International Comparative Legal Guides

Pharmaceutical Advertising 2026

A practical cross-border resource to inform legal minds

23rd Edition

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1 General – Medicinal Products

1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

The advertising of medicinal products in Kazakhstan is governed by:

- **The Advertising Law** – Law of the Republic of Kazakhstan No. 508-II dated 19 December 2003 "On Advertising".
- **The Advertising Rules** – Order of the Minister of Healthcare of the Republic of Kazakhstan No. ҚР ДСМ-288/2020 dated 20 December 2020 "On Approval of the Rules for Advertising Medicinal Products and Medical Devices".
- **The AI Law** – Law of the Republic of Kazakhstan No. 230-VIII dated 17 November 2025 "On Artificial Intelligence".
- **The Code of Honor** – Order of the Minister of Healthcare of the Republic of Kazakhstan No. ҚР ДСМ-319/2020 dated 23 December 2020 "On Approval of the Code of Honor for Medical and Pharmaceutical Professionals of the Republic of Kazakhstan".
- **The Health Code** – Code of the Republic of Kazakhstan No. 360-VI dated 7 July 2020 "On the Health of the Nation and the Healthcare System".
- **The Languages Law** – Law of the Republic of Kazakhstan No. 151-I dated 11 July 1997 "On Languages in the Republic of Kazakhstan".
- **The Mass Media Law** – Law of the Republic of Kazakhstan No. 93-VIII dated 19 June 2024 "On Mass Media".
- **The Online Advertising Law** – Law of the Republic of Kazakhstan No. 18-VIII dated 10 July 2023 "On Online Platforms and Online Advertising".
- **The Promotion Ethics Rules** – Order of the Minister of Healthcare of the Republic of Kazakhstan No. ҚР ДСМ-294/2020 dated 21 December 2020 "On Approval of the Rules of Ethics for the Promotion of Medicinal Products and Medical Devices".

And a number of other sectoral laws and subordinate acts, as well as professional association codes (e.g., Association of International Pharmaceutical Manufacturers in the Republic of Kazakhstan (AIPM)).

1.2 How is "advertising" defined?

It should be noted that the definition of advertising differs across various regulatory legal acts. For example, a general definition is provided in the Advertising Law. *Advertising* is information disseminated and/or placed in any form, by any means, intended for an indefinite circle of persons and designed to form or maintain interest in a natural or legal person, goods, trademarks, works or services, and to facilitate their sale or use.

The definition of advertising for medicinal products or medical devices is slightly different, with a key element being the presence of information about the medicinal product or medical device: *advertising of medicinal products and medical devices* is information disseminated and/or placed in any form, by any means, intended for an indefinite circle of persons, containing some information or a set of information about medicines or medical devices, facilitating their promotion and sale.

There is also a separate definition for online advertising.

1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

The necessary measures depend on the type of advertising and should be assessed individually. For example, if advertising of medicinal products or medical devices is planned, a positive opinion from the state expert authority must be obtained before launching the advertising campaign – namely, the Salidat Kairbekova National Scientific Center for Healthcare Development of the Ministry of Healthcare of the Republic of Kazakhstan (NSCHD).

According to the Good Pharmacovigilance Practice (GVP) standards, the marketing authorisation holder must obtain approval from the relevant competent authority regarding the content of *non-promotional safety information* intended for direct communication with healthcare system professionals and the associated information plan.

Outdoor visual advertising is not permitted for advertising of medicinal products and medical devices. However, in cases where outdoor visual advertising is allowed, a notification with the required documents (including confirmation of payment of the state fee) attached must be submitted to the local executive authorities at least five working days prior to the planned date of placement. We will not address issues related to outdoor advertising and its requirements further in this chapter, as it is permitted in the pharmaceutical sector only in a limited number of cases and is rarely used in practice.

1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?

Standard Operating Procedures (SOPs), in addition to other

internal regulatory and instructional documents, are mandatory in Kazakhstan within the Good x Practice (GxP) system (Good Manufacturing Practice, Good Distribution Practice, GVP, Good Clinical Practice (GCP), Good Pharmacy Practice and Good Laboratory Practice) to ensure consistent compliance with regulatory requirements for the manufacture and circulation of medicinal products, quality control, validation, pharmacovigilance, personnel and training, facilities, warehouse operations, document management and other operational processes. However, GxP standards do not regulate advertising and promotion, except for provisions aimed at adjusting promotional materials in response to identified risks within the framework of pharmacovigilance.

