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# PharmaUpdate Russland
## 2021/4

**Russlands Regierung und die Institutionen der Eurasischen Wirtschaftsunion (EAWU) greifen verstärkt in den Pharmamarkt ein. Kurzfristig verabschiedete Verordnungen und Gesetze stellen deutsche Arzneimittelexporteure vor enorme Hürden.**

Das PharmaUpdate Russland – ein Service der Exportinitiative Gesundheitswirtschaft – gibt Ihnen einen umfassenden Überblick über die Gesetzesänderungen und – initiativen der letzten Monate. Die Exportinitiative Gesundheitswirtschaft will Deutschlands Stellung als eines der führenden Exportländer gesundheitswirtschaftlicher Produkte und Dienstleistungen stärken. Die Initiative wurde vom Bundesministerium für Wirtschaft und Energie (BMWi) ins Leben gerufen.

In May 2021, despite the long holidays announced by the President of Russia, some new legislative initiatives were introduced. Most of them are aimed at providing pharmaceutical security to the state and preparing the groundwork for further localization initiatives. These developments are supported by likely tax benefits for EAEU producers and introducing new local production facilities.

## New legislative initiatives in Russia

### 1. The State Duma adopted a law on the production of drugs without the approval of the patent holder

On May 26, 2021, the State Duma adopted in the third reading a draft law giving the Government of the Russian Federation the right to use inventions to produce the pharmaceutical products for export without the consent of the patent holder, notifying the latter of this as soon as possible and with payment of compensation.

Such a decision should contain information on the volume of production of a pharmaceutical product determined by the needs of a foreign state, to whose territory the medicinal product is to be exported. The packaging of such a pharmaceutical product must have a special designation.

It is reported that this will allow the Russian Government, if necessary, to ensure state security, protection of the life and health of citizens.

All the procedures bound to the production of such pharmaceutical products will be approved by the Russian Government in accordance with an international treaty. Among such procedures there are: sending a notification to the patent holder, establishing the grounds and procedure for deciding on the use of an invention to produce a pharmaceutical product in Russia for the purpose of exporting, and later terminating its validity, the procedure for determining the validity period of the decision, as well as the procedure for determining the amount of compensation and the procedure for its payment.


BPI Bundesverband der Pharmazeutischen Industrie e.V.
.B.A.H Bundesverband der Arzneimittel-Hersteller e.V.
vfa. Die forschenden Pharma-Unternehmen

It was noted that the new law could be applied both for exporting the drugs to the country in need, and for importing into Russia the drugs produced by the "compulsory license" by other WTO member states.

**Link:** https://gxpnews.net/2021/02/minzdrav-predstavil-proekt-izmenenij-poryadka-vvoza-lekarstv-v-rossiyu-s-1-sentyabrya/

**Comments and recommendations:** For patent holders, the adoption of this law means that a new risk has appeared, that a patented drug may be used without its consent in emergency cases. Unfortunately, the year 2020 showed that emergency cases like COVID-2019 are quite real. It also should be noted that the amount and procedure for payment of compensation is determined by the government of the Russian Federation in accordance with an international agreement.

### 2. The new legislative initiative "second is a crowd" could change the government purchasing in the Russian pharmaceutical industry

The new draft law from May 19, 2021, proposes not to allow to participate in government purchases of drugs from the essential drug list those manufacturers who do not possess their own full production cycle (not only FPP, but also the substance).

Back in February, Deputy Prime Minister Tatyana Golikova instructed the legislative authorities to work out changes that would give an advantage in government purchases to drugs, all stages of production of which are carried out in the territories of the member states of the Eurasian Economic Union (EAEU).

In May 2021, the Ministry of Industry and Trade initiated the "second is a crowd" project, stating that if a company with a full production cycle of a certain INN from the essential drug list is present at the government tender, applications from other manufacturers, even Russian ones, without a full production cycle, will be rejected.

