

## **APPROACHES TO STANDARDIZATION OF LABELING FOR PRESCRIPTION DRUGS ABROAD**

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Today necessity for standardization of prescription drug labeling is still an actual problem in the whole world and, in particular, in the USA. According to reports of Food and Drug Administration (FDA) there are two main reasons for such a problem: the first one is inadequate patient understanding of prescription dosing instructions and warnings, the second one is lack of universal standards and regulations for medication labeling which leads to variability in labels on packages with prescription drugs.

The aim of our study was to highlight trends and approaches in standardization of labeling of prescription drugs abroad.

Now for such medications the FDA requires that certain information appear on the drug container label: drug name, pharmacy name and address, serial/lot number of the prescription, prescribing physician name, patient name, and instructions for use. Beyond the FDA requirements, state boards of pharmacy are responsible for establishing further standards. In response to such regulations, national pharmacy chains in the USA have developed 31 different label styles, resulting in variability in the clarity and complexity of medication use instructions.

The existing evidence base for label standards supports the following practices: use explicit text to describe dosage and interval in instructions; use a recognizable visual aid to convey dosage and use instructions; simplify language, avoiding unfamiliar words and medical jargon; when possible, include indication for use; include distinguishable front and back sides to the label; organize the label in a patient-centered manner; improve typography – use larger, sans serif font; when applicable, use numeric instead of alphabetic characters; use typographic cues (bolding and highlighting) for patient content only; use horizontal text only; use a standard icon system for signaling and organizing.

Beyond the content and format, one of the most important things on the prescription drug label is the “signal line” or dosage instruction. This information also causes the most difficulties. It is the information that patients are looking for, yet there are high levels of variability in how such information is presented.

Thus, elaboration of uniform, standard and substantiated design of labeling easily perceived by patient and pharmacist still remains the live issue in the world.