The laws of Kazakhstan do not establish a direct obligation to adopt a specific SOP regarding the administration of advertising within a pharmaceutical company, including when hiring relevant personnel. Nevertheless, the GVP standards in Kazakhstan and the Eurasian Economic Union (EAEU) require a clear separation between advertising and promotional materials and educational materials concerning product safety.

Due to the numerous regulatory requirements and restrictions on advertising in the healthcare sector, and because advertising and promotion are directly linked to product specifics, safety, scientific and clinical data, the approved registration dossier and the instructions for medical use, adopting internal SOPs for advertising is strongly recommended to ensure compliance.

In practice, it is advisable to implement SOPs (or other internal regulatory documents) addressing: anti-corruption policies; the development and approval of advertising and promotional materials; interactions with stakeholders in the healthcare sector, including healthcare professionals; gifts, hospitality and charitable activities; and compliance monitoring. It should be noted that both SOPs and other internal regulatory documents must be adopted strictly in forms permitted under Kazakh law, such as Instructions, Regulations, Rules and certain other document types.

1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?

Before placing advertising for medicinal products and medical devices, the advertiser must obtain a positive expert opinion from the NSCHD. To do so, the applicant enters into an agreement with the NSCHD, pays the service fee, submits an application in the prescribed form along with the advertising materials, and provides certain other information.

This approval verifies that the advertisement's content aligns with the established criteria for public distribution and adheres to current advertising regulations.

According to established practice and considering specific restrictions on advertising, the NSCHD does not issue opinions for advertising prescription (Rx) medicines, making such advertising effectively impossible.

It should be noted that there are certain products for which advertising is generally prohibited (e.g., narcotic substances, etc.); in this chapter, we will not focus on these types of products. For advertising of other objects (e.g., the company itself), obtaining an opinion is not required. Potentially, in disputed situations, the company may request the view of the NSCHD or the Ministry of Healthcare regarding contentious advertising issues; however, it is likely that the NSCHD will not conduct an expert review of materials for which the law does not establish such a requirement. Nevertheless, sometimes it is possible to obtain clarifications on other questions concerning the advertising of medicinal products and medical devices.

1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?

Under Article 19 of the Advertising Law, in the event of a confirmed violation of the advertising legislation of Kazakhstan, the person responsible for the violation is required to immediately, but no later than three calendar days, cease the dissemination and placement of the non-compliant advertisement and publish a corrective statement at its own expense. If the statement is not carried out within the prescribed period, it must be carried out by the advertising distributor, who then has the right of recourse to recover costs from the violator.

Additionally, under Article 426 of the Code of Administrative Offences, the Committee for Medical and Pharmaceutical Control may impose fines and, in some cases, prohibit further activity.

In general, challenging any decisions of the administrative authorities is possible in Kazakhstan, and this procedure is governed by a number of regulatory acts, including the Administrative Procedure and Procedural Code, the Health Code and some other laws.

Under Article 55 of the Health Code, in the case of disagreement with the violations indicated in the recommendation, a company has the right to submit an objection to the state authority in the field of circulation of medicinal products and medical devices within five business days from the day following the receipt of the recommendation.

In the case of control conducted in other forms (for example, inspections), the companies being inspected also have the right to challenge the requirements, to which other time limits may apply. It is important to note the deadline: a complaint regarding the inspection report and the order to remedy identified violations in the healthcare sector must be submitted to the higher authority within 10 working days after the inspection report has been signed (Article 29.5 of the Health Code). Subsequently, if one disagrees with the decision of the higher authority, it can be challenged in court.

1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases, please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?

The Code of Administrative Offences establishes more than 12 types of violations that may be related to advertising, including knowingly false advertising, unfair competition, participation of healthcare professionals in advertising, violations of the rules for advertising medicinal products, advertising of unregistered or unauthorised medicinal products, misleading advertising, advertising of prohibited goods, unethical or covert advertising, violations of language requirements in advertising, dissemination of false information in mass media and on online platforms, violations related to AI, and others.

In general, advertising matters fall within the competence of various national and local authorities, including the Ministry of National Economy, the Ministry of Culture and Information, the Ministry of Healthcare and local executive bodies. Direct oversight of advertising in the healthcare sector is carried out by the Committee for Medical and Pharmaceutical Control (for medicinal products and medical devices) and the Committee for Sanitary and Epidemiological Control of the Ministry of Healthcare (for products under its supervision, including biologically active food supplements and cosmetics).

