ADVANT Beiten

LEGAL DIGEST

HEALTHCARE RUSSIA – JULY / AUGUST 2025

Русская версия

Below for your attention we present a digest of significant legal news in the field of pharmaceuticals and medical goods in Russia for July and August 2025.

I. MEDICAL GOODS

1. Changes in legislation and legal regulation

Roadmap for the development of the common market for medical goods in the Eurasian Economic Union (EAEU)

The stated purpose for the adoption of the roadmap is the formation of a common market for medical goods that provides for equal access to medical goods in the EAEU[1]. The roadmap includes an analysis of the current state of the market and problematic aspects of the EAEU market for medical goods, and issues of improving the regulatory environment and digital processes.

Extension to 1 September 2026 of the deadline for foreign manufacturers to appoint authorised representatives and update information on representatives

Foreign manufacturers of medical goods have been given an additional year (until 1 September 2026) to appoint authorised representatives in Russia and to update information on authorised representatives already in Russia[2].

Under the previous regulations, this deadline expired on 1 September 2025. A lack of updated information on a representative constitutes grounds to revoke the state registration of a medical good.

However, the Russian Ministry of Healthcare estimated that in this case around 13,000 registration certificates would have to be annulled, which would lead to shortages in the country[3].

2. Measures against counterfeit and infringing medical goods

Sysmex Corporation vs. A.I. Melnikov, individual entrepreneur

Background

On 21 July 2025 the Intellectual Property Court upheld the decisions of the lower courts in the case of the Japanese manufacturer of medical diagnostics equipment *Sysmex Corporation vs. A.I. Melnikov, individual entrepreneur*[4], in which the courts had declared Sysmex-branded medical goods supplied by Mr Melnikov to state medical institutions to be infringing products. The courts also prohibited Mr Melnikov from unlawfully using the trademarks of Sysmex Corporation and ordered that the infringing products be taken off the market and destroyed.

Important conclusions of the Intellectual Property Court

- In determining whether products are infringing products, there is no legal difference between goods that are counterfeit and those that are genuine but which were brought into Russia without the consent of the rights holder;

- The court noted that "*because the case materials contain no evidence that the disputed goods are genuine, or that the rights holder … consented … to the use of the disputed trademarks, the disputed medical goods are infringing products, since they are on the market in contravention of the law, and the place of origin of the goods in question is unknown*";

- "*The entrepreneur did not disclose the entire chain of ownership of the goods within Russia, nor … evidence that confirms the origin and appropriate quality of the goods* ";

- "*The issue of establishing whether or not the goods are genuine is not a circumstance that is germane to the consideration … of the dispute, and accordingly there is no need for the court to appoint an expert review*".

The judgment of the Intellectual Property Court has already entered into force, but may be appealed to the Judicial Panel of the Russian Supreme Court within the following two months.

Survey of judgments of the appeals courts

A number of judgments were handed down in July and August 2025 by appellate commercial courts in cases on counterfeit and infringing medical products.

All of the court judgments ruled in favour of the foreign rights holders and their exclusive licensees in Russia:

- Sysmex Corporation vs. D.Yu. Buldakov, individual entrepreneur[5];
- OOO Roche Diagnostics Rus (exclusive licensee of Roche Diagnostics GmbH and F. Hoffmann-La Roche AG, Germany) vs. E.S. Melnikova, individual entrepreneur[6];
- OOO Roche Diagnostics Rus vs. OOO Avilon – CompanyKhim"[7].

In these cases, the courts agreed with the positions of the foreign rights holders; products branded with their trademarks and supplied by third parties were found to be infringing goods and were ordered destroyed.

II. PHARMACEUTICALS AND NUTRITIONAL SUPPLEMENTS

1. Intellectual property: Novo Nordisk A/S vs. the Russian Government

The appeals panel of the Russian Supreme Court dismissed the appeal by the Danish pharmaceutical company Novo Nordisk A/S of the decision of the Russian Supreme Court, which had declined to challenge a number of directives by the Russian Government. With these directives, the Russian government allowed third parties to use Novo Nordisk's patents (used in the production of the medication Semaglutide) without the consent of the rights holder[8].

We provided a detailed look at the case in the court of first instance, the background to the case, and the legal grounds for the suit in our digest for May 2025.

