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Russia

PHARMACEUTICAL ADVERTISING

Contributing firm

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This country-specific Q&A provides an overview of pharmaceutical advertising laws and regulations applicable in Russia.

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RUSSIA
PHARMACEUTICAL ADVERTISING

Vocabulary

Administrative Code – the Russian Administrative Offences Code

AIPM – Association of International Pharmaceutical Manufacturers

Codes of Ethics – AIPM and IMEDA Codes of Ethical Business Practice

FAS – Federal Antimonopoly Service of Russia

HCP – healthcare professional

HCO – healthcare organization

IMEDA – International Medical Device Manufacturers Association

Minzdrav – Ministry of Health of Russian Federation

Roszdravnadzor – Federal Service for Surveillance in Healthcare

38-FZ – Federal Law "On advertising" dated 13.03.2006 No. 38-FZ

61-FZ – Federal law "On drugs circulation" dated 12.04.2010 No. 61-FZ

323-FZ – Federal law "On fundamental healthcare principles in the Russian Federation" dated 21.11.2011 No. 323-FZ

1. What laws are used to regulate advertising on medicines in your jurisdiction?

In Russia, the advertising of medicines is regulated by 38-FZ, 61-FZ and 323-FZ. The 38-FZ is supplemented by the official clarifications of competent authorities. Codes of Ethics provide additional rules for member-companies.

2. Are there any self-regulatory or other codes of practice which apply to the advertising of medicines? a) If there are any such codes, to whom do they apply (companies, or healthcare professionals, for example)? b) What is the legal status of the self-regulatory codes?

a. If there are any such codes, to whom do they apply (companies, or healthcare professionals, for example)?

The Codes of Ethics apply to companies which are AIPM

and IMEDA members respectively and carry out developing, manufacturing, realization of medical drugs or medical devices. The purpose of the Codes of Ethics is to establish the minimum requirements to be observed by companies who are AIPM or IMEDA members in their educational, informational, charitable, and marketing activities in the Russian Federation.

b. What is the legal status of the self-regulatory codes?

Self-regulatory codes are not a statutory law, therefore, they are binding sets of rules only for AIPM and IMEDA members who have voluntarily agreed to comply with the Codes of Ethics.

3. Is there a statutory or generally accepted definition of "advertising"? a) What does the definition cover? – does it include patient information leaflets, for example, catalogues, disease awareness campaigns or correspondence, for example? b) Does the definition apply equally to all target audiences?

a. What does the definition cover? – does it include patient information leaflets, for example, catalogues, disease awareness campaigns or correspondence, for example?

According to the art. 3 of the 38-FZ, the definition of advertisement covers information distributed by any means, in any form and by any media which is addressed to a non-specific group of persons and aimed at drawing attention to the object of advertising, at shaping up or maintaining an interest in respect of it, and at promoting it in the market. Therefore, the list of possible means of advertisement is non-exhaustive and can include advertisement through catalogues, disease awareness campaigns and correspondence.

The art. 2 of the 38-FZ stipulates that the law does not cover informational and analytical materials, information which is subject to disclosure under the law on consumers' rights protection, any elements of a good's design and its packaging, etc.

b. Does the definition apply equally to all target audiences?

Yes, but bearing in mind that minors shall be excluded from target audience of medical drugs advertising.

4. Are press releases regarding medicines allowed in your jurisdictions, and if so what are the restrictions on these (bearing in mind the target audience)?

The 61-FZ allows to freely publish advertising materials on over-the-counter (OTC) medical drugs in compliance with instructions for their use. Advertising materials on prescription only (RX) medical drugs can be presented in specialized publications and special events, organized among and for HCPs.

5. Are there any processes prescribed (whether by law or Codes of Practice) relating to the approval of advertising of medicines within companies?

Rules on the advertising of medicines are enshrined in companies' local acts (so-called own operational procedures). The procedure generally involves lawyers, marketing and medical specialists approval.

6. Do companies have to have material approved by regulatory bodies prior to release?

There is no requirement for advertising materials preliminary approval by the regulatory bodies under the Russian law.

7. Is comparative advertising for medicines allowed and if so, what restrictions apply?

In 2018 FAS implemented Recommendations for advertising OTC medicines. According to the Recommendations, comparisons are allowed if they include the comparable characteristics of the medical drugs (i.e., similar composition, mode of action and administration) and do not discredit business reputation of a competitor. Besides, it is permitted to compare drugs having different international non-proprietary names (INN) but the same indications for use and providing clear and reliable criteria for comparison.

Incorrect comparison is prohibited in accordance with the clause 1 art. 5 of the 38-FZ.

