



On approval of the Rules for ethical promotion of pharmaceuticals and medical devices

Invalidated Unofficial translation

Order of the Minister of Healthcare of the Republic of Kazakhstan No. KR DCM-69 as of May 8, 2019. Registered with the Ministry of Justice of the Republic of Kazakhstan on May 13, 2019, No. 18654.

Unofficial translation

Footnote. It became invalid by Order of the Minister of Health of the Republic of Kazakhstan dated December 21, 2020 No. KR DCM -294/2020 (effective after the expiration of ten calendar days after the date of its first official publication).

In accordance with subparagraph 67-1) of paragraph 1 of Article 7 of the Code of the Republic of Kazakhstan “On Public Health and the Healthcare System” as of September 18, 2009, I hereby ORDER:

1. To approve the appended Rules for ethical promotion of pharmaceuticals and medical devices.

2. In accordance with the procedure established by the legislation, the Pharmacy Committee of the Ministry of Healthcare of the Republic of Kazakhstan shall:

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

2) within ten calendar days of the state registration of this order with the Ministry of Justice of the Republic of Kazakhstan, send its copy in Kazakh and Russian in paper-based and electronic forms to the Republican State Enterprise with the Right of Economic Management “Republican Center of Legal Information” of the Ministry of Justice of the Republic of Kazakhstan for its official publication and inclusion into the Reference Control Bank of Regulatory Legal Acts of the Republic of Kazakhstan;

3) place this order on the website of the Ministry of Healthcare of the Republic of Kazakhstan;

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

3. The control over the execution of this order shall be assigned to the supervising deputy minister of healthcare of the Republic of Kazakhstan, K.T.Nadyrov.

4. This order shall take effect ten calendar days of its first official publication.

Approved
by Order № KR DCM-69 as of
May 8, 2019 of the

Rules for ethical promotion of pharmaceuticals and medical devices

Chapter 1. General provisions

1. These Rules for ethical promotion of pharmaceuticals and medical devices (hereinafter referred to as the Rules) determine the order of ethical promotion of pharmaceuticals and medical devices.

2. The main terms used in the Rules are as follows:

1) pharmaceutical - a product containing either a substance or a combination of substances, coming into contact with the human body, intended for the treatment, prevention of human diseases or the restoration, correction or change of its physiological functions through pharmacological, immunological or metabolic effects, or for diagnosing diseases and human condition;

2) pharmaceuticals' turnover– activities including the development, preclinical (nonclinical) research, testing, clinical trials, examination, registration, pharmacovigilance, quality control, production, manufacturing, storage, transportation, import and export, dispensing, sales, transfer, use, destruction of pharmaceuticals;

3) advertising of pharmaceuticals and medical devices - information disseminated and placed in any form, by any means, intended for public at large, containing items of information or totality of data about pharmaceuticals and medical devices, contributing to their promotion and sale;

4) ethical promotion of pharmaceuticals and medical devices - activities carried out in the course of promoting safe, high-quality and effective pharmaceuticals and medical devices from the developer and (or) manufacturer of a pharmaceutical or medical device to their use by consumers, based on fair competition and responsibility of all parties involved;

5) facilities in the field of turnover of pharmaceuticals and medical devices - a pharmacy, a drugstore in healthcare organizations providing primary health care and (or) consultative and diagnostic assistance, a mobile drugstore for remote rural areas arranged by a pharmacy, a pharmacy (distribution) depot, temporary depot of pharmaceuticals, medical devices, optical store, medical device store, medical device depot, organizations manufacturing pharmaceuticals and medical devices;

6) entities in the field of turnover of pharmaceuticals and medical devices - individuals or legal entities engaged in pharmaceutical activities;

7) manufacturer of pharmaceuticals– an organization engaged in the production of pharmaceuticals and licensed to manufacture pharmaceuticals;

8) the authorized body in the field of healthcare (hereinafter referred to as the authorized body) - the central executive body exercising leadership and intersectoral

coordination in the field of public health, medical and pharmaceutical science, medical and pharmaceutical education, sanitary and epidemiological welfare of the population, turnover of pharmaceuticals and medical devices, quality control of medical services;