Important conclusions of the Appeals Panel of the Russian Supreme Court

After considering the case, the court came to the following conclusions:

- The lack of access to a medication, and thus the fact that it cannot be used in medical practice, may constitute an emergency related to protecting citizens' lives and public health;

- No statutory procedure has been established for notifying the rights holder of the issue of a permit to use its patent, and for this reason the official publication of the Directive of the Government of Russia constitutes due notice;

- The Directive of the Russian Government does not limit the circulation of patented medications and does not prevent the rights holder from doing business in Russia.

2. Early termination of a trademark for non-use: the case of Qmed BioTech Corp (Seychelles) vs. KC Pharmaceuticals Co., Ltd. (Japan)

Background

The Russian Intellectual Property Court granted the claim of the Seychelles company Qmed BioTech Corp. against the Japanese manufacturer of dermal fillers, biorevitalizers, and botulin toxin KC Pharmaceuticals Co., Ltd. for the early termination for non-use of the legal protection of the trademark under international registration No. 1520316 in respect of all goods in ICGS Class 10 (surgical implants, etc.) within the Russian Federation.

Conclusions of the Russian court

The claimant was able to show that it had an interest in the use of the disputed brand designation. For these purposes it submitted:

- a letter of the Russian company on its readiness to work together with the claimant on the issue of the production of medications "*only after receipt of the exclusive right to the trademark … by the claimant*";

- information on the registered domain name refinex.ru, in which the trademark was used, and the website hosted at this domain name;

- and others.

The court also noted that for the claimant the actual performance of operations within Russia (prior to the termination of legal protection of the disputed trademark) is fraught with persecution through the courts due to the possible violation of the exclusive right of the rights holder-respondent.

The court also found the respondent's use of the trademark to be spurious (merely symbolic).

Recommendations

More detail about possible options on how to act in such situations and what instruments are available to a foreign rights holder to protect their rights in Russia can be found in our information letter "Three years have gone by: how can foreigners avoid losing their trademarks in Russia for non-use?".

3. Anti-trust regulation

Refusal of pharmaceutical companies to conclude supply agreements

As we noted previously in our digest for May 2025, in 2025 the Federal Antimonopoly Service of Russia issued warnings to a number of companies to remove discriminatory provisions from their commercial policies. Among those warned were OOO Amgen, OOO Angelini Pharma Rus, and OOO Swixx Healthcare.

According to the information of the FAS, in July–August 2025 these companies complied with the warning of the anti-trust authority and reconsidered their decisions to refuse to conclude contracts with distributors on non-discriminatory terms:

- OOO Amgen removed from its commercial policy its economically and technologically unjustified requirements on the revenues of a potential distributor, and reconsidered its decision on the application of a distributor[9];
- OOO Angelini Pharma Rus reviewed the terms of its policy as concerns requirements on market share in the pharmacy segment and the minimum annual purchases of the potential distributor[10];
- OOO Swixx Healthcare removed from its policy requirements on the potential distributor's revenues and experience in state procurement[11].

4. Advertising of drugs

The Moscow Region Administration of the FAS fined OOO Geropharm and its director of public relations for violating Article 14.3(5) of the Russian Code of Administrative Offences, which bans the advertising of prescription drugs[12].

Advertisements for the prescription drug Semavic were shown in video clips at the Novaya Volna 2024 music festival and at a gala dinner of the

magazine "Hello".

The FAS Administration took into consideration the fact that these events were not medical or pharmaceutical exhibitions, seminars, or conferences, the video clips containing the advertising of the drug, and also the terms of the sponsorship agreement, which confirmed the company's intention to advertise both the drug and the company itself.

5. Changes in legislation and legal regulation

Roadmap for the development of the common market for medications in the Eurasian Economic Union (EAEU)

The roadmap was adopted by directive of the Eurasian Intergovernmental Council in order to support the stable operation of the EAEU common market for medications, based on unified principles of mandatory requirements on safety, efficacy, and quality[13].

Registration certificates of medications following national rules will remain in effect until 2026. In order to be marketed in EAEU customs territory from 1 January 2026, medications will have to have an EAEU registration certificate, except for those intended for use under military conditions and in emergencies.

Establishment of the concept of "strategically important medicines" in Russian law

The term "strategically important medicines" (SIM) has been added to Federal Law No. 61-FZ dated 12 April 2010 "On the Circulation of Medicines". This term covers medicines for medical use that meet high-priority healthcare needs for the prevention and treatment of illnesses, including those that predominate in the incidence pattern of diseases in Russia, and whose production within Russia should be supported.

