ALRUD

Legal Digest

on Healthcare and Pharmaceutical for March-June 2026

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Introduction

Dear Ladies and Gentlemen!

We are pleased to present our digest of legal news relevant to the Healthcare and Pharmaceutical industry, covering the period from March 2026 to June 2026. This review addresses legislative changes and initiatives, as well as key enforcement and case law developments, across the following areas:

- Regulation of the circulation of medicines and medical devices;
- Regulation of dietary supplements (biologically active additives, BAAs);
- Intellectual property: legislation and case law;
- Antitrust regulation;
- Data protection and information technology.

Regulation of the Circulation of Medicinal Products, Veterinary Medicinal Products and Dietary Supplements

Regulation of Medicinal Products

The Eurasian Economic Commission Plans to Tighten GMP Requirements for the Manufacture of Sterile Medicinal Products

The Board of the Eurasian Economic Commission (EEC) has submitted draft amendments to the Eurasian Economic Union (EAEU) Good Manufacturing Practice (GMP) Rules, introducing additional requirements for sterile medicinal products[1]. The amendments aim to strengthen quality control and reduce microbiological and other contamination risks.

Manufacturers would be required to implement a Contamination Control Strategy (CCS) covering premises, equipment, personnel, engineering systems, cleaning, disinfection and production monitoring.

The draft also tightens personnel requirements in sterile manufacturing areas. Staff working in critical areas would need to regularly confirm their qualifications and undergo microbiological monitoring, while manufacturers would conduct aseptic process simulations more frequently.

Sterilising filters would also be subject to mandatory integrity testing after sterilisation and before use. Where testing is technically impossible, manufacturers would need to justify an alternative approach through a risk assessment and additional quality control measures.

1 *Disposition № 49 of the Board of the Eurasian Economic Commission "On the Draft Decision of the Council of the Eurasian Economic Commission 'On Amendments to the Rules of Good Manufacturing Practice of the Eurasian Economic Union'"*

The Russian Ministry of Industry and Trade Proposed a Register-Based Model for Documents Confirming the Stages of Pharmaceutical Manufacturing

The Russian Ministry of Industry and Trade has proposed a register-based model for issuing documents confirming the stages of pharmaceutical manufacturing[2]. Such documents confirm that a medicinal product's full manufacturing cycle is carried out within the Eurasian Economic Union (EAEU). The relevant amendments would be made to the Federal Law "On the Circulation of Medicinal Products"[3].

The documents would be issued based on data submitted by manufacturers to the traceability system for medicinal products and raw materials operating within the state labelling system. They allow pharmaceutical companies to access state support measures and participate in state and municipal procurement, including under the planned "second one out" mechanism for strategically important medicinal products.

The proposal is intended to speed up application processing, reduce the administrative burden and prevent abuses, including cases where products made from foreign raw materials are presented as locally manufactured.

Regulation of Veterinary Medicinal Products

The Council of the Eurasian Economic Commission Extended the Transitional Period for the Common Market for Veterinary Medicinal Products until 31 December 2030

Until 31 December 2030, veterinary medicinal products may continue to be registered under national rules, and existing registration certificates will remain valid[4]. However, registration dossiers must be brought into compliance with EAEU requirements. If no application is submitted by that date, registrations granted for an extended or unlimited term will expire on 1 January 2031.

The decision also allows pharmaceutical inspections to be conducted remotely, including during emergencies, where inspectors' life or health may be at risk, or for other reasons beyond the parties' control.

GMP certificates issued by national authorities before 1 January 2021 will remain valid until the end of 2028. They may be replaced without a new inspection where the manufacturer's name or address changes or a technical error is identified.

2 *Draft Federal Law "On Amending Article 5 of the Federal Law 'On the Circulation of Medicinal Products'". Draft ID: 168568.*

3 *Federal Law № 61-FZ dated 12 April 2010 "On the Circulation of Medicinal Products".*

4 *Decision № 33 of the Council of the Eurasian Economic Commission "On Amendments to Decision № 1 of the Council of the Eurasian Economic Commission dated 21 January 2022".*

Procedure for Placing Russian Veterinary Immunobiological Medicinal Products on the Market Has Been Simplified

The Government of the Russian Federation has simplified the release of new Russian veterinary immunobiological medicinal products, including vaccines. From 15 April 2026, the first two batches may be placed on the market without separate authorisation, reducing the time needed for commercialisation[5].

