ALRUD

Legal Regulatory Guide Russia

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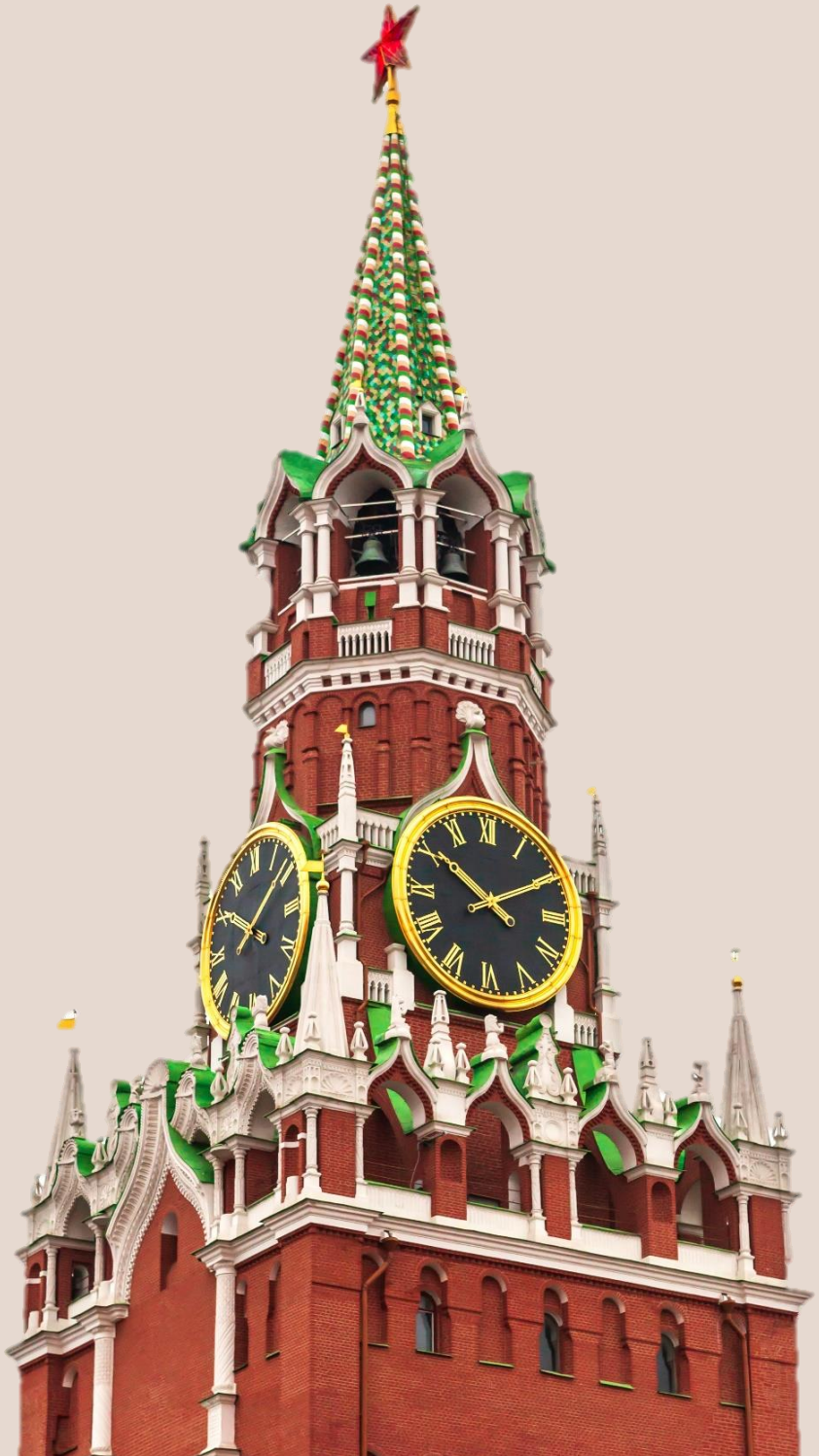

