ADVANT Beiten

LEGAL DIGEST

HEALTHCARE RUSSIA - OCTOBER/NOVEMBER 2025

Русская версия

We present for your consideration a digest of significant legal news in the field of pharmaceuticals and medical goods in Russia for October and November 2025.

I. MEDICAL GOODS

1. Amendments to legislation and legal regulation

1.1 The deadline for the transition of medical goods in the Eurasian Economic Union to a common market

A draft Protocol on the Introduction of Amendments to the Agreement on Common Principles and Rules for the Circulation of Medical Devices within the Eurasian Economic Union was approved by a Directive of the Government of the Russian Federation[1]. In particular, the final deadline for filing an application for the expert examination or registration of a medical good in accordance with the legislation of a member state was extended from 31 December 2025 to 31 December 2027.

In addition, the deadline for the re-registration or introduction of amendments to the registration documents of a medical good under national legislation has been extended from 31 December 2026 to 31 December 2028.

1.2 Plan for the development of competition in the Russian Federation for 2026-2030

The Government of the Russian Federation has approved a national plan for the development of competition for 2026-2030[2].

In the healthcare sector the national plan stipulates the submission of a report by the Federal Antimonopoly Service of Russia, the Ministry of Finance of Russia and the Ministry of Healthcare of Russia to the Government by 1 March 2027 based on the results of the implementation of measures regarding state procurements of medical goods.

It proposes incentivising clients, when describing the subject matter of the procurement, to use the technical and functional characteristics of a medical good from the respective catalogue of products, work and services in order to meet state and municipal needs (provided that such an item is listed in the catalog (in Russ.)).

1.3 The Russian Ministry of Healthcare proposes centralising procurements of medical devices and medicines

The Ministry of Healthcare of Russia has developed a draft resolution of the Russian Government on centralising the state procurements of a number of medicines and medical devices[3].

This concerns state procurements as part of the national projects "Long and Active Life" and "Family".

It proposes conducting such procurements on a centralised basis through the Federal Centre for the Planning and Organisation of the Provision of Pharmaceuticals for Citizens – an organisation which reports to the Russian Ministry of Healthcare.

The developers note that some Russian regions have already organised joint procurements, which enabled them to make budget savings. Furthermore, the experience of centralised procurements of cancer drugs through the indicated Federal Planning Centre demonstrated savings of approximately 10% in 2024.

It proposes, *inter alia*, applying the projected rules to the following medical devices:

No.	Code of the type of	

	Nomenclature Classification of Medical Devices	Name of the type of Nomenclature Classification of Medical Devices
1.	260250	Ultrasound Visualisation System, universal
2.	191220	Stationary General-Purpose X-ray Diagnostics System, digital
3.	135160	Full Body MRI Scanner, with superconducting magnet
…	…	…

The list (in Russ.) consists of 36 names of medical devices in total.

At present the draft resolution has been sent to the Russian Government for review. If adopted, it will enter into force from 2026.

2. Measures against counterfeit and infringing medical goods

2.1 OOO Roche Diagnostics Rus vs E.S. Melnikova, individual entrepreneur

The Intellectual Property Court has considered the cassation appeal of individual entrepreneur E.S. Melnikova against the court orders of lower courts which had satisfied the claims of OOO Roche Diagnostics Rus (the exclusive licensee of Roche Diagnostics GmbH and F. Hoffmann-La Roche AG, Germany) on the destruction of the counterfeit and infringing medical goods (as well as a number of other related claims)[4].

OOO Roche Diagnostics Rus insisted that the goods in principle were not genuine. The respondent failed to prove the contrary.

A distinctive feature of this case is that it did not concern the actual medical goods, but instead the containers used for samples for *in vitro* diagnostics – in other words, the test tubes indicated in the registration certificate as "accessories" to the medical goods.

Nevertheless, the court of cassation drew the important conclusion:

"*the accessories mentioned in the […] registration certificate constitute medical goods.*

Accordingly, the test tubes are included among medical goods for in vitro diagnostics".

This means that everything indicated in a registration certificate – the actual medical good and its component parts, as well as accessories to the medical good – is declared by the court to be a single medical good.

In turn, this makes it possible to apply the special norms of Russian legislation on the protection of public health.

Clause 18 of Article 38 of Federal Law No. 323-FZ dated 21 November 2011 "On the Fundamentals of Public Healthcare in the Russian Federation" stipulates only one consequence for counterfeit and infringing medical goods – confiscation and destruction.

The Intellectual Property Court agreed, upholding the court orders of the lower courts and supporting the position of the exclusive licensee – the Russian company Roche Diagnostics Rus.

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

The court dispute of Japan's Sysmex Corporation vs individual entrepreneur A.I. Melnikov[5] turned out differently.

The facts of the case were typical: Sysmex Corporation discovered that reagents for the Sysmex automated haematology analyser Sysmex in state procurements were actually being supplied by an unofficial dealer.

The courts of the first two instances agreed that the contested medical goods had been introduced into civil commerce illegally without the consent of the rights holder and satisfied the claims of Sysmex Corporation on the destruction of the contested goods, as well as other related claims.

However, the Intellectual Property Court overturned the court orders of the lower courts regarding the satisfaction of the claim on the destruction of the contested goods.

