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RECOMMENDATIONS FOR LEGISLATIVE COMPLIANCE REGARDING OTC DRUG ADVERTISING

(translation provided by the AEB)

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1. INTRODUCTION

These Recommendations for Legislative Compliance Regarding OTC Drug Advertising[1] ("Recommendations") were prepared by **the BRYAN CAVE LEIGHTON PAISNER (RUSSIA) LLP** legal firm jointly with the Association of International Pharmaceutical Manufacturers **(AIPM)**, Association of European Businesses **(AEB)**, Association of Russian Pharmaceutical Manufacturers **(ARPM)**; Union of Professional Pharmaceutical Organizations **(UPPO)**, the members of which include over 100 major Russian and international pharmaceutical companies manufacturing, supplying and distributing a wide range of modern medicines in the Russian Federation; the Association of Communication Agencies of Russia **(ACAR)** uniting over 200 leading participants of the commercial communications market in the Russian Federation, and the International Confederation of Consumer Societies (**ConfOP**), representing the interests of 42 leading consumer societies from Russia and the CIS. **The V. V. Vinogradov Russian Language Institute of RAS** provided consultancy support for the development of these Recommendations as concerns their linguistic component.

These Recommendations were prepared with support of the Federal Antimonopoly Service of Russia (FAS of Russia). Based on the results of discussions with the FAS of Russia, all comments made by the FAS of Russia were taken into account.

These Recommendations shall apply to consumer advertising and shall not apply to advertising for medical and pharmaceutical professionals (advertisements in venues of medical or pharmaceutical exhibitions, seminars, conferences and other similar events, and in specialized print media designated for medical and pharmaceutical professionals).

These Recommendations were prepared on the basis of an analysis of the practice of the FAS of Russia and courts as concerns the application of the Law on Advertising.[2]

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[1] Here and elsewhere herein, "OTC drugs" shall mean drugs sold over the counter. Here and elsewhere herein, "drugs" and "medicines" are used as synonyms.

[2] Hereinafter, the "Law on Advertising" shall mean Federal Law No. 38-FZ dated March 13, 2006 "On Advertising."

In the preparation of these Recommendations, the practice of AIPM as concerns the consideration of ethical disputes about advertising between its members under the Code of Proper Practice of AIPM, was also taken into account.

The purpose of preparing these Recommendations is to form a uniform and consistent practice to avoid errors in the preparation of advertisements, and decrease the scope of the required control and number of cases related to violations of advertising legislation.

These Recommendations are binding for the associations and companies that signed them. These Recommendations are open for signing by any associations and companies. These Recommendations shall be signed by an authorized person on the sheet attached to these Recommendations.

2. UNRELIABLE INFORMATION ON THE CHARACTERISTICS OF PRODUCTS. INFORMING OF PROPERTIES OF MEDICINES BEYOND THE INDICATIONS CONTAINED IN INSTRUCTIONS FOR USE

2.1. Statutory provisions

"Unreliable advertising shall be deemed advertising that contains untrue information: ... on any characteristics of the products, including their nature, composition, method and date of manufacture, designation, consumer properties, terms of application, place of origin, availability of the certificate of conformity or declaration of conformity, conformity marks and market circulation marks, useful life and shelf life" (Par. 2, Part 3, Article 5 of the Law on Advertising).

"Advertising of properties and characteristics of medicines and medical products, including methods of application and use, shall be allowed only within the indications contained in the instructions on the application and use of such advertised items approved pursuant to the established procedure" (Part 6, Article 24 of the Law on Advertising).

2.2. Proposed recommendations

2.2.1. Medicine advertisements shall be in compliance with the instructions for the medical use of the medicine (Part 2, Article 67 of Federal Law No. 61-FZ dated April 12, 2010 "On Drug Circulation").

Information on the characteristics of the therapeutic effect of an advertised medicine, its medicinal effect, and medicinal properties of the medicine contained in the advertisement, shall be evidenced by any of the following documents:

1) instructions for the medical use of the medicine approved pursuant to the established procedure

2) medical aid standards approved by the Ministry of Health of the Russian Federation

3) other documents approved and agreed by the Ministry of Health of the Russian Federation within its competence

2.2.2. Information on the characteristics of the therapeutic effect of an advertised medicine, its medicinal effect, and medicinal properties of the medicine contained in the advertisement may also be evidenced by other documents and sources, including electronically, if their content does not contradict the instructions for use.

