Kazakhstan Pharma Legal Alert – May 2026

Amendments Introduced to Price Regulation of Medicines and Pilot Project Launched for a Composite Service under the "One-Stop Shop" Principle

The Republic of Kazakhstan ("**Kazakhstan**") continues to reform the regulation of circulation of medicines ("**Medicines**") and medical devices ("**MDs**"). The latest amendments cover two key areas:

1. price regulation of Medicines;
2. implementation of a composite state service for registration of Medicines and MDs under the "one-stop shop" principle.

Amendments Introduced to the Rules for Regulation, Formation of Ceiling Prices and Mark-Ups for Medicines

Order of the Acting Minister of Health of Kazakhstan (the "**MoH**") dated 15 April 2026 No. 44 (the "Order No. 44") introduced amendments to Order of the MoH of Kazakhstan dated 11 December 2020 No. ҚР ДСМ-247/2020 "On Approval of the Rules for Regulation, Formation of Ceiling Prices and Mark-Ups for Medicines, as well as MDs, within the Guaranteed Volume of Free Medical Care and/or in the Compulsory Social Health Insurance System" (the "**Rules**"). Order No. 44 was registered with the Ministry of Justice of Kazakhstan on 17 April 2026 under No. 38453.

The main amendment concerns the formation of the list of Medicines subject to price regulation for wholesale and retail sale.

According to the new wording of paragraph 12 of the Rules, the state expert organization (the "**NCEM**") forms the draft list of Medicines subject to price regulation for wholesale and retail sale based on registered prescription Medicines, as well as Medicines holding a marketing authorization within the Eurasian Economic Union (the "**EAEU**"), as of 15 January and 15 July of the current year.

At the same time, prescription Medicines whose maximum retail sale price does not exceed one monthly calculation index ("**MCI**"), as established by the law on the republican budget for the relevant financial year as of the date of formation of the draft list, will no longer be included in the draft list.

Accordingly, prescription Medicines with a ceiling retail price not exceeding 1 MCI are removed from the scope of price regulation through the mechanism of non-inclusion in the draft list of Medicines subject to price regulation.

The NCEM submits the draft list of Medicines subject to price regulation to the MoH for coordination with the antimonopoly authority and approval no later than 40 calendar days before that list is approved by the MoH.

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Amendments have also been introduced to paragraph 38 of the Rules, in particular to the procedure for formation of the ceiling retail price for a Medicine trade name. The ceiling retail price for a Medicine trade name is formed at a level not exceeding the average value of sale prices in pharmacy chains, obtained from the integrated digital system of the authorized state revenue body (the "State Revenue Committee of the Ministry of Finance of Kazakhstan") based on cash register receipts (the "**SDF IS**").

In addition, paragraph 41 of the Rules has been revised: if the procedure for reference pricing and price registration changes, recalculation of ceiling prices for Medicine trade names for wholesale and retail sale is carried out by the NCEM at the initiative of the authorized body, without an application from the applicant, using available data and digital systems.

The NCEM also compares the data submitted by the applicant for compliance with the requirements of the Rules and data from the integrated digital system of the customs authorities (the "**Keden IS**").

Thus, the amendments are aimed not only at partial deregulation of low-cost prescription Medicines, but also at strengthening digital control over formation and revision of ceiling prices.

Pilot Project Launched for the Composite State Service under the "One-Stop Shop" Principle

Joint Order of the MoH dated 11 March 2026 No. 30 and the Deputy Prime Minister – Minister of Artificial Intelligence and Digital Development of Kazakhstan dated 12 March 2026 No. 140/НҚ (the "**Joint Order**") launched a pilot project for implementation of a composite state service for registration of Medicines and MDs under the "one-stop shop" principle (the "**Composite Service**"). The document has been in force since 6 April 2026.

The pilot project has been launched in all regions, cities of republican significance and the capital of Kazakhstan. The Joint Order enters into force from the date of its first official publication, applies to legal relations arising from 1 January 2026, and remains in force until 31 December 2026.

The Composite Service is a set of state services related to expert examination, registration, re-registration, amendments to the registration dossier of a Medicine or MD, registration of, or amendments to, the manufacturer's price, and formation of the Kazakhstan National Drug Formulary (the "**KNF**"). The service may be provided either jointly or separately.

The Composite Service combines the following procedures:

1. issuance of a conclusion on the safety, quality and efficacy of Medicines and MDs;
2. state registration, re-registration of a Medicine or MD, and amendments to the registration dossier;
3. price registration for Medicines and MDs;
4. professional expert examination for inclusion in the KNF.

To obtain the Composite Service, the applicant submits an application through the MoH information system, namely the e-Government web portal (Egov.kz) (hereinafter, "**Egov**"). The application is signed with an electronic digital signature or verified by a one-time password if the subscriber number is linked

to the account in the information system. The service recipient may choose all services included in the Composite service or individual services.

The state service is provided electronically. When documents are submitted through Egov.kz, the service recipient's personal account displays the status confirming acceptance of the application for provision of the state service.

Following provision of the state service, the service recipient is issued one of the documents provided for by the Rules, or a reasoned refusal to provide the state service. The relevant documents are sent to the service recipient's personal account in electronic form.

The term for provision of the Composite Service for expert examination, registration, re-registration, amendments to the registration dossier of Medicines and MDs, and professional expert examination for inclusion in the KNF is up to 100 business days. Registration of, or amendments to, the manufacturer's price is carried out within 10 business days.

The term for provision of the state service does not include the time required to remedy incompleteness of the registration dossier, the time for submission of documents and materials upon request at any stage of expert examination, the time required to organize and conduct an inspection, the time required to organize and hold a meeting of the Expert Council, and the time required for the service recipient to approve final documents.

If a manufacturing site inspection is required, the service recipient must provide a letter consenting to the inspection within 30 business days from receipt of the relevant notification. The organization and conduct of the manufacturing site inspection must not exceed 90 business days from the date the service recipient receives the relevant notification.

The Rules also provide that the service recipient is responsible for the accuracy, completeness and content of the submitted documents in accordance with the legislation of Kazakhstan and the Rules. Submission of inaccurate data constitutes grounds for refusal to provide the state service. In the event of a written refusal, the payment made is non-refundable.

Thus, the Composite Service is aimed at combining several related regulatory procedures into a single electronic route. The new mechanism covers not only registration and expert examination of Medicines and MDs, but also price registration and formulary expert examination, which may significantly reduce the overall time required to bring products to market and increase transparency of the document review status.

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