Unofficial translation of the Letter of the Ministry of Health of Ukraine

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To Whom It May Concern

Regarding compliance with the requirements of the Law of Ukraine No. 3910-IX dated August 21, 2024, on the labeling of medicinal products

In response to numerous inquiries from companies participating in Ukraine's pharmaceutical market regarding clarification on the practical application of the provisions of the Law of Ukraine No. 3910-IX dated August 21, 2024, "On Amendments to the Law of Ukraine 'On Medicinal Products' Regarding the Labeling of Medicinal Products" (hereinafter referred to as Law No. 3910-IX), which will come into effect on January 18, 2025, the Ministry of Health of Ukraine (hereinafter referred to as the Ministry) provides, within its competence, explanations for practical use regarding what information in the text of the medicinal product's packaging label can be considered as containing advertising elements. This includes any information about other legal or natural persons who are not the manufacturer of the medicinal product or the applicant (holder of the registration certificate) for the medicinal product.

In accordance with Article 19 of the Constitution of Ukraine, state authorities and local self-government bodies, as well as their officials, are obligated to act solely on the basis, within the powers, and in the manner prescribed by the Constitution and laws of Ukraine.

Relations associated with the production, distribution, and consumption of advertising in Ukraine are regulated by the Law of Ukraine "On Advertising" (hereinafter referred to as the Advertising Law).

According to Article 1 of the Advertising Law, "advertising is information about a person or product, disseminated in any form and in any manner, intended to create or maintain awareness among consumers of such advertising and their interest in the respective person or product."

Advertising - is the promotion of goods, services, and similar items with the aim of attracting the attention of buyers, consumers, or clients, as well as disseminating information about a person or product to create popularity. The objectives of advertising include, among other things, shaping the image of a trademark and creating and maintaining a company's image in the market.

At the same time, according to Clause 7 of Article 8 of the Advertising Law, the placement of information about the manufacturer of a product and/or the product itself at the points of sale or provision to consumers, including on elements of equipment and/or the design of retail spaces, as well as directly on the product and/or its packaging, is not considered advertising.

The provisions of Article 15 of the Law of Ukraine "On Consumer Protection" establish that consumers have the right to receive necessary, accessible, reliable, and timely information about products, enabling them to make an informed and competent choice. Information about products is not considered advertising.

Article 1 of the Law of Ukraine "On the Protection of Rights to Trademarks for Goods and Services" defines a trademark as a designation by which the goods and services of one entity are distinguished from those of another.

Additionally, Article 2 of the Advertising Law stipulates that the provisions of this law do not apply to relationships related to the dissemination of information whose publication and placement are mandated by other laws of Ukraine.

The mandatory information that must be included on the labeling of medicinal products is determined by Article 12 of the Law of Ukraine "On Medicines" (hereinafter referred to as the Law on Medicinal Products) and Annex 22 to the Procedure for conducting the examination of registration materials for medicinal products submitted for state registration (re-registration), as well as the examination of materials on changes to registration materials during the validity of the registration certificate, approved by the Order of the Ministry of Health of Ukraine No. 426 dated August 26, 2005 (with amendments) (hereinafter referred to as Annex 22).

Part one of Article 12 of the Law on Medicines specifies that "labeling applied to the label, outer packaging, and inner packaging of a medicinal product must include the following information: the name of the medicinal product; the name and address of its manufacturer; the registration number; the batch number; the method of administration; the dose of the active ingredient in each unit and its quantity in the package; the expiration date; storage conditions; and precautions."

Law No. 3910-IX amends Articles 12 and 19 of the Law on Medicinal Products with provisions effective January 18, 2025, as follows:

- It is prohibited to include any advertising information on the inner and outer packaging (if applicable) of medicinal products, as well as any information about other legal or natural persons who are not the manufacturer of the medicinal product or the applicant (holder of the registration certificate) for the medicinal product.
- Retail sale, wholesale trade, and/or import of medicinal products (except...) whose labeling contains any advertising information, as well as any information about other legal or natural persons who are not the manufacturer of the medicinal product or the applicant (holder of the registration certificate), are prohibited.

Law No. 3910-IX was adopted to harmonize Ukrainian legislation with the provisions of European Union law on the circulation of medicinal products, specifically Directive 2001/83/EC of the European Parliament and of the Council dated November 6, 2001, on the Community Code relating to medicinal products for human use. Article 62 of this directive provides that "outer packaging and the package leaflet may contain symbols or pictograms intended to clarify certain information specified in Articles 54 and 59(1), as well as other information equivalent to a brief summary of the product's characteristics, which is useful for the patient, but excludes any advertising elements."

A similar provision is included in the Requirements for the Labeling of Finished Medicinal Product Packaging, approved in Annex 22. According to subparagraph 1.1.2 of subparagraph 1.1, paragraph 1 of Annex 22, secondary packaging may also include symbols or pictograms that clarify the information specified in subparagraph 1.1.1 of subparagraph 1.1, paragraph 1 of Annex 22, as well as other information corresponding to the summary of product characteristics and useful to the patient, excluding any advertising elements that promote the medicinal product in the market.

Based on these legislative norms and to ensure the uninterrupted supply of quality medicinal products to patients in need, while fostering a balanced approach to the labeling of medicinal product packaging that complies with the requirements of Law No. 3910-IX and reflects the unique characteristics of each manufacturer/applicant operating in the Ukrainian market, the following recommendations should be taken into account.

