

ETHICAL AND LEGAL ISSUES IN DIRECT-TO-CONSUMER PHARMACEUTICAL ADVERTISING

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Advertising of pharmaceutical products is one of the most effective means of influencing the target audience. Medicines, medical products and dietary supplements are one of the most advertised categories of goods on television and in other media. Unfair advertising of drugs which misleads consumers and cause the erroneous self-medication is a huge problem in different countries.

In Ukraine, television is one of the main channels for advertising drugs. According to the All-Ukrainian Advertising Coalition, in 2019 the volume of the television advertising market, including direct advertising and sponsorship, amounted to about UAH 11.5 billion, which was about 47% of the total capacity of the advertising market of Ukraine

The average American TV viewer watches nine drug advertisements a day, totalling 16 hours per year, which far exceeds the amount of time the he spends with a primary care physician.

The purpose of this work is to describe the ethical and legal issues in direct-to-consumer pharmaceutical advertising in different countries.

Common legal issue in drug advertising in different countries is failure to comply with the requirements for the prohibition of advertising of drugs that are released on prescription. The United States and New Zealand are the only two countries in the world where direct-to-consumer advertising of prescription drugs is legal. Nevertheless, in some countries advertising of prescription drugs, being prohibited by law is distributed in the print media for general public, television programs and on the Internet.

The other problem is the dissemination in advertising of drugs calls for the use of drugs, the effectiveness of which has not been confirmed by clinical trials. The inaccurate drug advertising, which misleads consumers and manipulates them, is also very common. For example, in the advertising of dietary supplements it is often reported that these products are able to cure certain diseases. The advertising of drugs uses elements of manipulation: drugs can be purchased due to the formation of consumer confidence in advertising arguments and the impossibility of an objective assessment by the consumer of the results of drug use. Advertising also often violates the requirement of honesty and accuracy of information; advertising messages abuse the trust of consumers and their lack of medical knowledge.

Another example of ethical issues is verbose and ineffective advertising, which emphasizes the standard list of product characteristics rather than consumer benefits. In addition to this, advertising often imposes stereotypes on drug consumption. To prevent this situation, the United States and the European Union are implementing decisive measures to strengthen legislation on drug advertising.

According to the Food and Drug Administration (FDA), medicine advertisement is required to tell consumers: at least one approved use for the medicine, the generic name of the medicine and all the risks of using the medicine (or under certain circumstances, only the most important risks). Generally, the FDA does not review medicine advertising before people see it; this means false drug information could reach population before it reaches the FDA.

In most cases, the FDA does not ban pharmaceutical companies from advertising any prescription medicines, even if they have serious risks. Moreover, it is possible for medicines to be promoted before they have been fully tested to be safe. This situation happened with Vioxx, a blockbuster painkiller marketed from 1994 to 2004. Merck spent over \$100 million per year to advertise Vioxx, and patients requested it from doctors not knowing it could cause strokes or heart attacks. Finally, in September 2004, after numerous safety issues came to light, Vioxx was withdrawn from the market.

Drug advertising on television is often manipulative. For instance, advertisers make medicines seem more helpful than they really are by showing a person enjoying life outdoors while the narrator reads side effects in the background; listing the most serious side effects of a drug toward the end of the commercial to make viewers think they are less common; using subjective terms like “mild” or “may” to describe a risk to make the medicine-related risk seem less dangerous.

According to the Antimonopoly Committee of Ukraine (AMCU), the most common violations in the medicine advertising are: the incorrect use of information on the safety, effectiveness and quality of medicines; advertising of drugs without differentiation by dosage forms and precautions on their use; reference to the fact that the safety of medicines is proven by many years of experience in its consumption; exaggeration of the therapeutic properties of drugs; use of statements that mislead the consumer about the composition of drugs.

In 2020, the AMCU advised pharmaceutical manufacturers, advertising holdings and domestic TV channels to refrain from advertising drugs whose content relates to the treatment or prevention of coronaviruses, without proper justification in accordance with applicable law.

Thus, direct-to-consumer pharmaceutical advertising is related with both legal and ethical issues in different countries; the problem still needs proper regulation and control.