ALRUD

Newsletter

Head Start to 2021 for the Pharmaceutical Industry in Russia

February 9th,2021

Dear Ladies and Gentlemen,

We would like to inform you about several important news items, in the pharmaceutical industry, at the beginning of 2021.

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 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 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 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.

In this letter, 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.

1. 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 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.

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2. Changes in the registration procedure for medicines

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

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

3. Our recommendations

The Russian authorities and the EEC have repeatedly stressed that, in connection with the implementation of the Procedures under the new mandatory EAEU Rules, the load of the entire system of state regulation of the Procedures will increase many times over. Despite the fact that, in the near future, the EEC may decide on the possibility of using the results of inspections, for compliance with the national rules of good manufacturing practice for the implementation of the Procedures under the EAEU Rules, most likely this opportunity will remain short-lived.

In view of the above, we recommend planning, in advance, the process of organizing the Procedures, choosing a reference state and other stages of the transition to supranational regulation, in order to avoid significant delays in the implementation of the Procedures, the risk of suspension of medicines' circulation, or disruption, to the market entry of the EAEU member states.

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 patents holder for this medicine.

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

- by a judicial procedure;
- 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 patents 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 allows 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, are 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. Although 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.

We will continue to monitor the developments in this area and will be ready to provide the necessary legal support on issues related to the protection of patents and ensuring the interests of patent holders in Russia.

We hope that the information provided herein will be useful for you. If any of your colleagues would also 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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