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Pharma

Start of the year
for pharmaceutical companies

The Rules of registration and assessment of medicines, for medical use in the EAEU, come into force

According to the Decision of the Eurasian Economic Commission Council ("EEC"), dated November 3rd 2016 No. 78 ("Decision"), from January 1st 2021, medicines can only be registered, in the Russian Federation, in accordance with the Rules of registration and assessment of medicines for medical use, approved by the Decision ("EAEU Rules"). For the other member states of the Eurasian Economic Union ("EAEU"): the Republic of Armenia, the Republic of Belarus, the Republic of Kazakhstan and the Kyrgyz Republic, the EAEU Rules will become mandatory from July 1st 2021, in accordance with the Decision of the EEC Council, dated December 23rd 2020 No. 128.

According to the lawmakers, the new rules of registration, and renewal of registration of medicines for medical use, are aimed at the circulation of medicines in the EAEU market, the quality, efficacy and safety of which has been assessed in accordance with the requirements, that take into account the best world practices. The EAEU Rules apply to the following procedures, related to the release of medicines, onto the EAEU market ("Procedures"):

A. registration;
B. confirmation of registration;
C. making changes to the registration dossier; and
D. assessment of medicines.

We would like to highlight the main changes that will affect participants in the pharmaceutical market, in 2021, in connection with the application of the mandatory EAEU Rules.

Procedure for the transition to a new regulation

The transition period for the mandatory application of the EAEU Rules began on January 1st 2016. From this date, until January 1st 2021, applicants were able, among other things, to register new medicines, in accordance with national legislation, or the EAEU Rules, at their discretion.

From January 1st 2021, applicants in the Russian Federation are able to register medicines for medical use only in accordance with the EAEU Rules. For the other member states, the EAEU Rules will become mandatory only from July 1st 2021.

The transition period will end on December 31st 2025. Until this date, all registration certificates issued according to the national procedure remain valid, until December 31st 2025. Term registration certificates, with an expiry date earlier than this date, can be re-registered at the request of the applicant, under the national procedure and extended until December 31st 2025. Moreover, in the case of registration under the national procedure, the circulation of a medicinal product can only be carried out exclusively on the territory of such State.

Thus, from January 1st, 2026, only those medicines that have been registered, or re-registered, under the EAEU Rules, should remain on the territory of the EAEU.

Changes in the registration procedure for medicines

Registration will be carried out, at the request of the applicant, in two ways:

A. successively, in several EAEU member states, in accordance with the procedure for mutual recognition;

B. simultaneously in several EAEU member states, in accordance with the decentralized registration procedure.

Please note that, according to the EAEU Rules, applicants will have to take into account:

- the requirements for the stability of medicines and pharmaceutical substances;
- the list of stages of medicines production and;
- the classifier of units for measuring the dosage and concentration of active substances in the composition of medicines.

In general, the EAEU Rules are aimed at the transparency of the Procedures, clarification of new requirements. They contain a large number of examples, and also use international terminology.

Also, with the start of the mandatory validity of the EAEU Rules, the rules of good manufacturing practice of the EAEU, approved by the Decision of the EEC Council of November 3rd 2016 No. 77 ("EAEU GMP Rules"), become mandatory. At the same time, due to the spread of the COVID-19 pandemic and the closure of borders, the only way to inspect foreign production facilities could be remote verifications. However, the EAEU inspectorates are deprived of such an opportunity due to the lack of appropriate legal procedures. We believe that the EEC will resolve this situation, in the near future.

In addition, it is difficult to inspect foreign production facilities, for compliance with the EAEU GMP Rules, by Russian authorized persons, due to the lack of a sufficient volume of by-laws. We expect that the federal executive authorities will close all the gaps in local regulation, for the use of the EAEU Rules, in the near future.

