ADVANT Beiten

LEGAL DIGEST

HEALTHCARE RUSSIA - JANUARY 2026

Русская версия

We present for the consideration of foreign rights holders and manufacturers, as well as their Russian subsidiaries, a digest of significant legal news in the field of pharmaceuticals and medical goods in Russia for January 2026.

I. MEDICAL GOODS

1. Measures against counterfeit and infringing medical goods

1.1 Secondary liability of the directors of suppliers of infringing goods

Background

Russian legislation provides foreign rights holders and their exclusive licensees in Russia with a wide range of tools for fighting parallel imports.

In addition to requirements on the destruction of infringing goods, the ban on their introduction into civil commerce, and the declaration of

disputed medical goods as infringing goods, the rights holder and their exclusive licensees may file claims in court for compensation for infringement of their exclusive trademark rights.

This is how the Russian company OOO Roche Diagnostics Rus, exclusive licensee of F. Hoffmann-La Roche AG and Roche Diagnostics GmbH, acted. After hearing a case in 2017–2021, the court of first instance ordered a supplier of infringing medical goods, the Russian company OOO Belaya Pesochnitsa, to pay the sum of RUB 860,000 (approximately EUR 9,500/USD 11,000) in such compensation to OOO Roche Diagnostics Rus[1].

However, while the case was under consideration, the respondent's assets contracted from approximately RUB 8 million (about EUR 90,000/USD 100,000) to zero in the course of one year.

In 2023 OOO Roche Diagnostics Rus filed a petition with a Russian commercial court to declare the debtor OOO Belaya Pesochnitsa bankrupt. The court granted the petition but by that time, as indicated above, the company no longer had any assets left.

In 2024 the company's receiver filed suit in court to impose secondary liability on the General Director of OOO Belaya Pesochnitsa for the company's obligations in the amount of approximately RUB 1.9 million (about EUR 20,000/USD 25,000).

Conclusions of the commercial court of first instance

While hearing the case, the court noted the following in respect of the actions of the General Director of OOO Belaya Pesochnitsa:

- the director did not provide the receiver with information as to where the company's assets had gone;
- he made no effort to file suit in court against the supplier of the infringing goods (parallel importer) to recover losses;
- he filed a statement himself with the Federal Tax Service of Russia (the Russian authority that maintains the commercial register) to the effect that the commercial register (USRLE) contained inaccurate information about him as the director of OOO Belaya Pesochnitsa.

The court qualified these actions as an attempt to evade the need to settle debts: the General Director attempted to induce the liquidation of the company on the initiative of the registration authority instead of filing a petition in court to have the company declared bankrupt.

After hearing the petition of OOO Roche Diagnostics Rus, the Russian court ruled that the General Director of OOO Belaya Pesochnitsa was secondarily liable for the monetary obligations of the company and that he must pay RUB 1.9 million (approximately EUR 20,000/USD 25,000) – in other words, the court granted the receiver's claim in full[2].

1.2 Sysmex Corporation vs Individual Entrepreneur Ashkhotova

The court case of the claim of the Japanese Sysmex Corporation against the supplier of infringing medical goods, Russian entrepreneur Alina Ashkhotova, ended in January 2026 with the satisfaction in full of the claims of the Japanese rights holder of the Russian trademark No. 412281 Sysmex.

Background

The claimant discovered that the website www.zakupki.gov.ru, which publishes information on government procurement and procurement by state-owned companies, contained information on a contract between individual entrepreneur and Municipal Medical Clinic No. 34 in Saint Petersburg to supply consumables for immunological tests.

The clinic refused to accept the disputed goods bearing the Sysmex trademark, asserting that the packaging showed serious damage and that the packaging indicated a country of origin that is not included in the current Registration Certificate for the medical goods issued by the Russian Healthcare Supervisory Service (Roszdravnadzor).

Sysmex Corporation confirmed that it had not consented to the import of the goods into Russia.

At the petition of Sysmex Corporation, enforcement measures were ordered in respect of the goods: seizure and ban on use, destruction and ban on the transfer of the disputed goods to any other parties.

