers without participating in any public procurement procedures.

The main feature of centralised purchases of medical goods in Belarus is that organisers would not only carry out public procurement procedures, but would also conclude contracts with winners for further sales of medical goods to health care facilities. Thus, customers will be able to purchase medical goods from organisers without additional procedures. They will only have to conclude a supply contract or a commission contract.

Plans for medical goods purchases are prepared within the scope of nation-wide needs and are subject to annual approval by MPH¹.

Customers (state health centres, hospitals) are entitled to independently carry out centralised purchases:

- 1) of medical goods:
- where estimated costs of uniform medical goods amount to at most 2,000 basic units (54,000.00 BYN or ca. 25,257 USD), on the basis of customer's annual demand;

- by agreement with the organiser, in case organiser's centralised purchase procedure brings no results, in the volume not exceeding customer's quarterly demand;
- in case of emergency need of purchasing medical goods or spare parts (in an emergency situation, etc.)
 - 2) of spare parts worth below 2,000 basic units;
- 3) of medical goods not included in lists of medical goods subject to centralised purchases, but specified in the National Form of Medical Goods².

4.2. PECULIARITIES OF MEDICAL GOODS PURCHASES

Organisers normally arrange and carry out the following procedures of centralised purchases for medical goods:

- · electronic auctions;
- · open competitions;
- · price bid queries;
- · single-source purchases.

Such centralised purchases schemes are carried out according to a standard procedure in compliance with Law No. 419-Z dated 13.07.2012.

Website www.icetrade.by is the official Internet platform containing information on state purchases, in particular on bulk purchases of medical goods. Today, www.icetrade.by, along with the trading platform http://goszakupki.by/, are national information resources that furnish data on current needs and purchases of Belarusian enterprises and organisations.

These official websites contain such information as:

- annual bulk purchases plans, invitations to purchases procedures, in particular bulk 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 verified texts of regulatory acts pertaining to purchases, in particular bulk purchases,
 - · other information.

¹ Plan for bulk purchases of medical products funded through national budget as established by MPH for 2020, approved by MPH Order No. 1045 dated 03.09.2019. http://minzdrav.gov.by/upload/dadvfiles/1045_1.pdf

² MPH Resolution No. 90 dated 10.12.2014 http://minzdrav.gov.by/upload/lcfiles/000127_493889_-90.pdf

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 public procurement procedures, in particular centralised purchases of medical goods, 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/down-load/user_memo_rb.pdf
- for residents of the Russian Federation: http://zakupki.butb.by/auctions/template_docs/down-load/user_memo_notresident.pdf
- for other non-residents: http://zakupki.butb.by/auctions/template_docs/down-load/user_memo_world.pdf

4.3. PREFERENTIAL CORRECTION

Preferential correction may be applied to bid prices offered by participants of public procurement procedures. 'Preferential correction' 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 correction	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. ³
25 %	Participant offers in-house production (goods/works/services) of an entity having at least 50% of disabled persons on its staff schedule.

³ Countries enjoying the 'national regime of treatment' today are: Russian Federation, Republic of Armenia, Republic of Kazakhstan, Kyrgyz Republic.



Advertising and promotion

Belarus has special requirements to the advertising of medical goods that must be observed along with general advertising requirements¹.

'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:

- $\,\cdot\,\,$ 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.

5.1. PECULIARITIES OF MEDICAL GOODS ADVERTISING

Special rules	Description
Advertisements must be approved by MPH	All advertisements of medical goods must be approved by 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:
	 advertising 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 medical goods advertising in a number of cases	Advertising is prohibited for the following medical goods:
	1) non-registered medical goods. The only exception is advertising of non-registered medical goods during clinical trials, and only for the purpose of engaging volunteers (patients) to participate in such trials ⁴ .
	2) medical goods 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 medical goods adverts (and respective prohibitions) is quite broad. For instance, adverts must indicate that the information is of an advertising nature, that the advertised product has medical contra-indications and adverse reactions, etc.

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 Also, an approval from MPH is required – cl. 10.19.6. of the List of administrative procedures.

5.2. ANTI-BRIBERY RESTRICTIONS

Anti-bribery legislation restricts distribution and promotion of medical goods where officials are involved 5 .