In the event of a violation of the advertising requirements for products subject to sanitary and epidemiological control, in addition to administrative liability, operational measures may be applied, such as the seizure and withdrawal of the products from circulation (Article 45.7 of the Health Code). For medicinal products, confiscation is possible in cases of non-compliance with pharmacovigilance obligations (the Rules on Seizure were approved by Order of the Acting Minister of Healthcare of the Republic of Kazakhstan No. ҚР ДСМ-322/2020 dated 24 December 2020), as well as in cases of advertising unregistered or unauthorised medicinal products and medical devices (Article 426.3 of the Code of Administrative Offences).

A repeated violation of the advertising rules for medicinal products and medical devices within a year may result in the suspension of the company's pharmaceutical activity licence (Article 426.2 of the Code of Administrative Offences).

The amount of any fines imposed depends on the type of violation and the type of the liable party (official, individual or small, medium or large business entity). For example, under Article 426.1 of the Code of Administrative Offences, legal entities are subject to fines of 130, 200 or 1,000 monthly calculation indices (MCI) (currently ≈ USD 1,157, 1,780 or 8,900) per each violation subject to a certain cumulative limit. MCI is adjusted annually by law.

In the case of advertising unregistered or unauthorised medicinal products and medical devices, under Article 426.3, fines of 200, 300 and 1,500 MCI (≈ USD 1,780, 2,670 or 13,350) will be imposed for legal entities, along with additional measures such as confiscation of medical products, confiscation of revenue and suspension of the company's activities.

In the event that public health is harmed, an enhanced and more severe liability regime may be applied, and the individual may be held criminally responsible.

In recent years, the competent authority has not been very active in inspecting publicly placed advertising of medicinal products. The regulator's focus has primarily been on other pressing industry issues, such as price regulation and the transition to regional registration of medicines. At the same time, several administrative decisions regarding medicinal product advertising have been made publicly available, and there have been certain high-profile cases of advertising on marketplaces.

Notably, in 2020, a physician was held administratively liable for participating in the advertising of medicinal products in exchange for remuneration.

In 2025, following a complaint from one company, an inspection of another pharmaceutical company was conducted for violations of the rules on advertising and promotion of medicinal products; the offending company was held liable. However, in 2026, the decision was revoked on procedural grounds due to violations in the inspection process.

In 2025, due to widespread advertising and sales of an unregistered medicinal product (tirzepatide) on marketplaces, the Committee for Medical and Pharmaceutical Control issued instructions to territorial departments to conduct inspections based on these facts.

To strengthen oversight of advertising for medicinal products and medical services, the Ministry of Healthcare approved in the same year a Roadmap for identifying and preventing instances of illegal advertising of medicinal products, dietary supplements and medical services.

The publicly available database of court decisions in Kazakhstan provides valuable examples of actual cases; however, additional cases in this area may exist beyond what is currently accessible.

1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?

The AIPM Ethics Committee operates separately from the Committee for Medical and Pharmaceutical Control and the judicial system.

State authorities will not participate in resolving disputes concerning violations of an industry association's code, as their competence is limited to overseeing compliance with laws only.

Theoretically, if the bodies of an industry association identify a violation of the *law* in the activities of a pharmaceutical company, a report may be submitted to a state authority for initiating administrative liability. In practice, this measure appears to be highly unlikely.

It should be noted that the AIPM 2024 Code of Ethics is not binding for companies that are not members of the association. In other words, it is not a general regulatory document for the industry and applies only as sectoral regulation for association members.

1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?

Acts such as knowingly false, misleading or unreliable advertising and other unfair business practices are prohibited by the Entrepreneurial Code. The Agency for Protection and Development of Competition (APDC) has the power to: conduct investigations; request documents; have free access to premises, databases and products; take photographs and video recordings; impose administrative fines; and exercise other rights.

Any interested party, including a competitor, may file a complaint with the APDC.

1.10 Do the above rules apply to statements by healthcare providers (such as clinics or pharmacies) and members of the public (including influencers), as well as to pharmaceutical companies?

According to the Promotion Ethics Rules (Clause 4), the promotion of medicinal products and medical devices may be carried out by (1) manufacturers, (2) distributors, (3) their authorised representatives, and (4) other organisations and individuals legally engaged in pharmaceutical activities (including pharmacies) who are granted appropriate promotion authority. Promotion involves interactions among these entities/persons as well as with healthcare organisations and members of professional associations.

