

## The most significant changes to the Law of Ukraine “On Ensuring the Functioning of the Ukrainian Language as the State Language” directly or indirectly related to the circulation of products in health care

The Law of Ukraine “On Ensuring the Functioning of the Ukrainian Language as the State Language” comes into force on July 16, 2019, and transitional periods of 6 months have been set for a significant part of the provisions.

The Law has a significant impact on user information (product labeling, instructions, interface), marketing and promotional materials, websites, public events (seminars, conferences) etc.

The Law states that the only state (official) language in Ukraine is the Ukrainian language. The words "state" and "Ukrainian" will be used as completely identical terms later in the text.

This document is an expert opinion. The provisions of the Law are officially interpreted by the relevant competent authorities of Ukraine.

### 1. Labeling and instructions for use.

The new wording of the Law excludes the term “Labeling of goods”. The Law states that information about goods and services (including packaging labeling and instructions for use) is provided in the state language in the territory of Ukraine, but does not prohibit to duplicate information in any other language. It is not prohibited by Law to add additional labeling to products along with the original labeling (for example, using stickers).

The volume of information is provided in volume not less than the mandatory amount of information in accordance with the requirements established by the Law of Ukraine “On Consumer Rights Protection”. Obviously, products must also comply with the requirements of the industry specific legislation (for example, the relevant Technical Regulations), as well as the requirements of related legislation (for example, the Law of Ukraine "On State Market Supervision and Control of Non-Food Products", etc.).

The use of words, acronyms, abbreviations and symbols in English and/or using Latin and/or Greek alphabets is permitted in information about products (goods), works or services provided in the state language. We believe that this norm is extremely important for medical devices and in-vitro diagnostic products, since it legalizes the use of commonly-used professional abbreviations in Latin.

The Law states that trademarks are indicated in the language in which they are provided with legal protection. Accordingly, the product name may include the trademark in Latin ("Tradenname (in Latin)" instead of "Tradenname (in Cyrillic)") under the appropriate conditions.

The names of geographical objects and toponymic objects located on the territory of other states, when used in Ukraine, shall be provided in the state language **in transcription from the source language** taking into account the features of Ukrainian phonetics and spelling. We believe that manufacturer's address on labeling, instructions and other supporting documents should be provided in Ukrainian.

Please note that the requirements of the Law concerning trademarks and geographical objects do not have a transitional period and come into force on July 16, 2019, all other specified provisions regarding information on goods come into force on January 16, 2021. Despite the transition period of the implementation of such changes, we recommend revising the labeling of products in relation to the requirements of the Law “On Consumer Rights Protection”, which apply to any product sold in Ukraine, are taken into account during inspections of market surveillance authorities and considered when developing the labeling.

### 2. Requirements for the size of the text.

The Law has come through a long phase of finalization, amendments at the time of its signature and publication. The requirements for the size of the font of the text in Ukrainian, which for a long time remained one of the most controversial and critical innovations, were not included in the final version of the Law, but were consolidated with respect to the field of culture. The lack of requirements for the size of the font of the text in Ukrainian has greatly facilitated the implementation of the innovations of the Law for manufacturers of medical products, where the labeling is a production process.

At the same time, it should be noted that the Law does not abolish font size requirements that can be set by industry standards or regulations.

### 3. User interface (UI/GUI).

The language of the user interface of the computer program is the state language. The Law provides for two categories of user interface for a computer program:

- the one that is installed on goods sold in Ukraine, and
- the one that is sold in Ukraine.

A computer program with a user interface installed on goods sold in Ukraine should have an interface in the state language. A computer program with a user interface sold in Ukraine should have a user interface in the state language and/or English, or in other official languages of the European Union. The availability of a user interface for goods sold in Ukraine in the state language is a prerequisite when purchasing computer programs for state authorities, local self-government, enterprises, institutions and organizations of state and municipal forms of ownership.

However, these requirements apply to consumer goods and computer programs. **The Law contains an important exception for the medical industry:** specialized professional equipment that is not a commodity (including medical diagnostic equipment) may not have a user interface in Ukrainian, provided it is available in English.