The position of the Ministry of Industry and Trade is that introducing the new procedure will help to eliminate the strict dependence of manufacturers of finished dosage forms on the unstable volume of production of substances. The ministry notes that the rule will not be applied in cases where the drug offered for government purchasing is not produced in the EAEU countries or if an application from manufacturers with full cycle production has not been submitted to the tender.

Market players view the draft law as raw and unprepared at best. For example, the biopharmaceutical manufacturer of drugs "PSK Pharma" (Rus Biopharm Group of Companies) sent letters to the Ministry of Health, to the Ministry of Industry and Trade, and to the Federal Antimonopoly Service, and to the reception of the President of the Russian Federation. The company proposed to provide the necessary time (5 years for chemical substances and 7 years for biotechnological substances) for the industry in order to prepare for such innovations in a planned manner.

**Link:** https://gxpnews.net/2021/01/liczenzii-na-lekarstva-i-medizdeliya-s-1-yanvarya-dejstvitelny-tolko-v-elektronnom-vide/

**Comments and recommendations**: If this draft law will eventually pass the readings and come into force, only full-cycle producers will be able to participate in government tenders for essential drugs. The message from the Russian government to the producers for the necessity to localize in EAEU in order to sell is quite transparent.

### 3. A law on penalties for the circulation of unmarked products has been adopted

The State Duma adopted in the third and final reading a law on administrative responsibility for violation of the requirements for marking goods with means of identification. The fines for legal entities for failing to meet these requirements would make up to 500 000 rubles (a bit over 5 500 EUR).
The Code of Administrative Offenses establishes specific fines for selling drugs without labeling or with incorrect labeling if these actions do not contain signs of a crime.
At the same time, a law on criminal penalties for forgery of labeling has passed the first reading in the State Duma. If the law will be adopted, the use of counterfeit means of identification for labeling goods could lead to imprisonment of up to six years. Changes would be made to article 171.1 of the Criminal Code.

**Links:** https://gxpnews.net/2021/02/minzdrav-predstavil-proekt-izmenenij-poryadka-vvoza-lekarstv-v-rossiyu-s-1-sentyabrya/

**Comments and recommendations:** Administrative liability has already been introduced for violation of the requirements for labeling of drugs, and in perspective criminal liability for falsification of labeling may appear. The labeling requirements for pharmaceutical products apply to all pharmaceutical products circulating in Russia. It would be good for the manufacturers to pay extra attention to the correct labeling of their products.

### 4. The State Duma proposed to ban advertising of drugs

A bill aiming to establish a ban on advertising of drugs on television and in radio programs has been presented for review by the State Duma.
According to the author of the bill, even though advertising of drugs is accompanied by a warning about the presence of contraindications to their use and by the need to read the instructions for use or to obtain expert advice, citizens often do not pay attention to these messages when urgent pain relief is needed.
It is assumed that a total ban on advertising of drugs will contribute to more responsible attitude of the citizens to their health, instead of attempts of self-medication and purchasing of an unlimited amount of drugs. According to the author of the bill, this measure will also significantly reduce mortality from self-medication.

**Links:** https://gxpnews.net/2021/02/minzdrav-predstavil-proekt-izmenenij-poryadka-vvoza-lekarstv-v-rossiyu-s-1-sentyabrya/

**Comments and recommendations:** It is obvious that pharmaceutical companies account for the substantial part of advertising budgets on TV and radio. It might seem very unlikely that such draft law could pass the readings in the State Duma and turn into real law. However, in Russia one should not underestimate the possibility of unexpected solutions becoming reality. Therefore, the players in the pharmaceutical industry should follow the developments in this sphere and be prepared in case this bill is an early sign for limiting advertising options for drugs in general.

## Drug registration and licensing procedures

### 1. The rules for the implementation of the EAEU Trademark Agreement have been determined

The Council of the Eurasian Economic Commission approved the Instruction to the Agreement on Trademarks, Service Marks and Appellations of Origin (AO) of the Eurasian Economic Union.

