On approval of the rules for the ethics of promoting pharmaceuticals and medical devices

Unofficial translation

Order № KR DSM-294/2020 of the Minister of Healthcare of the Republic of Kazakhstan as of December 21, 2020. It is registered with the Ministry of Justice of the Republic of Kazakhstan on December 22, 2020 under № 21870

Unofficial translation

In accordance with paragraph 2 of Article 265 of the Code of the Republic of Kazakhstan "On Public Health and Healthcare System" as of July 7, 2020, **I** hereby **ORDER**:

1. To approve the appended rules for the ethics of promoting pharmaceuticals and medical devices.

2. To invalidate Order № KR DSM-69 of the Minister of Healthcare of the Republic of Kazakhstan as of May 8, 2019 "On approval of the Rules for ethical promotion of pharmaceuticals and medical devices" (registered in the State Registration Register of Regulatory Legal Acts under № 18654, published in the Reference Control Bank of Regulatory Legal Acts of the Republic of Kazakhstan on May 16, 2019).

3. In accordance with the procedure established by the legislation of the Republic of Kazakhstan, the Department for Drug Policy of the Ministry of Healthcare of the Republic of Kazakhstan shall ensure:

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

2) the posting of this order on the website of the Ministry of Healthcare of the Republic of Kazakhstan after its official publication;

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

4. Control over the execution of this order shall be entrusted to the supervising vice-minister of healthcare of the Republic of Kazakhstan.

5. This order shall be enforced ten calendar days of its first official publication.

Minister of Healthcare of the Republic of Kazakhstan — *A.Tsoi*

Appendix to Order
№ KR DSM-294/2020
of the Minister of Healthcare
of the Republic of Kazakhstan as of
December 21, 2020

Rules for the ethics of promoting pharmaceuticals and medical devices

Chapter 1. General provisions

1. These Rules for the ethics of promoting pharmaceuticals and medical devices (hereinafter referred to as the Rules) are developed in accordance with paragraph 2 of Article 265 of the Code of the Republic of Kazakhstan "On Public Health and Healthcare System" as of July 7, 2020 (hereinafter referred to as the Code) and establish the order of the ethics of promoting pharmaceuticals and medical devices.

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

1) pharmaceutical - a product that is either a substance, or the one containing 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) ethics of promoting 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, including the one performing online sales, a drugstore in healthcare organizations, 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) an authorized person of a manufacturer of pharmaceuticals - a person responsible for ensuring and controlling the quality of pharmaceuticals produced by the manufacturer in

accordance with the legislation of the Republic of Kazakhstan in the field of healthcare and included in the register of authorized persons of pharmaceuticals' manufacturers;

9) 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 in the Republic of Kazakhstan, 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 (care);

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

11) 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;

12) medical devices – medical products and medical equipment;

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 (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 regardless of whether he/she has or hasn't a disease or condition requiring medical care;

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

16) healthcare worker - an individual with a professional medical education and engaged in medical activities.

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

Chapter 2. The procedure for the ethics of promoting pharmaceuticals and medical devices

4. Pharmaceuticals and medical devices are promoted by a manufacturer, distributor or their authorized representatives, as well as other entities in the field of turnover of pharmaceuticals and medical devices duly authorized to promote pharmaceuticals and medical devices, through mutual interaction of entities in the field of turnover of pharmaceuticals and medical devices, as well as with healthcare entities and members of professional associations.

5. A manufacturer, distributor or their authorized representatives, as well as other entities in the field of turnover of pharmaceuticals and medical devices duly authorized to promote pharmaceuticals and medical devices, ensure:

1) the ethics of promoting pharmaceuticals and medical devices;

2) the distribution of advertising in accordance with applicable law;

3) professional training and advanced training of their representatives, also in the ethics of the promotion of pharmaceuticals and medical devices.

6. For the purposes of ethics of promoting pharmaceuticals and medical devices, 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, develop medical technology and innovation.

7. In relations with manufacturers, distributors or authorized representatives, as well as other entities in the field of turnover of pharmaceuticals and medical devices authorized to promote pharmaceuticals and medical devices, healthcare and pharmaceutical workers observe generally accepted moral and ethical standards, show politeness and tactfulness, deny financial and other collusion for personal gain when prescribing certain pharmaceuticals and medical devices to patients, and also make efforts to suppress such actions on the part of their colleagues.

8. When entities operating in the field of turnover of pharmaceuticals and medical devices interact with healthcare entities and members of professional associations, they:

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, scientific information material, instructions for medical use of registered pharmaceuticals and medical devices, including pharmaceuticals and medical devices unregistered in the Republic of Kazakhstan for the provision of medical care for life-saving indications of a particular patient or the provision of medical care to a limited patient cohort with rare (orphan) diseases and (or) conditions;

2) 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 healthcare 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 healthcare and pharmaceutical workers that business trip expenses do not obligate them to promote the entity’s pharmaceuticals and medical devices;

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

4) conclude contracts for conducting clinical trials, clinical and economic research, epidemiological and other types of research not prohibited by the legislation of the Republic of Kazakhstan (the results of clinical, economic and epidemiological research shall contribute to the rational use of pharmaceuticals).

5) conduct marketing research among pharmaceutical workers aimed at studying and analyzing various aspects of the functioning of the pharmaceutical industry and market.

9. To participate in daily medical conferences held by medical facilities and educational institutions in the field of healthcare, representatives of manufacturers and (or) distributors shall get written approval of the time and topic of the event from the head of a healthcare entity ten calendar days before their planned participation in a daily medical conference.

10. When conducting scientific events aimed at improving the professional level of healthcare and pharmaceutical workers, which are funded by an entity operating in the field of turnover of pharmaceuticals and medical devices, it is not allowed to prevent other entities manufacturing or selling pharmaceuticals and medical devices with a similar mechanism of pharmacological action from participation in these events, or discriminate against individual participants.

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

12. The head of a healthcare entity ensures that healthcare workers comply with the requirements of these Rules when interacting with manufacturers, distributors or authorized representatives, as well as other entities operating in the field of turnover of pharmaceuticals and medical devices that are authorized to promote pharmaceuticals and medical devices.

13. Manufacturers, distributors or authorized representatives, 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 healthcare and pharmaceutical workers during their working hours and at the workplace with the aim of promoting pharmaceuticals and medical devices.

14. 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.

15. Members of professional associations shall deny financial and other collusions to obtain benefits when promoting certain pharmaceuticals and medical devices, but make efforts to suppress such actions.

16. 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.

17. When representatives of manufacturers and (or) distributors interact with pharmaceutical workers of retail sales facilities, it is allowed to:

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

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

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

4) conduct marketing research aimed at studying and analyzing various aspects of the functioning of the pharmaceutical industry and market.

18. In the course of interaction of entities operating in the field of turnover of pharmaceuticals and medical devices, the below indicated is considered to be violations of the ethics of promoting pharmaceuticals and medical devices:

1) provision or offer of financial compensation or any other financial or nonfinancial incentives to healthcare 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 actions for prescribing and recommending pharmaceuticals and medical devices to patients with the involvement of healthcare workers, in order to obtain material benefits, except for written official agreements on biomedical, clinical and economic, epidemiological and other types of research not prohibited by the legislation of the Republic of Kazakhstan, as well as agreements on participation in ongoing marketing 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 pharmacies and pharmaceutical workers for achieving certain sales results.

19. Manufacturers, distributors or authorized representatives, 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 violations of the Rules.