9) healthcare entities - healthcare organizations, as well as individuals engaged in private medical practice and pharmaceutical activities;

10) daily medical conference - a planned meeting of a medical facility aiming to review the past day, discuss and analyze clinical cases, and inform the team about new achievements in medical science and clinical practice;

11) medical devices - any instruments, units, devices, equipment, materials and other products used for medical purposes either individually or in combination with each other, and also with accessories necessary for the intended use of these devices, including special software, are intended by the manufacturer of a medical device for the prevention, diagnosis, treatment of diseases, medical rehabilitation and monitoring of the human body, conducting medical research, restoration, substitution, changes of the anatomical structure or physiological functions of the body, prevention or termination of pregnancy, and the functional purpose of which is not realized through pharmacological, immunological, genetic or metabolic effects on the human body, and can be supported by the use of pharmaceuticals;

12) turnover of medical devices - design, development, prototyping, technical testing, research (testing) of the biological effects of medical devices, clinical trials, examinations of safety, quality and effectiveness of medical devices, registration, production (manufacturing), storage, transportation, sale, installation, commissioning, use (operation), maintenance, repair and disposal of medical devices;

13) manufacturer of a medical device - an entity in the field of turnover of pharmaceuticals and medical devices, responsible for the development and manufacture of a medical device, making it available for use on his/her/its own behalf, regardless of whether it is designed and (or) manufactured by this or another person (or other persons) on his/her/its behalf, and responsible for its safety, quality and effectiveness;

14) patient - an individual who is (was) a consumer of medical services;

15) pharmaceutical workers - individuals with a pharmaceutical education engaged in pharmaceutical activities.

3. These Rules apply to healthcare entities, entities in the field of turnover of pharmaceuticals and medical devices, medical and pharmaceutical workers, and members of professional associations.

4. For the purposes of efficient use of pharmaceuticals and medical devices, healthcare entities, members of professional associations and entities in the field of turnover of pharmaceuticals and medical devices shall comply with the conditions for ethical promotion of pharmaceuticals and medical devices in accordance with

paragraph 3 of Article 86-3 of the Code of the Republic of Kazakhstan “On Public Health and the Healthcare System” as of September 18, 2009 (hereinafter referred to as the Code).

Chapter 2. Procedure for ethical promotion of pharmaceuticals and medical devices

Clause 1. Ethical interaction in promoting pharmaceuticals and medical devices

5. The entities operating in the field of turnover of pharmaceuticals and medical devices, when interacting with each other, and also with healthcare entities, members of professional associations, shall follow the principles of legality, transparency, in order to improve the quality of medical care and develop medical technology and innovation.

6. Representatives of manufacturers and (or) distributors of pharmaceuticals and medical devices may promote pharmaceuticals and medical devices in medical facilities and medical educational institutions at daily medical conferences, scientific conferences and (or) specialized seminars.

7. Ten calendar days before their planned participation in a daily medical conference, representatives of manufacturers and (or) distributors shall get written approval of the time and topic of the event from the head of a healthcare organization.

8. Manufacturers, distributors or authorized representatives on the basis of a power of attorney, as well as other entities operating in the field of turnover of pharmaceuticals and medical devices authorized to promote pharmaceuticals and medical devices, are not allowed to have individual contacts with medical and pharmaceutical workers during their working hours and at the workplace with the aim of promoting pharmaceuticals and medical devices.

9. The below indicated is not allowed in the course of interaction of entities operating in the field of turnover of pharmaceuticals and medical devices:

1) provision or offer of financial compensation or any other financial or nonfinancial incentives to medical and pharmaceutical workers for their prescription and dispensing of specific pharmaceuticals;

2) payment for entertainment, recreation, travel to the place of recreation, except for the payment related to scientific and educational activities;

3) conclusion of agreements, organization of promo actions for prescribing and recommending pharmaceuticals and medical devices to patients with the involvement of medical workers, in order to obtain material benefits, except for written official agreements on medical research;

4) provision of samples of pharmaceuticals and medical devices to patients, except for cases not prohibited by the legislation of the Republic of Kazakhstan;

5) encouragement to prescribe pharmaceuticals and medical devices on non-standard prescription forms, including those containing advertising information, and also on those with pre-printed names of pharmaceuticals and medical devices;

6) organization of events with giving material and non-material prizes, gifts to the heads of pharmacy organizations and pharmaceutical workers for achieving certain sales results.

