Unofficial translation of the Notice of the State Service of Ukraine on Medicines and Drugs Control

Regarding the importation of medicinal products into the customs territory of Ukraine

In response to numerous inquiries from business entities regarding the import of medicinal products and to ensure the proper implementation of Ukrainian legislation in the field of medicinal product circulation, the State Service of Ukraine on Medicines and Drugs Control informs:

According to Part 1 of Article 17, Section V of the Law of Ukraine "On Medicinal Products" (hereinafter referred to as the Law), medicinal products registered in Ukraine may be imported into the territory of Ukraine provided that a quality certificate for the medicinal product batch, issued by the manufacturer, is available, along with an import License for medicinal products (except active pharmaceutical ingredients), issued to the importer (manufacturer or person representing the manufacturer in Ukraine) in accordance with the procedure established by law. The Annex to the License specifies the list of medicinal products permitted for import by the Licensee and the special conditions for conducting activities.

At the same time, in accordance with Article 9, Section II of the Law, medicinal products are allowed for use in Ukraine only after their state registration, except in cases provided for by this Law.

The state registration of medicinal products is carried out based on an Application submitted to the central executive authority implementing state policy in the healthcare field.

For a registered medicinal product, a certificate is issued to the Applicant (Marketing Authorization Holder), which specifies the validity period during which the medicinal product is permitted for use in Ukraine.

If changes are made to the registration materials for a medicinal product/medicinal product (medical immunobiological product) during the validity period of the registration certificate, an Annex or Letter from the Ministry of Health of Ukraine regarding amendments to the registration materials is added to the registration certificate (if the changes do not directly affect the registration certificate).

The Annex to the Registration certificate and Letters from the Ministry of Health of Ukraine regarding amendments to the registration materials issued to the Applicant (MAH) as a result of changes to the registration materials are an integral part of the original registration certificate. At the same time, the registration certificate number remains unchanged throughout the entire life cycle of the medicinal product.

According to Clauses 17 and 19 of Section VI of the “Procedure for the examination of registration materials for medicinal products submitted for state registration (renewal), as well as the examination of materials for amendments to the registration materials ruring the validity of the registration certificate”, approved by Order No. 426 of the Ministry of Health of Ukraine dated August 26, 2005, a conclusion is drawn based on the results of the examination regarding amendments to the registration dossier materials. This takes into account the period specified by the applicant in the registration form during which the proposed changes must be implemented (implementation period).

The implementation period is approved by the relevant order of the Ministry of Health regarding amendments to the registration materials.

Considering the above, amendments to the registration materials for a medicinal product, made during the validity of the registration certificate, come into force after their approval by the relevant order of the

Ministry of Health of Ukraine. Approved changes apply to those batches of the medicinal product that are manufactured and released for sale after the date the aforementioned changes come into force. *At the same time, batches of the medicinal product manufactured before the changes come into force must comply with the registration documents valid as of the date the authorized person signed the application for the batch certification of the medicinal product.*

Additionally, it is reported that, according to Part Two of Article 17, Section V of the Law, control over the importation of medicinal products into the customs territory of Ukraine is exercised by the central executive authority implementing state policy in the field of quality and safety control of medicinal products. *All medicinal products imported into the customs territory of Ukraine for the purpose of further sale (trade) or use in the production of finished medicinal products are subject to state quality control.*

In accordance with Clause 4 of the "Procedure for the state quality control of medicinal products imported into Ukraine", approved by Resolution No. 902 of the Cabinet of Ministers of Ukraine dated September 14, 2005 (hereinafter referred to as the Procedure), to ensure proper state quality control of medicinal products, the State Customs Service provides the State Service of Ukraine on Medicines and Drugs Control with information on medicinal products imported into the territory of Ukraine.

State quality control is carried out by the State Service of Ukraine on Medicines and Drugs Control and its territorial bodies.

Clause 13 of the Procedure stipulates that if a positive conclusion on the quality of a medicinal product imported into Ukraine is issued as a result of state quality control of medicinal products, the circulation of the imported medicinal product may be carried out throughout the entire territory of Ukraine without restrictions.

In the case of a negative conclusion, the business entity undertakes actions provided for by foreign economic contracts and/or regulatory legal acts (return to the supplier, disposal, destruction of medicinal products, etc.).

Considering the above, the State Service of Ukraine on Medicines and Drugs Control does not object to the importation into the customs territory of Ukraine of medicinal products that were manufactured, packaged, labeled, and controlled in accordance with the version of the registration materials valid at the time the batch was released.