The first out-of-court compulsory license for a medicine

On December 31st 2020, the Government of the Russian Federation adopted the Order No. 3718-p ("Order"), which allowed the Russian joint-stock company Pharmasintez to produce a medicine with an international non-proprietary name: Remdesivir, a medicine for the therapy of COVID- 19, during 2021, without the consent of Gilead Sciences, Inc., the patent's holder for this medicine.

Legal provisions

The Russian laws provide for obtaining a compulsory license for inventions, utility models, and industrial designs ("objects of patent rights") in two ways:

A. by a judicial procedure;

B. with the permission of the Government of the Russian Federation, in the interests of national security.

The first compulsory license for a medicine, in Russia, was obtained by a judicial procedure. In June 2018, the Moscow Arbitration Court issued Nativa LLC a compulsory, non-exclusive license for Lenalidomide. This medicine was protected by the patent of the American corporation Celgene. The parties have acknowledged that the new medicine is dependent on another. It cannot be used by the owner without violating the rights of the first patent holder.

The second procedure, for issuing a compulsory license, provides for the right, of the Government of the Russian Federation, to authorize the use of objects of patent rights, in the interests of national security, without the consent of the patent holder, notifying him/her promptly of this and with the payment of a proportional compensation. Precisely this right was exercised, for the first time, in relation to the patents for Remdesivir.

According to the Order, the Ministry of Industry and Trade of the Russian Federation must submit, to the Government of the Russian Federation, information, on the payment of a proportional compensation to the patent's holders from Pharmasintez, within 3 months. At the same time, the procedure for payment and the amount of compensation was not determined by the Government of the Russian Federation and will probably be determined and approved in the future.

The importance of the Order

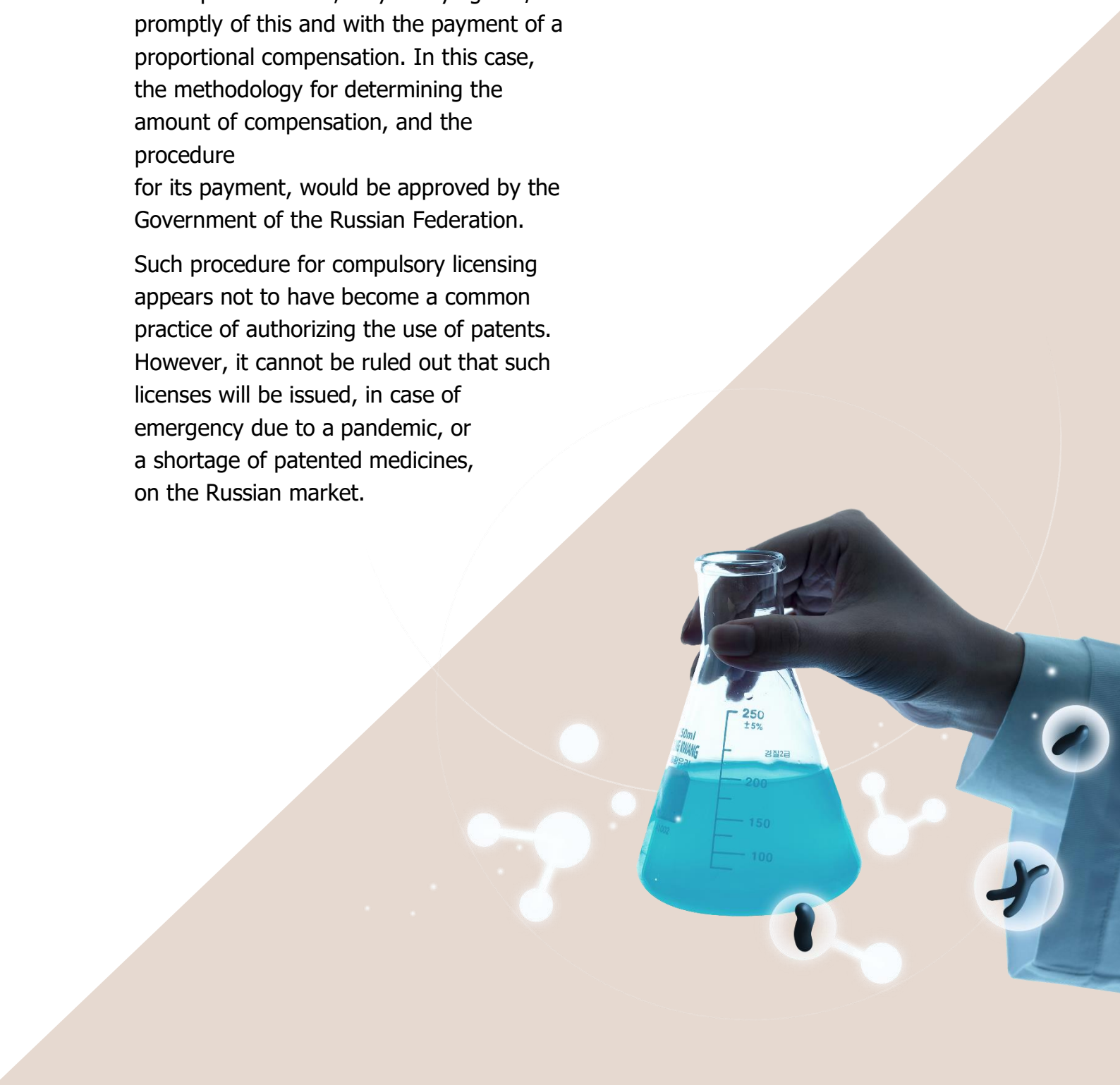
The Government of the Russian Federation used its right to issue a compulsory license for only the first time. This demonstrates that this decision is exceptional and associated with the COVID-19 pandemic.