The court stated that:

"*the establishment by the courts during the consideration of the cases regarding the import of goods of the legal status of the imported goods (whether they had been introduced previously into civil commerce by the actual rights holder on the territory of another state (parallel import), or were counterfeit and infringing goods, on which the marking of the trademark had been inserted without the consent of the rights holder) is material for the correct resolution of this case*".

Accordingly, the court stated that during a new hearing it would be necessary to assess the data of the European Database on Medical Devices submitted by the respondent, with a breakdown of the codes of the devices and the UDI of the manufacturer.

At present parallel importers are trying to use this case, declaring that foreign rights holders are demanding the destruction of goods that are "genuine" (in the opinion of the respondents).

At the same time, it should be borne in mind that legislation on intellectual property and the norms on the exhaustion of the exclusive right to the trademark are not based on the "authenticity" of goods. Legal regulation in this area is based on the issue of the "introduction into civil commerce" or, to put it another way, the issue of the "first sale" of a good. If the first sale occurred with the consent of the rights holder, then the good may to all intents and purposes be declared authentic.

However, in this case the burden of proving this fact is not vested with the rights holder, but instead with the parallel importer which should in the final analysis communicate it to the rights holder (the manufacturer) by submitting the chain of supply contracts.

The hearing in the court of first instance (the second round of hearings) is scheduled for 15 December 2025.

II. PHARMACEUTICALS AND NUTRITIONAL SUPPLEMENTS

1. Amendments to legislation and legal regulation

1.1 Criteria for entering information on the sale of nutritional supplements in the Unified Register of Prohibited Websites

The issue of the digest for May 2025 announced amendments to the regulation of the circulation of nutritional supplements (Supplements), in particular, the possibility to enter information on the sale of Supplements in the Unified Register of Domain Names, Web Page Links and Network Addresses Making it Possible to Identify Websites Containing Information Whose Dissemination in the Russian Federation is Prohibited.

The Federal Service for the Oversight of Consumer Protection and Welfare (Rospotrebnadzor) approved the criteria for assessing information [on a Supplement] for the adoption of a decision on its inclusion in the Register, provided that the information contains a proposal on the retail sale of the Supplement, *inter alia*, remotely[6]:

- Supplements which have not undergone state registration;

- Supplements which are dangerous under the legislation of the Russian Federation;

- The Supplements contain substances in quantities that are at variance with statutory values;

- The sale of Supplements under the guise of food additives.

1.2 Holding of scheduled inspections

The Government of the Russian Federation has cancelled scheduled checks conducted in respect of the circulation of medicines for medical use regarding any subject of state control assigned a significant, medium or moderate risk category[7]. Such scheduled inspections continue be conducted in the case of any subject classified as high risk.

2. Antitrust Regulation: Case of OOO KRKA-RUS vs the Federal Antimonopoly Service of Russia

OOO KRKA-RUS appealed in court the decision of the Federal Antimonopoly Service of Russia, declaring that the company's actions on increasing the prices of medicines constituted a breach of antitrust legislation. The petition was dismissed by the court of first instance. You can read a more detailed description of the dispute during its hearing in the court of first instance in the issue of the digest for May 2025.

The Commercial Court of Moscow District dismissed the cassation appeal of OOO KRKA-RUS and upheld without variation the court orders of the lower courts in case No. A40-297158/2024.

The court of cassation agreed with the conclusion that OOO KRKA-RUS holds a dominant position and that there were no grounds for increasing the prices of the medicine, in view of the following:

1. The change in the expenses required to manufacture and sell the product was at variance with the change in its price;

2. In order to assess the breach, the medicines of one dosage were not declared independent product markets based on the number of pills in the packing.

The court confirmed that the medicines would only be interchangeable if it were possible to take, instead of a medicine with one International Nonproprietary Name (INN) in a specific dosage, a medicine with the same INN, but with a different dosage.

Should you have any questions about protecting the rights of foreign companies in Russia, CIS countries and the Eurasian Economic Union,

rest assured that ADVANT Beiten is always at your disposal.

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[1] Directive No. 2920-r of the Government of the Russian Federation dated 17 October 2025 "On the Signing of the Protocol on the Introduction of Amendments to the Agreement on Common Principles and Rules for the Circulation of Medical Devices (Medical Products and Medical Equipment) within the Eurasian Economic Union dated 23 December 2014." (in Russ.).

[2] Directive No. 2816-r of the Government of the Russian Federation dated 8 October 2025 "On the Approval of the National Plan ("Roadmap") for the Development of Competition in the Russian Federation for 2026-2030." (in Russ.).

[3] Draft Resolution of the Government of the Russian Federation "On the Centralisation of the Procurements of Certain Types of Medicines for Medical Use and Medical Devices to Meet State Needs for the Purpose of Implementing the Measures (Results) of Federal Projects Included in the National Projects "Long and Active Life" and "Family", ID of the draft: 161319.

[4] Judgment No. S01-1345/2025 of the Intellectual Property Court dated 5 November 2025 in case No. A21-13317/2024 (in Russ.).

[5] Judgment No. S01-1151/2025 of the Intellectual Property Court dated 10 October 2025 in case No. A21-7985/2024 (in Russ.).

[6] Order No. 768 of the Federal Service for the Oversight of Consumer Protection and Welfare dated 1 November 2025 (in Russ.).

[7] Resolution No. 1811 of the Government of the Russian Federation dated 15 November 2025 "On the Introduction of Amendments to Resolution No. 1049 of the Government of the Russian Federation dated 29 June 2021." (in Russ.).

Kind regards,

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