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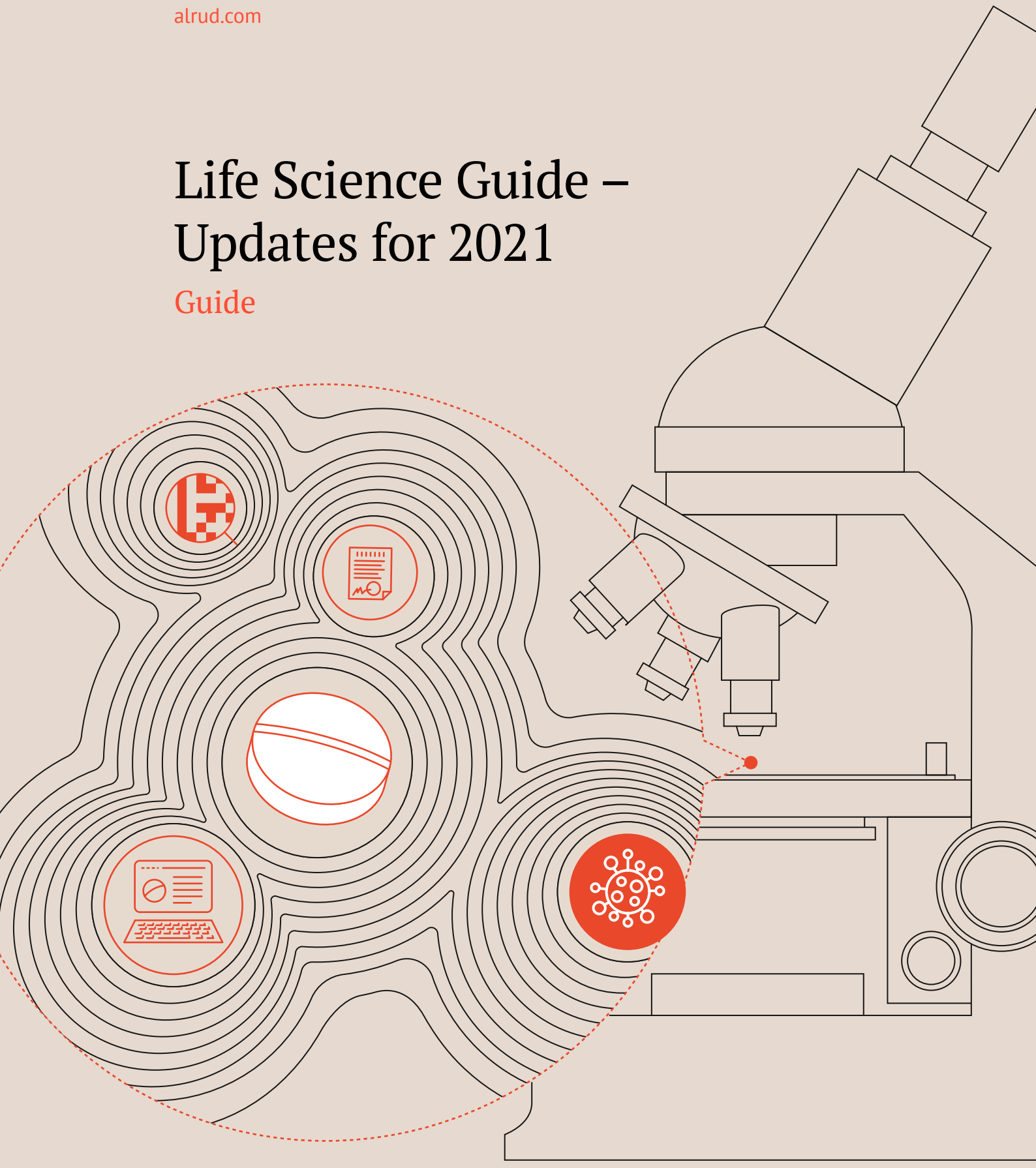
Life Science Guide – Updates for 2021

Guide



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Life Science Guide – Updates for 2021

Dear Readers!

Last year was challenging for people worldwide and has had a major impact on the way the business is done and the way governments want to regulate it. The Russian authorities did not stand back: they implemented many changes in different spheres of regulations, including in the pharmaceutical and healthcare market. Given its vital importance, especially in the current times, this market was, and remains, under the close supervision of the Russian authorities.