10. When entities operating in the field of turnover of pharmaceuticals and medical devices interact with healthcare entities and members of professional associations, it is allowed to:

1) provide complete, unbiased, accurate and confirmed information in the form of reference, medical literature, scientific journals to healthcare entities and members of professional associations during daily medical conferences, scientific and practical conferences and (or) specialized seminars;

2) provide targeted funding, grants for scientific and medical research, advanced training, purchase of a medical device, pharmaceuticals, medical services, charitable contributions, provided it is not aimed at prescribing pharmaceuticals and medical devices by healthcare entities.

The procedure for formalizing contractual relations between charity entities and users is established in accordance with the legislation of the Republic of Kazakhstan.

3) provide assistance for participation in scientific and practical conferences, congresses, symposia in a field appropriate to a healthcare entity or a member of professional associations.

The support of medical and pharmaceutical workers, which enables them to take part in scientific and practical conferences, congresses, symposia, shall not be conditional upon their obligations to facilitate the promotion of any pharmaceuticals or medical devices. In this case, the entity operating in the field of turnover of pharmaceuticals and medical devices signs an agreement with medical and pharmaceutical workers that business trip expenses do not obligate them to promote the entity's pharmaceuticals and medical devices.

4) supply healthcare organizations with unregistered pharmaceuticals and medical devices to provide medical care according to the vital indications of a particular patient or to provide medical care to a limited number of patients with rare and (or) especially severe pathology in accordance with paragraph 3 of Article 80 of the Code;

5) create patient registers subject to strict observance of legislation on the protection of personal data and medical confidentiality.

11. When entities operating in the field of turnover of pharmaceuticals and medical devices interact with members of professional associations, it is not allowed to

encourage members of professional associations to make decisions in the process of carrying out their statutory activities in favor of entities operating in the field of turnover of pharmaceuticals and medical devices.

12. Members of professional associations do not allow facts of financial and other conspiracies to obtain benefits when promoting certain pharmaceuticals and medical devices, but make efforts to suppress such actions.

13. Members of professional associations make decisions solely in the interests of patients, resist manifestations of corruption and contribute to improving the health of citizens of the Republic of Kazakhstan.

14. When representatives of manufacturers and (or) distributors interact with pharmaceutical workers of retail sales facilities, the below indicated is allowed:

1) informing pharmaceutical workers about manufactured or marketed pharmaceuticals and medical devices;

2) display (placement) of pharmaceuticals available without prescription and medical devices in the glass case of the shopping space of the pharmacy organization;

3) placement of information and advertising that must comply with the applicable law and these Rules in the pharmacy organization and on its website.

15. In the course of scientific activities aimed at professional development of medical and pharmaceutical workers financed by an entity operating in the field of turnover of pharmaceuticals and medical devices, it is not allowed to impede the participation in these activities of other entities that manufacture or sell pharmaceuticals and medical products with similar mechanism of action, or discriminate against individual participants.

16. When covering the results of clinical, post-marketing and other medical research at scientific and practical conferences, congresses, symposia, a speaker shall reveal a conflict of interest with entities operating in the field of turnover of pharmaceuticals and medical devices.

Clause 2. Information and advertising of pharmaceuticals and medical devices in ethical promotion of pharmaceuticals and medical devices

17. Information and (or) advertising of pharmaceuticals and medical devices in the Republic of Kazakhstan shall comply with the requirements of the current legislation of the Republic of Kazakhstan and these Rules.

18. Advertising of pharmaceuticals and medical devices shall be reliable, recognizable without special knowledge or use of special tools, exclude comparisons with other pharmaceuticals and medical devices, and not mislead consumers through abuse of their confidence, also in terms of characteristics, composition, consumer properties, cost (price), expected effect, research and testing results.