Other parties, such as bloggers or influencers, or service providers are not included among those authorised to promote products. Nevertheless, a wide range of promotional services are offered in Kazakhstan by specialised providers, including visits to healthcare professionals, information dissemination, educational events, physician surveys, "mystery shopper" services, mobile applications and digital systems, analytics programmes, targeted advertising, physician databases, selection of physicians for interactions based on prescribing patterns, patient demographics and position, advertising on e-commerce platforms including via AI and online platforms, patient support programmes, call centres and other promotion methods. Because these services fall under the same advertising and promotion rules, their use must be subject to compliance verification. For example, individual physician visits are not approved under legislation, and any operations involving physicians' personal data require informed consent for collection and processing. Anti-corruption obligations remain highly relevant. Algorithmic profiling of users' preferences and/or interests based on their health data is prohibited, including for the purpose of targeted advertising in the healthcare sector.

Under the Advertising Law (Article 6.4), advertisers engaged in licensable activities must indicate their licence in any advertising. Dissemination of advertising of medical services, methods, and means of prevention, diagnosis, treatment and rehabilitation by an entity without the relevant licence, as well as advertising of biologically active food supplements without state registration, constitutes an administrative offence under Article 428 of the Code of Administrative Offences. Moreover, the Health Code (Article 56.3.5) prohibits advertising of medicinal products and medical devices in organisations unrelated to their prescription, use or dispensing.

Healthcare professionals bear administrative responsibility for participating in medicinal product advertising, including referrals to pharmacies or other organisations for remuneration (Article 424.5 of the Code of Administrative Offences). Conversely, requiring a medical professional to perform an unlawful act (e.g., promoting medicinal products or meeting a medical representative during working hours) may result in liability for the pharmaceutical company (Article 80-1 of the Code of Administrative Offences). Influencers or bloggers may be liable under Article 456-2.5 for publishing unlawful content or other violations, such as advertising medical services or treatment methods without a licence, publishing medicinal product advertising without a positive NSCHD opinion or failing to label online advertising appropriately. Multiple provisions also impose liability for data protection violations.

Thus, the promotion of medicinal products and medical devices in Kazakhstan is strictly regulated, and all participants – including healthcare professionals, companies and influencers – are subject to legal, administrative and compliance obligations.

2 Providing Information Prior to Authorisation of Medicinal Product

2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?

Advertising of medicinal products and medical devices not registered in Kazakhstan is completely prohibited (Article 56.3.1 of the Health Code). Advertising of unregistered or unauthorised medicinal products and medical devices is considered an administrative offence and may result in a fine under Article 426.3 of the Code of Administrative Offences.

At the same time, the Promotion Ethics Rules permit providing healthcare professionals and members of professional associations with *non-advertising* – complete, objective, accurate and substantiated information in the form of reference materials, medical literature and scientific journals during daily medical conferences, scientific-practical conferences and/or specialised seminars, as well as scientific-informational materials and instructions for the medical use of registered medicinal products and medical devices. This includes medicinal products and medical devices *not registered in Kazakhstan*, provided they are used to deliver medical care based on life-threatening indications for a specific patient or to provide medical care to a limited group of patients with rare (orphan) diseases and/or conditions.

These rules apply regardless of who organises the events.

Regarding off-label use, this issue is not straightforward in law. In particular, the legislation recognises that such use is possible. For example, a clinical protocol may officially include treatment methods for indications not specified in the instructions for medical use and not approved by the state authority in the field of circulation of medicinal products, provided that they are included in the Kazakhstan National Medical Formulary guide and foreign clinical guidelines. Consequently, such information may be accessible to the medical community and legally used. For example, clinical protocols for the treatment of bronchopulmonary dysplasia, cytomegalovirus infection and certain other diseases include descriptions of the off-label use of some medicinal products.

At the same time, pharmacovigilance rules provide examples of off-label use that are not in accordance with the general characteristics of a medicinal product or its instructions for medical use – these include (1) intentional use for a different indication, (2) in a different patient group (e.g., another age group), (3) by a different method or mode of administration, or (4) at a different dosage. Such information may be important for performing data analysis and evaluating adverse reaction cases and should be included in the pharmacovigilance report under the section "Additional Information on the Medicinal Product". Within pharmacovigilance, an assessment is also conducted on the potential for using a medicinal product outside its approved indications.

In this regard, it should be noted that although off-label use is practically possible, it may be in certain cases (that are not specified by clinical protocol) identified as non-compliant use and may entail liability for the physician or liability for the company for improper advertising (which must comply with the approved instructions).