When considering a case with respect to signs of violation of the advertising legislation, the reliability and applicability of such documents shall be proved by the advertiser.

2.2.3. It is permitted to use common words in advertising that are synonyms of the indications contained in the instruction (e.g. runny nose, cough, cold), although the meaning of such words shall not go beyond the instructions.

When referencing research or publications in advertisements or the advertiser's letter, it is necessary to indicate the date and source of the respective information.

Advertising shall not reference additional indications for use, doses, dosage regimes, patient populations, therapy duration, or contain other information contradictory to the instructions for use.

3. INCORRECT COMPARISONS AND UNRELIABLE BENEFITS

3.1. Statutory provisions

"Unfair advertising shall be deemed advertising that: ... contains incorrect comparisons of the advertised products with circulated products manufactured by other manufacturers or sold by other sellers" (Par. 1, Part 2, Article 5 of the Law on Advertising).

"Unreliable advertising shall be deemed advertising that contains untrue information: ... on the benefits of the advertised products over circulated products manufactured by other manufacturers or sold by other sellers" (Par. 1, Part 3, Article 5 of the Law on Advertising).

"Unfair advertising shall be deemed advertising that: ... discredits the honor, dignity and business reputation of a person, including competitors" (Par. 2, Part 2, Article 5 of the Law on Advertising).

3.2. Proposed recommendations

When comparing one medicine with another medicine in an advertisement, it is necessary:

1) to make the comparison by comparable characteristics (similar composition, effect mode, form of administration, etc.) on the basis of accurate and scientifically proven data and reliable information

2) not to make statements discrediting the business reputation of competitors.

It is permitted to compare medicines with identical registered indications for use (including medicines with different international non-proprietary names (INPN)), subject to providing precise and reliable comparison criteria in the advertisement.

If necessary, the advertiser shall provide, at the request of the advertisement distributor or advertisement seller, a letter evidencing the information contained in the advertisement at the date of the advertisement's launch, and the documents referenced therein.

4. GUARANTEE OF EFFECTIVENESS

4.1. Statutory provisions

"Advertising of drugs shall not: … guarantee a positive effect of the advertised item, its safety, efficiency and absence of adverse reactions" (Par. 8, Part 1, Article 24 of the Law on Advertising).

"Advertisements shall not reference the medicinal properties, i.e. positive effect of the advertises item on the development of an illness, except for in advertisements of drugs and medical services including methods of preventive treatment, diagnostics, treatment and medical rehabilitation in the advertisement of medical products (Par. 6, Part 5, Article 5 of the Law on Advertising).

4.2. Proposed recommendations

4.2.1. Advertisements shall not be permitted to contain words and expressions indicative of a guaranteed occurrence of the final result and that do not provide for another interpretation.

References in advertisements to the therapeutic properties of medicines and effects from their interaction with the body using words, word combinations and expressions indicative of the process rather than the result of the effect, provided such properties are in compliance with the instructions for use of the advertised medicine, shall be permitted.

4.2.2. The open list of examples of words and expressions prohibited and permitted for use in advertising is provided below as an illustration of this approach.

To avoid forming the impression about a guarantee of effectiveness, words and expressions from the column "Permitted" shall be used with due account for the general context of the advertisement, including its other elements (visual imagery, audio, other text, etc.).

Table 1. The open list of examples of words and expressions prohibited and permitted for use in advertisements