Until now, the question of whether it is possible to issue compulsory licenses for medicines, based on the criterion "in the interests of national security", has remained open. In this case, the Government of the Russian Federation chose the path of broad interpretation, for prompt authorizing of the use of patents,

without the consent of the copyright holder, in the out-of-court procedure.

For the same purposes, the State Duma is considering a draft law that would allow the Government of the Russian Federation to make a decision on the use of an invention, without the consent of the patent holder, in case of emergency, related to ensuring the national defense and state security, protecting the life and health of citizens, without the consent of the patent holder, only notifying him/her promptly of this and with the payment of a proportional compensation. In this case, the methodology for determining the amount of compensation, and the procedure
for its payment, would be approved by the Government of the Russian Federation.

Such procedure for compulsory licensing appears not to have become a common practice of authorizing the use of patents. However, it cannot be ruled out that such licenses will be issued, in case of emergency due to a pandemic, or a shortage of patented medicines, on the Russian market.



Telecom

A step to digitalization of communication services

The era of digitalization, during with pandemic, requires the states to follow the latest trends of new technologies in communications and streamline existing ways of interaction. At the end of December 2020, it was announced that the President of the Russian Federation had signed amendments to the current Federal Law "On telecommunications" No. 126-FZ dated July 7th 2003 ("**Telecommunications Law**"), *entering into force on 1st June, 2021* [1] (the "**Amendments**").

As it has been declared, the new regulations aim to resolve a number of problems, experienced by telecom operators, as well as state bodies, among which are:

A. simplification of signing communication services contracts through the Internet and revision of identification process;

B. combating any illicit market of SIM cards; and

C. anti-theft measures to protect mobile phones.

Remote identification and signing

In contrast to the current regulation regarding remote conclusion of communication services contracts, the Amendments offer three ways of execution of an agreement[2]:

A. using a simple electronic signature, provided that the key (meaning usually login and password) is received, during a personal visit of the center of State services and the identification process is organized by means of specifically prescribed technologies;

B. an enhanced unqualified electronic signature; and

C. an enhanced qualified electronic signature.

Significant change could concern the possibility of telecom operators to use self-developed solutions for identification, when, for example, a customer used to send, to the operator, a photo of ID and a selfie. However, this option is excluded by adding, to the wording of law, the necessity to identify each person by means of the State and municipal services portal called Gosuslugi (in particular, the Unified Identification and Authentication System (the "**UIAS**")), along with biometric data from the Unified Biometric System (the "**UBS**"), operated by Rostelecom PJSC.