8. Is it possible to provide information on unauthorised medicines or unauthorised indications? Is it possible to provide information on unauthorised medicines or

unauthorised indications during a scientific conference directed at healthcare professionals, or to send information to healthcare professionals?

The Russian Administrative Offences Code expressly prohibits realization of unregistered drugs or medical devices either via social media or in the Internet. Thus, only registered pharmaceutical products may be promoted in the Russian Federation and only to the extent of their registered indications for use. An advertisement for pharmaceutical products should be such as to clearly identify the product as a pharmaceutical product. This requirement also does not suggest a breach of the scientific community's right to exchange of scientific information related to non-registered pharmaceutical products, provided that the provision of such information is not a way of promoting the pharmaceutical product.

9. Please provide an overview of the rules that apply to advertising to the general public for prescription only medicines and over the counter medicines, an indication of the information that must or must not be included.

The 38-FZ states that advertising shall be fair and truthful.

The advertising of medicines both OTC and RX shall not:

1) be addressed to minors;

2) contain references to specific cases of recovery from disease or improvement of health resulting from the use of the advertised product (except in advertising exclusively aimed at medical and pharmaceutical professionals);

3) contain an expression of gratitude by individuals in connection with the use of the advertised product;

4) create an impression of the advantages of the advertised object by making reference to the fact that the trials required for its state registration have been conducted;

5) contain statements or assumptions that the consumers of the advertisement have certain diseases or health impairments;

6) facilitate the impression that a healthy person needs to use the object of advertising;

7) create the impression that there is no need to consult with a doctor;

8) guarantee a positive effect of the advertised product, its safety, efficacy and absence of side-effects;

9) represent the object of advertising as a biologically-active supplement and dietary supplement or other goods that is not a medicine;

10) contain statements that the safety and/or effectiveness of the object of advertising are guaranteed by its natural origin.

Besides, advertising of RX medical drugs is limited to specialized publications and special events, organized among and for HCPs. Advertising of drugs or psychotropic substances permitted for use in medical purposes listed in narcotic drugs and psychotropic substances, the turnover of which is limited in accordance with the Russian legislation, is prohibited. It is forbidden to conduct advertising campaigns accompanied by distribution of samples of drugs containing narcotic drugs and psychotropic substances.

FAS introduced certain recommendation for companies advertising medical drugs to follow. Primarily, any information on therapeutical activity of an advertised product, its medicinal effect and medicinal characteristics shall be proven by either authorized indication, medical care standards authorized by the Minzdrav and any other documents and sources if they do not go beyond advertised product indications. Also, the advertisement should not guarantee the eventual effect of a product and can only describe the process of the medical drug action. It is recommended not to mention any symptoms which can possibly create an impression that a consumer has those symptoms or a disease.

Notably, the advertisement should contain warning about side-effects and necessity to read the instruction. In advertisements distributed in radio programs, the duration of such warning should be not less than three seconds; in TV programs and in film and video services – not less than five seconds and should be allocated not less than seven percent of the area of the space, and in advertising distributed in other ways – not less than five percent of the advertising space.

10. Are there any restrictions on interactions between patients or patient organisations and industry (e.g., consultation, sponsorship)? If so, please

describe those briefly.

The Codes of Ethics enshrine that a company shall not ask a patient organization to promote certain drugs. Neither a company can be a founder of a patient organization. A company can provide financial support for patient organization for an educational or scientific event to be held.

11. Which information must advertising directed at healthcare professionals contain, and which information is prohibited? For example can information about clinical trials, or copies of journal be sent?

It should be taken into account, that it is not permitted to promote a pharmaceutical product under the semblance of post-registration clinical (interventional) studies or observational (noninterventional) clinical, epidemiological studies, or marketing studies. It is also important that all supporting materials (e.g. flyers, brochures and website, copies of journal) are consistent with the scientific or promotional nature of the programme content as well as comply with the requirements to advertising within medical professional events.

12. May pharmaceutical companies offer gifts to healthcare professionals and are there any monetary limits?

The 61-FZ and the Codes of Ethics expressly prohibit gifts and donations from companies to HCPs.

13. Are pharmaceutical companies allowed to provide samples to healthcare professionals?

The 61-FZ directly prohibits the provision of samples of medicinal products to HCPs for a subsequent transfer to patients, with the exception of the provision of samples for the conduction of clinical trials.

14. Is sponsorship of scientific meetings or congresses and/or attendance by healthcare professionals to these events? If so, which restrictions apply? Do additional restrictions apply to events taking place abroad?