As discussed last year, there is a tendency to employ different modern technologies, which would allow achieving and monitoring compliance of the market participants, in more efficient way. While sometimes the Russian authorities permit digital solutions to answer the demands of the market and consumers, in most cases they are used to exercise stricter control and play "big brother" to the market itself.

We selected the following recent trends in Russian life sciences' regulations, as they would be vital for a variety of non-Russian companies interested in doing business in Russia:

- Status of the unified market of the EAEU
- Potential extension of track and trace requirements to food additives
- Introduction of e-commerce for medicines
- Compulsory licensing
- Simplified market entrance for medicines intended for the treatment of COVID-19
- Restrictions on marketing bonuses for pharmacies

With this Guide, we would like to provide you with an update about regulatory environment in Russia, with respect to the pharmaceutical and healthcare spheres. We aspire to make this information helpful and concise and hope that it gives you an insight on the Russian market and regulatory approach.

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Status of the unified market of the EAEU

Pharmaceuticals

According to the Decision of the Eurasian Economic Commission Council ("EEC"), dated November 3rd 2016 No. 78 ("Decision"), from January 1st 2021, medicines can be registered in the Russian Federation only 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 became 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 circulating 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"):

- registration;
- confirmation of registration;
- making changes to the registration dossier; and
- assessment of medicines.

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

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, either in accordance with national legislation, or the EAEU Rules, at their discretion.

From January 1st 2021, applicants in the Russian Federation have been able to register medicines, for medical use only, in accordance with the EAEU Rules. For the other member states, the EAEU Rules have 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 expiration 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 is 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.

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, contain a large number of examples, and also use international terminology.

Also, with the beginning 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.

Medical Devices

Similar to the unified market of pharmaceuticals, the EAEU member states have also agreed on an integration of the medical device regulations and approval systems, making them consolidated and uniform throughout the EAEU. According to the Agreement on Uniform Principles and Rules for the Circulation of Medical Devices (Medical Devices and Medical Equipment) within the EAEU (Moscow, December 23rd 2014), which establishes the legal basis for the new unified market, the execution of the regime will be ensured by:

- establishing unified safety and efficiency requirements for the medical devices;
- adopting consolidated circulation rules for medical devices, considering recommendations of the IMDRF;
- harmonization of the medical device nomenclature with the Global Medical Device Nomenclature;
- unification of the national legislation of the EAEU member states.

Among other things, the EAEU regulators have already implemented centralized medical device registration rules, labelling, information systems and mutual recognition of the conformity assessment certificates between EAEU member states.

On December 31st 2021, the provisional period when companies may apply for the registration of medical devices, under either national or EAEU rules, will be terminated. Starting on January 1st 2022, medical devices may be registered in the EAEU only in accordance with the mandatory supranational procedure. Simultaneously, it is expected that the EAEU member states soon will adopt adjustments, according to which the previously issued national marketing authorizations will be valid until their expiration, or December 31st 2026 (whichever comes first). At the same time, for medical devices circulating under such marketing authorizations, it will be allowed to re-register them, or adjust the concerned marketing authorizations, under national rules, until December 31st 2026.

Currently, the regulators do not consider the option of simplified EAEU registration procedures, for the medical devices that were earlier registered under national rules. Therefore, if national marketing authorization holders would like to issue an EAEU marketing authorization for the same medical device, there will be no derogations from the regular procedure, for such subsequent EAEU registration. Besides, it is still unknown how the national registration procedures will be conducted in 2022, if they were initiated in 2021.

Applicants should consider that, regardless of the more detailed and transparent new administrative regime for medical devices at the EAEU level, local authorities, laboratories and agencies still do not have enough experience to swiftly and flawlessly complete all stages required for the successful registration of medical devices under new EAEU rules. Considering this, we recommend that you thoroughly control all terms and activities of parties involved in registration ensuring the optimal proceedings.

Potential extension of track and trace requirements to food additives

Even though the implementation of the track and trace system, with respect to medicines, has met certain troubles and heavy criticism from the market players, the Government of the Russian Federation decided to extend the application of respective requirements to food supplements (currently as a temporary experiment).

On April 29th 2021, the Government of the Russian Federation adopted Decree No. 673 on the introduction of an experiment on the digital labelling of food supplements ("Decree") in the "Chestny Znak" labelling system. This experiment will last from May 1st 2021, to August 31st 2022, and will be entirely voluntary for business participants. According to the goals of this experiment, the digital labelling of food supplements is aimed at consumer protection, ensuring legal import, increase in the collection of taxes and duties, and prevention of distribution of counterfeit products.

