



Advertising of drugs: risk matrix

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1. INTRODUCTION

Advertising and promotion of drugs is a delicate and difficult task, since in this sphere, intersect the art of attracting attention to the product, principles of ethics, and mandatory rules of advertising legislation as well as legislation on the protection of competition.

In this regard, in order to facilitate the work of advertising and creative departments of pharmaceutical companies, as well as to simplify the work of advertising agencies – the counterparties of such companies, we have prepared a summary matrix of the main risks, based on the analysis of law enforcement practice in the field of advertising of medicinal products.

To do this, we analysed the practical decisions of FAS Russia and the courts for the years 2013-2014 on typical revealed violations, which occur in the advertising of medicines, as well as some practical solutions for the given period, from related industries, confirming the consistency of regulatory approaches. On the basis of this analysis, in the risk matrix below, we provide the appropriate generalizations and describe specific illustrative examples.

However, we would like to turn your attention to the fact that advertising, like any creative process, is always individual, and therefore in the assessment of the possible risks (in particular in determining the content of promotional materials, the recipients of such materials and the order of placement), one must use an individual approach.

2. ATTRIBUTES OF ADVERTISING

In accordance with Article 3 of the Federal Law dated 13 March 2006 No. 38-FZ "On Advertising" (hereinafter referred to as the "Federal Law On Advertising") advertising is information distributed by any means, in any form or by using any resources addressed to an unspecified group of people and aimed at drawing their attention to the object of advertising, the formation or maintenance of interest in it, and its advancement in the market. Thus, falling under the object of advertising are the goods, means of their individualization, the manufacturer or seller of the goods, and the results of intellectual activity or events, to draw attention to which the advertising is directed.

Thus, on the basis of this legal regulation, as well as interpretations, given in law enforcement practice¹, it can be concluded that the information, recognized as advertising, must satisfy the following fundamental conditions, namely:

- (a)** intended for an unspecified group of people² (which can – including the dissemination of information in periodic mass media, or the inclusion of relevant information in a booklet – be transmitted from one person to another, or by the holding of campaigns in pharmacies, aimed at an unspecified group of people – potential customers of pharmacies, etc.);
- (b)** to attract, develop and sustain an interest in the object of advertising³; and
- (c)** promote the object of advertising (goods) in the market.

¹ See for example, Tatarstan OFAS Russia Decision on Case No. 08-335/2014 dated 18 December 2014, decision of the Tatarstan OFAS Russia on Case No. 08-356/2014 dated 16 September 2014, decision of the Arbitration Court of St. Petersburg and the Leningrad Region on Case No. A 56-74059/2013 dated 3 April 2014, etc.

² Under the unspecified number of persons are those persons who cannot be defined in advance as the recipient of the advertising information and particular parties of violation detection, arising out of the sales of the object of advertising. (See for example, decision of Tatarstan OFAS Russia on Case No. 08-356/2014 dated 16 September 2014).

³ For example, in one case, the antitrust body said that the placement of certain non-prescription medicines at the pharmacy on a separate stand together with the gifts that are given to the buyer when purchasing these drugs, sets them apart from any other variety of pharmaceutical institutions, and is aimed at drawing attention to them, their progress, and, accordingly, has the purpose of advertising (Udmurt OFAS Russia Decision on Case No. SYU04-03/2014-107R dated 2 June 2014).

Moreover, in practice, analytical and informational materials such as articles, brochures, flyers, etc., can be classified as materials that are of an advertising nature, and therefore the advertiser's claim that such materials are for reference use only, is not taken into account by FAS Russia and the courts.

For example, information about a drug, which was placed in a separate unit next to an article in a magazine about beauty and health⁴, FAS Russia, in its Decision on Case No. RTS.08.12.58 dated 22 November 2012, recognized as advertising, despite arguments that this information is analytical material in which the object of advertising is not visible, because there is no information about the manufacturer, and place of distribution of said preparation.