The manufacturer must notify the Federal Service for Veterinary and Phytosanitary Supervision (Rosselkhoznadzor) within 5 business days after confirming compliance with the product's state registration requirements. For products manufactured under import substitution programmes, test results for product samples must also be submitted.

The amendments aim to support Russian manufacturers and improve the availability of veterinary medicinal products.

Regulation of Medical Devices

Roszdravnadzor Introduced a New Procedure for Transmitting Data on AI-Enabled Medical Devices to its Automated Information System

From 23 May 2026 to 31 December 2027, Roszdravnadzor is going to apply an updated procedure for the automated transmission of operational data on AI-enabled medical devices to its automated information system (AIS). The procedure applies to both manufacturers of devices authorised for circulation in Russia and their users[6].

Manufacturers will access the AIS through an electronic applicant account linked to the Unified Identification and Authentication System (ESIA). A separate account will be created for each medical device.

The submitted data must include the device's name and registration number, intended use, number of examinations performed, data processed, AI-generated results and the type of AI solution implemented.

5 Resolution of the Government of the Russian Federation № 417 dated 15 April 2026 *"On Amendments to Resolution of the Government of the Russian Federation № 353 dated 12 March 2022".*

6 Order of the Federal Service for Surveillance in Healthcare dated 10 February 2026 № 123 *"On Approval of the Procedure for the Automatic Transmission to the Automated Information System of the Federal Service for Surveillance in Healthcare of Information on Processed Data and the Results of the Operation of Software Employing Artificial Intelligence Technologies that Constitutes a Medical Device Intended for Circulation in the Russian Federation".*

Regulation of Dietary Supplements

The Russian Government Strengthens Control over the Labelling of Dietary Supplements

The Russian Government has introduced rules for verifying that products subject to mandatory labelling are manufactured in Russia[7]. Most amendments entered into force on 6 July 2026.

Verification may be initiated where a manufacturer claims Russian origin but its production facilities are not listed in the State Information System for Industry, or where no verification has been conducted for over 12 months. If supporting documents are not provided or actual manufacturing is not confirmed, the Centre for Research in Perspective Technologies (CRPT), the labelling system operator, may refuse to issue labelling codes, preventing the products from entering circulation.

The rules apply to dietary supplements, skin antiseptics and certain other labelled goods. Verification may be conducted remotely using photographs and videos submitted through a mobile application or through an on-site inspection.

Quality and Efficacy Criteria Established for the Inclusion of Dietary Supplements in the Medical Recommendation System

The Russian Government has approved quality and efficacy criteria for dietary supplements to be included in the list of products that healthcare professionals may recommend[8]. The rules entered into force on 1 May 2026.

A supplement must have valid state registration, correct labelling, proper recording in the monitoring system, documentary evidence of its safety and composition, and comply with EAEU technical regulations. Its efficacy may be confirmed by scientific publications, clinical guidelines or manufacturer-sponsored studies. Meeting any one criterion is sufficient.

The final rules do not include the previously proposed requirement that manufacturers have no violations of mandatory requirements during the preceding three years. Only products meeting the applicable quality, efficacy and EAEU requirements may be included in the recommendation list.

7 Resolution of the Government of the Russian Federation № 526 dated 7 May 2026 *"On Amendments to Certain Acts of the Government of the Russian Federation Concerning the Assessment of Manufacturers of Goods Subject to Mandatory Labelling with Means of Identification"*.

8 Resolution of the Government of the Russian Federation № 398 dated 13 April 2026 *"On Approval of the Criteria for the Quality and Efficacy of Dietary Supplements Depending on the Degree of Their Impact on Human Health"*.

Intellectual Property and Advertising: Legislation and Practice

Compulsory Licensing Provision Found Constitutional

Foreign pharmaceutical companies challenged the grant of a compulsory license for patents covering Trikafta, which had been issued due to insufficient market supply. They argued that Clause 1 of Article 1362 of the Civil Code of the Russian Federation created uncertainty and improperly allocated the burden of proof.

The Constitutional Court held that the provision does not contradict the Constitution. It found that compulsory licensing serves the public interest, particularly public health, but must remain proportionate to the actual shortage and demand on the Russian market[9].

The Court also clarified that the scope of the license must reflect the volume of supplies required and that a license may be granted only where the patent holder has no genuine intention to ensure adequate market supply. Relevant conduct may include abuse of rights or attempts to maintain a dominant market position.