The Decree covers different types of food supplements, such as vitamins, protein concentrate, finished products which include cocoa as a component, finished products based on coffee extracts in primary packages with a net weight of not more than 3 kg and other products. The purpose of this experiment is to assess the possibility of introducing such labelling on a permanent basis, to prepare a regulatory framework, as well as to partially prepare business participants.

Instructional guidelines for regulating the procedural aspects of the experiment are similar to the ones presented for the other products that are already subject to the mandatory digital labelling. Thus, upon entering the labelling experiment, manufacturers and importers of food supplements shall register in the State electronic system, order unique DataMatrix-format codes for the products, and put them on on each package of products, before marketing or importing them into Russia. After the release of the products into the turnover, the market participants shall provide information on each stage of transferring the ownership to them down to the end-users. The guidelines set out roles and obligations of each party participating in this process.

Considering the technical difficulties, the business experienced upon introducing mandatory digital labelling for other products (e.g., pharmaceuticals and dairy products) in the past, we recommend actively participating in the concerned experiment and/or discussions regarding it with the State authorities to present your own interests and opinions. According to our experience, the authorities are listening to businesses and may change some of their decisions.

Introduction of e-commerce for medicines

The possibility of introducing e-commerce in Russia, with respect to medicines, has been discussed between State authorities, legislative bodies and market participants for years, and it seems that, during COVID-19 crisis, push came to shove, in this particular area as well.

After prolonged and intense discussion, it was decided to grant rights to sell OTC medicines on the internet to pharmacy chains, subject to certain additional requirements being complied with. Now the customer can purchase medicines by applying to the pharmacy through its website, application or by phone, whereupon they should be informed about indications for the use of the medicine, its retail price, shelf life, conditions of dispensing, storage rules, interaction with other medicines.

The regulations set out the rights and obligations of consumers and pharmacies, the rules for the packaging of the orders and their deliveries. In particular, it is possible to deliver medicines, not only by an employee of the pharmacy organization, but also by an employee of another (third-party) organization that cooperates with the

pharmacy, on the basis of an appropriate contract. The delivered order is transferred to the buyer at his/her place of residence, or another address indicated by him/her. In the absence of the buyer, the order can be transferred to the person who presented the originals, or copies, (including in electronic form) of the receipt, or other document confirming the conclusion of the sales contract, payment for the order or registration of its delivery.

To be able to apply for permission to sell medicines online, a pharmacy chain should comply with the following requirements:

(A) pharmacy chain should hold pharmaceutical license for at least one year;

(B) pharmacy chain should have its own website, or application or engage an aggregator for this purpose;

(C) pharmacy chain should have duly-equipped storage places for placed orders;

(D) pharmacy chain should have its own courier service, or engage an organization with necessary capabilities;

(E) pharmacy chain should have online payment system, which would allow processing payments;

(F) pharmacy chain should ensure the confidentiality of the buyers' personal data.

Compulsory licensing

On May 11th 2021, amendments to Article 1360 the Civil Code of the Russian Federation ("Russian Civil Code") in terms of providing compulsory licenses to use an invention, utility model, or industrial design, ("patent rights") came into force.

These amendments allow the Russian Government to permit the use of patent rights, without the consent of the patent holder. This is to be achieved by notifying him/her of this decision and paying proportional compensation, in case of emergency, related to ensuring national defense, state security, and/or protecting the life and the health of Russian citizens. The methodology for determining the amount of compensation, and the procedure for its payment, shall be approved by the Russian Government.

The Russian laws provided for granting a compulsory license, for objects of patent rights, only in two cases:

- by a judicial procedure;
- with the permission of the Government of the Russian Federation, in the interests of national security.

In the first case, in June 2018, the Moscow Commercial Court, for the first time, used a judicial procedure, of granting a compulsory non-exclusive license to the Russian company Nativa for Lenalidomide, which is protected by the patent owned by the American corporation Celgene. The court acknowledged that the new medicine and new invention are dependent on another. It could not be used by the owner without violating the rights of the owner of the first patent holder, while the new invention had important technical achievements and significant economic advantages over Celgene's invention.

In the second case, on December 31st 2020, the Russian Government adopted the Order No. 3718-p ("Order"), which allowed the Russian 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 holder of patent for this medicine.