Generally, the Amendments, listing the ways of identification of customers and remote signing in a new order, have not eliminated the key problem – exclusion of the necessity to visit an office (either an

[1] Federal Law No. 533-FZ dated December 20th 2020 "On Amendments to the Federal Law "On Telecommunications".

[2] Current version of Telecommunications Law provides for two options: enhanced qualified electronic signature and simple electronic signature provided the key obtained during the face-to-face meeting of an operator with a client.

operator's or an authority's office for receiving keys for electronic signatures). Thus, the clients who have no account on the Gosuslugi web site, authorized by personal visits of the respective office, as well as no enhanced electronic signature of both types, run a risk to be unable to start receiving communication services online. As a result, the proposed Amendments have removed an obligation of telecom operators to arrange face-to-face meetings with clients, but at the same time require from them establishing ways of interaction with the Gosuslugi system, and from clients – visiting offices.

At the same time, it is pointed out that the Amendments contribute to the widespread use of e-SIMs, breaking down the main barriers (from the perspective of legislators), impeding development of a new business solution, such as implementation of a variety of remote ways to enter into a communication services contract and to the utmost – ensuring implementation of a reliable for the state bodies identification mechanisms. However, distant connection of devices with e-SIMs will be limited to options (A) and (C), above due to explicit provision of the Amendments.

Proof of identity for corporate services

Legal entities and sole proprietors, enabling communication services with a telecom provider, for the purpose of sharing them with the employees, will be obliged to transmit a certain list of data about each employee (one of them is to be adopted by the Government of the Russian Federation additionally) to the UIAS. Otherwise, if the telecom operator's control procedure finds discrepancies (or the information is simply absent), the operator will be entitled to stop rendering services to the specific employee. However, when the inconsistency occurs unintentionally, the employer has a chance to provide updated and authentic information for identification.

Register of IMEI

Persons registered with the UIAS and communicated so-called "*user equipment identifier*" (IMEI), assigned while the mobile device is manufactured, to the UIAS, will be entitled to make an entry in the system, so that the telecom operator will be obliged to terminate rendering communication services, to the certain holder of a phone number. Nevertheless, it shall be noted that IMEI may be doubled among the mobile manufacturers (*i.e.* IMEA can be not unique), thus, reducing efficiency of the idea.

New monitoring system

In order to ensure that the telecom operators verify the accuracy of information about the subscribers and users of communication services, rendered to the former, the Amendments set forth some basic provisions of operation of the informational monitoring system. The main control procedures, as follows from the law, will be connected with reconciliation of the received data[3] with that contained within UIAS.

[3] Such information is to be received by the authorized state bodies upon provision of access to it by telecom operators.

Summarizing the above, the reform of Telecommunications Law, aiming at simplifying ways of connection to telecom services through the Internet, actually does not reach its declared goals, in particular, connected with the remote signing of communication services contracts. However, some uncertainty with regard to e-SIM was eliminated, ensuring their legalization. Nevertheless, based on the statistics, the lack of subscribers, registered with the UIAS, together with the significant (according to telecom operator's estimations) costs, for implementation of new signing and identification procedures, may postpone the universal establishment of relations with subscribers with use of remote ways only.