When filing with the court, Sysmex Corporation asked for a declaration that the goods were infringing goods, for a ban on the unlawful use of the trademarks through the introduction of the disputed goods into civil commerce, and for the respondent to be ordered to withdraw the goods from circulation and destroy them.

Conclusions of the commercial court of first instance

The court established the following:

"*The goods delivered by the respondent are infringing goods due to the fact that they are in circulation in violation of the civil legislation, and the fact that their quality and original source are unknown*".

The court also noted that the place of origin listed on the packaging (the Czech Republic) was at odds with the data of the registration certificate for the medical goods which indicates Japan and China as the country of manufacture.

In view of the foregoing, the Commercial Court of Saint Petersburg and Leningrad Region granted the claim of Sysmex Corporation in full[3].

2. State procurement of medical products

2.1 Measures against counterfeit and infringing medical products: Individual entrepreneur Oleg Pachtusov vs municipal hospital

Background

The Russian entrepreneur filed a statement of claim in a commercial court asking the court to declare unlawful the refusal by the Municipal Hospital of Rostov-on-Don ("**Client**") to accept medical goods (reagents) allegedly produced by the Japanese Sysmex Corporation[4].

A letter from OOO Sysmex Rus, the manufacturer's official representative in Russia, served as the grounds for the Client's refusal to accept the reagent.

In the letter, Sysmex's Russian company stated the following:

- the rights holder did not consent to the use of the trademark in any form;
- the products supplied were not imported into Russia or sold to the offending entrepreneur by either the rights holder or an authorised importer.

The court of first instance dismissed the claim, and the court of appeal upheld the decision without variation; in other words, the courts supported the position of the Client and the accuracy of the arguments of OOO Sysmex Rus set out in the letter.

Conclusion of the commercial court of cassation

The court agreed with the conclusions of the lower courts that the Client's refusal to accept the goods was justified.

During consideration of the case, the cassation court agreed that the arguments of OOO Sysmex Rus, in the letter cited above, were correct.

The court also stated that the infringing entrepreneur had not provided the permission of the rights holder for the delivery of the trademarked goods and evidence of the legal origin of the disputed goods. In addition,

the entrepreneur had not disclosed the entire chain of origin of the goods within Russia and had provided no evidence that the goods were of appropriate quality.

The judgment of the cassation court has now come into effect, but may still be appealed with the Judicial Panel of the Russian Supreme Court within the next two months.

2.2 Issue of the compatibility of medical products: Sklifosovsky Institute for Emergency Medicine vs the FAS office for Moscow

Background

The Sklifosovsky Institute for Emergency Medicine has an angiographic injector for computerised tomography.

A complaint was submitted to the regional office of the Federal Antimonopoly Service of Russia ("**FAS**") regarding the actions of the Sklifosovsky Institute in conducting an electronic auction for the supply of medical goods (consumables for equipment). The complaint stated that the description of the medical goods to be procured corresponded to the products of a single manufacturer, and that it was not possible to offer an equivalent product due to the restrictive requirements.

In its decision, the antitrust authority declared that the complaint was justified, found violations in the actions of the Sklifosovsky Institute, and issued a directive to rectify the violations. However, the Institute successfully appealed in court – the court of first instance and court of appeal both found for the appellant.

Conclusions of the commercial court of cassation

The court[5] agreed with the lower courts that the decision and directive of the FAS office were unlawful, and that the Sklifosovsky Institute was correct to establish in its procurement request the requirement that bidders supply original consumables and that equivalent substitutes would not be acceptable, for the following reasons:

- The Equipment User Manual contained a requirement on the use of consumables that had undergone the necessary tests and which the manufacturer had sanctioned for use with the equipment;

- The after-sales warranty service does not cover defects resulting from the use of consumables not authorised by the manufacturer. According to the manual, the use of such equivalents might endanger both patient safety and the seamless functioning of the equipment;

- The courts duly considered the position of the German equipment manufacturer Ulrich GmbH & Co. KG that the possible use of analogues and injectors together had not been confirmed by supporting documentation in any country (including Russia, other EAEU countries, and China) and the use of such medical goods with injectors manufactured by Ulrich GmbH & Co. KG is not permitted until such confirmation is available. Evidence to the contrary had not been submitted to the case materials.

