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RECOMMENDATIONS ON COMPLIANCE WITH THE LEGISLATION ON ADVERTISING OF NON-PRESCRIPTION MEDICINE



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1. INTRODUCTION

These Recommendations for Compliance with the Laws on Advertising Non-Prescription Medicines¹ (hereinafter refers to as the Recommendations) have been prepared by **BRYAN CAVE LEIGHTON PAISNER (RUSSIA) LLP** jointly with the Association of International Pharmaceutical Manufacturers (**AIPM**), Association of European Businesses (**AEB**), Association of the Russian Pharmaceutical Manufacturers (**ARPM**), the Society of Professional Pharmaceutical Organizations (**SPFO**), whose members include over 100 of the biggest Russian and international pharmaceutical companies manufacturing, supplying and distributing a wide range of cutting-edge medicines within Russia, the Russian Association of Communications Agencies (**AKAR**) bringing together more than 200 leading Russian commercial communications market players, and the International Confederation of Consumer Societies (**KonfOP**) representing 36 key public consumer protection organisations from Russia and other CIS countries. Advisory support on the linguistic aspects of these Recommendations was provided by the **V.V. Vinogradov Russian Language Institute of the Russian Academy of Sciences**.

These Recommendations have been developed with support from the Federal Antimonopoly Service of Russia (FAS). As a result of discussion of the Recommendations with the FAS, all comments by the regulator were taken into account.

These Recommendations apply to advertisements targeting consumers but not to advertisements intended for medical and pharmaceutical staff (advertisements at healthcare or pharmaceutical exhibitions, workshops, conferences and other similar events and in dedicated publications intended for medical and pharmaceutical professionals).

These Recommendations rely on our analysis of FAS and judicial law enforcement practice in the context of the Law on Advertising².

The Recommendations also factor in the AIPM practice of examining ethical disputes between Association members under the AIPM Code of Practice.

¹ Hereinafter Non-Prescription Medicines means medicines freely available without prescription. The terms “medications” and “medicines” are hereinafter used as synonyms.

² Hereinafter the Law on Advertising means Federal Law No. 38-FL dated 13 March 2006 “On Advertising”.

These Recommendations are designed to shape uniform and unambiguous practice precluding errors in producing promotional materials and reduce the degree of control required, as well as the number of cases involving breach of advertising laws.

The Recommendations are binding on signatory associations and companies. The Recommendations are open for signature by any associations and companies and are signed by an authorised representative affixing their signature to the signature page attached hereto.

2. INACCURATE INFORMATION ABOUT THE PRODUCT. CLAIMING ATTRIBUTES THAT ARE BEYOND THE INDICATIONS FOR USE IN THE MEDICINE INSTRUCTIONS

2.1. Legal provisions

“An advertisement is recognised as unreliable if it contains untrue information about: ... any characteristics of goods, including their nature, formula, method and date of manufacture, purpose, consumer properties, conditions of use, origin, availability of a compliance certificate or declaration, compliance marks, technical regulation compliance marks, service life or expiry date” (Article 5(3)(2) of the Law on Advertising).

“Statements in advertisements about attributes and characteristics, including the mode of administration and use, of medicines and medical devices are only permissible to the extent of the indications described in duly approved medicine instructions to such advertised products” (Article 24(6) of the Law on Advertising).

2.2. Proposed Recommendations

2.2.1. Materials promoting a medicine must comply with the duly approved instructions for medical use thereof (Article 67(2) of Federal Law No. 61-FL dated 12 April 2010 “On Drugs’ Circulation”).

Information about the characteristics of the advertised medicine’s therapeutic action, medicinal effect and curative properties contained in the advertising is to be confirmed by one of the following documents:

- 1) duly approved instructions for medical use of the medicine;
- 2) standards of medical care approved by the Ministry of Healthcare of the Russian Federation;
- 3) other documents approved or endorsed by the Ministry of Healthcare of the Russian Federation within its powers.