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)
- chief executives and officials of local health care departments

These are the principal restrictions and prohibitions established by the Anti-Bribery Law.

The principal restrictions and prohibitions established by the Anti-Bribery Law

Prohibitions for officials	Исключения из запретов
Taking presents	Exceptions from the prohibition
Making trips at the expense of another person relationship to whom are connected with official activities	 Allowed in case it is: an official business trip; on invitation of spouse or close relative (including relatives in law); in accordance with an international treaty or an arrangement between state authorities of different states; upon senior officer's consent and at the expense of a non-government association (fund)

⁵ Law No. 305-Z dated 15.07.2015.



Regulation of medical goods turnover at the EAEU level

At the moment, the single EAEU market of medical goods is legislated and is growing.

The 'single market' of medical goods implies that all medical goods conforming to EAEU legislation are freely traded within the EAEU.

The single EAEU market of medical goods and medical equipment is regulated by the Agreement on uniform principles and rules of medical goods (products and equipment) turnover within EAEU dated 23.12.2014 and acts of Eurasian Economic Commission (hereainfter – the EEC). General principles of the single market are stipulated in article 31 of EAEU Treaty dated May 29, 2014.

EAEU uniform rules are aimed at unifying and harmonising the legislation of member states in a number of spheres for the purpose of creating a single market of medical goods¹.

6.1. REGISTRATION OF MEDICAL GOODS

For the purpose of unhindered circulation of medical goods within the EAEU, the Uniform Rules for registration and evaluation of safety, quality and efficiency of medicinal products have been prepared and put into effect as from May 6, 2017².

The Uniform Rules provide for a transition period to secure a smooth transition from the national regulation system to EAEU uniform regulation system.

Period	Procedure
till 31.12.2021	Applicants are entitled to choose the type of rules (national or EAEU) to be used for the registration of medical goods. However, national registration will only be valid in a respective member country and only till 31.12.2021.
as from 31.12.2021	Only medical goods registered under uniform EAEU rules will be allowed within EAEU.

The Uniform Rules stipulate, in particular:

 procedure for registration and evaluation of safety, quality and efficiency of medical goods; • procedure for the introduction of amendments into registration dossiers;

procedure for issuing duplicates of registration certificates;

grounds for refusal to register medical goods;

procedure for suspending or annulling registration certificates.

These Rules do not apply to medical goods used in emergency situations or to diagnose new zoonotic or extremely dangerous infectious diseases. Turnover of such goods is regulated by national legislation.

Registration according to EAEU uniform rules implies equal requirements for medical goods manufactured in the EAEU and outside EAEU.

Procedures for registration and expert evaluation of medical goods are depicted in the following scheme.

An authorised agency/organisation of EAEU reference state will carry out an expert evaluation of medical goods at applicant's option. Results of such surveys/trials and expert evaluations obtained in accordance with EAEU rules will be mutually recognised by all member states.

Then an authorised agency/organisation of EAEU reference state will prepare an expert report and will furnish it to authorised agencies of other EAEU states (recognition states) for harmonisation, whereupon a registration certificate will be issued.

In respect of several modifications of a medical product, one registration procedure and one registration dossier will be required, where the following condition are fulfilled:

- 1) such products fall within one category in accordance with the EAEU uniform nomenclature of medical goods. The nomenclature is published at the General Information Resources and Open Data Portal: https://portal.eaeunion.org/sites/odata/_layouts/15/Registry/PCLS064/View.aspx³.
- 2) such products have been produced by the same manufacturer;
- 3) such products differ only in configuration sets and/ or technical parameters not affecting their operation principles and functionality;
- 4) such products fall within the same category of potential operation risks⁴;

¹ Criteria for medical products within EAEU have been established by EEC Board Recommendation No. 25 dated 12.11.2018.

² Approved by EEC Council Decision No. 46 dated 12.02.2016

³ The formation procedure for the EAEU uniform nomenclature of medical goods has been established by EEC Council Decision No. 177 dated 29.12.2015 and EEC Council Decision No. 46 dated 03.04.2018.