This amendment enters into force from 1 September 2025; the list of SIMs and the procedure for creating the list will be approved by the Russian Government.

Deferral of the start of preferential measures for medicines on the SIM list

1 September 2025 had been scheduled to see the entry into force of a provision of Russian Government Resolution No. 1875 dated 23 December 2024[14], pursuant to which in state procurements of medicines on the SIM list, a bid to supply medicines from EAEU countries would be equivalent to a bid from a foreign state unless all stages of production were performed within the EAEU (including the synthesis of the molecules of the active ingredient in the production of pharmaceutical substances).

If even one bid was received from an EAEU manufacturer, foreign bids would be rejected.

The new resolution of the Russian Government establishes that this provision will enter into force from 1 January 2026[15].

Electronic registration and re-registration of release prices for medicines on the LEM list; new method for determining maximum release prices

From 1 September 2025 the registration and re-registration of manufacturers' release prices on medicines included on the list of life-saving and essential medicines (LEM) for medical use will be conducted in electronic form in the unified state healthcare information system[16].

A new methodology also went into effect from 1 September 2025 for calculating maximum manufacturer release prices for medicines included on the LEM list for medical use[17].

ADVANT Beiten is always at your disposal for any questions you may have related to protecting the rights of foreign companies in Russia, the CIS, and the EAEU.

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[1] Directive No. 10 of the Eurasian Intergovernmental Council dated 15 August 2025 "On the Roadmap for the Development of a Common Market for Medical Goods in the Eurasian Economic Union ".

[2] Resolution No. 1206 of the Government of the Russian Federation dated 13 August 2025 "On Amending Resolution No. 1684 of the Government of the Russian Federation dated 30 November 2024"

[3] Explanatory note to the Draft Resolution of the Russian Government "On Amending Resolution No. 1684 of the Government of the Russian Federation dated 30 November 2024" (prepared by the Russian Ministry of Healthcare, project ID 01/01/07-25/00157889) (Resolution No. 1206 was signed on 13 August 2025).

[4] Judgment No. S01-731/2025 of the Intellectual Property Court dated 21 July 2025 in case No. A21-4334/2024.

[5] Judgment No. 08AP-2279/2025 of the Eighth Commercial Court of Appeals dated 14 July 2025 in case No. A70-16582/2024.

[6] Judgment No. 13AP-12197/2025 of the Thirteenth Commercial court of Appeals dated 1 July 2025 in case No. A21-13317/2024.

[7] Judgment No. 14AP-3054/2025 of the Fourteenth Commercial Court of Appeals dated 31 July 2025 in case No. A13-69/2025.

[8] Decision of the Supreme Court of the Russian Federation dated 6 May 2025 in case No. AKPI25-102.

[9] https://fas.gov.ru/news/34092.

[10] https://fas.gov.ru/news/34104.

[11] https://fas.gov.ru/news/34156.

[12] Resolution of the Moscow Region Administration of the FAS dated 24 July 2025 on imposing an administrative punishment in administrative offence case No. 050/04/14.3-1581/2025; Resolution of the Moscow Region Administration of the FAS dated 19 August 2025 on imposing an administrative punishment in administrative offence case No. 050/04/14.3-1668/2025.

[13] Directive No. 9 of the Eurasian Intergovernmental Council dated 15 August 2025 "On the Roadmap for the Development of a Common Market for Medications in the Eurasian Economic Union".

[14] Resolution No. 1875 of the Russian Government dated 23 December 2024 "On Measures to Provide National Treatment in the Procurement of Goods, Work, and Services for State and Municipal Needs, and the Procurement of Goods, Work, and Services by Certain Categories of Legal Entities".

[15] Resolution No. 1326 of the Government of the Russian Federation dated 29 August 2025 "On Amending Resolution No. 1875 of the Government of the Russian Federation dated 23 December 2024".

[16] Resolution No. 462 of the Government of the Russian Federation dated 8 April 2025 "On the State Regulation of Prices for Medicines Included on the List of Life-Saving and Essential Medicines for Medical Use".

[17] Resolution No. 805 of the Government of the Russian Federation dated 30 May 2025 "On Approving the Methodology for Calculating the Maximum Manufacturer Release Prices for Medicines Included on the List of Life-Saving and Essential Medicines for Medical Use".

Kind regards,

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