In addition, the courts can reject the argument that a leaflet of a pharmacy organization (including those containing information on prescription medicines) is aimed at promoting the trademarks of their respective network of pharmacies, not at advertising specified in the booklet medicines. For example, in the Decision on Case No. A56-74059/2013 dated 29 July 2014, the Thirteenth Arbitration Court of Appeals found that a booklet of a pharmacy organization lacked any significant information about the trademark (service mark or other means of individualization of a legal entity – the pharmacy organization), but listed were addresses of pharmacies, provided was information on applicable discount system in pharmacies, and the remaining pages contained information about medicines and services of partners of the corresponding pharmacy organization. In this regard, the court found no basis for concluding that the contained on these pages information about medicines was aimed at drawing attention to any other object of advertising, except for the actual drugs.

The Decision of OFAS Moscow Region on Case No. 08-21/1-14 dated 10 July 2014, also shows that as advertising can be considered the publication of information in print mass media about a particular pharmacy, indicating the names of medicines and their prices, despite the arguments of the pharmacy that such information belonged to reference and informational materials.

As another example, we can mention the Decision of the Novgorod OFAS on Case No. 13, dated 22 October 2014, imposing a fine for an administrative offense. In it, the antitrust authority rejected the arguments that the broadcasting of the TV show "Beauty and Health" was not advertising, but rather informational in character. During examination, the antitrust body established that: (i) these broadcasts contained detailed information about certain products – progressive optical lenses and eyeglass lenses of a particular brand; and (ii) before the end of the TV show, broadcast was information in text form, which in the context of the preceding program content, obviously pointed to a specific entity to which one could turn to obtain the relevant goods. In this regard, the antitrust body concluded that these broadcasted TV programs "Health and Beauty" were aimed at attracting attention, the formation of consumers' interest in particular products (medical products – optical glass lenses) and the entity selling them (network of salons selling lenses and glasses). In such circumstances, the antitrust body could not conclude that the TV shows served only informational purposes, and the object of advertising was absent, since the purpose of dissemination of this information on television was to promote the products of a particular seller on the market, by specifying the benefits and features of using these products, and messages showing contact data for a particular distribution network.

⁴ This information is also accompanied by warning of side effects and the need to read the instructions or obtain professional advice.

3. WHEN IS IT ADVERTISING, AND WHEN IS IT UNFAIR COMPETITION?

The offenses referred to in Article 5 of the Federal Law On Advertising and Article 14 of the Federal Law dated 26 July 2006 No. 135-FZ "On Protection of Competition" (hereinafter referred to as the "Federal Law On Protection of Competition") contain a number of similar provisions in respect of dissemination of untrue information, misleading of consumers, incorrect comparison of goods among themselves. Moreover, in law enforcement practice of the courts and by FAS Russia, given were explanations as to what rules should be applied when considering a specific situation.

According to the legal position set out in Paragraph 7 of the Resolution of the Plenum of the Supreme Arbitration Court of the Russian Federation dated 08 October 2012 No. 58 "On some issues in the practice of arbitration courts applying the Federal Law On Advertising", in the delimitation of the scope of these articles, it is necessary to proceed from the fact that if they contain false, inaccurate or distorted information, which can cause damage to an economic entity or damage its business reputation, or incorrect comparison between an economic entity producing or selling its goods, with the goods produced or sold by other economic entities, which are in a position to compete with the said entity, as well as other dissemination of other information,

which meets unfair competition attributes, contained in the advertisement, then the administrative liability is established by Article 14.3 of the RF Administrative Code (establishes liability for violation of legislation on advertising) rather than Article 14.33 of the RF Administrative Code (establishes liability for unfair competition).

In the Information Letter No. AK/25319/14 dated 25 June 2014 on the relationship between regulations of the Federal Law On Advertising and Article 14 of the Federal Law On Protection of Competition, FAS Russia pointed out that, if the information that contains untrue information, thus misleading of consumers, incorrect comparison of the goods among themselves, distributed exclusively in advertising, such information shall be assessed for compliance with the legislation on advertising. If such information is disseminated not only through advertising, but also in other ways (e.g., on labels of goods, in correspondence with contractors under agreements, etc.), it will be evaluated for compliance with the antimonopoly legislation (regarding unfair competition).

Thus, during the determination of strategy to promote products (including drugs) or a specific brand in the market, one must always take into account the risks associated with the application of both the advertising legislation and legislation on the protection of competition.