⁴ Medical goods classification procedure subject to potential risk degree to patients' and personnel health has been established by EEC Council Decision No. 173 dated 22.12.2015

5) some other conditions⁵.

Registration certificate shall also indicate ingredients of each medical product, its component parts, accessories and consumables⁶.

The following medical goods are exempt from registration in EAEU:

- imported into EAEU customs territory by natural persons and intended for personal use;
- manufactured in another member state under patients' individual orders exclusively for personal use; these are subject to special requirements in accordance with prescription issued by medical specialist;
- imported into EAEU customs territory and intended for officers of diplomatic/consular missions;
- imported into EAEU customs territory for the purpose of medical treatment of passengers and crew members of vehicles, train crew and transport drivers arriving in the EAEU;
- imported into EAEU customs territory for the purpose of medical treatment of participants of international cultural/sportive events and international expeditions, and for the purpose of exhibition holding;
- imported into EAEU customs territory for the purpose of research/trials, in particular for scientific purposes;
- imported into EAEU customs territory as humanitarian aid, in cases stipulated by national legislation.

All information about medical goods registered within the EAEU, agencies authorised to carry out evaluations/ trials, about undesired event/incidents related to medical goods and corrective measures for the purpose of promoting medical goods safety is accumulated at the EAEU General Information Resources and Open Data Portal: https://portal.eaeunion.org/_layouts/15/Cit.Eec. Impop/Portal.Landings/MedicalDevices.aspx⁷

6.2. TECHNICAL, CLINICAL AND LABORATORY TRIALS, BIOLOGICAL EFFECT TRIALS

A number of procedures are required in order to

prepare a registration dossier and to carry out medical product registration, including technical trials, biological effect trials, clinical trials, measurer trials, and evaluation of product safety, quality and efficiency.

Rules for these procedures have been determined at the EAEU level.

1) Technical trials.

At the EAEU level, Uniform rules for technical trials of medical goods have been approved by EEC Council Decision No. 28 dated 12.02.2016.

Technical trials are carried out in order to assess the conformity of medical goods to general safety and efficiency requirements, marking requirements and operational documentation requirements. Technical trials are not carried out in respect of medical goods and medical equipment for in vitro diagnostics (reagents or reagent sets).

General requirements for medical goods safety and efficiency, marking requirements and operational documentation requirements have been established by EEC Council Decision No. 27 dated 12.02.2016.

General requirements are subdivided into:

- general requirements for safety and efficiency applicable to all medical goods;
- requirements applicable to medical goods for in vitro diagnostics;
- requirements applicable to medical goods, except medical goods for in vitro diagnostics.

Trials are carried out under agreements with authorised agencies on samples furnished by applicant. Protocols of technical trials will be issued to applicants based on trial results.

2) Clinical/laboratory trials.

Uniform Rules for clinical and laboratory trials of medical goods have been approved by EEC Council Decision No. 29 dated 12.02.2016.9

These Rules determine the procedures used for:

• clinical trials on humans carried out for the purpose of studying safety and efficiency of medical goods/

⁵ Criteria for including several medical product modifications into one registration certificate have been established by EEC Council Decision No. 123 dated 24.07.2018.

⁶ Regarding medical product's element its 'ingredient/component' for the purposes of registration will be carried out in accordance with EEC Council Decision No. 116 dated 24.07.2018.

⁷ Information system maintenance procedures are established by the Commission. These procedures have been approved by EEC Council Decision No. 30 "On approving maintenance procedures for Medical goods turnover information system".

⁸ Applies to medical goods described as 'measurers' in accordance with EEC Council Decision No. 42 dated 12.02.2016. Measurer approval procedures have been endorsed by EEC Council Decision No. 98 dated 18.10.2016.

⁹ Also, clinical trials are regulated by principles established by EEC Board Recommendations No. 11 dated 17.07.2018 No. 11.

equipment and relevant diagnostics or treatment techniques;

• clinical/laboratory trials of medical goods used for in vitro diagnostics, i.e. systemic trials of analytical characteristics and, where applicable, of clinical efficiency, for the purpose of identifying such goods' conformity to manufacturer's description.

Based on the results of trials, a report of clinical proof of efficiency/safety or a report of laboratory trials of medical product used for in vitro diagnostics will be compiled.