The AIPM 2024 Code of Ethics provides more direct regulation regarding pre-registration information. A pharmaceutical product may not be *promoted* before its registration is approved in Kazakhstan. This provision is not intended to restrict the right of the scientific community or the public to access complete information on scientific and medical progress. It does not aim to limit the full and proper exchange of scientific information regarding pharmaceutical products, including the dissemination of research results through scientific or public media, as well as at scientific conferences, in accordance with the legislation. Public disclosure of information to shareholders and other parties regarding any pharmaceutical product is also not restricted, provided such disclosure is not prohibited by applicable law. Providing information about unregistered

pharmaceutical products, or about indications not included in the instructions for use of a registered medicinal product, is not considered promotion and is permissible if some of the conditions specified by the AIPM 2024 Code of Ethics are met. All responses must be based on the principles of evidence-based medicine, available scientific data and clinical research findings.

Therefore, actively promoting off-label use or unregistered medicines could potentially be viewed as non-compliant with the law, as a general approach with some exemptions.

2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?

Information on medicinal products and medical devices approved for use and circulation in the territory of Kazakhstan (through registration or import authorisation, or other relevant procedure), *on medicinal products that have not undergone state registration*, that do not comply with the legislation of Kazakhstan in the field of healthcare, on the withdrawal of a state registration decision, as well as on Rx medicines, may be provided in *specialised print publications intended for medical and pharmaceutical professionals*.

However, this pertains to *non-advertising* information and does not constitute advertising, since the advertising of unregistered medicinal products and medical devices is completely prohibited by the Health Code.

The line between advertising and *non-advertising* information is very thin, and every communication should be carefully reviewed to avoid violating the law.

Advertising of off-label use is not permitted. However, if such information is officially included in a clinical protocol, the clinical protocol may be published in a *non-advertising* manner.

Any other types of publications should be carefully reviewed for compliance and permissibility under the law.

Additionally, we would like to highlight that the GVP standards in Kazakhstan and the EAEU provide for a comprehensive set of information to be disseminated through various channels to ensure the safety and proper use of registered medicinal products. The primary target audiences are healthcare professionals, patients and the media. Means of communication include direct contact with healthcare professionals, materials for non-specialists, press materials, press conferences, press releases, websites, web applications, informational letters and bulletins, publications in scientific journals, educational programmes, preparation of manuals and other formats.

Such materials must be completely separated from advertising: no elements of product promotion, whether direct or indirect, are permitted. The main focus is on the risks associated with the medicinal product and their management, including risk minimisation measures, rather than on promoting or advertising the product. For educational materials, a procedure for approval and endorsement by the competent state authority is required. Additionally, the materials must include a disclaimer stating that they do not constitute advertising.

It should be emphasised that these rules legally apply to *registered* medicinal products within the pharmacovigilance system (including related core documentation). The use of similar mechanisms for unregistered medicinal products legally present in Kazakhstan (for example, imported under one-time authorisations) is not formally provided for by GVP. Nevertheless, from a practical perspective, it would be logical, since the purpose of disseminating information is exclusively to ensure patient safety. In this context, it is recommended to request the competent state authority about the possibility of sharing such safety information through various channels before such distribution.

2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. mainstream public media), please specify.

It is assumed that a press release in this context has a high promotional character, rather than, for example, serving as a notice regarding responsibility for improper use of a medicinal product or safety issues.

It should be noted that advertising in such cases is prohibited.

In particular, the communication should avoid: promotional claims regarding efficacy or safety; encouragement to prescribe, purchase or use the product; comparative or superiority claims; references suggesting availability on the Kazakhstan market; and other elements that may be interpreted as advertising.

At the same time, in the public domain in Kazakhstan, neutral news can be occasionally published. For example, a series of news reports was published regarding the financing by a charitable foundation for the purchase of the unregistered drug Zolgensma ("Help for Special Children: "Qazaqstan Khalqyna" will purchase the world's most expensive medicine for four children", "In Kazakhstan, the world's most expensive injection, Zolgensma, was administered for the first time",[1] "Four children in Kazakhstan received the world's most expensive drug"[2]).

We can also cite a recent press conference and subsequent publication titled: "Why the Launch of the Kazakh Cancer Drug Was Delayed". At a government press conference on 31 March 2026, the Minister of Science and Higher Education, Mr. Sayasat Nurbek, provided details on a Kazakh cancer medicine, not yet registered at the time, including when it would become available.[3] This example demonstrates that general news information is not treated by state authorities as advertising, and such information is even communicated by government bodies to the public.