The Court therefore confirmed that compulsory licensing is an exceptional mechanism, the use of which depends on actual market needs.

9 *Ruling № 13-П of the Constitutional Court of the Russian Federation dated 13 March 2026 in the Case Concerning the Review of the Constitutionality of Clause 1 of Article 1362 of the Civil Code of the Russian Federation.*

Russian Company Secures Compulsory License for Semaglutide

On 20 May 2026, the Arbitrazh Court of the City of Moscow granted Biokhimik JSC a compulsory non-exclusive license under Novo Nordisk's patents relating to medicinal products containing semaglutide[10].

The claim followed Novo Nordisk's discontinuation of supplies of Ozempic and Rybelsus to Russia at the end of 2023 and its failure to respond to a proposal to enter into a license agreement. The company referred to high global demand, but the court held that prioritising foreign markets over Russian patients did not justify refusing the license and noted the absence of plans to resume supplies.

The license was granted for the remaining patent term, with royalties set at 1.75% of sales revenue. The judgment is final and binding.

Government Order No. 1208-p subsequently authorized Promomed Rus LLC to use these and other Novo Nordisk patents until the end of 2027 under Article 1360 of the Civil Code of the Russian Federation, due to an extreme necessity related to the protection of citizens' lives and health[11].

The Supreme Court of Russia Upheld a Number of Decisions of the Federal Antimonopoly Service of Russia Finding that the Launch of Generic Medicinal Products by a Russian Pharmaceutical Company in Violation of Exclusive Rights Constituted Acts of Unfair Competition

The AkselPharm and AstraZeneca AB Case Concerning Osimertinib

In November 2024, the Federal Antimonopoly Service of Russia (FAS) found that AkselPharm had committed an act of unfair competition by launching a generic osimertinib medicinal product before expiry of AstraZeneca AB's patent protection for the originator product, Tagrisso. FAS ordered AkselPharm to cease placing the product into civil circulation and transfer more than RUB 567 million to the federal budget.

The courts of first instance and appeal set aside the FAS decision, citing insufficient evidence of use of the patented invention and the absence of direct competition between AkselPharm and the patent holder.

The Court for Intellectual Property Rights overturned those judgments and upheld the FAS decision. It found that AkselPharm had infringed AstraZeneca AB's exclusive rights and noted that the company had previously acknowledged that its invention depended on AstraZeneca AB's patent when seeking a compulsory licence[12].

In March 2026, the Supreme Court refused to refer AkselPharm's cassation appeal to the Judicial Chamber for Economic Disputes[13].

10 *Decision of the Arbitrazh Court of the City of Moscow dated 20 May 2026 in Case № A40-253959/25-51-1903.*

11 *Order of the Government of the Russian Federation № 1208-p dated 23 May 2026.*

12 *Ruling of the Court for Intellectual Property Rights dated 7 April 2026 in Case № A40-315385/2024.*

13 *Ruling of the Supreme Court of the Russian Federation № 305-ЭС26-6873 dated 11 June 2026.*

The AkselPharm and Pfizer / Agouron Pharmaceuticals Case Concerning Axitinib

In October 2024, FAS found that AkselPharm had violated competition law by launching a generic axitinib medicinal product through the unlawful use of an invention owned by Agouron Pharmaceuticals. FAS ordered the company to cease placing the product into civil circulation and transfer more than RUB 513 million to the federal budget.

The lower courts set aside the FAS decision, citing insufficient evidence of patent use and the absence of direct competition between AkselPharm and Agouron Pharmaceuticals. The originator product, Inlyta, is marketed in Russia through distributors, including Pfizer Innovations.

In March 2026, the Supreme Court overturned the lower-court judgments and, in May 2026, refused to refer AkselPharm's supervisory appeal to the Presidium.

In both cases, the higher courts confirmed that unlawful use of intellectual property may constitute unfair competition even where the patent holder operates through distributors rather than competing directly with the infringer. They also accepted AkselPharm's previous conduct as evidence of infringement of the foreign patent holders' exclusive rights.

Antimonopoly Regulation

FAS of Russia Included Russian Generic Manufacturer Geropharm in the Register of Bad-Faith Suppliers Following Termination of a Contract for the Supply of Dapagliflozin

The Volgograd Regional Office of FAS included Geropharm, a Russian pharmaceutical company, in the Register of Bad-Faith Suppliers following the termination of a contract for the supply of Floldapi, a generic dapagliflozin medicinal product[14].