Interaction between pharmaceutical companies and HCPs should be designed to benefit patients and enhance the practice of medicine. The purpose of this interaction should be to provide HCPs with new information about pharmaceutical products, supply them with scientific data, and support scientific and clinical research. The purpose of all the events should be the same: to inform HCPs about pharmaceutical products and/or to provide them with scientific information in the fields of healthcare or pharmaceutics. Companies should not organize or finance events for HCPs outside their country of residence unless it is justified in terms of logistics or security. International scientific congresses and symposia that attract participants from many countries are therefore justified and permitted.

15. What are the restrictions on the organisation of cultural, sports or other non-scientific events in relation to scientific conferences by pharmaceutical companies?

The use of any entertainment or sporting events to attract HCPs to promotional or scientific events is prohibited. The location of the event should not be primarily known for its touristic or recreational offering or the main attraction of the event or be perceived as such. At some occasions such event in the location that is primarily known for its touristic or recreational offering may be organized or supported provided that it's targeted for the audience residing at this location or in direct proximity to it; the event is an annual international or national event, organized by internationally or nationally recognized professional associations and the event does not take place during high touristic season for this geographical location. The time of the event should not coincide with internationally recognized sporting or cultural events taking place in the same location (e.g. the location directly or indirectly facilitates participation in such event) at the same day. Such sporting or cultural events should not be the attraction for the event or be perceived as such.

16. Is it possible to pay for services provided by healthcare professionals and if so, which restrictions apply?

Pharmaceutical companies may engage HCPs to provide scientific and pedagogic services and services in the course of performance of clinical studies of pharmaceutical products. Pharmaceutical companies may pay fees to these HCPs for the provision of these

services.

17. Are pharmaceutical companies permitted to provide grants or donations to healthcare professionals or healthcare institutions? Does it matter if the grant or donation is monetary or in kind?

Pharmaceutical companies may make donations to non-commercial organizations for publically beneficial purposes. Such donations may be in the form of educational grants made available to support medical education and ultimately intended to raise the quality of medical care provided to patients. No in-kind donations to non-commercial organizations are permitted if intended, directly or indirectly, for specific HCPs or made in their interests. This is why it is not permitted to donate any items which are generally seen as being intended for individual use rather than for use by the relevant non-commercial organization. It does not matter if the grant or donation is monetary or in kind. According to the Russian legislation every donation shall have socially useful goal. Nevertheless, pursuant to AIPM Code of Ethics it is prohibited to make donations in the form of cash. However, IMEDA Code of Ethics does not stipulate the same limitations. Donations may be made on the basis of a relevant donation agreement.

18. Are pharmaceutical companies required to disclose details of transfers of value to healthcare professionals or healthcare institutions? If so, please indicate whether this is a legal requirement or not, and describe briefly what the companies must report and how. Do these transparency requirements apply to foreign companies and/or companies that do not yet have products on the market?

The 61-FZ stipulates the obligation of pharmaceutical companies to disclose information about scientific events to Roszdravnadzor, as well as to ensure the publicity of information about events by posting information about the event on their website. The Codes of Ethics stipulate that each company shall document and disclose transfers of value it makes, directly or indirectly, to or for the benefit of any HCP or HCO being a recipient, given the provisions of Russian data protection laws. The Codes of Ethics stipulates special templates for information disclosure. Requirements of the Codes of Ethics covers only members of an appropriate organization. Generally, such template contains information regarding HCP's or HCO's full name, country of principal practice, donations and grants, contribution to costs of events (registration fees, travel & accommodation, fee for services and consultancy, etc.). For more detailed information please refer to Annex II of the AIPM Code of Ethics and Annex 2 of the IMEDA Code of Ethics.

19. When if at all with a competent authority have to get involved in authorising advertising? Is advertising on the internet (including social media) for medicinal products regulated, and if so, how? Should companies include access restrictions on websites containing advertising or other information intended for healthcare professionals?

FAS is the main regulator which monitors the proper advertising of medical drugs and devices as well as punishes for non-compliance with limitations to advertising of medical drugs and devices. The advertising on the Internet (including social media) is regulated on the general basis with no any additional requirements. RX medical products can be promoted only at medically professional events or in specialized publications. That's why to minimize risks companies include access restrictions on websites containing advertising or other information intended for HCPs.

20. Are there any anti-bribery rules apply to communications between pharmaceutical companies and healthcare professionals or healthcare organizations?

There are no specific anti-bribery rules applying to communications between pharmaceutical companies and HCPs or HCOs. Cooperation between pharmaceutical companies and HCPs should not result in a conflict of interest for HCP, in particular, a conflict between their professional duties and personal interests. In particular, no such conflict should arise when a doctor prescribes a pharmaceutical product or a pharmaceutical professional recommends a pharmaceutical product.