19. The advertising of pharmaceuticals and medical devices shall not contain:

1) comparison of advertised products with other pharmaceuticals and medical devices;

2) statements, images discrediting the honor, dignity and business reputation of individuals or legal entities engaged in the sale of pharmaceuticals and medical devices ;

3) information prompting suggestions that a pharmaceutical is a food, cosmetic or consumer product;

4) information that suggests guaranteed therapeutic effect from the use of a pharmaceutical, medical device, that the intake or use of a pharmaceutical, a medical device, as the most effective and safe one, does not imply the development of adverse reactions or events;

5) comparison of changes in the human body, organs before and after the use of pharmaceuticals and medical devices;

6) statements that contribute to the emergence or development of the fear of getting sick or worsening one's state of health because of non-use of advertised pharmaceuticals and medical devices;

7) references to specific cases of successful use of pharmaceuticals and medical devices, recommendations of medical workers, healthcare organizations, including medical educational institutions, regarding advertised pharmaceuticals, medical devices ;

8) expressions of gratitude, letters, excerpts from them with recommendations, stories about the effects of advertised pharmaceuticals and medical devices;

9) images and references to the names of popular people, heroes of cinema, television, and animated films, credible organizations;

10) information that may give the impression that it is not required to consult with a medical worker when using a pharmaceutical and medical device;

11) incomplete, inaccurate, unconfirmed, biased and false information;

12) statements enabling to diagnose diseases, pathological conditions independently and treat them independently using advertised pharmaceuticals and medical devices.

20. The information used in the promotion of pharmaceuticals and medical devices complies with medical instruction, published evidence-based data on the proven clinical efficacy and safety of a pharmaceutical; it does not contain misleading conclusions that may entail unreasonable use of pharmaceuticals and medical devices with possible risks for the patient.

21. All statements about pharmaceuticals and medical devices in the information and advertising used for their promotion shall be confirmed by links to published data. The links shall precisely indicate the source of information, date of publication, author (s) of the study. In order to avoid misinterpretation of the results, it is necessary to

indicate how the research data were obtained (invitro, or animal studies, or studies involving patients).

22. The advertising of pharmaceuticals and (or) medical devices shall contain a requirement to see a doctor before using them and a text warning that: “Self-medication can be harmful to your health”.

Clause 3. Ethical promotion of pharmaceuticals and medical devices by entities and facilities operating in the field of turnover of pharmaceuticals and medical devices

23. The manufacturer, distributor or their authorized representatives on the basis of a power of attorney, as well as other entities operating in the field of turnover of pharmaceuticals and medical devices, authorized to promote pharmaceuticals and medical devices, ensure:

- 1) ethical promotion of pharmaceuticals and medical devices;
- 2) dissemination of advertising in accordance with current legislation;
- 3) professional training and advanced training of its representatives, also in issues of ethical promotion of pharmaceuticals and medical devices.

24. Medical and pharmaceutical workers comply with the obligations established by paragraph 6 of Article 182 of the Code.

25. Specialists of retail facilities of pharmaceuticals and medical devices comply with the conditions specified in paragraph 4 of Article 86-3 of the Code when dispensing a pharmaceutical.

Clause 4. Ethical promotion of pharmaceuticals and medical devices by healthcare entities

26. In accordance with paragraph 4 of Article 86-3 of the Code, medical workers prescribing pharmaceuticals are not allowed to participate in the advertising of pharmaceuticals and medical devices and recommend certain retail facilities of pharmaceuticals and medical devices to their patients motivated by receipt of remuneration for their services.

27. Medical workers are governed by paragraph 4 of Article 86-3 of the Code when prescribing pharmaceuticals with international nonproprietary names within their competence given appropriate medical indications, except for cases of individual patient intolerance. If a pharmaceutical has no international nonproprietary name, it is allowed to write its composition in a prescription.

28. When contacting manufacturers, distributors or authorized representatives on the basis of a power of attorney, as well as other entities operating in the field of turnover of pharmaceuticals and medical devices authorized to promote pharmaceuticals and medical devices, medical and pharmaceutical workers observe generally accepted moral and ethical standards, show courtesy and civility, do not

allow financial and other conspiracies to obtain personal benefits from prescribing specific pharmaceuticals and medical devices to patients, and also make efforts to suppress such actions taken by their colleagues.