4. RISK MATRIX⁵

Description of risk	Examples of proceedings	Signs of violation, indicating the presence of risk	Possible qualifications
Advertising content			
Indicating in advertising, properties of the drug, not listed in the instructions for use or at variance with the instructions for use	Advertising leaflet of the drug reported on the absence of bacteria of a certain type of primary and acquired resistance to the corresponding drug, and also contained a reference to the stimulation of the regeneration of epithelium as a result of the drug. At the same time, corresponding information was absent in the instructions for use of the drug ⁶ .	If in the advertisement it was reported about characteristics of a drug, which are absent in the instructions for use of the drug — there is high risk of violation of the provisions of the Federal Law On Advertising, according to which the advertising of any properties and characteristics, including the methods of taking and use of the drug, is only permitted within the indications contained in the duly approved instructions for the use of such drug.	Part 6 of Article 24 of the Federal Law On Advertising
Using in advertising of an image, similar to an image of a pharmaceutical or medical worker	In the advertising leaflet of a pharmaceutical establishment, used was an image of a man in a white jacket ⁷ .	If in the opinion of consumers, the image used in advertising (including a man in a white coat/ white uniform) is perceived as the image of the pharmaceutical or health care professional, such advertising contains signs of violation of the ban on the use of corresponding images (except for the use of such images in the advertising of medical services, personal care products, in advertising, the consumers of which are exclusively medical and pharmaceutical workers in an advertisement distributed in places of medical or pharmaceutical exhibitions, seminars, conferences and other similar events, in advertisements placed in specialized press).	Paragraph 4 of Part 5 of Article 5 of the Federal Law On Advertising

⁵ The risk matrix is made based on an analysis of key decisions, which were issued during law enforcement practice by FAS Russia and the courts in 2013-2014 (as well as a preliminary analysis of some of the proceedings initiated in 2015) for assessing the legality of the various ways to promote medicines and health care products. In addition, this matrix of risks refers to the practice of related industries, which indicate the uniformity of regulatory approaches to the assessment of certain circumstances.

⁶ See FAS Russia's Decision on Case No. 3-24-29/00-08-14 dated 11 July 2014. Determination of FAS Russia to initiate Case No. 3-24-47/00-08-14 dated 20 August 2014 also points out that the inclusion in an advertising article of information on the cosmetic properties of the preparation for hormonal contraception is not specified in the instructions, may present evidence of violation of the provisions of paragraph 6 of Article 24 of the Federal Law On Advertising, according to which the message in the advertising on the properties and characteristics, including the methods of application and use of drugs, is only permitted within the indications contained in the duly approved instructions for taking and use of such objects of advertising.

⁷ See decision OFAS Nizhny Novgorod Region on Case No. 803-FAS52-07/14 dated 22 August 2014.

Reference to a study, required for state registration of the drug ⁸	The advertising message contained the following information: "... biocorrector clinical trials have been successfully carried out in nearly two dozen medical clinics and research institutes, both in Russia and abroad ... As it turned out, well-known scientists gave feedback on the biocorrector, and the production [of the advertised product] was recommended by 19 research institutes and clinics " ⁹ .	Mentioning in the advertising of a drug's pre-clinical studies and clinical trials of medicines and the creation of the view that the medicine has any advantages, in accordance with the Federal Law On Advertising, is unacceptable. The ban is aimed at protecting competition and consumers from fraud, as drugs that have passed, in the established order, state registration, are absolutely equal in terms of the fact that they were required to register the study, and such mentioning can indicate that some are better than others.	Paragraph 4 of Part 1 of Article 24 of the Federal Law On Advertising
Incorrect comparison of drugs with different INN	In an advertising article compared were two prescription drugs for weight loss, indicating that they contained the same active ingredient in the same dosages, and the difference between these drugs is only their price ¹⁰ .	When comparing the two drugs, GRLS data and instructions for use confirmed that these drugs have different INN and have differences in the composition of pharmacologically active substances, the use of advertising claims, creating a distorted view of the identity of such drugs and price attractiveness of one of them, entails appropriate existence of significant risks of unfair advertising.	Paragraph 1 of Part 2 of Article 5 of the Federal Law On Advertising
Incorrect comparison of drugs with placebo	In a commercial video clip for a drug, it was asserted that the drug works "twice as fast [...]. Clinically proven ", meanwhile, the video was accompanied by an explanatory footnote" in comparison with the placebo group" ¹¹ .	The fact that the drug must possess a therapeutic effect in comparison with placebo, is a prerequisite for its registration as a medicament. Comparison with placebo or placebo effect, however, is compared to the "absence of any effect", due to the fact that any therapeutic effects, including therapeutic characteristics are absent in a placebo. Thus, by comparing the drug with a placebo, there are significant risks that such a comparison will be qualified as a comparison, with an indication of a benefit offered by the corresponding product, to the goods in circulation from other manufacturers, which also creates risks of acceptance of this comparison as unfair advertising.	Paragraph 1 of Part 2 and paragraph 1 of Part 3 of Article 5, paragraph 4 of Part 1 of Article 24 of the Federal Law On Advertising