2.2.2. Information about the characteristics of the advertised medicine’s therapeutic action, medicinal effect and curative properties contained in the advertising may also be confirmed by other documents and sources, including electronic, unless their contents contradict the medicine instructions.

Should a case be initiated for alleged breach of the law on advertising, the burden of proving reliability and relevance of such documents would lie on the advertiser.

2.2.3. Advertisements may use common words synonymous with those specified in the instructions for use (such as a running nose, cough, cold), yet their meaning should not go beyond the instructions.

If an advertisement or the advertiser's letter refers to research or publications, the source and date of the information is to be specified.

Advertisements may not state any extra indications, dosage, dose regime, patient populations or duration of therapy or offer other information contravening the instructions for use.

3. IMPROPER COMPARISONS AND UNRELIABLE BENEFITS

3.1. Legal provisions

“An advertisement is recognised as unfair if it: ... contains improper comparisons between the advertised product and currently marketed goods produced by other manufacturers or sold by other vendors” (Article 5(2)(1) of the Law on Advertising).

“An advertisement is recognised as unreliable if it contains untrue information: ... about advantages offered by the advertised product over currently marketed goods produced by other manufacturers or sold by other vendors” (Article 5(3)(1) of the Law on Advertising).

“An advertisement is recognised as unfair if it: ... impairs the honour, dignity or business reputation of any person, including a competitor” (Article 5(2)(2) of the Law on Advertising).

3.2. Proposed Recommendations

If an advertisement compares one medicine to another, the comparison:

- 1) must refer to comparable characteristics (similar formulae, mode of action, administration route, etc.) on the basis of accurate and scientifically proven and reliable data,
- 2) may not contain statements tarnishing the business reputation of competitors.

Comparison is possible between medicines with similar registered indications (including with various international nonproprietary names (INN)), on the condition that clear and reliable comparison criteria are provided in the advertising materials.

If requested by the advertising distributor or seller, the advertiser will furnish a letter confirming the information contained in the advertising materials on the date the advertisements are launched, as well as documents mentioned in the letter.

4. GUARANTEED EFFECTIVENESS

4.1. Legal provisions

“Medication advertisements may not: ... guarantee positive effects of the advertised product, its safety, effectiveness and absence of any side effects” (Article 24(1)(8) of the Law on Advertising).

“Advertisements may not mention curative properties of the advertised product, i.e., its positive impact on progression of the disease, unless such properties are mentioned in advertisements of medicines, medical services, including methods of prophylaxis, diagnostics, treatment and medical rehabilitation, and medical devices” (Article 5(5)(6) of the Law on Advertising).

4.2. Recommendations

4.2.1. Advertisements may not use words or phrases signifying a guaranteed ultimate result to the exclusion of other interpretations.

Advertisements may describe therapeutic properties of medicines and effects of their impact on the body using words, phrases and expressions referring to the process rather than the result, providing such properties match the advertised medicine’s instructions for use.

4.2.2. As an example of this approach, an open list of words and phrases that may and may not be used in advertising is provided below.

In order to avoid forming the impression that effectiveness is guaranteed, use of words and expressions from the Admissible column should be made with reference to the general context of the advertising material, including its other elements (visual imagery, audio, other text, etc.).

Table 1. Open list of words and phrases that may and may not be used in advertising (examples)

Inadmissible*	Admissible*
* Mere use of the below words and expressions does not automatically mean that the advertisement actually guarantees or does not guarantee a positive effect. Each advertising material is to be analysed specifically with reference to all its elements and text semantics.	
Perfective aspect (finite) verbs and verbal forms (participles, gerunds) signifying that the ultimate result was achieved and allowing for no other interpretation (including combination with imperfective	Imperfective aspect (non-finite) verbs and verbal forms (participles, gerunds) denoting a process rather than a result.

