NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** UKRAINE  **If applicable, name of local government involved (Article 3.2 and 7.2):** |
| **2.** | **Agency responsible:**  Verkhovna Rada of Ukraine, Ministry of Health of Ukraine, State Service of Ukraine on Medicines and Drugs Control  **Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:** |
| **3.** | **Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [X], 5.7.1 [ ], 3.2 [ ], 7.2 [ ], other:** |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Medicinal products |
| **5.** | **Title, number of pages and language(s) of the notified document:** Law of Ukraine No. 3910 "On Amendments to the Law of Ukraine "On Medicinal Products" on Labelling of Medicinal Products" of 21 August 2024; (2 page(s), in Ukrainian) |
| **6.** | **Description of content:** The Law aligns the requirements of national legislation on the labelling of medicinal products with the provisions of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.  The Law stipulates that the packaging of medicinal products shall not contain any advertising information, as well as any information about other legal entities or individuals who are not the manufacturer or applicant (holder) of the registration certificate for the medicinal product. The Law also provides that wholesale and retail trade, and import of medicinal products that do not comply with the labelling requirements set out in this Law are not allowed.  The established requirements do not apply to medicinal products imported into Ukraine with labelling and instructions for use/brief description of the medicinal product in the original language (a language other than the state language), based on the results of procurement conducted by a person authorized to carry out procurement in the healthcare sector, or procurement conducted with the involvement of a person authorized to carry out procurement in the healthcare sector, at the funds of local budgets, and/or based on the results of the procurement procedure conducted by a specialized procurement organization to fulfil the procurement agreement between the central executive body of Ukraine responsible for healthcare policy and the relevant specialized procurement organization. Additionally, this exemption covers medicinal products imported as humanitarian aid and unregistered medicinal products, import of which into Ukraine is permitted under conditions specified in Article 17 of the Law of Ukraine No. 123/96-ВР "On Medicines" of 4 April 1996 (amended). |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Consumer information, labelling; Prevention of deceptive practices and consumer protection; Quality requirements |
| **8.** | **Relevant documents:**  Law of Ukraine No. 123/96-ВР "On Medicines" of 4 April 1996, <https://zakon.rada.gov.ua/laws/show/123/96-%D0%B2%D1%80#Text> |
| **9.** | **Proposed date of adoption:** 21 August 2024  **Proposed date of entry into force:** 18 September 2024; This Law shall be enacted on 18 January 2025. |
| **10.** | **Final date for comments:** 60 days from notification |
| **11.** | **Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:**  Ministry of Economy of Ukraine  Department for Trade Agreements and Export Development  12/2 Hrushevskoho Str.  Kyiv 01008  Tel: +(38 044) 596 6839  Fax: +(38 044) 596 6839  Email: [ep@me.gov.ua](mailto:ep@me.gov.ua)  Website: <https://www.me.gov.ua>  <https://zakon.rada.gov.ua/laws/show/3910-20#Text>  <https://members.wto.org/crnattachments/2024/TBT/UKR/24_06116_00_e.pdf>  <https://members.wto.org/crnattachments/2024/TBT/UKR/24_06116_00_x.pdf> |