⁸ Similar logic can be seen in the Definition of the FAS Russia to initiate Case No. 3-5-1/00-08-15 on the grounds of violation of the legislation on advertising dated 22 January 2015 (discussed in more detail below).

⁹ See decision of the Tatarstan OFAS Russia on Case No. 08-356/2014 dated 16 September 2014.

¹⁰ See decision of FAS Russia on Case No. 3-5-82/00-08-13 dated 31 January 2014.

¹¹ See definition of FAS Russia to initiate a case No. 3-5-1/00-08-15 for violating the law on advertising dated 22 January 2015. Please note that this definition refers to the very existence of the risk, but this risk can be objectively assessed only after the final decision on the case.

Absence in advertising of essential information	<p>On an advertising structure was placed this information: "Social pharmacy LOW PRICES on drugs", however, the shown information did not indicate for which particular drugs, the prices in this pharmacy were lower than in other pharmacies, which could mislead consumers about the price of drugs in the said pharmacy¹².</p> <p>The pharmacy conducted an advertising campaign, under which the issuance of preparations was carried out in the amount of one unit of each name from a list established by the pharmacy for each handed out leaflet. At the same time, the advertising in question did not contain information on the timing of the campaign, as well as on the number of dispensed drugs, within the promotion, for each handed out leaflet¹³.</p>	<p>The advertising announcement generates interest in the product or service and is aimed at building consumer desires to use them. Therefore, of significance is information that can deceive the expectations generated in the consumer by such advertising. Absence in the advertising of a substantial part of the information leads to a distortion of advertising and contributes to misleading of consumers, intending to take advantage of the advertised product or type of service. Misleading advertising is able to cause harm to the consumer of the advertising information and a competitor of the advertiser. Thus, misleading of consumers through the dissemination of advertising, in which is absent a part of the essential information about the product and conditions of purchase or use, can lead to an incorrect choice by the consumer of goods with the necessary set of properties needed by the consumer, and at the same time, lead to a reduction in the sales of similar goods by the competition. Thus, the information, which introduces confusion to consumers about the advertised product, through abuse of the trust of individuals, or their lack of experience or knowledge, including the absence in advertising of the relevant information, is considered as unfair advertising.</p> <p>At the same time, within the meaning of the Federal Law On Advertising, bringing public information to an unspecified number of people, the essential information should be in the form and format that will allow each of the unspecified number of people to perceive the essential information on an equal basis with other information that is attractive to consumers.</p>	Part 2 and Part 7 of Article 5 of the Federal Law On Advertising
Word indicators			
Use in advertising of the words "effective and safe"	<p>Placement in a journal of advertising of a drug with the statement "effective for the seasonal prevention and safe treatment of influenza and [...] safe"¹⁴.</p>	<p>Law on Advertising allows in the advertising a message about the properties and characteristics of the drugs contained in the duly approved instructions for use. However, the efficacy and safety cannot be recognized properties or characteristics of the drug as are indicators of physico-chemical, biochemical, and other parameters, measurable via objective control and measurement. At the same time, in accordance with the Federal Law On Advertising, the advertising of medicines should not guarantee a positive effect of the object of advertising, its safety, efficacy, or the absence of side effects.</p>	Paragraph 8 of Part 1 of Article 24 of the Federal Law On Advertising

¹² See definition of Tatarstan FAS Russia to initiate Case No. 08-442/2014 dated 19 August 2014. Please note that this definition refers to the very existence of the risk, but this risk can be objectively assessed only after a final decision on the case. At the same time, similar logic in relation to similar infringements can be seen in the decision of OFAS of the Republic of Tatarstan on Case No. 08-298/2013 on the grounds of violation of the legislation of the Russian Federation on advertising dated 18 June 2014.

