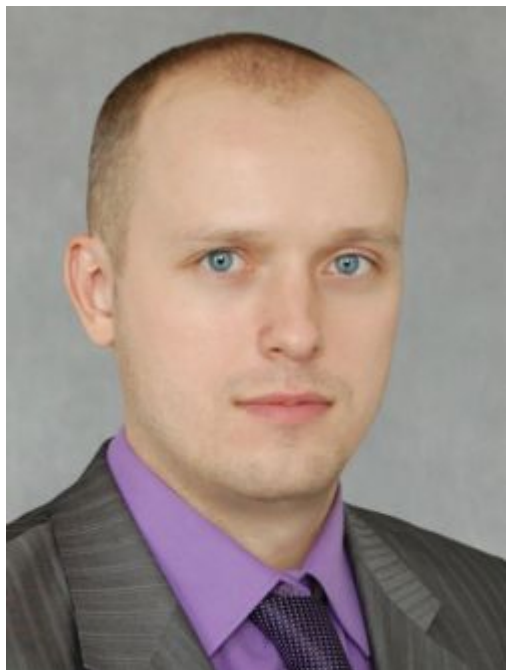


Advertising and Marketing Medicines: How Does One Adhere to the Law?

By [Vsevolod Tyupa](#)

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Vsevolod Tyupa

Senior Associate, Head of Lifesciences
CMS, Russia

Advertising and promoting medicines is not only a part of the pharmaceutical business, it is also needed to develop health care in general. However, for obvious reasons, the rules of the game that the laws set in this area are especially strict and require heightened attention to the legal issues of advertising medicines.

Among the most common violations of legislation on advertising medicines committed by pharmaceutical companies in Russia are the guarantees of safety and positive results from using a medicine, as well as incorrect comparisons of one kind of medicine to that of its competitors, showing the advantages of one medicine over the competitor's analogue.

Comparative advertisement to a competitor's product is a risky practice in Russia. The Federal Anti-Monopoly Service of the Russian Federation (the "FAS") keeps strict watch over this type of advertising of medicines, and it responds quickly and efficiently to one company's claims against its competitors in terms of incorrectly comparing medicines in advertising. In recent years, Pfizer, Ewalar, MNPK BIOTIKI (the recent Glicin case) have been among those pharmaceutical companies penalized for such violations (e.g. Pfizer's slogan, "'Diflyukan' is 2-4 times more effective than generics!" which was ruled as an incorrect comparison of Diflyukan to its generics).

The main reason for such a large number of actions against "the incorrect comparison with competitive goods" is the lack of comparison methodology approved by the law. Thus, nearly every comparison could be interpreted as "incorrect" by the opposite party if said party uses a slightly different comparison methodology from that used by the other party.

In the absence of legal methodology to compare goods, it could be reasonably assumed that a correct comparison of medicines must include (i) the same parameters of comparison; (ii) the comparison of all the parameters which are to be of importance for the compared goods

(e.g., rate of action of compared medicines, the probability of adverse reaction and its nature, etc.); and (iii) using the same methodology of comparison.

The other issue is a violation of the prohibition to guarantee the safety and positive effect from using of a medicine. Indeed, there is a temptation to state, "This medicine is really effective against something." Yet the FAS considers such a statement — as well as "absolutely/completely safe," "will cure you headache," etc. — to be a guarantee of the medicine's safety and/or that the patient will get better. Both guarantees are restricted. In recent years, the FAS and its regional departments have taken action against GlaxoSmithKline, Ebewe Pharma, Materia Medica Holding, Pharmaval, and other companies for using wording that promises their medicines' safety and effectiveness in their advertising materials. Indeed, the most well-known precedent is the Coldrex case, when GlaxoSmithKline was penalized for the slogan, "Coldrex is stronger than a cold," based on the grounds that the adjective "stronger" must be deemed as a guarantee of recovery and the "victory" of a certain "stronger" thing (Coldrex) over another thing that is "weaker" (the cold).

The main legal possibility here would be to use such words of "probabilistic" connotation, which cannot be considered a 100 percent guarantee of anything, but, rather, as close to this as possible ("perhaps," "probably," "arguably," etc.).

All the aforementioned matters also apply to Internet advertising. Indeed, it is difficult to overestimate the possibilities of this kind of advertising in the 21st century; but it should be noted that all legal restrictions applicable to ordinary advertising are also applicable to Internet advertising. For example, only the advertising of non-prescribed medicines may be placed on websites. Each web page that promotes a medicine must contain a warning of the possible side effects and the need to read the instructions before using, and this warning must cover at least 5 percent of the advertising area calculated "in pixels." Furthermore, if any web materials are intended solely for the attention of health care professionals, it is highly recommended not only to use a text warning, "addressed to healthcare professionals," but also to use a protected "subscribers' area" on the website, accessible only by personal login and password provided exclusively to health-care professionals. Such a measure increases the level of website security and may serve as a good argument in favor of a pharmaceutical company if any claims of unlawful placement of information about prescription-only drugs on the website are submitted.

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