Prohibited*	Permitted*
* Using the words and expressions specified below in and of itself shall not automatically mean the presence or absence of the guarantee of a positive advertisement effect. Each advertisement shall be subject to separate analysis as regards the aggregate of all its elements and text semantics.	
Perfective verbs and verb forms (participles, adverbial participles) indicating the occurrence of a final result and not providing for any other interpretation (including in word combinations with imperfective verbs). They answer the questions *what shall be done? what has someone (something) finished doing? what has been done before something else?* etc. Examples: will get rid of, will cure, will win, will resolve (a problem), will destroy, will eliminate, will relieve (pain, paroxysm, etc.), will recover, will make feel better, will cure, will help (remedy, cure, win, destroy), etc.	Imperfective verbs and verb combinations (participles, adverbial participles) indicative of the process rather than the result. They answer the questions *what shall be done over time? what is something (somebody) doing right now? what is being done?* etc. Examples: treats, helps treat, provides aid, helps resolve, protects, helps eliminate, helps recover, provides, recovers, acts, relieves (symptoms, etc.), combats, attacks, etc.
Nouns indicative of the occurrence of a final result and do not provide for any other interpretation, and word combinations with such words (including word combinations with verbs including "facilitates," "helps," etc.) Examples: victory, recovery, complete elimination, issue resolution, facilitates recovery, helps cure, etc.	Nouns and word combinations with them that are not indicative of the inevitable occurrence of a result. Examples: reason, disease, symptoms (including certain types of symptoms), issue, process, treatment, effect, helps release, helps treat (facilitates treatment), protection, helps recover (facilitates recovery), etc.
Adverbs that are indicative of the occurrence of a final result and do not provide for any other interpretation. Examples: unambiguously, certainly, inevitably, guaranteed, forever, never, etc.	Adverbs that are indicative of the characteristics of the effect of the advertised drug, including adverbs used figuratively. Examples: simultaneously, carefully, significantly, insignificantly, conveniently, gently, tenderly, softly, etc.
	Figures of speech. Examples: fast response bacteria, first aid, etc.

Prohibited*	Permitted*
Adverbs indicative of the time or speed of the effect of the medicine with respect to its medicinal properties and the result of its effect. Examples: quickly (except for phrases indicated in the Permitted column), slowly, continuously, rapidly, instantly, for a long time, etc.	Reference to the time of absorption, allocation, elimination and other similar characteristics of the medicine in seconds, minutes, hours and other similar units. Examples: the medicine starts being absorbed in two minutes, the medicine is absorbed/allocated quickly (subject to the availability of such information in the instructions), etc. The comparison of the speed of absorption, allocation, elimination and other similar characteristics, including comparison with the use of the word "quicker," etc. shall be permitted (subject to compliance with the requirements of the correctness and reliability of a comparison; see Section 3 of these Recommendations).
	The reference to indications for use and the properties of the medicine. Examples: for pain relief, designed to treat, has a relaxing effect / combats ...., to relieve ..., against pain, etc.

4.2.3. Demonstrating the process of achieving the therapeutic effect in itself is not a guarantee of the positive effect and effectiveness of the advertised medicine. To assess the presence or absence of a guarantee of a positive effect and the effectiveness of an advertised medicine, the general content of the advertisement, including visual imagery, shall be taken into account.

Commercials about drugs may use the standard advertising method of demonstrating the potential symptoms of a disease, methods of use of the medicine, and the process of achieving the therapeutic effect, provided the audio and visual imagery does not guarantee a positive effect from the advertised item, its safety or efficiency.

4.2.4. Using the words "quickly," "for a long time" and analogous phrases shall not be permitted with respect to the characteristics of the therapeutic effect of an advertised medicine, its medicinal effect or medicinal properties. As regards other

consumer properties of the medicine, the words "quickly," "slowly," etc. shall be allowed (e.g. "the tablet dissolves on the tongue slowly," "the medicine can be stored for a long time," etc.).

5. ABSENCE OF A PORTION OF ESSENTIAL INFORMATION ABOUT THE ADVERTISED PRODUCTS

5.1. Statutory provisions

"Advertising that is missing a portion of essential information on the advertised products or terms of their acquisition or use, if said absence results in the distortion of the meaning of information and misleads consumers, shall not be permitted" (Part 7, Article 5 of the Law on Advertising).

5.2. Proposed recommendations

5.2.1. Footnotes may contain clarifying information that does not change the meaning of the primary statement. To avoid misleading consumers, providing a portion of information with essential value for the proper perception of the advertisement shall not be permitted in fine print or as a footnote. Such information shall be reflected in the primary statement of the advertisement. The primary statement shall mean the written or verbal statement that attracts the most attention of consumers or expresses the central idea of the advertisement.

5.2.2. In general, the volume and scope of footnotes in advertisements shall be at a reasonable minimum.

5.2.3. When composing footnotes, the following factors shall be taken into account (individually and collectively).

Footnotes shall be made in a readable print, and reading footnotes shall be possible without using additional optical means. In the case of commercials, they shall be readable without pausing the shot. Footnotes shall be made in a contrasting color (full-fledged colors contrasting with the primary color of the background, rather than middle tones, shall be used, and changes in the background shall not affect the readability of footnotes).

Footnotes shall be brief and simple for consumer perception. Using elongated or thin fine print significantly hampering perception shall not be permitted.