What information on medicinal product packaging can be considered advertising? Would including information on the medicinal product packaging that aligns with the approved instructions for medical use be considered advertising?

Information placed on medicinal product packaging that complies with the approved instructions for medical use and/or the summary of product characteristics, as well as symbols or pictograms that clarify the

mandatory information specified in subparagraph 1.1.1 of subparagraph 1.1, paragraph 1 of Annex 22, and information about the manufacturer or applicant (if desired), is not considered advertising.

The term "advertising information" is not defined in Ukrainian legislation and is absent from regulatory and legal acts in Ukraine.

Would the placement of a company's trademark (logo), for which the manufacturer or applicant holds legal usage rights, on the packaging of a medicinal product be considered advertising information? Would the simultaneous placement on the packaging of a medicinal product of a company's trademark (logo), for which the manufacturer or applicant holds legal usage rights, and a trademark (logo) belonging to the manufacturer or applicant under a licensing agreement, be considered advertising information or information about other legal or natural persons?

The inclusion of the logo (trademark) of the manufacturer or (if desired by the applicant) the applicant company on medicinal product packaging is not considered advertising. Instead of the manufacturer or applicant's logo, the logo of a group of companies (corporation, consortium, association, international pharmaceutical company) to which the manufacturer and/or applicant legally belongs may be used. This is permissible if the given logo is used by the manufacturer or applicant company in the official business documentation of the company.

Additionally, we inform you that according to Article 1 of the Law of Ukraine "On protection of rights to inventions and utility models," a license is the permission granted by the patent holder (licensor) to another person (licensee) to use the invention (utility model) under specified conditions.

Provisions of Article 28, Section V of the Law of Ukraine "On protection of rights to inventions and utility models" establish that a patent holder may use a warning marking indicating the patent number on a product or its packaging manufactured using a patented invention (utility model). At the same time, the patent holder has the right to grant any person permission (issue a license) to use the invention (utility model) under a licensing agreement.

Furthermore, under paragraph 5 of Article 10 of Regulation (EC) No. 816/2006 of the European Parliament and the Council of May 17, 2006, on compulsory licensing of patents related to the manufacture of pharmaceutical products for export to countries with public health problems: "Products manufactured under the license must be clearly identified by special marking or labeling as having been produced in accordance with this Regulation."

Thus, in cases where the manufacture of medicinal products patented in Ukraine or globally is carried out under a license from the patent holder, the inclusion of information indicating that the medicinal product was manufactured under a license from the patent-holding company or under a limited patent license from the patent-holding company for use in the licensed territory, including the name of the patent-holding company and/or its logo, constitutes information about the manufacturer and is not considered advertising information.

It is prohibited to include additional information on the packaging of a medicinal product that is not specified in the approved instructions for use or does not correspond to the summary of product characteristics. Such information includes, for example:

- Information presented arbitrarily to detail data provided in the instructions, if such details are absent in the instructions. For instance, if a medicinal product is approved for use in children under one year of age and older, labeling the packaging with statements such as "suitable for use from the first days of life" or "from birth."
- Information about a company representing the manufacturer and/or applicant's interests in Ukraine.
- Information about a company involved in the distribution of the medicinal product, such as a distributor, pharmacy network, or a company that commissioned the manufacture of the medicinal product.
- Use of multiple original layouts for the same medicinal product (registration certificate) considering all approved packaging forms (number of dosage forms in one package), even if the labeling text is identical but presented in different color schemes.

However, to comply with the requirements of Article 15 of the Law of Ukraine "On Consumer Protection" regarding the consumer's right to receive necessary, accessible, reliable, and timely information about a product, including the name and location of the enterprise responsible for handling consumer complaints, the inclusion of contact details and information about the representative of the applicant/manufacturer to whom consumers should address quality and safety claims is allowed.

This applies if the manufacturer/applicant is an entity from a foreign country, including European countries, and its representative differs from the manufacturer/applicant. Such information must be included in the instructions for medical use of the medicinal product, in compliance with the requirements of Annex 19 to the Procedure for Conducting the Examination of Registration Materials for Medicinal Products Submitted for State Registration (Re-registration) and the Examination of Materials for Amendments to Registration Materials During the Validity of the Registration Certificate. This procedure was approved by Order No. 426 of the Ministry of Health of Ukraine dated August 26, 2005 (as amended by Order No. 460 of the Ministry of Health of Ukraine dated July 23, 2015), registered with the Ministry of Justice of Ukraine on September 19, 2005, under No. 1069/11349, and does not contradict the requirements of Law No. 3910-IX.

Regarding the sale of medicinal product batches manufactured before the effective date of Law No. 3910-IX (before January 18, 2025)

According to Clause 2 of Section II "Final Provisions" of Law No. 3910-IX, the Cabinet of Ministers of Ukraine is obligated to align its regulatory legal acts with this Law within three months of its effective date. Additionally, ministries and other central executive bodies are required to review and align their regulatory legal acts with this Law.

Currently, work is underway to develop subordinate regulatory legal acts intended to regulate the import into Ukraine and sale of medicinal products manufactured and/or released by the manufacturer in accordance with the approved labeling texts that were authorized prior to the effective date of Law No. 3910-IX.

It is planned to allow the import and/or sale of batches of medicinal products that were manufactured and/or released by the manufacturer’s authorized person before January 18, 2025, in accordance with the approved registration documents corresponding to valid registration certificates for medicinal products.

Deputy Minister **Edem ADAMANOV**