

Peculiarities of drugs advertising in Ukraine

For the last couple of years the Ukrainian Parliament and Government are constantly making efforts to simplify regulations for import and certification of drugs on the territory of Ukraine. The latest development is adoption of the law on simplification of state registration of drugs, which have been already registered with the competent authority of the USA, Switzerland, Japan, Australia, Canada or the EU. This law was signed by the President of Ukraine on 16 June 2016.

However, the importers/manufacturers of drugs are fully aware that certification of drugs is one issue whilst the question of their distribution at the new market is quite different. Given the fact of Ukrainian strict advertising rules, advertising of drugs should be carefully crafted and structured.

Liability

Failure to comply with the legislative requirements for advertising of drugs results in disciplinary, civil, administrative and criminal responsibility according to the law. Thus, a fine in the amount of five times the value of advertising is imposed.

In the last couple of years Ukraine experienced cases when breach of advertising regulations resulted in severe fines for pharmaceutical companies in the amount of several millions hryvnias, including due to breach of antimonopoly legislation. Therefore, it is strongly advised to undergo legal examination of the content of drug advertisement before its official publication.

Definition of a drug

Pursuant to the Law of Ukraine "On drugs", drug is defined as any substance or combination of substances (one or more APIs and excipients), which has the qualities and is intended for the treatment or prevention of human diseases, or any substance or combination of substances (one or more APIs and excipients), which can be designed to prevent pregnancy, restore, correct or change physiological functions of human beings through pharmacological, immunological or metabolic action, or for medical diagnosis.

Pre-requisites for drug advertisement

Manufacturing of drugs and their distribution in Ukraine require a special licence. Thus, failure of the manufacturer, importer or supplier (as the case might be) to obtain a licence results in prohibition to advertise such drug. The same prohibition applies in the event such licence was

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suspended or annulled.

Furthermore, some specific provisions apply to advertisement of drugs as provided by the Law of Ukraine "On advertising" pursuant to which advertising of drugs is only possible if such drugs are:

permitted for use in the territory of Ukraine by the Ministry of Health of Ukraine;

permitted for use without the doctor's prescription;

not included into the list of drugs prohibited for advertising maintained by the Ministry of Health of Ukraine. Such list is accessible through the official register of drugs in Ukraine.

Requirements for drug advertisement

In the advertisements the following requirements should be followed:

- objective information about a drug to be made in such a manner so that it is clearly understandable that this is an advertisement and the advertised product is a drug;
- requirement to consult a doctor before any use of the drug;
- recommendation for the mandatory familiarization with instructions on the drug;
- disclaimer as follows: "Self-medication could be harmful to your health", which takes at least 15 percent of the area (length) of all advertisement.

Furthermore, Ukrainian legislation is rich on the type of information, which should be avoided in drug advertisements, such as that can give the impression that drug use does not require expert consultation or that the therapeutic effect following use of a drug is guaranteed, etc. However, the abovementioned restrictions do not apply if the drug is advertised in specialized publications intended for healthcare institutions and doctors, and/or which are distributed at seminars, conferences, symposia on medical topics.