21. What are the rules (whether statutory or self-regulatory) which govern the offering of benefits or inducements to

healthcare professionals?

There is no exhaustive list of admissible interactions with HCP in Russian legislation. The procedure of such interaction also remains unregulated. Instead, the law provides for certain bans for pharmaceutical companies when dealing with HCP. In particular, under clause 1 art. 67.1 of the 61-FZ it is prohibited for the company to perform the following activities in relations with HCP:

- Present gifts, pay out monetary funds, including paying for HCP's entertainment activities, leisure time activities, travel to resting place, involve them into entertainment events held at the Client's expense;
- Enter into an agreement with HCP designed to incentify HCP's recommendation or prescription of the company's medical drugs to healthcare consumers;
- Provide with medical drugs samples for distribution among consumers (with the exception of clinical research studies);
- Provide with inaccurate and/or limited information in medical drugs;
- Visit them at their work facilities during work hours unless for clinical research, for professional development events coordinated with the administration of medical institution, or for the purposes of providing pharmacovigilance information;
- Incentify to prescribe drugs on prescription blanks with marketing information or bearing particular names of medical drugs. Similar restrictions for HCPs in connection with their interaction with pharmaceutical companies are provided in clause 1 art. 74 of the 323-FZ.

The only exception for activities connected with payment of money to HCP comprises payment of a reward to HCP for his performance of pedagogical and (or) scientific work, as well as rendering services in the course of performance of clinical studies of medical drugs.

Provisions regarding admissible interaction between a pharmaceutical company and an HCP when engaging HCP to provide services are envisaged by the Codes of Ethics as well. The Codes of Ethics, in particular, stipulates certain requirements to be observed by the member-company while engaging HCP to provide services, including the need to execute a written contract, provide for a reasonable remuneration, engage a reasonable amount of HCP (which are selected appropriately) in a particular program.

22. Which bodies are responsible for enforcing the rules on advertising and the rules on inducement? Please include regulatory authorities, self-regulatory authorities and courts.

FAS, Roszdravnadzor, AIPM and IMEDA as self-regulatory authorities, state arbitrazh courts as a venue of appeal of FAS decisions.

23. On what basis and before which bodies or courts can companies initiate proceedings against competitors for advertising infringements?

On the basis of art. 14. 3 of the Administrative Code before FAS.

24. What are the penalties, sanctions or measures that regulators or courts can impose for violating medicines advertising rules and rules on inducements to prescribe in your jurisdiction?

The breach of legislation regarding pharmaceutical advertising entails a penalty for officers up to 20 000 RUB, for legal entities up to 500 000 RUB. Violation of admissible interaction between a pharmaceutical company and an HCP may be revealed during inspection held by Roszdravnadzor. In this case relevant requirement to remedy a violation will be issued. Failure to execute the requirement will entail administrative penalty under clause 21 art. 19.5 of the Administrative Code:

- For officers: in amount of RUB 10,000 up to RUB 20,000;
- For legal entities: in amount of RUB 30,000 up to RUB 50,000.

Violation of procedure for the state authorities' notification of the events entails administrative penalty under art. 19.7 of the Administrative Code in the following amount:

- For officers: in amount of RUB 300 up to RUB 500;
- For legal entities: in amount of RUB 3,000 up to RUB 5,000.

25. What is the relationship between

procedures before or measures taken by the self-regulatory authority and the procedures before or measures taken by courts/government competent authorities?

The main difference is that measures taken by the self-regulatory authority entails mainly reputational risks for a company. For example, AIPM may impose the following sanctions:

- Oblige the company's employees to complete an online training session on AIPM Code of Ethics;
- Inform the company's parent company about the violation;
- In the case of a serious violation, impose a financial fine in an amount not to exceed the current AIPM annual membership fee;
- Make the fact of the violation public on AIPM web-site, including, but not limited to, the identity of the offending company, if the violation is serious or repeated;
- Recommend the expulsion of the company from AIPM;
- A combination of the sanctions mentioned above.

26. Are there any recent enforcement trends in relation to pharmaceutical advertising in your jurisdiction? Please report any significant (publicly known) enforcement actions in the past two years.

The regulation of pharmaceutical advertising becomes more and more severe. FAS pays certain attention to compliance of advertising with instruction for use of a relevant medical drug. Advertising via social media (Instagram, Youtube) is recognized as advertising even if there is nor a mark "advertising". FAS argues that there can be more than one advertiser even if there is a special agreement with an advertising agency.

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