

Unofficial translation of the Law №3910-IX “On amendments to the Law of Ukraine "On medicinal products" regarding the labeling of medicinal products”

LAW OF UKRAINE

On Amendments to the Law of Ukraine "On Medicinal Products" Regarding the Labeling of Medicinal Products

The Verkhovna Rada of Ukraine resolves:

I. To amend the Law of Ukraine "On Medicinal Products" (Bulletin of the Verkhovna Rada of Ukraine, 1996, No. 22, Article 86, as amended) as follows:

1. Article 12 shall be supplemented with Parts eleven and twelve as follows:

"It is prohibited to include any advertising information on the inner and outer (if applicable) packaging of medicinal products, as well as any information about other legal or physical entities that are not the manufacturer of the medicinal product or the applicant (holder of the registration certificate) for the medicinal product. The requirements of this part shall not apply to medicinal products imported into Ukraine with labeling and instructions for use/summary of product characteristics in the original language (a language other than the state language) as a result of procurement conducted by an entity authorized to carry out procurement in the field of healthcare, or procurement conducted with the involvement of an entity authorized to carry out procurement in the field of healthcare using local budget funds, and/or as a result of a procurement procedure conducted by a specialized procurement organization under an agreement on procurement between the central executive authority of Ukraine responsible for shaping and implementing state healthcare policy and the relevant specialized procurement organization; medicinal products imported into Ukraine as humanitarian aid; unregistered medicinal products whose importation into Ukraine is permitted in cases defined by Article 17 of this Law.

In the event of non-compliance with the requirements for the labeling of a medicinal product, the central executive authority responsible for shaping and implementing state healthcare policy shall make a decision, in accordance with its established procedure, to temporarily suspend the registration certificate for such a medicinal product until the labeling is brought into compliance with the requirements of this Article and a decision is made to reinstate the registration certificate."

2. Article 19 shall be supplemented with Part thirteen as follows:

"It is prohibited to conduct retail trade of medicinal products, wholesale trade of medicinal products, and/or import medicinal products (except for: medicinal products imported into Ukraine with labeling and instructions for use/summary of product characteristics in the original language (a language other than the state language) as a result of procurement conducted by an entity authorized to carry out procurement in the field of healthcare, or procurement conducted with the involvement of an entity authorized to carry out procurement in the field of healthcare using local budget funds, and/or as a result of a procurement procedure conducted by a specialized procurement organization under an agreement on procurement between the central executive authority of Ukraine responsible for shaping and implementing state healthcare policy and the relevant specialized procurement organization; medicinal products imported into Ukraine as humanitarian aid; unregistered medicinal products whose importation into Ukraine is permitted in cases defined by Article 17 of this Law), if their labeling contains any advertising information or any information about other legal or physical entities that are not the manufacturer of the medicinal product or the applicant (holder of the registration certificate) for the medicinal product."

II. Final provisions

1. This Law shall enter into force on the day following its publication and shall come into effect four months after the date of its entry into force.
2. The Cabinet of Ministers of Ukraine, within three months from the date of entry into force of this Law, shall:
 - bring its regulatory legal acts into compliance with this Law;
 - ensure the review and alignment of regulatory legal acts of ministries and other central executive authorities with this Law.
3. The Ministry of Health of Ukraine is recommended, within three months from the date of enactment of this Law, to take measures to temporarily suspend the registration certificates for medicinal products whose labeling does not comply with the established requirements until their labeling is brought into compliance with this Law.
4. The State Service of Ukraine on Medicines and Drugs Control is recommended, within three months from the date of enactment of this Law, to take measures to establish a ban on the circulation of medicinal products on the territory of Ukraine whose labeling does not comply with the established requirements.

President of Ukraine

V. ZELENSKY

Kyiv
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