In commercials, the duration of a footnote on the screen shall not be shorter than the duration of the shot, in which the phrase or image accompanying that footnote is used. Footnotes shall have a size, color and contrasting effect that enables consumers to perceive them when consuming the advertisement (with due account for the advertising nature: TV, print, etc.).

The duration and speed of reading any information in oral statements (including advertising on radio) shall enable consumers to perceive their essence.

6. ADVERTISING SHALL NOT FACILITATE THE IMPRESSION THAT A HEALTHY PERSON NEEDS TO USE THE ADVERTISED PRODUCT

6.1. Statutory provisions

"Advertising of drugs shall not: ... facilitate the impression that a healthy person needs to use the advertised product" (Par. 6, Part 1, Article 24 of the Law on Advertising).

"The requirements of Par. 6, Part 1 of this clause shall not apply to advertising medicines used for preventive treatment" (Part 2, Article 24 of the Law on Advertising).

6.2. Proposed recommendations

The advertising of medicines shall not facilitate an impression of the necessity of their usage by healthy persons, except for advertising medicines used solely for preventive treatment, which shall be evidenced by their instructions for medical use.

When advertising medicines that are designated, pursuant to the instructions for medical use, both for preventive treatment and for the treatment of illnesses, it is necessary to ensure that advertising contains the respective information, i.e. it shall be stated that the advertised medicine is designated both for the treatment of an illness and for preventive treatment (e.g. via a cautionary warning). Referencing preventive properties is not compulsory when advertising the medicinal properties of medicines exclusively, without reference to their designation for preventive treatment.

Using reliable statistical data and information statements of reputable international and Russian organizations with reference to the source of such data in advertisements (subject to the absence of any additional statements about the need to take the medicine for healthy persons) shall be permitted if the medicine, pursuant to the approved instructions for medical use, may be used for the preventive treatment of one or more illnesses or deficiencies (examples of incorrect statements: "everybody should take," "a lot of people suffer from").

7. ASSUMPTIONS ABOUT DISEASE PROBABILITY

7.1. Statutory provisions

"Advertising of drugs shall not: ... contain affirmations or assumptions about the probability of an illness or health impairment for an advertisement's consumers" (Par. 5, Part 1, Article 24 of the Law on Advertising).

7.2. Proposed recommendations

Advertising shall not contain a list of symptoms with the subsequent affirmation or concrete assumption about the probability of illness for a consumer, or phrases containing an appeal to an indefinite group of persons with a question/assumption about the probability of an illness/health impairment (e.g. "Are you coughing?", "Are you sneezing?", "Do you get headaches?", "You're probably getting sick", "You have the flu", etc.).

A simple assumption about the probability of a particular illness without listing its symptoms (e.g. "You have a cold") shall not be permitted either.

It is permitted in advertisements to specify symptoms corresponding to the instructions for use according to which the advertised medicine is used, e.g.: "if you have a cough …", "when your nose is running…", "when you have a sore throat…", and phrases containing information on the target/intention to relieve a symptom: "to stop a cough …", "to clear a stuffy nose …".

It is permitted to make affirmations or assumptions about the probability of an illness or other health impairment not appealing to a particular group of persons/person when affirmations, assumptions or questions obviously relate to a character in a commercial.

It is not recommended to use a first name, middle name or last name of a person in advertisements of medicines for the treatment of illnesses, as advertisements of this type may result in the mockery of people with such a first name, middle name or last name.

8. USING IMAGES OF MEDICAL AND PHARMACEUTICAL PROFESSIONALS IN ADVERTISING

8.1. Statutory provisions

"The following shall not be allowed in advertising: ... using images of medical and pharmaceutical professionals, except for in advertising of medical services or personal hygiene products; in advertising, the consumers of which are solely medical and pharmaceutical professionals; in advertising in venues of medical or pharmaceutical exhibitions, seminars, conferences and other similar events, or in advertising in print media designated for medical and pharmaceutical professionals" (Par. 4, Part 5, Article 5 of the Law on Advertising).

8.2. Proposed recommendations

Advertising shall not contain any references to the image of a doctor or pharmacist, verbal or graphic, based on either a realistic representation of an image or its conditional representation, e.g. by a drawing or animated cartoon, including the image of a fantasy character.