2.3 Positions of regional FAS offices

In January 2026 several regional FAS offices had, after considering appeals against the actions of clients in the case of procurements of medical goods, expressed their opinion on the issue of the compatibility of medical goods.

- A FAS Office considered and rejected an appeal against a client's actions in the procurement of haemodialysis kits for use with equipment manufactured by Fresenius[6]. The FAS Office noted that the client had drafted requirements on the medical goods being procured in order to maintain the manufacturer's guarantees for existing equipment, and also took account of the manufacturer's manuals. In addition, the client declared that there were no production facilities in Russia for such goods with characteristics that meet the client's needs, in accordance with the requirements of the Russian Government on measures to ensure national treatment in procurements[7].

- After considering the appeal against the client's actions in the procurement of consumables for the Gemini automatic analyser, the FAS Office concluded that it had not been confirmed that the medical good that the appellant was offering to supply was compatible with the client's equipment. The agency stated that "*the possible use of the medical equipment of one manufacturer together with the accessories of another manufacturer is determined by the manufacturer of the medical equipment, which is subsequently confirmed by a registration certificate issued by Rosdravnadzor*"[8].

II. PHARMACEUTICALS AND NUTRITIONAL SUPPLEMENTS

1. Amendments to legislation and legal regulation

1.1 Alignment of the registration certificates of medicines with the regulation of the Eurasian Economic Union

The circulation and the effective term of the registration certificate of medicines, regarding which applications for the alignment of the respective files with EAEU acts had not been submitted by 31 December 2025 and which had been introduced into civil commerce for at least

three calendar years on the date of 1 December 2025, is permitted and extended until 1 January 2027[9].

In January 2026 the Russian Ministry of Health reported that the "*current effective term of registration certificates of medicines issued in accordance with the legislation of member states should be considered to be the record entered in the State Register of Medicines*"[10].

1.2 Deferral of the start date of the "national regime" for strategically important medicines

The start date of the protective measures of the "national regime" stipulated by Russian Government Resolution No. 1875 for strategically important medicines, which must be manufactured in Russia, has been deferred from 1 January 2026 to 30 June 2026[11].

2. Administrative liability for the sale of counterfeit and infringing medicines on Russian marketplaces

A large range of medicines are offered for sale on Russian marketplaces, for example, OZON and Wildberries. However, counterfeit and infringing medicines can be found on these marketplaces.

2.1 Case of the sale of a counterfeit and infringing veterinary medicine on the OZON marketplace

The OZON marketplace offers for sale a number of medicines in the "Pharmacy" section with one-hour delivery. For particularly demanding customers, the marketplace even offers an "original good" filter (which is disabled by default).

At the same time, it is worth noting here that administrative liability is stipulated for the sale (and not only) of infringing and counterfeit medicines under Part 1 of Article 6.33 of the Code of the Russian Federation on Administrative Offences ("**Russian Code on Administrative Offences**") – in the case of legal entities, this is an administrative fine of up to RUB 5 million (approximately EUR 55,000/USD 65,000) or the suspension of operations for up to 90 days.

In autumn 2025 the employees of Russia's Federal Service for Veterinary and Phytosanitary Supervision ("**Rosselkhoznadzor**") made a test procurement on the OZON platform from the individual entrepreneur Anna Klintsova of one ampoule of the veterinary medicine Immiticide (the trademark for which is held by the French company Boehringer Ingelheim Animal Health France).

Study of the product purchased by the employees identified that there was no Russian-language information on the name of the medicine's

manufacturer, the series number, shelf life, method of administration, dosage or concentration, volume, unitage or number of doses.

These facts made it possible to declare the contested medicine to be counterfeit and infringing and through the decision of a commercial court to hold the entrepreneur administratively liable and fine her RUB 50,000 (approximately EUR 550/USD 650)[12].