3) Biological effect trials.

Rules for biological effect trials of medical goods have been approved by EEC Council Decision No. 38 dated 16.05.2016.

These trials are conducted in respect of medical goods and/or medical appliances intended to contact human body surface, mucous tunic and/or internal environment, as long as such goods/appliances are sold within the EAEU market.

They are aimed at assessing medical goods' conformity to general safety and efficiency requirements, marking requirements and operational documentation requirements.

6.3. PRODUCTION OF MEDICAL GOODS

Manufacturer of medical goods designed for the EAEU market is obliged to:

- 1) procure proper implementation and maintenance of a quality management system in respect of medical goods¹⁰.
- 2) create and properly maintain a data system to collect and analyse data pertaining to the application of medical goods, detection of adverse effects of medical goods; deliver reports to authorised agencies based on clinical use of some medical goods with high risk potential¹¹.
- 3) within 30 calendar days from the date of decision on the termination of medical product production, it shall be communicated to the authorised agency that issued registration certificate.

Requirements for medical goods quality management system vary subject to their potential risk.

Medical goods (except medical-care products for in vitro diagnostics) fall into 4 categories **subject to their potential risk:**

- class 1 comprises medical goods with low degree of potential risk;
- class 2a comprises medical goods with average degree of potential risk;
- class 2b comprises medical goods with higher degree of potential risk;
- class 3 comprises medical goods with extreme degree of potential risk.

Each medical product may be ranged in one class only.

Ranging medical goods in classes involves considering each product's functionality, application conditions and also the following criteria:

- · duration of medical product application;
- · invasiveness of medical product;
- possibility of medical product's contact or interrelation with human body;
- mode of medical product administration (via a natural opening or surgically);
- application of medical product for vital parts/systems (heart, blood circulatory system, central nervous system);
 - use of energy sources.

Medical goods for in vitro diagnostics are also ranged in 4 classes subject to their potential risk:

- class 1 low degree of potential risk for individuals and public health;
- class 2a average degree of potential risk for individuals and low degree for public health;
- class 2b high degree of potential risk for individuals and/or average degree of potential risk for public health;
- class 3 high degree of potential risk for individuals and public health.

Each medical product for in vitro diagnostics may be ranged in one class only.

¹⁰ Requirements to implementation, maintenance and evaluation of a quality management system in respect of medical goods in terms of their potential risk have been approved by EEC Council Decision No. 106 dated 10.11.2017.

¹¹ Rules for medical goods safety, quality and efficiency monitoring have been established by EEC Council Decision No. 174. Monitoring includes collection and analysis of data pertaining to undesired incidents and relevant decision making. 'Undesired incidents' mean any failure or deterioration of characteristics of a medical product, insufficiency or inadequacy of accompanying information/documentation, or an adverse effect not specified by core data sheet that has resulted or might result, directly or indirectly, in death or serious deterioration of health of users or third parties.

6.4. MARKING OF MEDICAL GOODS

Medical goods registered according to EAEU rules are marked with a special sign confirming that such medical product is allowed in the EAEU market. This marking is used instead of the single EAEU market sign that is used to mark other goods.

Subject to surface colouring, this sign looks as depicted in pic. 1 and 2.

EAC abbreviation means 'Eurasian Conformity', and MED means 'medical'12.

Marking with the special circulation sign shall be performed by manufacturer or its authorised representative before putting a medical product into EAEU circulation.

Along with the special circulation sign, medical goods labelling shall also contain a prescribed set of data.

Information to be mandatorily indicated in medical product labelling has been defined by EEC Council Decision No. 27 dated 12.02.2016.