29. The head of a healthcare organization ensures employees' compliance with these Rules when interacting with manufacturers, distributors or authorized representatives on the basis of a power of attorney, as well as other entities operating in the field of turnover of pharmaceuticals and medical devices authorized to promote pharmaceuticals and medical devices.

30. Manufacturers, distributors or authorized representatives on the basis of a power of attorney, as well as other entities operating in the field of turnover of pharmaceuticals and medical devices, authorized to promote pharmaceuticals and medical devices, take measures to eliminate and prevent unethical promotion of pharmaceuticals and medical devices, also based on recommendations of the Commission for ethical promotion of pharmaceuticals and medical devices set up in accordance with Clause 5 of these Rules.

Clause 5. Activities of the Commission for ethical promotion of pharmaceuticals and medical devices

31. The Commission for ethical promotion of pharmaceuticals and medical devices (hereinafter referred to as the Commission) is a permanent collegial body set up by territorial bodies of the office of the authorized body in the field of healthcare to consider complaints, materials and issues on unethical promotion of pharmaceuticals and medical devices.

32. The Commission consists of representatives of local public health authorities, health organizations, and professional associations. The number of the Commission members shall be odd and consist of at least 5 people, including the chairman.

33. The composition of the Commission is approved by the head of the territorial body of the office of the authorized body in the field of healthcare, who is the chairman of the Commission.

34. Performing its functions, the Commission:

1) considers complaints on unethical promotion of pharmaceuticals and medical devices;

2) upon agreement, hears at its meetings representatives of local public health authorities, healthcare organizations, representatives of professional associations, manufacturers, distributors or authorized representatives on the basis of a power of attorney, as well as other entities operating in the field of turnover of pharmaceuticals and medical devices authorized to promote pharmaceuticals and medical devices;

3) requests necessary information;

4) makes recommendations to the heads of local public health authorities, healthcare organizations, professional associations, manufacturers, distributors;

5) makes proposals to the authorized body in the field of healthcare for the development of measures aimed at preventing unethical promotion of pharmaceuticals and medical devices.

35. The Commission's chairman:

- 1) heads the Commission, organizes and supervises its work;
- 2) determines the agenda of meetings of the Commission;
- 3) convenes and chairs meetings of the Commission;
- 4) appoints a speaker on a specific issue to be considered at a meeting of the Commission;

5) based on the results of the Commission's work, sends recommendations and proposals;

6) on a quarterly basis, provides a report on the Commission's performance to the office of the authorized body in the field of healthcare.

In the absence of the Commission's chairman, one of the members of the Commission acts as chairman.

36. The Commission's secretary is an employee of the territorial body of the office of the authorized body in the field of healthcare who:

- 1) keeps the minutes of a meeting of the Commission;
- 2) manages the Commission's paperwork.

37. The decision of the Commission shall be documented in the minutes signed by the Chairman of the Commission and sent to interested parties and organizations within ten working days.

38. The Commission's secretary notifies the members of the Commission of the date, place of a meeting, its agenda and familiarizes with relevant materials three working days before the meeting of the Commission.

39. The Commission's meetings:

- 1) are considered competent if attended by at least two-thirds of the total number of the Commission members;
- 2) are held as necessary and in case of complaints.

40. The Commission takes decisions by a majority vote of attending members of the Commission. If the vote is a tie, the casting vote belongs to the chairman.

41. Based on the results of the consideration of complaints on unethical promotion of pharmaceuticals and medical devices, the Commission makes one of the following decisions:

- 1) to send recommendations on calling to account and taking necessary measures to prevent unethical promotion of pharmaceuticals and medical devices to the heads of local public health authorities, healthcare organizations, professional associations (in

case of membership), manufacturer or distributor, as well as other entities operating in the field of turnover of pharmaceuticals and medical devices authorized to promote pharmaceuticals and medical devices;

2) does not confirm facts of unethical promotion of pharmaceuticals and medical devices.

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