Food & Beverages

Changes in Russian legislation on turnover of alcohol

On January 1st 2021, a number of provisions, changing the requirements for production, import and turnover of ethyl alcohol, alcoholic and alcohol-containing products, came into force. We have analyzed the new regulation, separated the key changes and have listed them below:

Replacement of excise stamps by special federal stamps

According to the amendments introduced to the Federal Law "On state regulation of production and turnover of ethyl alcohol, alcoholic and alcohol-containing products and on restriction of consumption (drinking) of alcoholic products" ("**Alcohol Law**") as a general rule, all imported alcohol (save for several exceptions such as beer and cider) now shall be marked with federal special stamps ("**FSS**"), but not with excise stamps, as it was before.

The procedure for obtaining FSS is regulated by the new regulation[3] providing for the rules of production, purchase, destruction and labelling of FSS. These have certain amendments compared to procedures that existed before. New samples of FSS and the list of their details and elements were introduced as well[4].

The new regulations provide for transition period which implies the following terms:

A. the customs authorities will continue to issue excise stamps, for applications accepted before the end of 2020, until March 31st 2021;

B. it will be possible to import alcohol, with excise stamps, until December 31st 2021;

C. it is allowed to purchase, supply and sell such products until the expiration date.

Other amendments to Alcohol Law and sub-laws

Apart from replacement of excise stamps by FSS and change of the respective procedures, there are a number of other amendments which came into force:

A. The new regulation has adjusted the system of accounting and reporting on production, turnover and use of ethyl alcohol, alcoholic and alcohol-containing products, capacity utilization, volume of the harvested grapes used for the production of wine products by establishing a mandatory transfer, of the specified data, to and within the Unified State Automated Information System (EGAIS)[5].

B. The new law defines the requirements for road transport, used for transportation of

[3] The Resolution of the Government of the Russian Federation of 29.12.2020 N 2348 "On the labeling of alcoholic beverages with federal special stamps"

[4] The Decree of the Government of the Russian Federation of 09.06.2020 N 841; The Order of Rosalkogolregulirovanie of 17.12.2020 N 401

[5] For more information, see Article 14 of Alcohol Law.

ethanol and bulk alcohol products, with an ethanol content of more than 25% of the volume of finished products, and in excess of 200 gallons per year[6].

C. The Government has updated the rules for submitting notifications about customer, date, time and place of retail sale of alcoholic beverages, during the provision of public catering services on-site[7]. It is established that the applicant draws up and submits a notification to the licensing authority in the prescribed form by e-mail, or by using other telecom channels, in the form of an electronic document, signed with an enhanced qualified electronic signature of an applicant, or an applicant's representative.

D. New rules for determining the boundaries of adjacent territories, where the retail sale of alcoholic beverages is prohibited, are introduced. The exact borders of the adjacent territories shall be determined by a municipal legal act[8]. Municipal legal acts of local bodies, adopted before January 1st 2021, continue to be applied, until the relevant local body decides to establish new borders of adjacent territories.

E. The revised provisions have established a new procedure for the purchase of basic technological equipment for the purpose of its use for the production of ethyl alcohol, alcoholic and alcohol-containing products[9].

F. The Rules for maintaining the unified state register of capacities of the main technological equipment for production of ethyl alcohol, or alcoholic beverages, have been updated[10]. The Government has amended the list of grounds for entering the information in the register.

We continue to trace the development of Russian legislation and practice on turnover of alcohol and alcohol-containing products and will keep you updated.

[6] Article 18 of Alcohol Law.

[7] The Resolutions of the Government of the Russian Federation of 09.06.2020 N 841 and of 23.12.2020 N 2232

[8] The Resolution of the Government of the Russian Federation of 23.12.2020 N 2220

[9] Article 8 of Alcohol Law.

[10] The Resolutions of the Government of the Russian Federation of 09.06.2020 N 841 and of 23.12.2020 N 2231

Extension of the regulator's supervisors' authorities for the categories of corn and agrochemicals

Traceability of grain

The Federal Law N 520-FZ "On Amendments to the Law of the Russian Federation "On Grain" and Article 14 of the Federal Law "On the Development of Agriculture" (hereinafter - "**the Law**") was adopted on December 30th 2020.

