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LATEST AMENDMENTS TO THE KAZAKHSTAN LEGISLATION ON THE ETHICS OF PROMOTION AND ADVERTISING OF MEDICINES AND MEDICAL PRODUCTS

IMPORTANT!

The adoption of the new <u>Code</u> on People's Health and Healthcare System (hereinafter, the "Code") in Kazakhstan in 2020 entailed the update of a number of subordinate regulatory legal acts, including the <u>Rules</u> for Advertising¹ and the <u>Ethics of Promotion</u>² of medicines and medical products, as well as the adoption of new regulations, for example, the <u>Code</u> of Honor of Healthcare Professionals and Pharmaceutical Employees³.

Please see below the most important amendments in this sphere.

Detailed Description of the Types of Advertising Materials

- The concept of an advertising module was updated. From now on, understood as an advertising module is a text and graphic message of advertising nature about a medicine and a medical product prepared on paper (flyer, leaflet, etc.), which is distributed in healthcare organizations and/or placed in printed mass media.
- The law-maker determined the types of advertising materials for the use at radio and television channels and on the Internet resources (audio advertisement, video advertisement and advertising banner).

Sources for Placing and Disseminating the Advertising

Advertising of medicines and medical products may be disseminated and placed in mass media and electronic information resources at healthcare organizations, i.e. in the framework of healthcare organizations advertising of medicines and medical products is literally allowed only in the form of electronic information resources. Please note that it is prohibited to advertise prescription medicines in mass media (according to Article <u>56.3</u> of the Code, which is also referenced in the subordinate act).

Change of Procedure for Expert Review of Advertising Materials as to Compliance with Requirements of the Kazakhstan Legislation

- Expert review is a fee-paid service according to a price list of an expert organization, which is conducted under a relevant contract.
- The term of expert review was reduced from 20 to 11 business days; however, in the

¹ Order No. ҚР ДСМ-288/2020 of the Minister of Health of the Republic of Kazakhstan "On Approval of the Rules for Advertising of Medicines and Medical Products" dated 20 December 2020 (entered into force on 4 January 2021).

² Order No. KP ДCM-294/2020 of the Minister of Health of the Republic of Kazakhstan "On Approval of the Rules for Ethical Promotion of Medicines and Medical Products" dated 21 December 2020 (entered into forced on 8 January 2021).

³ Order No. KP ДCM-319/2020 of the Minister of Health of the Republic of Kazakhstan "On Approval of the Code of Honor of Healthcare Professionals and Pharmaceutical Employees of the Republic of Kazakhstan" dated 23 December 2020 (put into effect on 29 December 2020).

event of discovering incompleteness of the submitted documents or unreliable data, a letter is sent once to an applicant containing respective comments and an indication on the necessity to eliminate the drawbacks in full within 10 business days, and such period is not included in the general expert review term.

Updated Conceptual Framework in the Sphere of Ethics of Promotion of Medicines and Medical Products

Along with clarification of a number of concepts (patient, object in the sphere of circulation of medicines and medical products, etc.), the law-maker introduced the concept of an authorized person of a medicine manufacturer, which means a person liable for assurance and control over the quality of medicines manufactured by the manufacturer in accordance with the Kazakhstan legislation in the healthcare sphere, which is included in the register of authorized persons of the medicine manufacturers.

Re-Consideration of Allowed Methods of Interaction between the Subjects in the Sphere of Circulation of Medicines and Medical Products

- The list of allowed methods of interaction of subjects in the sphere of circulation of medicines and medical products between themselves and healthcare entities and members of professional associations no longer contains the provision of specialpurpose financing, grants for scientific and medical researches, advanced training, procurement of medicines, medical products, medical services, charitable contributions; and provision to healthcare organizations of non-registered medicines and medical products for provision of medical care according to living conditions of a specific patient or provision of medical care to a limited range of patients with a rare and/or supersevere pathology.
- At the same time, the law-maker introduced the conclusion of contracts for clinical trials, clinical feasibility studies, epidemiological and other types of studies not prohibited by the Kazakhstan legislation into the allowed methods of interaction of subjects in the sphere of circulation of medicines and medical products between themselves and healthcare entities and members of professional associations; and added a possibility to conduct market researches aimed at review and analysis of various aspects of functioning of pharmaceutical industry and market to the list of allowed methods of interaction of representatives of manufacturers and/or distributors with pharmaceutical employees of medicines and medical products retail trade facilities.

Key Rights and Obligations of Healthcare Professionals and Pharmaceutical Employees Included in the Code of Honor

Along with other obligations, healthcare professionals and pharmaceutical employees are not allowed to use official position to solve personal issues, advertise medicines and accept gifts and services from individuals and legal entities in connection with the performance of official duties. In the event of presenting the groundless public accusations of corrupt practices, healthcare professionals and pharmaceutical employees must take measures to refute them within one-month period of the date of discovering such accusations.

Should you have any additional questions in connection with this Legal Update, we would be happy to provide more detailed information.

Contact details:

Yuliya Chumachenko Partner y.chumachenko@aequitas.kz

Legal Updates shall not be treated as a legal advice or a reason for making specific decisions on the Kazakh law issues. Should you need a legal advice, we would be happy to assist.

www.aequitas.kz 47 Abai Ave., Office 2, Almaty 050000 Republic of Kazakhstan +7 727 3 968 968 aequitas@aequitas.kz