DRAFT BILL OF AMENDMENTS TO LAW ON MEDICINES

Law No. 208-IIIQ of the Republic of Azerbaijan, *On Medicines*, of 22 December 2006, regulates handling and circulation of medicines. The Law covers registration, expert examination, and certification, licensing of production, wholesale, and retail sale, export and import, advertisement, as well as compensating damage from the use, of medicines.

Per the Law, the following are subject to the State registration: (i) brand-name (original) medicines; (ii) generics; (iii) new combinations of medicines; (iv) medicines under expired State registrations; and (v) substances used in the manufacture of medicines. The following medicines are not subject to registration: (i) exhibition samples; (ii) prepared in pharmacies based on prescriptions; (iii) imported for use in emergencies; (iv) intended for research, preclinical studies, and clinical trials; (v) imported as samples as well as substances used in manufacture; (vi) imported by individuals for personal use in appropriate quantities; (vii) recommended for use by the World Health Organization; (viii) intended to treat rare diseases; and (ix) prescribed by participating States for use by their athletes and personnel in sport competitions.

The most recent draft bill of amendments to the Law passed the first reading at the parliament, Milli Maclis, on 23 June. The amendments modernize the Law by, for instance, aligning with the tax laws the requirement for drugstores to be operated by businesses.

Concepts, such as a simplified examination of medicines, tracking and tracing system of medicines, prescription of medicine, clinical protocol, and Good Manufacturing Practice (GMP), are introduced. Further, the amendments provide for the following new key definitions and procedures:

- a definition of the State registration of a medicine: a system of measures encompassing entering into the State register based on an expert examination, including the simplified examination, of medicines and medicinal substances as well as medical devices of higher, high, and/or medium risk ranking and authorizing their local mass manufacturing, importation, and use;

- a definition of the State register of medicines: an information system consisting of data of medicines, medicinal substances, and medical devices registered according to the Law;

- a definition of a medical device: instrument, device, accessory, software, tangible and other means, as well as special devices for cleaning of such instrument, device, and accessory, that do not have a pharmacological, immunological, or metabolic effect on the human body, but can help the function of the agents that so do;

- the process of recognition of a foreign (international) registration of medicines: entering into the State register, based on a simplified examination, of medicines manufactured, State-registered and authorized for sale in at least one country from the list of approved countries, or authorized for use by foreign (international) organizations, as well as manufactured in other countries and authorized for sale in at least two countries from the list;

- a permitting authority – the authority responsible for registering medicines and permitting their importation;

- a permit to import a medicine – there would be a separate permit issued by the permitting authority;

- a process for issuing pursuant to clinical protocols of a prescription for the use of a medicine, a medical document in an electronic form; an unregistered medicine listed in a prescription can be imported in the quantities listed in the prescription only after the authority has approved the prescription (the process is introduced to prevent a distribution of unregistered medicines requiring such registration by, for instance, an importation by individuals in quantities exceeding their needs);

- a provision of instructions for the use of a medicine: where the instructions in the Azerbaijani are missing from or not accompanying the packaging of the medicine, drugstores must provide to their customers the instructions in the Azerbaijani language provided by the holder of the registration certificate; and

- a regulation of dietary supplements: changes are made regarding the details to be indicated on the product leaflet next to the information of the supplement.

These changes will come into effect in stages: while the rules for recognition of foreign (international) registrations of medicines and new requirements for accompanying information on dietary supplements will take effect from 1 November this year and new rules for issuing medical prescriptions will come into force from 1 January 2024, the rest of the amendments will come into effect upon an expected prior promulgation.

The draft bill is expected to pass at the parliament two more readings before being approved into law.

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