The Law provides for the creation of the Federal State Information System of traceability of grain and its processed products. The System is being created in order to ensure accounting for the batch volume of grain and the batch volume of grain products in their circulation, as well as to analyze, process the submitted data and information and control their reliability.

This System should include information about producers, owners, carriers of grain and those who store it, as well as about batches of grain and products of its processing, their consumer properties, about results of the State monitoring of grain and so on.

The Law also prohibits importing to, and exporting from, Russia grain without any shipping documents for the batch. In order to execute such a document, it is envisaged that it will be provided by a laboratory that is accredited.

The provisions on State monitoring of grain, and the procedure for exercising federal State control (supervision) in the field of quality and safety of grain and processed grain products, have been established. At the same time, the chapter regulating State support of grain production and processing becomes invalid.

These changes are adopted, in the framework of the Strategy of development of the grain complex of the Russian Federation, for the period up to 2035, prepared by the Ministry of Agriculture.

According to this Strategy, after the adoption of the Law, it is planned to develop a draft Government decree "On the Federal State Information System of traceability of grain and its processed products ". This decree should approve the rules of creation of the System. It aims to automate the processes of collection, processing, storage of information, to ensure access to it, its presentation and dissemination.

The Government decree should also determine federal executive body authorized for introduction of the State information system of traceability of grain and its processed products.

The Law will come into force on January 1st 2022, and State control in the field of quality and safety of grain and its products will be implemented from July 1st 2021, by the federal bodies authorized by the Government decree.

Changes in regulation of pesticides and agrochemicals

Federal Law N 522-FZ "On Amendments to the Federal Law "On the Safe Handling of

Pesticides and Agrochemicals" in terms of improvement of state control (supervision) in the field of safe handling of pesticides and agrochemicals" was adopted on December 30th 2020 (hereinafter - the "**Law**").

The Law provides for amendments aimed at strengthening State control in the field of safe handling of pesticides and agrochemicals, through the establishment of mandatory requirements for their safe handling, as well as to regulate the State's supervision in this area. Such responsibilities include checking the status of the certificate of State registration of a pesticide, or agrochemical, and assessing the compliance of imported substances, with the requirements of the document. In some cases, regulatory authorities will take samples for laboratory tests of pesticides and agrochemicals, to assess compliance with the registration certificate. The Law also defines the rights and duties of officials of the federal executive authorities, to control the safe handling of substances.

In accordance with the Law, mandatory requirements for safety of pesticides and agrochemicals, processes of their application, rules and forms of assessment of their compliance with these mandatory requirements are established by international treaties of the Russian Federation, law of the Eurasian Economic Union and legislation of the Russian Federation, in the fields of technical regulation, environmental protection and ensuring sanitary and epidemiological welfare of population.

The Law provides for determination, by the Government of the Russian Federation, of specialized customs checkpoints, across the state border of the Russian Federation, through which pesticides and agrochemicals will be imported. The Government of the Russian Federation is also authorized to approve regulations on state control over safe handling of pesticides and agrochemicals.

Also, the Federal State Information System of Traceability of Pesticides and Agrochemicals is to be established.

This System is to be created to ensure accounting for batches of pesticides and agrochemicals in their handling, storage, transportation, application and sale, as well as analysis, processing of data and information submitted to it and control over reliability of such data and information.

The procedure for creating the system, its development and operation, including the rules for registration and submission of data and information to it, terms, forms for submission of data and information, as well as other rules and procedures will be established by the Government of the Russian Federation.

The amendments under the Law come into force on June 29th 2021.

