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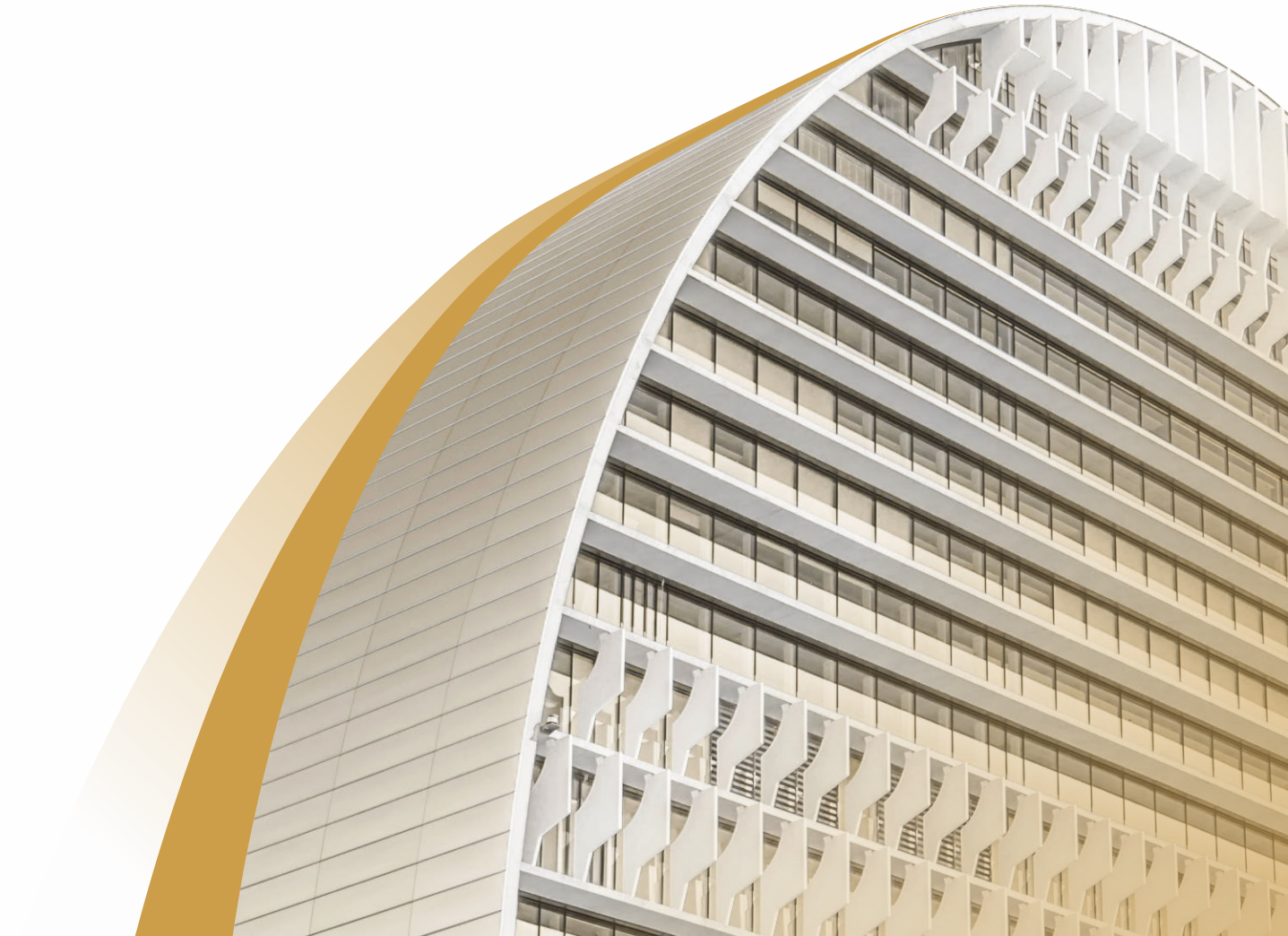
Regulatory Vocabulary. Industry Regulatory Documents, April 2025



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News Desk
Healthcare Industry, Pharmaceutical Industry, Regulators

As requested by Vademecum, VERBA LEGAL's Healthcare and Pharmaceuticals Practice has prepared an overview of the regulatory acts that took effect in April 2025 and relate to circulation of medicines and medical products. Additionally, the lawyers discussed other documents that are expected to take effect later on and industry-specific future regulations that are being drafted at present. These documents are described in detail below in this Digest.