1. Requirements with regard to medical goods labelling (except medical goods for in vitro diagnostics).

Medical product labelling must contain the following information:

- · name and/or trade name of medical product;
- information required to identify medical product and information on its therapeutic indications (if needed);
 - · data on manufacturer;
- information on presence of any medicinal agents, biological material or nanomaterial (where such nanomaterial is in unbound state) with the aim of excluding their absorption by consumer when using medical product strictly according to the intended purpose as indicated by manufacturer;
- batch code/number, or medical product's serial number:
 - safe use life (indicating year and month);
- year of manufacture of medical product, where medical product's safe use life is not indicated.
- information on special storage conditions and/or circulation of medical product (if needed);
- information on medical product's sterility (where medical product is supplied as sterile) specifying sterilisation technique;
- information on medical product's sterility (where medical product is supplied as sterile), specifying sterilisation technique;



- warnings or safety precautions meant to attract user's or third party's attention.
- information on one-time use of medical product (where it is a one-time use product);
- information on medical product's reconstitution, specifying number of reconstitution cycles and any pertinent restrictions (where a one-time use medical product is a reconstituted product);
- information on production of medical product by user's individual order exclusively for personal use in accordance with a written health professional's prescription;
- information on medical product's intended use for clinical trials for the purpose of registration only;
- information on medical product's intended use for exhibition or demonstration purposes only; in such a case marking requirements as specified in previous clauses are not obligatory;
- information on inactivation of possible viruses and other infectious agents in the medical product presented as caption "no antibodies to VIH/VIH2 and hepatitis C/hepatitis HBsAg found" (where medical product includes any human blood serum or human tissues).

Where medical goods or their components intended for administration into, or excretion from human body of any medications, body fluids or other substances, or for transportation or storage of such components/ fluids/substances contain any harmful agents that are (depending on concentration) cancerogenic, mutagenic or toxic for reproductive function, or contain phthalates, such medical goods are subject to special marking. Such special marking will be placed on medical product, its package or secondary package used for storage and transportation.

¹² A detailed description of the special sign of circulation of medical goods in the EAEU market is given in EEC Council Decision No. 26 dated 12.02.2016.

Marking of sterile and non-sterile medical goods must enable differentiation of identical or similar types of medical goods issued as sterile or non-sterile products: i.e. it must enable users to differentiate a sterile medical product from a non-sterile product.

Marking must be placed onto medical product itself. Where it is impossible or inadvisable, marking (partially or fully) shall be placed onto packages of each medical product unit, and/or onto collation pack, and/or onto core data sheets.

Marking may be complemented by medical product information in machine-readable format, in particular using radio frequency identification or bar codes.

2. Additional requirements to marking of medical goods for in vitro diagnostics

Marking of medical goods for in vitro diagnostics must comply with requirements for other medical goods and also contain the following information:

- information on intended use of medical product for in vitro diagnostics;
- data on (net) mass of content (in weight units or volume units), quantity of units or any combination of parameters that fairly presents package content (where possible);
- data on basic ingredients contained in the package of medical product for in vitro diagnostics;
- caution sign, where medical product for in vitro diagnostics contains any hazardous substances;
- information on special microbiological status or purity of medical product for in vitro diagnostics (if needed);
- information specifying that medical product for in vitro diagnostics is intended for user's self-testing or for testing in user's presence (where possible).

6.5. RULES OF COMPETITION IN THE SINGLE MARKET OF MEDICAL-CARE PRODUCTS

General competition rules as established by the EAEU Treaty:

- prohibition of any actions (omissions) of an economic agent (market participant) having a dominant position (i.e. where individual domination amounts to at least 35%, and collective domination to at least 50% or 70%) resulting in actual or potential exclusion, restriction, elimination of competition and/or infringement of interests of other entities/participants;
 - · unfair competition is not allowed;
- prohibition of agreements between economic agents (market participants) of member states who are market competitors acting in the same product market which actually entail or may entail certain consequences;
- prohibition of 'vertical' agreements between economic agents (market participants), except for 'vertical' agreements which are acknowledged permissible pursuant to the permissibility criteria;
- prohibition of other agreements between economic agents (market participants), except for 'vertical' agreements which are acknowledged permissible pursuant to the permissibility criteria, provided it has been found that such agreements actually result or may result in restriction of competition;
- prohibition of coordination of business activities of economic agents (market participants) of member states by natural persons, business entities and/or non-commercial organisations, where such coordination actually results or may result in any of the effects specified in clauses c. and d., provided they cannot be acknowledged permissible pursuant to the permissibility criteria.

Manufacturers of medical goods will have to comply with general competition rules when realising medical products in the EAEU single market.

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