New basis for biosafety

The end of 2020 was heralded by a number of laws and amendments implemented in the Russian legislation, in particular, ones covering a previously unregulated area – biosafety, reflecting the spirit of pandemic times. A year after introduction in the State Duma of the Russian Federation the Federal Law No. 492-FZ "On Biological Safety in the Russian Federation" (hereinafter the "**Biosafety Law**") was enacted on December 30th 2020. [1]

The Biosafety Law aims to establish the legal basis for the system ensuring biosafety in Russia, as declared in the explanatory note, made by the law's drafters. The law, inter alia, specifies the key definitions, sets forth the main principles of ensuring the biosafety, main biological threats, rights and obligations of entities and citizens in connection with the subject matter of the Biosafety Law etc., as well as the respective authority of the state bodies assuring implementation of the stated rules. It is also planned to create a unified, biological risk-monitoring network to assist in tracking of developments in the field of biosafety, development of products, including those created with use of genetic engineering technologies and synthetic biology technologies. Currently, it seems hard to say precisely whether the monitoring will impose additional reporting obligations, as the only prescribed purpose for it is to assess efficiency of the laws and regulations on biosafety that are now in force. Besides, in order to manage biological risks and exchange information, between the State bodies effectively, the State information system is going to be launched, whereas the procedure for provision of information there will be adopted additionally, by the Government of the Russian Federation.

Among many framework provisions, the Biosafety Law imposes, on drug sellers, an obligation to deposit the strains of pathogenic microorganisms and viruses used in production of medicines, for medical use and veterinary use, registered and admitted to circulation in the territory of the Russian Federation, as well as medical products, in collections of pathogenic microorganisms and viruses. As far as we understand, and based on the wording, such depositing differs from one prescribed by the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, as the aim of the former is to prevent biological threats, but not to ensure the patent procedure. Nevertheless, despite the fact that it is to establish some special protection measures of such collections, we expect that without the precise definition of the strains (differentiating maternal and non-maternal ones) the intellectual property rights to inventions of some manufacturers may be violated by means of such depositing. Moreover, the Biosafety Law requires entities to provide information about scientific research in the sphere of biosafety that, without a certain elaborated procedure of reporting, is hardly likely to be assessed correctly, in terms of IP security.

A separate block of Biosafety Law provisions is assigned to reduce the spread of infectious diseases caused by pathogens with resistance, for purpose of which the following restrictions are supposed to be implemented :

A. restrictions on release and sale of drugs intended for treatment of infectious and parasitic diseases, caused by pathogenic and potentially pathogenic microorganisms, in order to exclude their use, in the absence of medical reasons;

B. a ban on use of pharmaceutical substances in breeding, raising and keeping animals;

C. a ban on use of medical drugs intended for treatment of infectious and parasitic diseases in animals, caused by pathogenic microorganisms and potentially pathogenic microorganisms, without clinical confirmation of a diagnosis, as well as a ban on the continuation of use of such drugs in the absence of treatment efficacy (except for some cases to be established by the authorized federal executive body); and

D. a restriction on use for medical purposes, including for the treatment of farm animals, using medical drugs specified in clause (C) above and which list is approved by the State body.

Moreover, we expect that some new requirements will be set forth for potentially dangerous biological objects, when its activity (both current and the planned one) is presumed to be dangerous.

In addition, the Biosafety Law gives a direct opportunity to (i) apply special economic measures to ensure biological safety; and (ii) establish a procedure for import and export of the pathogenic microorganisms and viruses.

Speaking about positive issues, we see that the text of the Biosafety Law often refers to the notion of human microbiota, ones of plants and some livestock in the context of its safety, recovery, creation and manufacturing of food products, feed made to normalize the microbiota, as well as its opportunities used for development of new means and biological technologies. The context and wording of the Biosafety Law let us suppose that the activity connected with researches and inventions, in the sphere of microbiota, may receive State support, in some form, or at minimum may not be subject to serious restrictions.

To sum up, it is important to note that most provisions of the Biosafety law are of a general nature and it has been already stated that, at minimum sixteen laws shall be elaborated in furtherance of the adopted regulations. In the light of the nature of the Biosafety Law, it seems impossible to estimate exactly the full effect that these may cause to the industry, thus, we will follow the respective developments in order to provide with the essential information in a timely manner.

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