Circulation of Medicines

There was enacted a new procedure for registration of prices of vital and essential drugs

Russian Federation Government Regulation dated April 8, 2025, No. 462, On Government Regulation of Prices of Pharmaceuticals included in the List of Vital and Essential Medical Drugs

The Russian Government passed a regulation enacting new Rules of State Registration of Pharmaceutical Manufacturers' Maximum Sale Prices of Pharmaceuticals included in the List of Vital and Essential Medical Drugs.

Under the new procedure, price registration and re-registration applications shall be submitted electronically via the Integrated e-Portal of Government Services or Healthcare Ministry's Personal Account in the Uniform State Health Information System. Applications shall be verified by an enhanced qualified digital signature

The new procedure has also changed certain deadlines:

- the deadline for submission of additional information as requested by a regulatory authority was cut to seven business days (instead of 10 business days in case of the Healthcare Ministry's requests and 25 business days in case of the FAS' requests, previously);
- the deadline for consideration of an application by Russia's Healthcare Ministry was cut from 15 to 10 business days;
- the total period of registration may not exceed 26 business days (10 business days in case of the Healthcare Ministry, and 15 business days in case of the FAS).

VERBA LEGAL lawyers recommend pharmaceutical manufacturers and marketing authorization holders take note of the tightened deadlines and transition to the electronic submission of applications for registration or re-registration of prices of pharmaceuticals included in the List of Vital and Essential Medical Drugs.

The document shall come into effect on September 1, 2025, and remain effective for six years.

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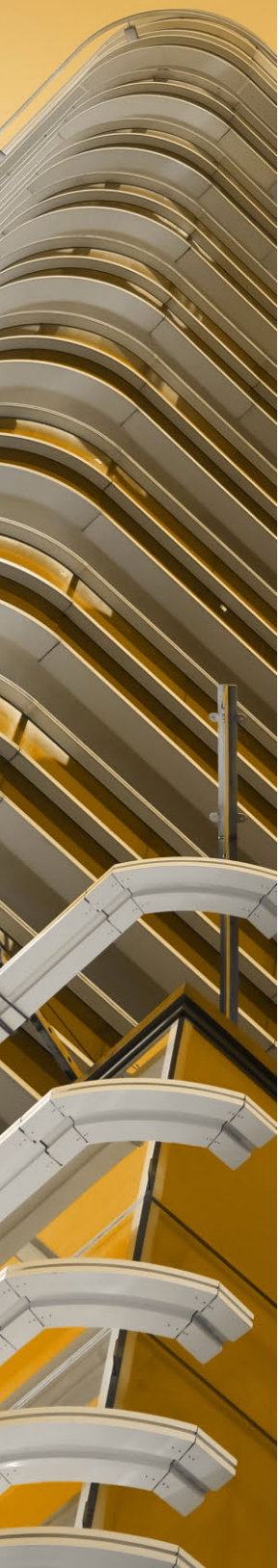

/ New Rules of Keeping the State Register of Medicines (or GRLS in its Russian acronym)

Russia's Healthcare Ministry Order dated March 1, 2025, No. 129n On Amendments to Russia's Healthcare Ministry Order dated February 9, 2016, No. 80n, On Approval of the Procedure of Keeping the State Register of Medicines

/ Under the new procedure, the following information will be required to be specified in the GRLS:

- registration of a marketing authorization holder or a pharmaceutical manufacturer as a taxpayer (Taxpayer Identification Number (INN)) in case of Russian companies; name, registration authority, registration number and tax code in case of foreign companies);
- information relating to the classification of the medicine (orphan drug, immunobiologicals, homeopathic medicine, radiopharmaceuticals, biopharmaceutical, etc.).

The requirement to specify information relating to interchangeability of medicines will become inoperative.

In addition, with effect from January 1, 2026, an application to de-register a pharmaceutical substance or a medical drug from the GRLS shall be authenticated by an enhanced qualified digital signature and submitted via the Uniform State Health Information System.

/ Council of the Eurasian Economic Commission Prepares a Draft Resolution to Extend Validity Period of National Marketing Authorizations

EEC Board Directive No. 46, Draft Resolution of the Eurasian Economic Commission "On Amendments to Eurasian Economic Commission Board Resolution dated November 3, 2016, No. 78"

According to the draft resolution, a marketing authorization issued before December 31, 2025, will remain valid provided that an application for marketing authorization file harmonization has been submitted to a Reference State in accordance with EAEU's regulations and subject to mandatory indication of a Concerned State.