¹³ See decision of the Voronezh OFAS Russia on Case No. 454-269r on violations of advertising legislation dated 30 October 2014.

¹⁴ See decision of the Ninth Arbitration Court of Appeal dated 25 June 2014 on Case No. A40-38162/2014.

Use of the word "only" ¹⁵	Posting on the website of the allegation that certain silicone gel products "is the only product that is associated with epidermis and provides 24-hour treatment and protection" ¹⁶ .	If in the comparison of the described means with similar products, including by analysing the instructions, medical experts have concluded that several products provide the said shown effect (in particular, if both of the means applied to the skin (epidermis) twice a day in the same dosages provide 24-hour medical effect), the risks of the relevant sales promotion being recognized as unfair practices are extremely high.	Paragraph 2 of Part 1 of Article 14 of the Federal Law On Protection of Competition
Using the phrase "Number 1" ¹⁷	Posting on the website of the allegations that silicone gel from a specific manufacturer is the "number one choice of plastic surgeons all over the world" ¹⁸ .	Using the phrase "Number 1 choice" gives the impression of the superiority of the product over all other similar products, which makes people choose especially that means. However, if medical experts, by comparing the drug, in respect of which was placed the assertion of its superiority, with similar goods of another manufacturer, come to the conclusion that such means have the same composition, the same medicinal properties, the same indications for use, are equivalent in terms of clinical efficiency and yield identical results from their application, as well as are interchangeable in terms of value, with the result that such medical experts cannot confirm that, in practice, the corresponding remedy is really option number 1 for health care professionals, there are high risks that such practice will be recognized as an unfair sales promotion.	Paragraph 2 of Part 1 of Article 14 of the Federal Law On Protection of Competition
Using the phrase "gold standard"	Posting on the website of the allegations that silicone gel from a specific manufacturer is "the gold standard in the treatment of scars" ¹⁹ .	Standard (from the English word standard – a norm, sample) refers to the sample, the standard used for comparison. However, if the comparative findings of medical experts, as well as instructions on how to apply similar drugs should be that one remedy is identical in specifications, consumer properties and quality to another remedy, there exist extremely high risks of this being recognized as an unfair practice, by indicating that one of the remedies is the "gold standard" ²⁰ .	Paragraph 2 of Part 1 of Article 14 of the Federal Law On Protection of Competition

¹⁵ Similar logic is applicable for use in promoting a product using the word "best", as evidenced by the practice of related industries. Thus, in particular, the decision of OFAS in the Stavropol Region on Case No. 5 on violations of Russian legislation on advertising dated 3 June 2014 indicates about the following. In the advertising article, it was stated that the regional catering business [...] was the best in the nomination "The best enterprise in the consumer catering market of Stavropol Territory", during their respective regional competition. However, in the investigation of the case, the antitrust body established that during the contest, there were two first-place winners in the catering nomination in Stavropol Territory, (one organization based in the city, and one located in a municipal district). In this regard, the corresponding advertising was recognized as misleading.

¹⁶ See decision of FAS Russia on Case No. 4-14.33-505/00-08-14 on an administrative offense dated 16 October 2014.

¹⁷ In the period under review, the associated risks are confirmed also in the practice of allied industries. See decision of the FAS of Moscow District dated 20 February 2014 on Case No. A40-72706/2013 regarding advertising of fixing products, containing, among other things, the statement "Building hardware number 1". Assessing the nature of the statement "Building hardware number 1", the courts stated that this judgment clearly indicates the superiority of the advertised product in comparison with other commodities, as "number 1" means that the advertised product is the first among a number of other similar goods, having a higher value and advantage over them. Moreover, no comparative criteria justifying such an indication was given in the disputed advertisement. The courts did not recognize as supporting the controversial statement found in the footnote about winning an award as "Brand No. 1", because this prize was awarded in the field of brand development, and could not be regarded as a positive recognition of consumer qualities produced under a specific brand name of products.

