On approval of the Rules for advertising of medicines and medical products

Unofficial translation

Order of the Minister of Health of the Republic of Kazakhstan dated December 20, 2020 No. ҚР ДСМ -288/2020. Registered in the Ministry of Justice of the Republic of Kazakhstan on December 22, 2020 No. 21872.

Unofficial translation

In accordance with paragraph 1 of Article 56 of the Code of the Republic of Kazakhstan " On the health of the people and the health care system" **I hereby ORDER**:

Footnote. Preamble - in the wording of the order of the Minister of Healthcare of the Republic of Kazakhstan dated 05.09.2022 № RK MH-94 (shall enter into force upon expiry of ten calendar days after the day of its first official publication).

1. To approve the attached rules for advertising of medicines and medical products.

2. To declare invalid:

1) Order of the Minister of Health and Social Development of the Republic of Kazakhstan dated February 27, 2015 № 105 "On approval of the Rules for advertising of medicines and medical products" (registered in the Register of state registration of regulatory legal acts under № 10667, published on April 17, 2015 in the information and legal system "Adilet");

2) paragraph 2 of the List of orders in the field of health care, which are amended, approved by the order of the Minister of Health of the Republic of Kazakhstan dated April 22, 2019 № ҚР ДСМ -44 "On amendments to some orders of the Ministry of Health of the Republic of Kazakhstan and the Ministry of Health and Social Development of the Republic of Kazakhstan" (registered in the Register of state registration of regulatory legal acts under № 18582, published on May 2, 2019 in the Reference Control Bank of regulatory legal acts of the Republic of Kazakhstan).

3. The committee of medical and pharmaceutical control of the Ministry of Healthcare of the Republic of Kazakhstan in the procedure prescribed by the legislation of the Republic of Kazakhstan shall:

1) ensure state registration of this order in the Ministry of Justice of the Republic of Kazakhstan;

2) place this order on the Internet resource of the Ministry of Healthcare of the Republic of Kazakhstan after its official publication;

3) within ten working days after the state registration of this order in the Ministry of Justice of the Republic of Kazakhstan, submit to the Legal Department of the Ministry of Healthcare of the Republic of Kazakhstan of information on the implementation of the measures provided for in subparagraphs 1) and 2) of this paragraph.

Footnote. Paragraph 3 - in the wording of the order of the Minister of Healthcar of the Republic of Kazakhstan dated 05.09.2022 № RK MH-94 (shall enter into force upon expiry of ten calendar days after the day of its first official publication).

4. The supervising vice minister of health of the Republic of Kazakhstan is authorized to control the execution of this order.

5. This order comes into force upon the expiration of ten calendar days after the day of its first official publication.

Minister of health of the Republic of Kazakhstan *A. Tsoi*

Approved
by the order of the
Minister of health of the
Republic of Kazakhstan
dated December 20, 2020
№ ҚР ДСМ-288/2020

Rules for advertising of medicines and medical products

Chapter 1. General provisions

1. These Rules for advertising of medicines and medical devices (hereinafter referred to as the Rules) shall be developed in accordance with paragraph 1 of Article 56 of the Code of the Republic of Kazakhstan "On the health of the people and the health care system" (hereinafter referred to as the Code), as well as the Law of the Republic of Kazakhstan "On advertising" and determine the procedure for advertising of medicines and medical devices.

Footnote. Paragraph 1 - in the wording of the order of the Minister of Healthcare of the Republic of Kazakhstan dated 05.09.2022 № RK MH-94 (shall enter into force upon expiry of ten calendar days after the day of its first official publication).

