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MISREPRESENTATION OF PRODUCT CHARACTERISTICS. INFORMATION ABOUT DRUG PROPERTIES FALLING OUTSIDE INDICATIONS IN INSTRUCTIONS FOR USE

Provisions of law

"Commercials that misrepresent: ... any characteristics of the product, including its nature, composition, method and date of manufacture, purpose, consumer properties, conditions of use of the product, place of origin, existence of a certificate of conformity or declaration of conformity, conformity marks and marketing authorization marks, life time, shelf life of the product, shall be found to be false" (Article 5 Part 3 Paragraph 2 of the Law on Advertising).

"Information in commercials about properties and characteristics, including the methods of application and use of medicinal products and medical devices is permitted only within the limits of therapeutic indications specified in the duly approved instructions for application and use of such advertised item" (Article 24 Part 6 of the Law on Advertising).

Examples in practice

No.	Advertised item, Decision of the FAS / courts	Commercial content, Conclusions of the FAS / courts
Advertising was found to be false and falling outside instructions for use¹		
1.	Isoprinosine Decision of the FAS Russia on Case No. 3-24-46/00-08-15 dated March 25, 2016. Inappropriate advertising	<i>Commercial:</i> "Fast and gentle ARVI treatment without excessive drug burden". <i>Conclusions of the FAS:</i> "According to the instructions, the duration of treatment with the drug is usually <u>between 5 and 14 days</u> . The duration of treatment corresponds to the normal duration of the disease and does not differ from the duration of treatment with analogues"

¹ The FAS classified the cases given in this table, according to one of the two above-mentioned provisions of the Law on Advertising, but in all the instances the advertising information was actually checked for consistency with the instructions for use - therefore the cases were consolidated in one section.



2.	<p>Oflomil Nail Polish Decision of the FAS Russia on Case No. 3-5-54/00-08-16 dated December 5, 2016. Inappropriate advertising</p>	<p><i>Commercial:</i> "Kills fungus even under cosmetic nail polish". <i>Conclusions of the FAS:</i> "According to the instructions, <u>cosmetic nail polish shall not be used during treatment</u>. The possibility of using the drug together with cosmetic nail polish is <u>not in accordance with the instructions</u>; the information in the commercial is false".</p>
3.	<p>Escapelle Decision of the FAS Russia on Case No. 3-24-10/00-08-15 dated June 1, 2015. Inappropriate advertising</p>	<p><i>Commercial:</i> It is reported that there is no need of taking a pregnancy test before use. A high probability of teratogenic action (the ability to cause structural and functional disorders in the fetus) is reported for competitive products. <i>Conclusions of the FAS:</i> "The instructions says that the <u>drug is counter-indicative in pregnancy</u>. The commercial is inappropriate due to inconsistency between the commercial and the instructions as well as false information about the competitive products".</p>
4.	<p>Modelle line Decision of the FAS Russia on Case No. 3-24-13/00-08-16 dated May 23, 2016. Inappropriate advertising</p>	<p><i>Commercial:</i> "MODELLE is a unique collection of oral contraceptives... Besides protection against unwanted pregnancy, it helps to fix one of the problems: ... does not affect the lactation and development of a baby". <i>Conclusions of the FAS:</i> "For a portion of drugs their respective instructions state they are <u>counter-indicative during breastfeeding</u>. The commercial reported that the drug from the line of drug products does not affect the development of a baby, which is inconsistent with the characteristics of individual drugs specified in the</p>
5.	<p>Miramistin Decision of the FAS Russia on Case No. 3-24-41/00-08-16 dated November 7, 2016. Inappropriate advertising</p>	<p><i>Commercial:</i> "... the drug can be used for treatment of flu, ARVI, tracheitis, bronchitis". <i>Conclusions of the FAS:</i> "The instructions <u>contain no indications for use in flu, ARVI, tracheitis and bronchitis</u>. The methods of application and use of the drug reported in the commercial fall outside the indications provided in the instructions for use".</p>
6.	<p>Drugs: Dimia, Belara, Silhouette, Regulone, Lindilet 30, Mediana Order of the Ninth Arbitration Court of Appeal on Case No. A40-205545/15 dated April 25, 2016. Inappropriate advertising</p>	<p><i>Commercial:</i> The indications were: acne, dysmenorrhea, endometriosis, rehabilitation after abortion and gynecological surgeries, PMS. <i>Conclusions of the courts:</i> "According to the instructions... <u>the only indication for use is oral contraception</u>. The commercial reported the possibility of using the drugs outside the indications provided in the instructions for use".</p>