¹⁸ See decision of FAS Russia on Case No. 4-14.33-505/00-08-14 on an administrative offense dated 16 October 2014.

¹⁹ See decision of FAS Russia on Case No. 4-14.33-505/00-08-14 on an administrative offense dated 16 October 2014.

²⁰ This is due to the fact that baseless allegations about the superiority of one agent over another allows the obtaining of unwarranted advantage in entrepreneurial activity, and can cause damage to an economic entity – a competitor, due to redistribution of the demand of consumers, being misled about consumer properties and quality of offered products.

Using the phrase "only remedy for"	Indication in a TV commercial that the advertised product is the only option for pregnant and lactating women. Meanwhile, on the bottom of the screen were given specifying disclaimers * "among the products of the company [...]" (however, the video with footnotes was shown for only three seconds, and the text of the footnote was made in small print and in dark blue colour on a blue background, thus depriving consumers of the possibility of becoming familiar with its contents) ²¹ .	If an explanation to an advertising statements is formally present in advertising, but the presentation of the information is such that the information cannot be perceived by consumers, there are significant risks that the controlling body will make a decision that this information was not brought to an unspecified number of persons properly, due to which, the consumer actually has not received the information prescribed by law and had been misled about the proposed remedy.	Paragraph 1 of Part 3 of Article 5 of the Federal Law On Advertising.
Risks related to the incorrect addressing of advertising			
Advertise of drugs on TV or radio programs that are addressed to minors	Placing a video clip touting the drug for children on a "Children's Radio" station ²² .	If the station's corresponding program is aimed at children, this creates a risk of violating the provisions of the Federal Law On Advertising, that advertising should not be directed at minors.	Paragraph 1 of Part 1 of Article 24 of the Federal Law On Advertising
Conducting advertising campaigns, in which the packaging of the drug includes gift items for children	In carrying out the advertising campaign to promote non-prescription drugs, in the form of placing these remedies in pharmacy organizations on a specially designed stand, next to the gifts that are given to the buyer when purchasing these drugs, one of the drugs was placed on the bottom shelf of the stand together with a gift — the disc with a cartoon movie ²³ .	As a rule, visitors to pharmacies are persons who have reached eighteen years of age, but a pharmacy can also be visited by parents with children. A child may insist that parents purchase the advertised medication for the disc with a cartoon movie (other similar product). Moreover, there is absence of experience of self-medication, as well as specialized knowledge, which are distinguishing features of minors in this context. Minors without having special knowledge, cannot make the right choice of a drug, since they are not able to correctly establish the causes of illness in their body. Furthermore, minors are generally not aware of the degree of necessity of using a medicament. In this regard, there are high risks that these actions to promote drugs will be considered as a violation of the Federal Law On Advertising and rejection of arguments that the corresponding advertising is not aimed at attracting the attention of minors to the medicine, because it contains no specific written appeal to children.	Paragraph 1 of Part 1 of Article 24 of the Federal Law On Advertising

²¹ See decision of FAS Russia on a case involving the grounds for violations of the law when advertising medical products No. 3-5-91/00-08-13 dated 03 December 2013.

²² See definition of FAS Russia on the termination of proceedings on Case No. 3-24-47/00-08-13 on the grounds of violation of the legislation of the Russian Federation on advertising dated 12 November 2013. Although the case was dismissed on formal grounds (placing video on the air at a specified time, in the complaint was not supported by evidence), the risks of corresponding qualifications remain high.

²³ See decision of OFAS Russia Udmurt on Case No. SYU04-03/2014-107R dated 02 June 2014.