2. The following terms and definitions are used in these Rules:

1) advertising of medicines and medical products (hereinafter - advertising) - information disseminated and (or) placed in any form, using any means, intended for an indefinite group of persons, containing individual information or a set of information about medicines and medical products, contributing to their promotion and implementation;

2) scientific information material - information or a set of information about a medicine and a medical product containing scientific and analytical data, disseminated in the form of scientific articles, guidelines, teaching aids;

3) applicant - an individual or legal entity (organization - manufacturer, distributor, representative office) or their authorized representative authorized to submit an application, documents and materials for assessment of advertising materials for medicines and medical products;

4) advertising material - documents and materials used in the assessment of advertising of medicines and medical products for compliance with the requirements of the legislation of the Republic of Kazakhstan in the field of healthcare, received from the applicant;

5) advertising module - a text and graphic message of an advertising nature about medicines and medical products, made on paper (booklet, leaflet, etc.) and distributed in health care organizations and (or) placed in print media;

6) advertising article - an informational article containing an advertisement for a medicine and a medical device;

7) advertising audio - an audio product of an advertising nature about medicines and medical products posted on radio and Internet resources;

8) advertising banner - one or a series of text and graphic images of an advertising nature about medicines and medical products, posted on Internet resources;

9) advertising video - an audiovisual work of an advertising nature about medicines and medical products posted on television channels and Internet resources;

10) storyboard - a sequence of drawings that serve as an auxiliary tool for creating videos and advertising banners;

11) advertising distributor - an individual or legal entity that distributes and places advertising information by providing and (or) using property, including technical means of television and radio broadcasting and in other ways;

12) As excluded by the order of the Minister of Healthcare of the Republic of Kazakhstan dated 05.09.2022 № RK MH-94 (shall enter into force upon expiry of ten calendar days after the day of its first official publication).

Footnote. Paragraph 2 as amended by the order of the Minister of Healthcare of the Republic of Kazakhstan dated 05.09.2022 № RK MH-94 (shall enter into force upon expiry of ten calendar days after the day of its first official publication).

Chapter 2. Procedure for advertising of medicines and medical products

3. Distribution and placement of advertising of medicines and medical products is carried out in the media, electronic information resources in healthcare organizations.

4. Advertising is provided in the Kazakh and Russian languages and contains complete and reliable information about the medicine or medical product, contributing to their rational use.

5. Advertising corresponds to the instructions for medical use of the medical product (leaflet), instructions for medical use or operational document for the medical product.

When changes are made to the instructions for medical use of a medicine and medical product that affect the content of advertisements distributed, the changes are reflected in the advertising materials.

6. Advertising does not exaggerate the pharmacological properties and therapeutic indications of the advertised medicine, the field of application for medical products, and also excludes comparisons with other medicines and medical products.

Advertising does not mislead consumers through abuse of their trust, including in relation to characteristics, composition, consumer properties, cost (price), intended results of use, research and test results.

The advertisement is easy to read, printed in a clear and legible font, is reliable and recognizable (no special knowledge or the use of special tools).

7. Advertising of medicines contains the following information:

1) trade name;

2) international non-proprietary name or information about the active ingredients included in the composition;

3) the main indications for use;

4) method of administration and dose;

5) the main side effects;

6) main contraindications;

7) special instructions for use by children, pregnant women, as well as during breastfeeding (if any);

8) release conditions;

9) a clear and understandable recommendation before prescribing and using, carefully read the instructions for medical use and the text of the warning with the following content " Self-medication can be harmful to your health;

10) name, address of the manufacturer and (or) sales representative in the Republic of Kazakhstan;

11) the number and date of issue of the registration certificate;

12) the expiration date of the registration period.

Advertising intended for TV channels and Internet resources contains the information specified in subparagraphs 1), 3), 7), 9), 11), 12), for radio channels the information specified in subparagraphs 1), 3), 7), 9) of this paragraph.

8. Advertising of medical products contains the following information:

1) trade name;

2) the main indications for use (scope);

3) main side effects (if any);

4) main contraindications (if any);

5) a clear and understandable recommendation before prescribing and using, carefully read the instructions for medical use (operational document) of the medical product and the text of the warning with the following content "Self-medication may be harmful to your health" (as applicable);

6) name, address of the manufacturer and (or) the authorized representative in the Republic of Kazakhstan;

7) number and date of issue of the registration certificate;

8) the expiration date of the registration period.

Advertising intended for TV channels, Internet resources contains the information specified in subparagraphs 1), 2), 5), 6), 7), 8), for radio channels the information specified in subparagraphs 1), 2), 5), 6) of this paragraph.