2.2 Case of the sale of a counterfeit and infringing veterinary medicine on the Wildberries marketplace

The Russian marketplace Wildberries also has a section with medicines with an optional filter for "original" goods (which is disabled by default).

If this filter is enabled, the number of medicines on offer decreases from approximately 11,000 to approximately 7,000. However, if the consumer wants to purchase a medicine from the other 4,000 which are not marked "original", they will not encounter any obstacles from the marketplace.

Similarly to the aforementioned OZON case, in January 2026 a Russian commercial court heard a case regarding a seller from the Wildberries marketplace.

In autumn 2025 the employees of Rosselkhoznadzor made a test procurement on the Wildberries platform from individual entrepreneur Pavel Andrianov of the veterinary medicine Bravecto used to protect dogs from fleas and ticks (the trademark is owned by the Dutch company Intervet International B.V.).

Furthermore, it was established that the seller did not have a pharmaceutical licence to distribute veterinary medicines (the register of licences is accessible online).

In addition, at the time of the receipt of the medicine, it was established that the secondary packaging did not have comprehensive Russian-language information (the name of the medicine (International Nonproprietary Name or Group Name, or chemical or trade name), series number, shelf life, method of administration, dosage, dispensing rules, warning notices, while all the information on the primary package was only provided in a foreign language.

The court concluded that the medicine had been distributed illegally in Russia and was counterfeit and infringing.

This infringement was qualified under Part 3 of Article 6.33 of the Russia Code on Administrative Offences – the sale of counterfeit and infringing medicines online, which stipulates a maximum penalty for legal entities of

up to RUB 6 million (approximately EUR 66,000/USD 78,000) or the administrative suspension of operations for up to 90 days.

In this specific case, the infringing party received an administrative penalty in the form of a warning[13].

Should you have any questions regarding the protection of the rights of foreign companies in Russia and in CIS countries and in the Eurasian Economic Union, rest assured that ADVANT Beiten is always at your disposal.

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[1] Decision of the Commercial Court of Chelyabinsk Region dated 4 February 2021 in case No. A76-35494/2017.

[2] Ruling of the Commercial Court of Chelyabinsk Region 29 January 2026 in case No. A76-6205/2023 "On Imposing Secondary Liability ".

[3] Decision of the Commercial Court of Saint Petersburg and Leningrad Region dated 23 January 2026 in case No. A56-81797/2025.

[4] Judgment No. F08-7961/2025 of the Commercial Court of the North-Caucasus District dated 15 January 2026 in case No. A53-32872/2024.

[5] Judgment No. F05-22000/2025 of the Commercial Court of Moscow District dated 19 January 2026 in case No. A40-71117/2025.

[6] Decision of the Nizhny Novgorod Office of FAS dated 12 January 2026 in case No. 053/06/105-756/2025.

[7] Resolution No. 1875 of the Government of the Russian Federation dated 23 December 2024 "On Measures to Ensure 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" ("**Russian Government Resolution No. 1875**").

[8] Decision of the Chelyabinsk Office of FAS dated 19 January 2026 in case No. 074/07/3-3188/2025.

[9] Resolution No. 2202 of the Government of the Russian Federation dated 29 December 2025 "On the Introduction of Amendments to Certain Acts of the Government of the Russian Federation" introduced amendments to Resolution No. 353 of the Government of the Russian Federation dated 12 March 2022 "On the Specifics of Licensing in the Russian Federation".

[10] Letter No. 25-6/894 of the Ministry of Health of the Russian Federation dated 29 January 2026.

[11] Resolution No. 2225 of the Government of the Russian Federation dated 30 December 2025 "On the Introduction of Amendments to Certain Acts of the Government of the Russian Federation".

[12] Decision of the Commercial Court of Krasnodar Territory dated 26 January 2026 in case No. A32-74750/2025.

[13] Decision of the Commercial Court of the Republic of Karelia dated 16 January 2026 in case No. A26-9772/2025.

Kind regards,

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