In a Reference State, a marketing authorization may be extended for up to three years from the date of submission of the application, while in a Concerned State, a marketing authorization may be extended for up to two years from the date of submission of the application to the respective state.

A possibility of providing a set of documents verifying compliance with the applicable requirements in lieu of a EAEU GMP certificate has become unlimited subject to an undertaking to an inspection upon expiry of three years following the obtaining of the marketing authorization. It has been emphasized that in the event of a failure to meet the above deadline, the inspection will be regarded as failed. Such failed inspection will be treated as a failure to comply with marketing authorization conditions.

If adopted, the amendments will take effect within 30 days after the publication of the resolution by the Council of the Eurasian Economic Commission.

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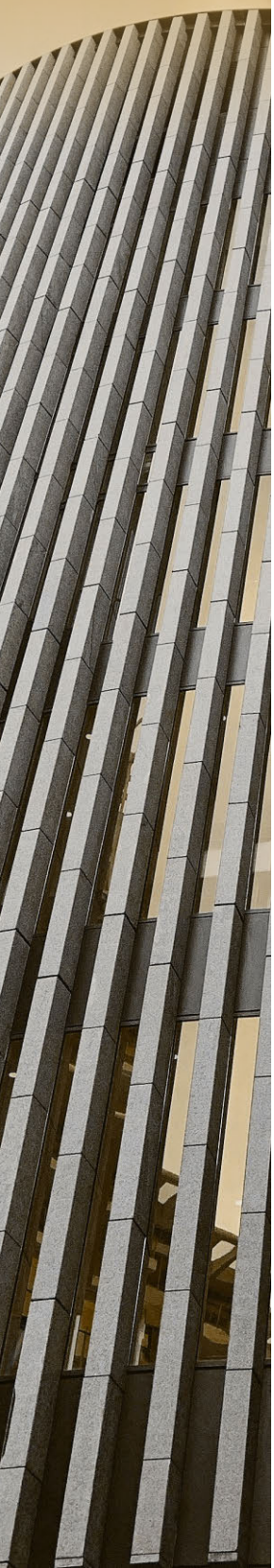

Circulation of Medical Products

Russia's Healthcare Ministry Proposes to Update the List of Non-VATable Medical Products

Draft Government Regulation, On Amendments to the Russian Federation Government Regulation dated September 30, 2015, No. 1042

Russia's Healthcare Ministry has worked out amendments to the list of VAT-exempt medical products sold in, or imported to, the Russian Federation. The drafters has taken note of the proposals of Russia's Ministry of Industry and Trade and medical products market participants.

The key amendments involve adjustment of the codes of the All-Russian Classifier of Products by Types of Economic Activities (OKPD 2):

- In Line Item 6 (Catheters and Bougies), it is proposed to replace the code "32.50.11.110" with «22.21.29.120" and "32.50.11.110".
- In Line Item 9 (Functional Test Measuring Instruments), a new code ("26.60.12.140") is proposed.
- In Line Item 14, (Medical Treatment Equipment and Devices, including Anesthesia Machines), new codes ("32.50.22.191" and "8509 80 000 0") are proposed.
- In Line Item 43 (Prosthetic Devices), the following codes ("32.50.23.110" to "32.50.23.119", and "32.50.23.120") are proposed to be replaced with one code ("32.50.23").

Further, it is proposed to clarify the following line items:

- Line Item 22 (Prescription Lenses);
- Line Item 35 (Bespoke and Adaptive Disability Clothing).

Currently, the draft regulation is at the public hearing stage which is expected to last till May 6, 2025.

Once adopted, the amendments will take effect a month after its official publication date, but not earlier than the first day of the next VAT period.

General Regulatory Update

/ Mandatory 3-Percent Online Advertising Fee Introduced

Federal Law dated December 26, 2024, No. 479-FZ, On Amendments to the Federal Law "On Advertising" and Certain Regulations of the Russian Federation

With effect from April 1, 2025, online advertising distributors (e.g. bloggers, website owners, advertising agencies, advertising system operators) shall be obliged to pay a 3-percent quarterly fee charged on a performer's advertising revenues. The fee shall be payable on or before the 5th day of the third month of a quarter following the reporting quarter. The amount of the fee shall be calculated automatically based on the information in the Unified Online Advertising Register.

VERBA LEGAL lawyers recommend advertising market participants (both advertising distributors and advertisers) to monitor clarifications of the fee collection mechanism, since the applicable regulations and clarifying provisions are still at the development and approval stage.

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