ALRUD

Newsletter

Key changes in Life Sciences for the June-October 2022 period

November 1st, 2022

Dear Ladies and Gentlemen,

We are glad to present you a current digest of the most significant bills, regulatory changes, and measures affecting the pharmaceutical and healthcare industry for the period from June to October 2022.

Extension of the national procedure for registration of medical devices until 2025

Medical devices ("**MDs**") in the territory of the EAEU can be registered under the national procedure until December 31, 2025.

The draft minutes with these amendments to the Agreement on Uniform Principles and Rules for Circulation of Medical Devices (Devices for Medical Use and Medical Equipment) within the EAEU dated December 23, 2014 were approved by the Council of the Eurasian Economic Commission in August 2022.

The changes will come into force after the minutes are signed by the EAEU member states. The current rules provide for the possibility of MD registration under to the national procedure until the end of 2022.

Extension of the simplified registration of medical devices until 2025

On September 26, 2022 Decree of the Government of the Russian Federation dated September 19, 2022 No. 1643 "On Amendments to Decree of the Government of the Russian Federation dated April 1, 2022 No. 552" came into effect, extending the simplified registration of the most demanded MDs up to January 1, 2025.

The list of MDs that can be registered under the simplified procedure is drawn up by a special interdepartmental commission.

Simplification of MDs import for registration purposes

From August 8, 2022 importing the MDs for the purpose of state registration requires only sending a respective notification via the "*Gosuslugi*" (Public Services) portal.

It is no longer necessary to obtain permission provided for by Order of the Ministry of Health of Russia dated June 30, 2020 No. 661n for importing medical devices into the territory of the Russian Federation for the purpose of state registration thereof.

Ministry of Industry and Trade has updated the list of goods for parallel imports

The List includes selected pharmaceutical manufacturers and reagents and consumables for cancer treatment equipment.

A clarification was made about the exclusion from the List of goods registered as medicines and MDs regarding a certain group of goods.

The bill on online sales of prescription medicines

On October 20, 2022 a law was signed amending Federal law dated April 12, 2010 № 61-FZ "On Circulation of Medicines", which will allow online sale of prescription medicines from March 1, 2023 to March 1, 2026 in Moscow, Moscow region, and Belgorod region;

In order to purchase medicines, it will be necessary to provide electronic prescriptions. At the same time, online sales of medicines that are available for free or at a discount for certain categories of citizens, as well as medicines that contain narcotic drugs and psychotropic substances, and medicines with an ethanol content over 25 percent will be prohibited.

The list of medicines allowed for sale will be approved separately.

Access of the Ministry of Industry and Trade to trade secrets of medicine production

Federal Law No. 311-FZ dated July 14, 2022 "On Amending Article 6 of the Federal Law "On Trade Secrets" and Article 45 of the Federal Law "On Circulation of Medicines" gave the Ministry of Industry and Trade the right to obtain information

on the production of medicines that constitutes a trade secret.

The purpose of the law is to regulate licensing of medicines production and inspections for compliance with the good manufacturing practice rules within the EAEU.

The Ministry of Health is obliged to provide the Ministry of Industry and Trade at its request with documents containing information on the production process and quality control of medicinal products contained in the registration dossier for the medicinal product. The Ministry of Health will have to notify the manufacturer of such a transfer.

Simplified procedure for confirmation of compliance of imported and manufactured products

By Decree of the Government of the Russian Federation dated August 31, 2022 No. 1522 "On Amendments to Annex 18 to Decree of the Government of the Russian Federation dated March 12, 2022 No. 353" the simplified procedure for confirmation of compliance with mandatory requirements for products imported from abroad or released into circulation in the country was extended until September 1, 2023.

Thus, legal entities and individual entrepreneurs will have the right to assess the compliance of goods with mandatory requirements in the form of declaration of compliance on the basis of their own evidence.

There is also provided a list of cases in which a national accreditation body suspends a declaration of compliance issued under a simplified procedure, as well as the procedure according to which the accreditation body suspends the declaration of compliance and recognizes it as invalid or resumes its validity.