Inadmissible*	Admissible*
<p>aspect (non-finite) verbs).</p> <p>Examples: will remedy, treat, overcome, resolve (the problem), destroy, eliminate, kill (the pain, spasm, etc.), restore, ease, cure, help (cure, treat, defeat, extinguish), etc.</p>	<p>Examples: treats, helps in treating, helping, helps in resolving, protects, helps in relieving, helps in restoring, affects, rehabilitates, works, addresses (the symptoms, etc.), fights, attacks, etc.</p>
<p>Nouns denoting the ultimate result achieved and precluding any other interpretation, as well as combinations of these words (including with verbs, such as promotes, helps, etc.).</p> <p>Examples: a win over, recovery, problem solution, promotes treatment, helps recovery, etc.</p>	<p>Nouns and combinations with nouns that do not suggest an inevitable result.</p> <p>Examples: causes, disease, symptoms (including particular types of symptom), problem, process, treatment, effect, helps relief, helps treat (promotes treatment), protection, helps (facilitates) restoration, etc.</p>
<p>Adverbs signifying that the ultimate result is achieved and precluding other interpretation.</p> <p>Examples: definitely, invariably, inevitably, guaranteeing, forever, never, etc.</p>	<p>Adverbs characterising the effect of the advertised medicine, including adverbs with a figurative meaning.</p> <p>Examples: simultaneously, gently, considerably, somewhat, conveniently, softly, tenderly, mildly, etc.</p>
	<p>Metaphors.</p> <p>Examples: rapid response bacteria, first aid, etc.</p>
<p>Adverbs denoting duration or speed of the medicine's effect with reference to its curative properties and result.</p> <p>Examples: quickly (with the exception of the phrases listed in the Admissible column), slowly, lastingly, enduringly, swiftly, instantly, for a long time, etc.</p>	<p>References to the time of absorption, distribution, excretion and other similar aspects of the medicine in seconds, minutes, hours or similar time measurement units.</p> <p>Examples: absorption starts within two minutes, the medicine is absorbed quickly, distributed swiftly (provided this information is contained in the instructions for use), etc.</p> <p>Absorption, distribution and excretion speed and other similar features of different medicines may also be compared, including using the words "more quickly", etc. (provided the</p>

Inadmissible*	Admissible*
	requirement on comparison correctness and truthfulness is met, see Section 3 of the Recommendations).
	References to the indications and properties of the medicine. Examples: to relieve pain, designed to treat, produces a spasmolytic effect/has spasmolytic properties, to fight..., to relieve..., against pain, etc.

4.2.3. Mere demonstration of how the therapeutic benefit is achieved does not guarantee positive effects or effectiveness of the advertised medicine. For assessing whether the impression is given that the medicine guarantees a positive effect or its efficacy or positive effects are guaranteed, the general content of the advertising material, including its audio and video elements, needs to be taken into account.

Commercials promoting medicines may use the typical advertising device of demonstrating possible symptoms, methods for using the medicine and the process of achieving the therapeutic effect, provided the audio and visual elements of the commercial do not guarantee positive effects of the advertised medicine, its safety or efficacy.

4.2.4. The words “quickly”, “slowly” and the like may not be used in advertisements to characterise the therapeutic effects of the advertised medicine, its medicinal effect and curative properties. With respect to other, consumer attributes of the medicine, the words “quickly”, “long”, “slowly”, etc. are admissible (e.g., “the tablet dissolves quickly on the tongue”, “the medicine has a long shelf life”, etc.).

5. OMITTING CERTAIN ESSENTIAL INFORMATION ABOUT THE ADVERTISED PRODUCT

5.1. Legal provisions

“Advertisements omitting a portion of essential information about the advertised product, including the terms for its purchase or use, are not permitted, if such omission distorts the meaning of the information or misleads consumers” (Article 5(7) of the Law on Advertising).

5.2. Proposed Recommendations

5.2.1. Annotations may supply clarifying information, provided they do not change the principal message. To preclude misleading consumers, no portion of the information that is material for correct perception of the advertisement may be provided in fine print or in footnotes. All such information must be given as part of the advertisement’s principal message. The principal message means a verbal or written message attracting most consumer attention or reflecting the key idea of the advertisement.

5.2.2. The number and extent of annotations in advertisements should generally be reasonable.

5.2.3. When drafting annotations, the following requirements must be taken into account (both individually and in aggregate).