The instruction contains the rules for the implementation of the norms established by the Trademark Agreement. Among them are the requirements for registration and the procedure for filing applications for the EAEU trademark and the AO of the EAEU; the procedure for the examination of the declared designations; the procedure for registering a trademark in EAEU and the AO of the EAEU; the procedure for maintaining unified registers of trademarks of the EAEU and the AOs of EAEU; the procedure for information exchange between the national patent offices of the countries of the Union among themselves and with the Commission, as well as all necessary forms of procedural documents.

In addition, the Council of the Commission approved a list of types of legally significant actions during the registration, legal protection and use of the EAEU and AO of the EAEU trademarks, and fees for executing these actions. Each of the Member States will establish in its legislation the fees to be paid by applicants based on the uniform rates approved by the Council.

**Link:** https://gxpnews.net/2021/02/eek-razreshila-proveryat-farmproizvoditelej-na-sootvetstvie-gmp-distanczionno/

**Comments and recommendations**: Instruction to the Agreement on Trademarks provides all necessary explanations to the Agreement. It is a full guide for the producers for submitting applications for the EAEU trademark, which is part of the registration process by EAEU rules.

### 2. Regulations on licensing the production of drugs and licensing control will be approved

The Ministry of Industry and Trade of the Russian Federation has developed a draft resolution of the Government of the Russian Federation "On Approval of the Regulations on Licensing the Production of Drugs and Federal State Licensing Control over Activities for the Production of Drugs."

The draft resolution has been published on the official website regulation.gov.ru for public commenting and evaluating its regulatory impact.

The draft resolution was developed in order to bring the regulation on licensing the production of drugs in accordance with the requirements provided for by Federal Law No. 248-FZ of July 31, 2020 "On State Control (Supervision) and Municipal Control in the Russian Federation" and draft Federal Law No. 1051647 -7 "On Amendments to Certain Legislative Acts of the Russian Federation in Connection with the Adoption of the Federal Law "On State Control (Supervision) and Municipal Control in the Russian Federation" as amended by the State Duma of the Russian Federation in the second reading on May 19, 2021.

**Link:** https://gxpnews.net/2021/01/farmproizvoditeli-chetyreh-stran-eaes-smogut-registrirovat-novye-lekarstva-po-naczionalnoj-proczedure-do-30-iyunya-2021-goda/

**Comments and recommendations:** This resolution affects both domestic and foreign manufacturers of drugs, which are subject to licensing their production. In fact, this Resolution was developed to bring the Regulation on licensing the production of medicines into compliance with the requirements of Federal Law No. 248-FZ of July 31, 2020 and draft Federal Law No. 1051647-7 as amended by the State Duma of the Russian Federation in the second reading on May 19, 2021. The frequency and volume of control measures carried out at the present time are fully preserved and have not been changed. In addition, it does not make any significant changes in the licensing of the production of drugs.

### 3. Terms of validity for registration certificates of anti-COVID-2019 medical products will be extended

On May 12, 2021, the Prime Minister of Russia Mikhail Mishustin announced the prolongation of the validity of registration certificates for anti-COVID-2019 products during his report to the State Duma.
More specifically, the Prime Minister announced the extension of the registration certificates for drugs against COVID-2019, registered earlier under a simplified scheme, so that they could quickly enter the circulation. The government intends to prepare appropriate amendments to the legislation.
Mr. Mishustin said that 12 main antiviral drugs, as well as vaccines of domestic production, registered under a simplified registration procedure, have been introduced to the Russian market.

**Link:** https://pharmvestnik.ru/content/news/Mishustin-zayavil-o-prodlenii-deistviya-registracionnyh-udostoverenii-antikovidnyh-lekarstv.html

**Comments and recommendations**: It should be noted that re-registration of the drugs registered under the simplified scheme will not be required. The producers still can use simplified registration scheme for anti-COVID-2019 drugs, test systems and PPE.