7.	<p>Cholisal (dental gel) Decision of the FAS Russia on Case No. 3-5-6/00-08-17 dated March 30, 2017.</p> <p>Inappropriate advertising</p>	<p><i>Commercial:</i> "The effect of the drug occurs in 3 minutes, the duration of its action is up to 8 hours".</p> <p><i>Conclusions of the FAS:</i> "The instructions indicate that the analgesic effect occurs in 2-3 minutes, and its duration is 2 to 8 hours. Alleviation of mere one of the inflammation symptoms in 3 minutes is not indicative of expedite recovery process; the treatment regimen provides for a course of medication".</p>
8.	<p>Lasolvan Max Decision of the FAS Russia on Case No. 3-24-41/00-08-17 dated September 5, 2017.</p> <p>Inappropriate advertising</p>	<p><i>Commercial:</i> "Lasolvan Max for cough relief. 24-hour action, only one capsule per day".</p> <p><i>Conclusions of the FAS:</i> "There is no indication of the 24-hour action of the drug in the instructions for medical use of Lasolvan Max"</p> <p>The reviewed commercial reported the action of Lasolvan Max outside limitations of indications in the instructions for use".</p>
<p>Advertising was found to be appropriate</p>		
9.	<p>Mycosan Decision of the FAS Russia on Case No. 3-24-62/00-08-14 dated March 27, 2015.</p> <p>Appropriate advertising</p>	<p><i>Commercial:</i> "Mycosan penetrates deep into the nail structure, causing death of the fungus and protecting the nail".</p> <p><i>Conclusions of the FAS:</i> "As it follows from the instructions for use, Mycosan has a destructive effect on the lipid membrane of fungi, causing their death".</p> <p>The statement in the commercial: "causing death of the fungus" is consistent with the instructions, so there are no violations [Article 5 Part 3 Paragraph 2 of the Law on Advertising] in advertising this medical product".</p>
10.	<p>Tantum Verde Forte Decision of the FAS Russia on Case No. 3-24-26/00-08-17 dated June 15, 2017.</p> <p>Appropriate advertising</p>	<p><i>Commercial:</i> "Kills the pain and relieves inflammation in a minute".</p> <p><i>Conclusions of the FAS:</i> "According to the instructions, <u>the drug has a local and anti-inflammatory analgesic effect</u>. The <u>statements</u> "Kills the pain" and "Relieves inflammation", reported in the commercial, <u>fully correspond to the indications</u> provided in the instructions for use. Therefore, there is no violation of Article 24 Part 6 of the Law on Advertising".</p>

Degree of practice uniformity: ■ **The practice is uniform**

Most of the practice of the FAS and the courts indicates that with respect to medicinal products, the main criterion for false information in commercials is inconsistency between the advertised information and the instructions for use, particularly:

1. Reference in the commercial to diseases or conditions that are not listed in the instructions for use of the advertised drug;



2. Reference to the possibility of using the drug in certain periods (for example, during breastfeeding), while such periods are listed as counter-indicative in the instructions for use;
3. Reference to time intervals required for drugs to take effect, that are inconsistent with the information in the instructions for use.

One can also identify a separate category of cases related to false information about characteristics of the drugs in commercials reporting rapid overall action of the drug, while the instructions contain information about rapid action relevant only to one of the symptoms of the disease (see Section 11 of this Review).



MISSING PIECE OF ESSENTIAL INFORMATION ON ADVERTISED PRODUCT

Provisions of law

"Commercials are not permitted when they miss a piece of essential information about the advertised product, the conditions for its purchase or use that distorts the meaning of information and misleads the consumers of advertising" (Article 5 Part 7 of the Law on Advertising).