Geropharm was required to supply 32,800 packs by 23 January 2026 but failed to do so, attributing the delay to the manufacturer's late delivery. Although the company later offered to supply part of the consignment, the contracting authority unilaterally terminated the contract.

Geropharm sought to challenge the FAS decision, but its statement of claim was returned[15].

FAS of Russia is Developing Enhanced Antimonopoly Regulation Mechanisms to Maintain Competition

At the Antimonopoly Forum in May 2026, FAS Deputy Head Sergey Puzyrevsky highlighted the effectiveness of warnings as a faster alternative to fines[16].

In 2025, FAS issued warnings to several pharmaceutical companies for unjustified refusals to deal with Russian manufacturers. All were complied with, which FAS expects to increase the number of distributors and ultimately reduce medicine prices.

14 *Information on Inclusion in the Register of Bad-Faith Suppliers by the Volgograd Regional Office of FAS in Connection with Procurement № 26002498.*

15 *Case № A12-5161/2026.*

16 *FAS Is Improving the Antimonopoly Regulation Mechanism – FAS.*

FAS also referred to two excessive-pricing cases. KRKA-Rus LLC reduced the price of Co-Dalneva and paid a RUB 1 million fine, while Zambon Pharma LLC was ordered to set justified prices for Fluimucil-Antibiotic IT and transfer more than RUB 418 million in unjustified income to the federal budget.

FAS of Russia Clarified the Procedure for Procuring Medicinal Products by Trade Name

As a general rule, medicinal products must be procured under their international non-proprietary names. A trade name may be used only where a medical commission prescribes the product due to individual intolerance or for vital indications[17].

FAS clarified that the commission's decision must be recorded in minutes stating the grounds for the prescription[18]. In cases of intolerance, the minutes must list all interchangeable medicinal products registered when the procurement documentation is prepared. For prescriptions based on vital indications, the decision must be duly justified.

17 *Resolution of the Government of the Russian Federation № 1380 dated 15 November 2017 "On the Specific Requirements for Describing Medicinal Products for Human Use Procured to Meet State and Municipal Needs".*

18 *FAS Clarified the Specific Requirements for Procuring a Medicinal Product by Trade Name – FAS.*

Data Protection and Information Technology

Laws Strengthening Liability in the Field of Critical Information Infrastructure (CII) were Adopted

Two federal laws were signed strengthening liability for violations involving critical information infrastructure (CII).

The Code of Administrative Offences now establishes liability for breaches of the rules governing the operation of CII facilities and access to them where the conduct does not constitute a criminal offence. Fines range from RUB 5,000 to RUB 10,000 for individuals, RUB 10,000 to RUB 50,000 for officials, and RUB 100,000 to RUB 500,000 for legal entities[19].

Article 274.1 of the Criminal Code was also amended to clarify that criminal liability arises where unlawful access to CII facilities or breaches of their operating rules result in the destruction, blocking, modification or copying of computer information, including through malicious software[20].

A person may be released from criminal liability if they actively assist in detecting or investigating the offence.

19 Federal Law № 77-FZ dated 9 April 2026 *"On Amendments to the Code of Administrative Offences of the Russian Federation".*

20 Federal Law № 76-FZ dated 9 April 2026 *"On Amendments to Article 274-1 of the Criminal Code of the Russian Federation".*

FSTEC Proposed Amendments to Presidential Decree № 250 dated 1 May 2022 "On Additional Measures to Ensure the Information Security of the Russian Federation"

The Federal Service for Technical and Export Control (FSTEC) prepared draft amendments to Presidential Decree № 250 dated 1 May 2022 introducing security indicators for state and other information systems, as well as significant critical information infrastructure facilities, including in healthcare[21].

The draft provides for separate indicators at organisational, sectoral and regional levels. For industries and regions, at least 80% of facilities would need to be protected against current information security threats.

The Government would establish the methodology for calculating these indicators in coordination with the Federal Security Service and FSTEC.

21 *Draft Decree of the President of the Russian Federation "On Amendments to Presidential Decree № 250 dated 1 May 2022 'On Additional Measures to Ensure the Information Security of the Russian Federation'", Draft ID: 167660.*

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We hope that the information provided herein will be useful for you.

If you would like to learn more about our Healthcare and Pharmaceutical Industry Group, please let us know. We will be happy to provide you with our materials.

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