Placement of advertising			
Placement on stands of promotional advertising without prior notice	When carrying out in a pharmacy organization an advertising campaign to promote non-prescription medicines by the placing of these remedies in a specially decorated booth next to the gifts that are given to the buyer upon purchase of these drugs, for a few days at this booth there was no warning about the presence of contraindications to their consumption and use, and need to become familiar with the instructions for use or to consult experts ²⁴ .	In accordance with the legislation of the Russian Federation, all drugs undergo studies to ensure their safety. Nevertheless, the very definition of a "safe drug" there is a risk of injury to health. Not all persons have special knowledge in the field of medicine and can choose the right drug. The physician prescribing a specific drug to a specific person, basis this on the specific symptoms, found in the person, indications of various analyses, examination data, the absence or presence of allergic reactions to certain substances, and many other factors. All this may lead to unnecessary taking of drugs and undesirable consequences. In this regard, due to the fact that the proliferation of advertising, without writing about the possible contraindications and need to consult a specialist, can take place over a period of a few days, there is a risk of these drugs creating side effects on the body, when people are uninformed that the advertised drugs contain possible contraindications and that they need to consult a specialist.	Part 7 of Article 24 of the Federal Law On Advertising
Placement of promotional articles about prescription drugs in specialized mass media	Highlighting the topic of contraception in a television program, the program hosts demonstrated the packaging of certain prescription drugs and described the positive effects of their use, and their therapeutic properties ²⁵ .	Information about drugs, placed in a television program may be regarded as advertising, since it is addressed to an unspecified number of people, and is aimed at drawing attention to certain drugs, as well as the formation and maintenance of interest in them and to promote them in the market. However, if the drugs are prescription medications, there arises a high risk, that the placement of such information, will be considered a violation of the Federal Law On Advertising, according to which the advertising of medicines, available by medical prescription, shall not be allowed, except in the field of medical or pharmaceutical exhibitions, seminars, conferences and other similar events, and for medical and pharmaceutical professionals in specialized printed media.	Paragraph 8 of Part 1 of Article 24 of the Federal Law On Advertising
Distribution of publicly available brochure containing a note that it is intended for medical workers	Information brochure, which among other things, contained a description of a prescription hormonal drug, was distributed to students in medical universities, and women attending schools for expectant mothers, health care workers, as well as by placing them in hospitals and clinics on racks and tables with public access (these contained a note that it is intended for medical workers) ²⁶ .	In accordance with the Federal Law On Advertising, the advertising of medicines, available by medical prescription, shall not be allowed, except in the field of medical or pharmaceutical exhibitions, seminars, conferences and other similar events, and for medical and pharmaceutical professionals in specialized printed media. Also in accordance with the Federal Law On Advertising, the advertising of medicinal products must be accompanied by a warning of the presence of contraindications to their taking and use, as well as the need to read the instructions for use or to consult a specialist. Thus, if the advertising material containing information on prescription drugs, distributed in the public domain, does not contain an appropriate warning, there are extremely high risks that the dissemination of such information will be considered a violation of the advertising legislation.	Part 7 and Part 8 of Article 24 of the Federal Law On Advertising

²⁴ See decision of OFAS Russia Udmurt on Case No. SYU04-03/2014-107R dated 02 June 2014.

²⁵ See decision of FAS Russia on Case No. 3-24-60/00-08-13 dated 24 January 2014.

²⁶ See definition of FAS Russia to initiate a case No. 3-24-47/00-08-14 on the grounds of violation of legislation on advertising of the Russian Federation dated 20 August 2014. Please note that this definition refers to the very existence of the risk, but this risk can be objectively assessed only after the final decision on the case.

5. CONCLUSION

Ensuring "compliance" with antitrust legislation, part of which is compliance with the legislation on advertising and fair competition, is a complex multi-step process.

Tools for building such a system could be internal company policies and procedures describing the main risks arising from the promotion of drugs, as well as the procedure for interaction between the different divisions of the company, when negotiating the content and placement of advertising materials.

In addition, market participants may adopt and effectively use internal training and education programs for their staff, based

on constant analysis of enforcement practices and updating the corresponding risks "compliance" matrix, which will on a regular basis show the main indicators of risk zones to internal creative departments and marketing departments.

Such a system can be constructed by analogy with the construction of a "compliance" system, which is needed to comply with FCPA²⁷, and which is used by large international pharmaceutical companies. This solution will enable companies that are manufacturers of medical products to minimize the risks of violating advertising legislation and legislation on protection of competition, as well as to build up relationships with contractors – advertising agencies.

²⁷ The Foreign Corrupt Practices Act of 1977 (Law on the Foreign Corrupt Practices).

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