In April 2021, Gilead Sciences Inc. filed a claim against the Russian Government with the Russian Supreme Court. However, in May 2021, the Russian Supreme Court dismissed this claim, stating that the decision of the Russian Government is aimed at protecting the interests of national security. Therefore, Pharmasintez received a license and began production of the medicine Remdesivir.

Another important case is the first Russian case, where Federal Antimonopoly Service (FAS Russia) recognized unfair practice in the production and sale of generics, before the expiration of patents for original drugs. In 2017, the arbitration court banned Nativa from selling the generic Nilotinib-nativ, produced under the Novartis patent. Despite the ban, Nativa company transferred the rights to the drug to its distributor, Mammoth Pharm, which in 2020 began to offer the generic for the supply in the procurement of essential drugs. Having considered this case, FAS Russia recognized the actions of Mammoth Pharm as unfair competition and ordered it to stop the violation and transfer the illegally-obtained income to the budget.

By adopting the new edition of Article 1360 of the Russian Civil Code, the powers of the Government to apply compulsory licensing are expanded, namely, the article is supplemented by the right to make a decision on compulsory licensing, not only in the interests of the national defense and security, but also "to protect the life and health of citizens". At the same time the wording of the article was supplemented by the reservation that this right should be applied only "in case of emergency", which, in our opinion, does not limit the discretion of the Government.

The new edition of this article may stimulate the increase of compulsory licenses issued in the Life Sciences industry. Until the systematic practice of applying this rule has developed, it is rather difficult to give estimates and forecasts for its further application.

It is expected that the Russian Government shall adopt the methodology for determining the amount of compensation, and the procedure for royalty payments, for the issuance of a compulsory license.

At the moment this methodology does not exist, the draft of this document has not been designed and is therefore not available to the public.

Simplified market entrance for medicines intended for the treatment of COVID-19

Simplified procedure for the registration of medicines and medical devices for emergency situations (including for the treatment of COVID-19) was prolonged, until the beginning of 2022. Registration certificates, which were already issued under simplified procedure and were initially valid until January 1st 2021, are prolonged, as well, till January 1st 2022.

The same applies to the permits for temporary circulation of a batch of a medicine, not registered in Russia, but successfully used in other countries, which will be valid until January 1st 2022 and should be replaced before the new year.

According to public sources, this procedure was used for the registration of three favipiravir-based pharmaceuticals for the treatment for COVID-19, as well as two of the Russian vaccines – Sputnik V and EpiVacCorona.

Restrictions on marketing bonuses for pharmacies

In February 2021, the State Duma of the Russian Federation adopted, in second reading, the draft law on the restriction of the monopolization of pharmaceutical market in part of the pharmacy chain. In particular, it proposes to limit the maximum amount of payment for advertisement services at 5% of turnover and to prohibit any one pharmacy chain from owning more than 20% of pharmacies, within one municipal district.

As one of the draft's initiators noticed, it has become a common practice for pharmacy chains to charge bonuses – from 30 to 60% of the drug turnover – to place medicine on a shelf, market and train personnel to

work with this medicine. In the opinion of the legislator, these bonuses are additional expenses for the local manufacturer(s), which may have instead spent these funds on the development of new drugs, the introduction of new technologies, and the reduction in the price of existing drugs. In addition, he noted that pharmacy chains have unevenly located their points of sale and the purpose of new measures is to ensure the availability of medicines, primarily the availability of new domestic medicines and to limit price increases.

The market participants have different opinion about proposed limitations and believe that they instead will lead to the increase of prices, growth of "grey" part of the market and lower availability of the medicines.

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In times of rapid changes in the technological process of the pharmaceutical and healthcare development, State regulators try to keep pace with the innovations, often missing the impact of their decisions on the future of the industry and social sphere. With the acceleration of progress, the activity of the regulators also escalates, which constantly shifts the regulatory winds. To increase the efficiency of the business and apply new technologies, it is important to anticipate and comply with all existing and future regulations, as well as continually drawing regulators' attention to the raised issues.

ALRUD Law Firm will be happy assisting you in overcoming challenges and addressing pharmaceutical and healthcare compliance issues raised on domestic and international levels including, among others, the Eurasian Economic Union that consists of Russia, Armenia, Belarus, Kazakhstan and Kyrgyzstan.

Note: Please be aware that all information provided in this letter was taken from open sources. Neither ALRUD Law Firm, nor the author of this letter, bear any liability for consequences of any decisions made in reliance upon this information.

Key contacts

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

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