The Pharma Legal Handbook

Russia

Regulatory, Pricing and Reimbursement Overview · Preclinical and Clinical Trial Requirements · Marketing, Manufacturing, Packaging and Labeling Advertising · Traditional Medicines and OTC Products · Product Liability · Patents and Trademarks · Regulatory Reforms · Cannabinoid Drugs, Medicinal Cannabis and Opioid Drugs · Orphan Drugs and Rare Diseases · Localization · Biosimilars and Biologics

PHARMA BOARDROOM

Russia

The Pharma Legal Handbook answers essential questions about this environment for pharmaceuticals in Russia.
It is a must have for any company operating in the country or looking to enter the market.

Prepared in association with Lidings, a leading Russian law firm, it should answer any questions linked to Regulation, Pricing, Clinical and Preclinical Trials, Marketing, Manufacturing, Trademarks and Patents.

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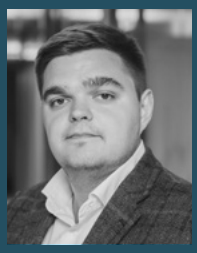

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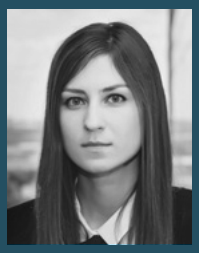

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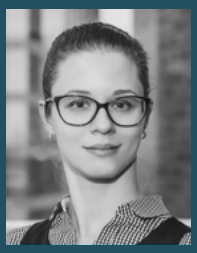

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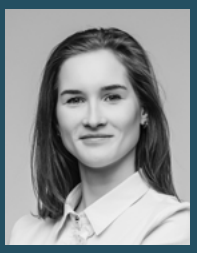

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Specializing in all areas of the legal practice, we particularly focus on the regulatory issues important to the global pharmaceuticals and healthcare companies operating in Russia and CIS region

Leading Russian and international legal directories highlight Lidings as the TOP Russia law firm advising Life Sciences sector companies

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Leading legal adviser in dispute resolution, corporate and M&A, intellectual property and life sciences fields in Russia

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Health Care Law and Life Sciences

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Ranked for an outstanding industrial expertise in healthcare and pharmaceuticals (dispute resolution and medical and pharmacology)

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Life Sciences - Patent Litigation

Who is Who Legal, 2021

TOP legal advisor in arbitration, employment, corporate, intellectual property, TMT and pharmaceuticals and healthcare

Pravo.ru-300, 2020 »

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01 REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

1. What are the regulatory authorities with jurisdiction over drugs, biologicals, and medical devices in your country?

The authorities responsible for applying and enforcing the regulatory framework shall be:

- concerning drugs and biologicals – the Ministry of Healthcare of the Russian Federation (the "**Minzdrav**") and the Federal Service for Surveillance in Healthcare (the "**RZN**");
- concerning medical devices – RZN.

2. What is the regulatory framework for the authorization, pricing, and reimbursement of drugs, biologicals, and medical devices?

The regulatory framework for pricing and reimbursement of drugs and biologicals includes Federal Law dd 21.11.2011 No. 323-FZ "On Fundamental Healthcare Principles in the Russian Federation" (the "**Law on Fundamental Healthcare Principles**"), Federal Law dd 12.04.2010 No. 61-FZ "On Circulation of Drugs" (the "**Law on Circulation of Drugs**"), which provisions are supplemented with the regulations, adopted by the Government of the Russian Federation and Minzdrav.

Russia, being the member state of the Eurasian Economic Union (the "**EAEU**"), complies with the EAEU provisions regarding the formation of the Common Market of medicines and medical devices under Art. 30 and Art. 31 of the Eurasian Economic Union Treaty dd 29.05.2014. Starting from 2021, authorization (i.e. registration) of new medical drugs in Russia is performed under the regulations of the EAEU that include the Rules of registration and examination of medical drugs approved by the decision of the Council of the Eurasian Economic Commission dd 03.11.2016 No. 78 (the "**EAEU Rules**") and other applicable regulations of the EAEU.

The are no specific requirements for the pricing of drugs in the private sector, except common antitrust regulations that shall be considered. As well there is no reimbursement in the private sector. As for the public sector and the drugs included in the list of vital essential and necessary drugs, please, refer to **Question 12 of this Chapter**.

The regulatory framework for authorization, pricing and reimbursement of medical devices includes the Law on Fundamental Healthcare Principles, the provisions of which are supplemented with the regulations, adopted by the Government of the Russian Federation and Minzdrav. Starting from 2022, registration of new medical devices is to be performed under the applicable EAEU regulations. Before that registration of new medical devices can be performed under national laws.

Cl. 2 Art. 38 of the Law on Fundamental Healthcare Principles provides for the segregation of medical devices for classes, depending on the degree of the potential risk of use of medical devices, and types, depending on the

nomenclature classification of medical devices (i.e. the purpose of their use), that is set forth by Decree of Minzdrav dd 06.06.2012 No. 4н. The class of the medical device affects its registration, i.e. procedure for obtaining marketing authorization (please, refer to **Question 4 of this Chapter**), and post-registration control.

The classes of the medical devices include the following:

- class 1 - medical devices with a low degree of risk (for instance, medical gauze);
- class 2b - medical devices with an increased degree of risk (for instance, solution for lens);
- class 2a - medical devices with an average degree of risk (for instance, X-ray apparatus);
- class 3 - medical devices with a high degree of risk (for instance, coronary stent).

The are no specific requirements for the pricing of medical devices in the private sector, except common antitrust regulations that shall be considered. As well there is no reimbursement in the private sector. As for the public sector, please, refer to **Question 12 of this Chapter.**

3. What are the steps to obtaining authorization to develop, test, and market a product?

The manufacturers or their authorized representatives in Russia shall obtain marketing authorization from Minzdrav for drugs and biologicals and from RZN – for medical devices. The registration procedures are outlined in Administrative regulations of Minzdrav on the provision of state services for the state registration of medical drugs intended for circulation in the EAEU common market of medical drugs under the EAEU Rules in respect of drugs, and by the Law on Fundamental Healthcare Principles and supplementary regulations of the Government of the Russian Federation and Minzdrav – in respect of medical devices.

3.A. DRUGS

The EAEU Rules provide for 2 different registration procedures:

A. Mutual recognition procedure
B. Decentralized procedure

A. Mutual recognition registration procedure

Within this procedure, the applicant chooses one of the EAEU member states as a reference state that will be responsible for a full-fledged cycle of procedures, including tests and inspections, resulting in an expert report. In other chosen member states (recognition states) only examination of the expert report from the reference state and particular modules of the registration dossier takes place. Registration in the reference state is first completed and then recognition in other EAEU member states (recognition states) follows. The applicant independently chooses the reference state and recognition state(s) between the EAEU member states.