9. Advertising of medicines and medical products does not include:

1) information related to human health or diseases;

2) instructions for medical use, trade catalogs, price lists, reference materials, scientific information material, methodological and educational materials of a medical nature;

3) information about an individual and (or) legal entity that manufactures or sells a medicine and (or) a medical product;

4) as excluded by the order of the Minister of Healthcare of the Republic of Kazakhstan dated 05.09.2022 № № RK MH-94 (shall enter into force upon expiry of ten calendar days after the day of its first official publication).

Footnote. Paragraph 9 as amended by the order of the Minister of Healthcare of the Republic of Kazakhstan dated 05.09.2022 № RK MH-94 (shall enter into force upon expiry of ten calendar days after the day of its first official publication).

10. Advertising of medicines and medical products is prohibited in the cases provided for by paragraph 3 of Article 56 of the Code.

11. The advertising distributor shall place advertising when the applicant provides the conclusion of the subordinate organization of the authorized body, whose competence includes the assessment of health technologies (hereinafter referred to as the Center) on the compliance of advertising with the legislation of the Republic of Kazakhstan in the field of healthcare.

Footnote. Paragraph 11 - in the wording of the order of the Minister of Healthcare of the Republic of Kazakhstan dated 05.09.2022 № RK MH-94 (shall enter into force upon expiry of ten calendar days after the day of its first official publication).

12. In order to obtain an opinion on the compliance of advertising with the requirements of the legislation of the Republic of Kazakhstan in the field of health care, the applicant shall conclude an agreement with the Center on the assessment of advertising materials for medicines and medical devices and shall provide the following documents and materials:

1) application in the form according to Annex 1 to these Rules;

2) advertising material on paper and electronic media in Kazakh and Russian (module, article, storyboard of video advertising or banner, advertising text of audio advertising);

3) video, audio recordings of advertising in Kazakh and Russian when distributed on video, radio channels;

4) operational document of the medical device (in case of advertising for medical devices)
;

5) information confirming the payment by the applicant to the settlement account of the Center of the amount for the evaluation of advertising materials for medicines and medical devices.

The cost of evaluation of promotional materials for medicinal products and medical devices shall be paid by the applicant in accordance with the price list approved by the Center
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Footnote. Paragraph 12 - in the wording of the order of the Minister of Healthcare of the Republic of Kazakhstan dated 05.09.2022 № RK MH-94 (shall enter into force upon expiry of ten calendar days after the day of its first official publication).

13. The responsible executive of the Center, after receiving within one working day, shall register the documents provided for in paragraph 12 of these Rules.

Footnote. Paragraph 13 - in the wording of the order of the Minister of Healthcare of the Republic of Kazakhstan dated 05.09.2022 № RK MH-94 (shall enter into force upon expiry of ten calendar days after the day of its first official publication).

14. After receiving the documents provided for in paragraph 1 to the Rules, the Center shall verify the completeness of the submitted documents and materials within ten (10) working days and evaluate the advertising materials of medicines and medical devices for compliance with the requirements of the legislation of the Republic of Kazakhstan and these Rules.

Footnote. Paragraph 14 - in the wording of the order of the Minister of Healthcare of the Republic of Kazakhstan dated 05.09.2022 № RK MH-94 (shall enter into force upon expiry of ten calendar days after the day of its first official publication).

15. If in the submitted documents and materials non-conformities with the requirements stipulated by Article 56 of the Code and paragraphs 5-8 of these Rules are detected, the Center send a letter to the applicant once indicating the identified comments and the need to eliminate them in full within 10 (ten) working days from the date of receipt of the letter by the Center.

Footnote. Paragraph 15 - in the wording of the order of the Minister of Healthcare of the Republic of Kazakhstan dated 05.09.2022 № RK MH-94 (shall enter into force upon expiry of ten calendar days after the day of its first official publication).

16. The term for the applicant's elimination of comments is not included in the general term for the assessment of advertising materials for medicines and medical products provided for in paragraph 14 of these Rules.