Notes are to be in a legible font and readable without additional optical means and, in the event of commercials, without pausing the video. The notes are in contrasting colour (no half-tones are used, rather full colour casts contrasting with the prevailing background colour and note legibility must remain unaffected by a change of background colour).

Notes are brief and easily comprehensible for consumers. No elongated or thin fonts may be used if they considerably hamper text perception.

For commercials, the notes must appear at least for the duration of the specific frame containing the phrase or image to which the note refers. Size, colour and sharpness of the notes must enable consumers to perceive them when looking at the advertisement (in consideration of the advertisement’s nature – TV, printed, etc.).

The duration and reading speed of any information delivered verbally (including in radio advertisements) must enable them to be perceived by consumers.

6. ADVERTISEMENTS MAY NOT GIVE HEALTHY PERSONS THE IMPRESSION THAT THEY NEED TO USE THE ADVERTISED ITEM

6.1. Legal provisions

“Medication advertisements may not: ... give healthy persons the impression that they need to use the advertised item” (Article 24(1)(6) of the Law on Advertising).

“The requirements of Article 24(1)(6) hereof do not apply to advertisements of preventive medicines” (Article 24(2) of the Law on Advertising).

6.2. Proposed Recommendations

Medicine advertisements may not give healthy persons the impression that they need the medicines, unless medicines are advertised whose sole function is prevention, which must be confirmed by the instructions for medical use.

If medicines intended for both disease prophylaxis and treatment (according to the instructions for medical use) are advertised, the advertisement must state so, i.e., say that the advertised medicine is intended both for treatment and prophylaxis of the disease (e.g., give a warning inscription to this effect). References to prophylactic effects are not mandatory if only the curative properties of medicines are advertised without mention of their prophylactic uses.

Advertisements may use reliable statistics and informative communications by recognised international and Russian organisations with reference to the data source (provided there are no additional statements regarding the need for healthy people to take the medicine) if, according to the approved instructions for medical use, the medicine may be used for prophylaxis of a disease or deficiencies (examples of incorrect statements: “everyone should take...”, “many people often feel...”).

7. SUGGESTED DISEASES

7.1. Legal provisions

“Medication advertisements may not: ... state or suggest that advertisement consumers suffer from any diseases or health impairments” (Article 24(1)(5) of the Law on Advertising).

7.2. Proposed Recommendations

Advertisements should not list symptoms accompanied by a statement or specific suggestion that consumers suffer from diseases or phrases addressed to the general public with the question/suggestion of the disease or symptoms of the disease (such as, “Are you coughing?”, “Are you sneezing?”, “Have a headache?”, “You seem to be coming down with something”, “You’ve got the ‘flu’”, etc.).

Simple suggestions of a specific disease, without listing the symptoms, are also not permitted (such as, “You’ve caught a cold”).

Even so, advertisements may name symptoms that match the medicine’s instructions in terms of the symptoms addressed by the medicine, such as: “for coughs...”, “for runny nose/rhinitis...”, “for sore throats...” and phrases with information about the objective/intention being symptomatic relief, such as: “for getting rid of cough...”, “for relieving nasal blockage...”.

Statements or suggestions about potential diseases or other conditions are admissible without reference to a particular group of persons/specific person, when the statements, suggestions or questions obviously refer to a character in the commercial.

It is not recommended to use any name, surname or patronymic if the advertisement relating to the disease might give rise to derisive jokes about people with the same name, surname or patronymic.

8. IMAGES OF MEDICAL OR PHARMACEUTICAL STAFF IN ADVERTISEMENTS

8.1. Legal provisions

“Advertisements may not: ... use images of medical or pharmaceutical staff, unless the advertisement promotes medical services and personal care products, is intended solely for persons employed in healthcare and the pharmaceutical business, is distributed exclusively at healthcare or pharmaceutical exhibitions, seminars, conferences and other similar events, or is placed in specialised printed media intended for healthcare and pharmaceutical business staff” (Article 5(5)(4) of the Law on Advertising).

