NEW RULES FOR STATE REGISTRATION OF MEDICATIONS

Resolution No. 345 of 18 July 2024 of the Cabinet of Ministers approves the *Rules of State Registration, Entry into, and Maintenance of State Register of Medications, Medicinal Substances, and Medical Appliances*. The Resolution repeals effective 20 July the *Rules of State Registration and State Register of Medications* previously in effect under Resolution No. 108 of 13 July 2007. The new Rules do not require that registrations obtained under the previous Rules be updated (unless nearing expiration).

With reference to the Law of Medications, the following are subject to the state registration (market authorization):

- medications, including original medicines and analogues (generics), new combinations of previously registered medicines, medicines with expired registration period, bulk medicines (active pharmaceutical ingredients, APIs), and medicines packaged for medical institutions (institutional drugs);
- medicinal substances; and
- medical appliances categorized by varying levels of risk (higher, high, and (or) medium).

Medications, substances, and appliances are registered with the Ministry of Public Health acting through the Center for Analytical Expertise public entity under the Ministry. The registration requires an expert report issued under the rules governing the respective issuance. The Ministry issues the registration certificate within seven business days of receipt of a positive report.

Upon an application, instructions for use of a medication, substance, and appliance must be translated into the Azerbaijani and the translation notarized. The Center verifies the translation and submits it for approval by the Ministry. Instructions for use of all medicines and substances state-registered in Azerbaijan are displayed on the Center's website in a PDF format.

After passing the state registration, the Ministry of Public Health includes a medicine, substance, and appliance into the state register, enabling their importation, production, sale, and use in Azerbaijan. The state register is maintained by the Ministry through the Center for Analytical Expertise.

A separate registration certificate is issued for each medication, substance, and appliance. The registration is valid for five years.

Grounds for a refusal to state register (re-register) and make changes to a registration are:

- a failure to submit complete or accurate application and package (or to update incomplete application and package);
- a negative expert review by the Center for Analytical Expertise; and
- an inconsistency in the documents submitted for quality, effect, and safety of a medical appliance.

Where a deficiency in the package is identified, the Ministry requests in five business days an applicant to eliminate them. The applicant is obliged to so eliminate in ten business days. The lapse of time to register shall be suspended until all deficiencies have been eliminated and shall resume upon submission of a corrected package.

Bureau 28a

In case of a refusal to state register (re-register or amend a registration of) a medication, substance, or appliance, an applicant is notified thereof in two business days by registered mail.

Medicines, substances, and appliances with expired registrations are subject to re-registration. To ensure uninterrupted importation, an application to re-register must be made at least 90 days before expiration of the registration.

Amendments to registration documents also require the state registration.

The Ministry may suspend an effective state registration upon *inter alia*:

– discovering side effects of a medicine; and

– a determination of absence of a therapeutic effect of a medicine or substance.

A new certificate comes into effect on the day next to the day of expiration of a previous certificate (unless the registration is obtained for the first time).

In case of a suspension of the state registration, import, production, sale, and use of the respective medicinal product is likewise suspended. The Ministry of Public Health resolves on withdrawing medicinal products guided by the rules of withdrawal approved by Resolution No. 460 of 27 November 2019 of the Cabinet of Ministers.

The state registration of a medicinal product is cancelled upon *inter alia*:

– an inadequate pharmacovigilance control by the registrant;

– a negative benefit/risk ratio assessment under the rules of pharmacovigilance control;

– an opinion by the Center that a medicine or substance does not comply with the Good Manufacturing Practices; and

– a discovery of inconsistencies of quality standards of at least three batches of state registered medicinal products.

The cancellation is publicly announced through the press.

* * *

For Further Information: **ContactUs@Bureau28a.com**

67, Neftcilar Avenue Baku, AZ1095 Republic of Azerbaijan www.bureau28a.com

*Information does not, and is not intended to, constitute legal advice