## Market and competition

### 1. An experiment on labeling dietary supplements as part of the total labeling plan in pharmaceutical industry

From May 1 of 2021 to August 31 of 2022, an experiment on the labeling of dietary supplements will be held in Russia. Manufacturers of dietary supplements will participate in the experiment on a voluntary basis. The participants will be given special equipment for labeling dietary supplements free of charge.
The Cabinet of Ministers recommended that CDPT (Center for the Development of Perspective Technologies), the operator of the information system that will be used for the experiment, develops requirements for the system and for the protection of the information contained in it by June 1, 2021. The Ministry of Industry and Trade will coordinate the creation and operation of the system. By November 30, 2021, by February 1 and by August 1, 2022, the government must receive reports on the results of the experiment and evaluate them.
At the same time, the manufacturers of dietary supplements considered the experiment meaningless, since, in their opinion, this would not help to stop sales of counterfeit products. Manufacturers noted that labeling would increase the cost of dietary supplements and discourage buyers from legal dietary supplements.

**Link:** https://pharmvestnik.ru/content/news/Pravitelstvo-opredelilo-sroki-provedeniya-eksperimenta-po-markirovke-BAD.html

**Comments and recommendations**: Further actions and intentions of the government on the labeling of dietary supplements are still unknown. Industry experts believe that the issue of nutritional supplements labeling is premature and there are more acute problems in the field of nutritional supplements circulation and regulation. However, the general dynamics of the introduction of labeling for drugs, for a number of medical devices, as well as plans for labeling all medical devices, antiseptics and disinfectants indicate that systematic labeling will be introduced for all products in the pharmaceutical sector. The foreign players should be prepared to the trend.

### 2. VAT issue: The Ministry of Health insists on the extension of tax benefits for medical products from EAEU

The Ministry of Health applied to the special committee of the State Duma on health protection, with the suggestion of keeping tax benefits for the medicines and medical devices from EAEU.
If changes are not promptly made to the Tax Code of the Russian Federation, then pharmaceutical products from the EAEU countries, including the anti-COVID-19 ones, may increase in price from 2022. If the preferential tax regime is not extended for them for the next year, they will be subject to VAT of 20%. It not only affects over 30 000 products, but also imposes risks for government purchasing for the national program “Zdravookhranenie” (“Healthcare”).
Currently some medical products from EAEU countries are not taxed, and some are imported at a 10% VAT rate. The period of preferential taxation is limited to December 31, 2021.

**Comments and recommendations:** For foreign manufacturers (outside the EAEU), the extension of tax incentives for EAEU goods is unprofitable. However, it will almost certainly be approved, as the 20% VAT is negatively influencing fulfilling of the national healthcare program. There is no option to profit from price increase of the EAEU drugs connected with VAT increase.

### 3. A plant for cancer drugs will appear in Moscow's Technopolis free economic zone

The first stage of a new pharmaceutical production complex has been commissioned on the territory of the Technopolis Moscow free economic zone. Investments into the project at this stage amounted to more than one billion rubles (over 11 million EUR).

The enterprise will produce about 120 types of drugs for the treatment of neurological and oncological diseases. The declared volume of products is up to 100 million packages of various dosage forms annually. The plant should start manufacturing the first batches of drugs in August 2021, and to bring production to full capacity in the second quarter of 2022.

At the first stage of construction, the complex occupies 3.4 thousand square meters. After the second stage, the territory of the enterprise will increase to 5.5 thousand square meters, and the area of clean rooms will be 1.8 thousand square meters. The complex includes its own R&D center and a microbiological laboratory for the development of new drugs.

The manufacturer will be the resident of the free economic zone, full cycle company "OncoTarget", together with its partner organizations. It plans to consolidate efforts in order to create socially significant drugs that are not produced in Russia, including drugs for the treatment of cancer. Most of the drugs will be sold to the municipal medical institutions as part of government orders.

**Comments and recommendations**: In connection with the government initiatives to leave only full cycle local producers for government purchasing of essential drugs, OncoTarget might create competition for foreign producers of cancer drugs. It is well known that Russian government has been already purchasing local drugs that were cheaper and worse in quality than foreign cancer drugs as part of the import substitution program.

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