17. If the applicant fails to provide a response to the Center's letter or fails to eliminate the comments made within the established time frame, the Center shall send the applicant a reasoned refusal to evaluate the advertising materials of medicines and medical devices.

In cases of motivated refusal based on the results of evaluation of advertising materials for medicines and medical devices or withdrawal by the applicant of the application for evaluation of advertising materials for medicines and medical devices after the start of evaluation of advertising materials for medicines and medical devices by the Center, the cost of the work is not returned to the applicant.

Footnote. Paragraph 17 - in the wording of the order of the Minister of Healthcare of the Republic of Kazakhstan dated 05.09.2022 № RK MH-94 (shall enter into force upon expiry of ten calendar days after the day of its first official publication).

18. The result of the assessment of advertising materials for medicines and medical products is drawn up by an act of expert assessment of advertising materials for medicines and medical products for compliance with the requirements of the legislation of the Republic of Kazakhstan in the field of healthcare in the form in accordance with Appendix 2 to these Rules (hereinafter - the act).

19. On the basis of the act, the applicant shall be issued a Conclusion on the compliance of advertising of medicines with the requirements of the legislation of the Republic of Kazakhstan in the field of health care in the form according to Annex 3 or a Conclusion on the compliance of advertising of medical devices with the requirements of the legislation of the Republic of Kazakhstan in the field of health care in the form according to Annex 4 to these Rules or a reasoned refusal in writing.

Upon completion of the evaluation of advertising materials for medicines and medical devices, the Center shall return to the applicant advertising information in paper form in Kazakh and Russian (module, article, video ad or banner storyboard, audio ad text) with the stamp of the Center "Assessment for compliance with the legislation of the Republic of Kazakhstan has been carried out" indicating the number and date of the expert assessment report and the signature of the individual who assessed the advertising materials of medicines and medical devices.

Footnote. Paragraph 19 - in the wording of the order of the Minister of Healthcare of the Republic of Kazakhstan dated 05.09.2022 № RK MH-94 (shall enter into force upon expiry of ten calendar days after the day of its first official publication).

Annex 1 to the Rules
for advertising
medicines and medical devices
Form

Application

Footnote. Annex 1 – in the wording of the order of the Minister of Healthcare of the Republic of Kazakhstan dated 05.09.2022 № RK MH-94 (shall enter into force upon expiry of ten calendar days after the day of its first official publication).

Applicant: _____

legal address: _____

telephone: _____

__

fax: _____

applicant's email address: _____

Applicant's representative:

_____

_

(Full name (if any), position, power of attorney attached) phone:

_____

_

fax: _____

email address: _____

Please _____

(full name of the Center)

Evaluate the promotional materials of the medicinal product, medical device (underline as necessary) for compliance with the legislation of the Republic of Kazakhstan in the field of healthcare. trade name

_____

international non-proprietary name (if any)

_____

dosage form, strength, packaging (for drug product)

_____

dispensing conditions (for drug product)

_____

at the same time, we hereby inform you that the specified medicinal product, medical device (to be emphasized) shall be registered in the Republic of Kazakhstan.

Registration certificate No _____ "____" _____ _____

Medicinal product, medical device passed quality assessment in the Republic of Kazakhstan.

Certificate of conformity No ___, date of ___, issued by the _____ name of the organization

We hereby attach to the application: advertising on paper in Kazakh and Russian (module, article, storyboard of video advertising or banner, advertising text of audio advertising) and on electronic media in PDF format in Kazakh and Russian (underline as necessary); video, audio recording of advertising in Kazakh and Russian when placing advertising on television channels and radio (underline as necessary).

№	Paying entity	
1.	Name	

3.	Legal address	
4.	Actual address	
5.	Full name (if any), position	
6.	Phone number	
7.	Fax	
8.	e-mail	
9.	BIN	
10.	IIN	
11.	Bank	
12.	Settlement account	
13.	Currency account	
14.	Code	

Applicant _____

Decryption of signature (personal signature)

Annex 2 to the Rules
for advertising
medicines and medical devices
Form

Certificate of expert evaluation of advertising materials for medicinal products and medical devices for compliance with the requirements of the legislation of the Republic of Kazakhstan in the field of health care from "___" _____ ___ № _____

Footnote. Annex 2 – in the wording of the order of the Minister of Healthcare of the Republic of Kazakhstan dated 05.09.2022 № RK MH-94 (shall enter into force upon expiry of ten calendar days after the day of its first official publication).