Labeling of dietary supplements and antiseptics

Decree No. 1466 of the Government of the Russian Federation dated August 20, 2022 "On Amending Certain Acts of the Government of the Russian Federation as regards Extension of the Duration of the Experiments on Labeling Goods with Identification Means" extended the experiment on the labelling of dietary supplements ("biologically active additives" or "**BAAs**") and antiseptics until February 28, 2023.

The Ministry of Industry and Trade of the Russian Federation plans to approve mandatory labeling of cosmetic products for hand hygiene with a declared antimicrobial effect, as well as skin antiseptics, from 01 April, 2023. The draft decree of the Russian Government is currently at the stage of public discussion and independent anticorruption expert review.

The Ministry of Industry and Trade of the Russian Federation also proposed to start mandatory labeling of nutritional supplements from April 1, 2023. At this stage, the conclusion of the regulatory impact assessment procedure on the draft resolution of the Government of the Russian Federation is being prepared.

The Ministry of Industry and Trade Commission for self-regulation of marketplaces

The Commission for the creation of conditions for self-regulation in electronic commerce under the Ministry of Industry and Trade of the Russian Federation (the "**Commission**") began accepting applications from sellers and marketplaces which may report problems in interaction. The Commission will consider only those issues that have not been resolved bilaterally.

The Commission is an advisory body formed to implement self-regulation mechanisms in the trade sector and to prepare, if necessary, proposals for their legislative fixation. Decisions made by the Commission are of advisory nature.

The Commission comprises representatives of the Ministry of Industry and Trade of the Russian Federation, associations and unions, marketplaces, manufacturers and suppliers (if necessary, representatives of other relevant authorities will also be invited to participate).

When reviewing applications, the principles enshrined in the Standards for Interaction between Marketplaces and Merchandisers will be taken into account.

A package of temporary measures of the EAEU to accelerate the introduction of medicines into the market

Bodies of the EAEU member states authorized to regulate circulation of medicines have the right to establish a special procedure for registration of medicines in case of actual or anticipated shortage due to external economic impact measures.

The Council of the Eurasian Economic Commission adopted a package of temporary special measures in the field of circulation of medicines to be in force until December 31, 2023:

- To automatically extend until the end of 2023 the validity of all permits issued in accordance with the EAEU law (registration certificates for medicines and GMP compliance certificates of EAEU production sites);
- Allow to perform simultaneously inspections of manufacturing sites for compliance with

GMP requirements, including by remote inspection, and registration of medicines under the rules of the Union, as well as to conduct such GMP inspections in post-registration mode.

New rules for online advertising

From September 1, 2022 amendments to Federal law No. 38-FZ dated March 13, 2006 "On Advertising" came into effect. Advertising on the Internet is now subject to mandatory marking and accounting, which significantly complicates the procedure for advertising campaigns on the Internet.

An overview of the key changes that companies need to consider when placing online ads starting September 1, 2022 is available here.

Reform of legislation on personal data and information

In July 2022 the President of the Russian Federation signed several laws providing for sweeping changes in the regulation of personal data, privacy, and data protection.

An overview of the legislative novels is available here.

Reservation of employees of pharm business for purposes of military deferment

Military deferment from call-up to military service due to mobilization is to be provided to the reserved employees of pharm business. Russian Ministry of Industry and Trade is preparing the list of the employees of pharm business subject to the reservation. Pharm companies wishing to explore the options of reservation of their employees should apply to the reservation committee leading by the Ministry of Industry and Trade.

We will continue to monitor developments in this area and will be ready to provide necessary legal support on issues related to the daily activities and interests of participants in the Russian pharmaceutical market.

We hope that the information provided herein will be useful for you. If any of your colleagues would like to receive our newsletters, please send them the link to complete a Subscription Form. If you would like to learn more about our Healthcare and Pharmaceutical Industry, please let us know in reply to this email. We will be glad to provide you with our materials.

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If you have any questions, please, do not hesitate to contact ALRUD partner

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