In addition, in the near future we plan to get an explanation whether this exclusion applies to medical devices intended for use by the consumer (for example, glucometers, tonometers, etc.).

### 4. Websites and e-commerce.

Websites, social networking pages of enterprises and online stores that sell goods and services in Ukraine shall be in the state language. The use of versions of web resources in other languages along with the state one is allowed, but the volume and content of the information in the state language shall not be less than in the other languages.

The website of the representative office, affiliate and subsidiary of the non-resident company shall be in the state language and shall contain information for clear navigation and disclosure of the purpose of the activity.

The version of the website in the state language for users in Ukraine should be displayed by default.

Please note that the link to the web page in brochures and catalogs, on the labeling of products and in the instructions should lead to the corresponding page in Ukrainian. Accordingly, the documentation and information for the user (consumer) on the web page, such as an instruction or user manual, brochure, catalog, etc., must be available in the state language.

The overwhelming majority of these requirements come into force on January 16, 2021.

### 5. Advertising and promotion.

The language of advertising in Ukraine is the state language. The Law establishes a transitional period of 6 months, i.e. printed, television and radio advertising must comply with the requirements since January 16, 2020.

Since information about goods and services in the territory of Ukraine is provided in the state language, it is reasonable to assume that the language of promotional materials is also Ukrainian. In this case, the transition period is set at 18 months, that is, until January 16, 2021.

The Law defines public events, public scientific events and events for a limited number of people. Public events are paid or free of charge, open or invitation-based events organized in whole or in part by state authorities, state institutions and organizations owned by the state irrespective of the share of ownership.

The language of public events is the state language, and the language of public scientific events (scientific conferences, round tables, symposia, seminars, etc.) may be the state language and/or English. If a public event is held in a language other than the state language, its organizer is obliged to provide simultaneous or sequential translation into the state language if at least one participant of the public event requires it. Please note that these provisions come into force on July 16, 2019, without a transitional period.

The above provisions do not apply to events for a limited number of people. If a scientific event is conducted in a foreign language, the organizers are obliged to inform the participants of the event in advance. In this case, the translation into the state language is not obligatory.

Printed mass media in Ukraine are published in the state language. Printed mass media may be published in languages other than the state language, provided that the circulation of this publication in the state language is published simultaneously with the corresponding circulation of the publication in a foreign language. Scientific publications are published in the state language, in English and/or in other official languages of the European Union.

#### **6. Technical and project documentation.**

The language issue in terms of technical and project documentation is determined by its customer. The technical and project documentation developed under an agreement with state authorities, local self-government authorities, enterprises of state or municipal ownership, shall be provided in the state language.

The technical and project documentation developed under an agreement with a foreigner, a stateless person or a legal entity registered under the legislation of another country, shall be provided in a language determined as agreed by the parties.

These provisions come into force on July 16, 2020 and should be taken into consideration by manufacturers whose quality management system is based on the OEM-OBL model and companies that develop technical and project documentation for custom orders.

**Our expert opinion:** The Law ensures the priority of the Ukrainian language in many spheres of public life and regulates most of the open language issues. Among the most important achievements from the regulatory point of view are the following:

- the possibility to use generally accepted professional names, abbreviations and symbols using the letters of the Latin and/or Greek alphabets is provided;
- the possibility to use registered trademarks in Latin is determined;
- requirements for the submission of transcription in the state language of geographical names are established;
- the issue of the user interface for medical diagnostic equipment is resolved;
- clear obligations of the subjects regarding the language of the website, information on products in electronic form are established.

At first glance, among the products in the healthcare sector, the Law has the least impact on medicines, and the biggest – on medical devices. The transitional provisions set the gradual implementation of the requirements, but taking into account the time period required by manufacturers to coordinate and implement labeling and instructions, and the translation of information into Ukrainian, we recommend that you take into account the new requirements and review the information regarding your product in advance.

*Sincerely,*

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