№	Advertising requirements	Fulfillment of requirements in the submitted information
1. General information		
1.	Trade name	
2.	International nonproprietary name or composition (if any)	
3.	Release form, dosage of active substance (s) (if any)	
4.	Manufacturing organization	
5.	Applicant name of the advertisement	
6.	Medicinal product, medical device registered in the Republic of Kazakhstan	Marketing authorization № ___ date of issue_____
7.	Medicinal product, medical device shall have a certificate of conformity	№, date of issue, name of the issuing organization
8.	Medicinal product subject to (not subject to) control in the Republic of Kazakhstan	

9.	The advertised drug product shall be dispensed from pharmacy organizations (by prescription, without a doctor's prescription)	
10.	Advertising shall be presented in Kazakh and Russian	
11.	The content of advertising in Kazakh shall be authentic to the content of advertising in Russian	
2. Evaluation of advertising material for compliance with the requirements established by the legislation of the Republic of Kazakhstan		
12.	Advertising shall be recognized without special knowledge or the use of special means and shall show that the advertised product is a drug, a medical device	
13.	Advertising shall contribute to the rational use of advertised products contains the following information:	
	main indications	
	main contraindications	
	mode of administration and dose	
	main side effects	
	drug interactions (for prescription drugs)	
14.	Advertising of medicinal products, medical device shall contain information on special indications, contraindications and side effects when used for children, pregnant and lactating women	
15.	Inappropriate advertising:	
	Advertising shall be unfair	
	contain a comparison of advertised products with products of other individuals or legal entities	
	contain statements, images discrediting the honor, dignity and business reputation of individuals or legal entities	
	mislead consumers about the advertised products by copying the brand name, trademark, brand packaging, external design of the goods of another manufacturer, formulas, images and other commercial designations or by abuse of their trust	

15.1	contain indications or statements, the use of which is misleading about the nature, method of manufacture, properties, suitability for use or quantity of the product	
	suggest that the effectiveness of treatment or use of advertised drugs and medical devices is guaranteed, the reception or use of advertised products is not accompanied by the development of side effects	
	present the medicinal product, medical device as unique, most effective and safe	
	there shall be comparative characteristics of changes in the human body, organs before and after the use of drugs and medical devices	
	discredit, humiliate or ridicule individuals who do not use advertised means	
15.2	Advertising shall be unreliable there are false information regarding:	
	nature, composition, method and date of manufacture, purpose, consumer properties, conditions of use, product quality, certification marks and signs of compliance with state standards, quantity, origin, shelf life, cost (price)	
	official recognition, receiving medals, prizes, diplomas and other awards	
	exclusive rights to the advertised product	
	statements discrediting the activities of others	
	status or level of competence of the manufacturer, individuals selling and advertising the product	
	there shallbe claims that the safety and effectiveness of drugs is due to its natural origin	
15.3	Advertising shall be unethical:	
	contains textual, visual, audio information that violates generally accepted standards of humanity and morality by using offensive words, comparisons	
	Advertising shall be knowingly false :	

15.4	deliberately misleading the advertising consumer	
	be accompanied by incorrect or misleading terms	
15.5	Advertisements shall be hidden:	
	has an unconscious impact on the consumer's perception, instincts in video, audio products, as well as other products, through the use of special video inserts, double sound recording and other methods	
16.	The presence in advertising of information prohibited in accordance with the legislation of the Republic of Kazakhstan	
16.1	on exclusive or preferential use for children (except for medicinal products intended for children)	
16.2	information leading to erroneous self-diagnosis (description of disease symptoms)	
16.3	on the absence of the need for medical consultations or surgical operations	
16.4	use of the image of a medical, pharmaceutical worker, famous individuals	
16.5	mention in advertising for the population of sexually transmitted diseases, cancer, mental, dangerous infectious diseases, HIV, tuberculosis, chronic insomnia, diabetes mellitus	
16.6	mention in advertising for the population about alcohol and smoking	
16.7	contains links to recommendations of scientists, health workers, public servants, famous individuals	
17.	Advertising contains subscript information about the registration of the advertised product in the Republic of Kazakhstan	
18.	Advertising contains interlinear information on the need to study the instructions for medical use or operational documents for medical devices (the time duration of the recommendation in advertising distributed on television and radio	