Examples in practice

No.	Advertised item, Decision of the FAS / courts	Commercial content, Conclusions of the FAS / courts
Advertising was found lacking the essential information		
1.	<p>Contact lenses DAILIES TOTAL 1</p> <p>Decision of the FAS Russia on Case No. 3-5-23/00-08-17 dated June 15, 2017.</p> <p>Inappropriate advertising</p>	<p>Commercial: "Alcon - No. 1 in ophthalmology"</p> <p>*According to the databases of IMS Health LLC, Alcon Pharmaceuticals LLC is the leader in sales scope expressed in money terms...".</p> <p>The text of the reference note, indicating the criterion for comparing products in the market of ophthalmology, is made in small print, covering 1/6 of the frame area and shown in the commercial for 3 seconds.</p> <p><u>Conclusions of the FAS: "A form of presentation and conditions of advertising do not allow consumers to perceive (read) the text with the criteria justifying the statement "No. 1", due to the small print and short display time, in contrast with the information about the superiority of Alcon products..., which is given in large print and grabs the attention of consumers.</u></p> <p><u>At the same time, the information on the criteria for comparing products is essential..., however, the form of presentation of the data does not allow consumers to perceive it making it de facto missing in advertising.</u></p> <p><u>In instances when essential circumstances, which if omitted could deceive customer expectations formed by the advertising, were formally present in the commercial, yet presented in a form that did not allow consumers to perceive such information, it has to be acknowledged that such information was not brought to the notice of an indefinite number of persons".</u></p>



<p>2.</p>	<p>Detralex Decision of the FAS Russia on Case No. 3-5-1/00-08-17 dated March 29, 2017. Inappropriate advertising</p>	<p><i>Commercial:</i> "World No.1 vein tonic!"* *According to IMS Health LLC, among systemic vein tonics (phlebotropics) in sales share in money terms (Euro) throughout Quarter 1, 2015 on yearly basis in the global pharmaceutical market» The text of the reference note is made in small print, covering 1/30 of the frame area and shown in the commercial twice for 3 seconds.</p>
		<p><i>Conclusions of the FAS:</i> "<u>The formal presence of the criterion for comparison of vein tonics in the commercial does not allow consumers to perceive the information clarifying the advertising statement and cannot be deemed as information made available.</u> <u>At the same time, the information on the criteria for comparing vein tonics is essential to explain the meaning of the statement "World No. 1 vein tonic!". Yet, the form of presentation prevents consumers from perceiving this information making it actually missing from the advertising".</u></p>
<p>3.</p>	<p>Voltaren Therapy Patch Decision of the FAS Russia on Case No. 3-5-21/00-08-17 dated July 18, 2017. Inappropriate advertising</p>	<p><i>Commercial:</i> "This is the only therapy patch ... *within the Voltaren family in Russia" The text of the footnote is made in small print, covering 1/17 of the frame area. <i>Conclusions of the FAS:</i> "A form of presentation and conditions of advertising <u>do not allow consumers to perceive (read) the text justifying the statement "This is the only therapy patch", due to the small print and short display time.</u> <u>At the same time, the information about Voltaren being the only therapy patch within the Voltaren family in Russia is essential since its absence distorts the meaning of the statement "This is the only therapy patch".</u></p>
<p>4.</p>	<p>Cholisal Decision of the FAS Russia on Case No. 3-5-6/00-08-17 dated March 30, 2017. Inappropriate advertising</p>	<p><i>Commercial:</i> "The dental gel Cholisal will help to relieve inflammation and to kill the pain. The effect of the drug occurs in 3 minutes, the duration of its action is up to 8 hours. Active components of the gel have a quick and complex effect, restoring the health of the gums." <i>Conclusions of the FAS:</i> "The commercial <u>does not report any information that a positive effect on the state of the disease occurring in 3 minutes from the use of the drug refers only to its analgesic effect, but not to the complex effect directly aimed to treat the oral disease.</u>"</p>



The FAS Russia and the courts in the course of their practice have shaped the definition for the essential information as follows

"Essential information is the information (or a piece of information) about the advertised product, which is significant and necessary for correct conclusion about the properties of the advertised product for the purpose of its purchase and further use in accordance with the intended use of the product"².

Degree of practice uniformity



The practice is not uniform

Not only the information missing from the commercial, but also the information improperly presented in the commercial (for example, done in small print and with reference covering small area, etc.) shall qualify as missing.

+ There is an established unified approach regarding

- 1) too small print or short display time of the text = violation;
- 2) a significant difference in the size of the slogan and reference notes = violation;
- 3) lack of information specifying the information reported in the commercial = violation.

- There is no unified approach regarding

- 1) proper font size - there is no uniform practice;
- 2) duration of the specifying information - there is no uniform practice.

² See, for example: Order of the Ninth Arbitration Court of Appeal No. A40-34325/2013 dated July 15, 2013; Decision of the OFAS Russia in Khabarovsk No. 4-05/19 dated February 26, 201