9. SURROGATE ADVERTISING[3]

9.1. Statutory provisions

"Unfair advertising shall be deemed advertising that: ... advertises products, the advertising of which is prohibited by a certain method, at a specific time or place, or if the advertisement is under the guise of advertising different goods, the trademark or service mark of which is identical or confusingly similar to the trademark or service mark of the goods, with respect to the advertising of which respective requirements and restrictions have been set, or under the guise of advertising as the manufacturer or seller of such goods" (Par. 3, Part 2, Article 5 of the Law on Advertising);

"The special requirements and restrictions set by this Federal Law with respect to advertising particular types of products shall also apply to the advertising of means of individualization of such goods and their manufacturers and sellers, except for when advertising the means of individualization of the particular products, their manufacturer or seller does not apparently relate to the goods, with respect to the advertising of which special requirements and restrictions are set by this Federal Law (Part 4, Article 2 of the Law on Advertising).

9.2. Proposed recommendations

Surrogate advertising of OTC drugs shall not be permitted. Advertising targeting an OTC medicine shall clearly and obviously follow from the advertising material (with due account for a text or voice statement, plot, video sequence and other elements).

Advertising an OTC medicine shall be permitted provided that during a review of the advertisement, the general impression is that it is aimed at advertising an OTC medicine, including a clear reference that the advertised medicine is OTC, or by reference to INPN, form of presentation, dosage and other aspects that distinguish this OTC medicine from a prescription medicine.

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[3] Hereinafter, surrogate advertising shall mean the advertising of goods prohibited for advertising through the advertising of another product.

10. WARNINGS ABOUT CONTRAINDICATIONS, NECESSITY TO REVIEW THE INSTRUCTIONS OR CONSULT WITH A PROFESSIONAL

10.1. Statutory provisions

"The advertising of medicines and medical services, including methods of preventive treatment, diagnostics, treatment and medical rehabilitation shall be accompanied by a warning about contraindications based on their application and use, and the necessity to review the instructions for use or consult with a professional..." (Part 7, Article 24 of the Law on Advertising).

The provisions of said article also contain a requirement on the duration of warnings of that type:

Advertising type	Requirements for warnings
Radio programs	At least 3 seconds
TV programs and during movies or videos	At least 5 seconds At least 7% of the shot area
Other methods of advertising	At least 5% of the advertising area

Requirements for the inclusion of warnings shall not apply to advertising in venues of medical or pharmaceutical exhibitions, seminars, conferences and other similar events, in specialized print media designated for medical and pharmaceutical professionals, or to other advertising, the consumers of which are solely medical and pharmaceutical professionals.

10.2. Proposed recommendations

Warnings about contraindications for the application and use of a medicine, the necessity to review its instructions for use or consult with a specialist (Part 7, Article 24 of the Law on Advertising) shall be indicated in advertising, irrespective of the form of its presentation. The respective warning shall be made in readable print using a contrasting color, and it shall be readable without using additional optical means, and in the case of commercials, without stopping the shot.

In the event of video advertisements online, warnings in such video advertisements are required to have the same duration and size of warnings as on TV (at least 5 seconds and at least 7% of the shot area). Analogous requirements for other

advertising means are set for other types of advertising (warnings shall occupy at least 5% of the advertising area).

11. OBSCENE AND OFFENSIVE IMAGES

11.1. Statutory provisions

"Using swear words, obscene and offensive images, comparisons and expressions in advertising, including with respect to gender, race, nationality, profession, social category, age, language, official state symbols (flags, emblems, anthems), religious symbols, cultural heritage items (historical and cultural monuments) of peoples of the Russian Federation, and cultural heritage items included in the World Heritage List, shall not be permitted" (Part 6, Article 5 of the Law on Advertising).

11.2. Proposed recommendations

When advertising drugs, it is necessary to refrain from using, directly or indirectly, obscene images and word combinations, including cases when obscenity is the result of ambivalence.

Advertisements shall take into account the cultural and religious features of where it will be shown, and the vicinity of advertising venues to cultural institutions, medical institutions, religious facilities, educational institutions, cult items, cemeteries, etc.

SIGNATURES OF COMPANIES, ASSOCIATIONS AND OTHER PERSONS PLEDGING TO ADHERE TO THE RECOMMENDATIONS FOR LEGISLATIVE COMPLIANCE REGARDING OTC DRUG ADVERTISING:

No.	Name of the company, association or other signatory of the Recommendation	Full name of the representative and source of authority	Date of signature	Signature
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