	channels is not less than three seconds, not less than 7% of the frame area)	

Conclusion: The submitted advertising materials comply (do not comply) with the legislation of the Republic of Kazakhstan in the field of healthcare.

We hereby consider it possible (impossible) to carry out advertising (in the media) to the act attached:

1. Advertising on paper in Kazakh and Russian languages (module, article, storyboard of video advertising or banner, advertising text of audio advertising) and on electronic media.

2. Video, audio recording of advertising in Kazakh and Russian when distributed on television and radio channels.

3. Conclusion on the compliance of advertising of medicines, medical devices with the requirements of the legislation of the Republic of Kazakhstan in the field of health care or a reasoned refusal in writing.

Title, personal signature, and signature transcript of the advertising evaluator

Annex 3 to the Rules
of advertising
of medicines and medical devices
Form

Conclusion on compliance of drug advertising with the requirements of the legislation of the Republic of Kazakhstan in the field of healthcare

Footnote. Annexx 3 – in the wording of the order of the Minister of Healthcare of the Republic of Kazakhstan dated 05.09.2022 № RK MH-94 (shall enter into force upon expiry of ten calendar days after the day of its first official publication).

The center reports the results of the assessment of the advertising material of the drug for compliance with the requirements of the legislation of the Republic of Kazakhstan in the field of health

	Trade name of the medicinal product (indicating the dosage form, strength, concentration and filling volume, number of doses in the package - for	International	Manufacturing	Marketing authorization	Certificate of conformity (	Advertising material submitted	
						(module, banner, article, video, audio)	number of pages, video

№ r/n	the medicinal product)	Nonproprietary Name (INN)	organization, manufacturing country	number, date, validity period	number, date, issued by whom)		sec, audio sec
1	2	3	4	5	6	7	8

Conclusion: _____

Application advertising _____

_

(Module, article, storyboard of video advertising or banner, text of audio advertising on paper media, audio-video recording on electronic media)

The presented advertising materials do not contradict the legislation of the Republic of Kazakhstan in the field of healthcare; we hereby consider it possible to carry out advertising

_____

_

(in mass media)

Position, personal signature and decryption of the signature of the head of the center

_____ Date of _____

Annex 4 to the Rules
of advertising
of medicines and medical devices
Form

Conclusion on compliance of medical device advertising with the requirements of the legislation of the Republic of Kazakhstan in the field of healthcare

Footnote. Annex 4- in the wording of the order of the Minister of Healthcare of the Republic of Kazakhstan dated 05.09.2022 № RK MH-94 № KP (shall into force upon expiry of ten calendar days after the day of its first official publication).

The center reports the results of the assessment of the advertising material of the medical device for compliance with the requirements of the legislation of the Republic of Kazakhstan in the field of health

№ r/n	Trade name of the	Manufacturing	Marketing authorization	Certificate of conformity	Promotional material submitted		

	medical device	organization, manufacturing country	number, date, validity period	number, date, issued by	(module, banner, article, video, audio)	number of pages, video sec, audio sec	
1	2	3	4	5	6	7	

Conclusion: _____

Application advertising _____

_

(Module, article, storyboard of video advertising or banner, text of audio advertising on paper media, audio-video recording on electronic media)

The presented advertising materials do not contradict the legislation of the Republic of Kazakhstan in the field of healthcare; we hereby consider it possible to carry out advertising

_____

_

(In mass media)

Position, personal signature and decryption of the signature of the head of the Center

_____ Date of _____

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