8.2. Proposed Recommendations

Advertisements should not include any references to images of physicians or pharmaceutical chemists, whether verbal or figurative, using realistic or notional representation of the images, such as a painted or cartoon representation, including depiction as a fairy tale character.

9. SURROGATE ADVERTISING³

9.1. Legal provisions

“An advertisement is recognised as unfair if it: ... features products that are prohibited from being advertised in this particular manner, at the specific time or place or is distributed on the pretext of promoting other products with a trade mark or service mark identical or confusingly similar to the trade mark or service mark of a product subject to relevant advertising requirements and restrictions, or on the semblance of an advertisement promoting the manufacturer or vendor of such products” (Article 5(2)(3) of the Law on Advertising);

“Special requirements and limitations established by this Federal Law on advertisements of specific types of product also apply to advertisements featuring their means of identification, manufacturers or vendors, except for when an advertisement promoting the means of identification of specific products, their manufacturer or vendor is evidently irrelevant to the products that are subject to the special advertising requirements and limitations under this Federal Law” (Article 2(4) of the Law on Advertising).

9.2. Proposed Recommendations

Surrogate advertising of prescription medicines is not permitted. Advertising materials (in consideration of the text or verbal message, plot, video sequence and other elements) must make it clear and evident that they are promoting non-prescription medicines.

Non-prescription medicines may be advertised provided the commercials give the general impression of promoting non-prescription medicines, including by clear indication that the advertised medicine does not require a prescription or by reference to the INN, presentation, dosage and other aspects distinguishing the non-prescription medicine from the prescription medicine.

³ Hereinafter, surrogate advertising means advertising promoting items banned from advertising in the guise of another advertised item.

10. WARNING OF CONTRAINDICATIONS, THE NEED TO READ THE INSTRUCTIONS OR CONSULT A SPECIALIST

10.1. Legal provisions

“Advertisements of medicines, medical services, including prophylaxis, diagnostics, treatment and medical rehabilitation methods, and medical devices must be accompanied by a warning of any contraindications to taking or using them, of the need to read the instructions or get advice from specialists...” (Article 24(7) of the Law on Advertising).

The article also contains requirements on the duration of such warnings:

Type of advertising	Requirement on the warning
Radio	At least three seconds
TV and during films and videos	At least five seconds At least 7% of the image area
Other distribution methods	At least 5% of the advertising space

The warning requirements do not apply to advertisements distributed at medical or pharmaceutical exhibitions, workshops, conferences or other similar events or placed in specialised printed media intended for healthcare and pharmaceutical staff or to other advertisements intended exclusively for healthcare and pharmaceutical staff.

10.2. Proposed Recommendations

The warning about contraindications to using or taking a medicine or the need to read the instructions or consult specialists (Article 24(7) of the Law on Advertising) must be included in an advertisement irrespective of its format. The relevant note must be in legible font and contrasting colour and readable without additional optical means and, in the event of commercials, without pausing the video.

Promotional videos posted on the web are subject to the same requirements on warning duration and size as for TV commercials (at least five seconds and 7% of the image area). Other types of advertisement on the Internet are subject to requirements similar to those applicable to other methods of distribution (the warning should occupy at least 5% of the advertising space).

11. OBSCENE AND OFFENSIVE IMAGES

11.1. Legal provisions

“Advertisements may not contain swearwords, obscene or offensive images, comparisons or phrases, including with respect to sex, race, nationality, profession, social status, age, language, official symbols of state (flags, national emblems, anthems), religious symbols, cultural heritage sites (historical and cultural monuments) of the peoples of the Russian Federation or cultural heritage sites included on the World Heritage List” (Article 5(6) of the Law on Advertising).

11.2. Proposed Recommendations

When advertising medicines, it is recommended to refrain from using, directly or indirectly, obscene images and phrases, including when the obscenity results from any potential ambivalent perception.

Cultural and religious specifics of the regions in which the advertisements are to be distributed must also be taken into account, as well as proximity to cultural, healthcare, religious, educational facilities, places of worship, cemeteries, etc.