However, if information describing the benefits of a future medicinal product were presented publicly by a pharmaceutical company in an appealing manner, it could be interpreted as advertising of an unregistered medicinal product, which is expressly prohibited under the Health Code.

In this regard, certain publications of brief, neutral news may generally be considered permissible according to the rational practice approach. For example, such *non-advertising* news can cover the inclusion of an unregistered medicinal product or indication in a clinical protocol, or general scientific news. However, due to the lack of sufficiently clear regulation on this matter in Kazakhstan, there always remains a risk of violating advertising compliance. Therefore, any such communication should be carefully assessed on a case-by-case basis, taking into account its wording, context, target audience, dissemination channel and overall promotional effect.

Please also note that the AIPM 2024 Code of Ethics prohibits the promotion of medicinal products prior to their official registration. This prohibition applies only to members of the association.

2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?

Direct individual interactions between medical sales representatives and healthcare professionals during working hours and at their workplace *for promotional purposes* are prohibited by the Promotion Ethics Rules.

In medical and educational organisations in the healthcare sector, the *promotion* of medicinal products and medical devices by representatives of manufacturers and/or distributors is prohibited by the Health Code, except during daily medical conferences, scientific-practical conferences and/or specialised seminars.

It is permissible to provide healthcare professionals and members of professional associations with complete, objective, accurate and substantiated information in the form of reference materials, medical literature and scientific journals during daily medical conferences, scientific-practical conferences and/or specialised seminars, as well as scientific-informational materials and instructions for the medical use of registered medicinal products and medical devices. This also includes medicinal products and medical devices *not registered* in Kazakhstan, provided they are used to deliver medical care based on life-threatening indications for a specific patient or to provide medical care to a limited group of patients with rare (orphan) diseases and/or conditions.

If a physician contacts the company directly and requests information about medicines, the company is obliged to provide it upon the physician's request. This is because, according to the Health Code (Article 265.3.2), patients, pharmaceutical and medical professionals must receive necessary and accessible information about medicinal products and their side effects. During promotion, it is necessary to ensure that all information provided regarding medicinal products and medical devices is complete, accurate and reflects their safety, quality and efficacy. It is important to note that such requests cannot be used to provide the physician with advertising information, unverified information or information that could pose any risks in the use of the medicinal product. Particular caution should be exercised in relation to unauthorised medicinal products and off-label information, as Kazakhstan legislation does not contain a clear and comprehensive framework expressly permitting promotional dissemination of such information.

It should be noted that, in order to regulate this issue, a draft law was submitted to the Parliament of Kazakhstan in December 2024 to amend the Health Code, allowing the use of medicinal products off-label (outside the approved instructions) when providing medical care based on life-threatening indications, provided there is proven efficacy in clinical protocols and/or international clinical guidelines (recommendations), and upon the decision of a medical consilium. However, to date, the law has not been adopted.

2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?

Kazakhstan is not an EU Member State and is not subject to EU directives or ECJ rulings. The *Ludwigs* case and Article 5 of Directive 2001/83/EC have no direct legal effect in Kazakhstan.

At the same time, according to the Advertising Rules, the following are not considered advertising of medicinal products and medical devices in Kazakhstan:

1) Information relating to human health or diseases.
2) Instructions for medical use, trade catalogues, price lists, reference materials, scientific-informational materials, and medical methodological and educational materials (please note that most of these materials have specific definitions).
3) Information about a natural or legal person manufacturing or marketing a medicinal product and/or medical device.

At the same time, the distribution of unregistered medicinal products in Kazakhstan is possible, provided that specific import authorisation requirements are met.

In general, indicating the price of a medicinal product may be interpreted as an offer for sale. Such an offer can only be made when the product is authorised for circulation or will be authorised for circulation (with an appropriate disclaimer regarding future application of the price, for example, in the case of obtaining a one-time permit for the import of an unregistered medicinal product). However, indicating the price should be considered impermissible in this context if the product is unregistered for adverse reasons, such as safety concerns.

2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?

Instructions for medical use, trade catalogues, price lists, reference materials, scientific-informational materials, and medical methodological and educational materials are not considered advertising.

The Promotion Ethics Rules explicitly permit providing healthcare organisations with complete, objective, accurate and substantiated information in the form of reference materials, medical literature and scientific journals during daily medical conferences, scientific-practical conferences and/or specialised seminars, as well as scientific-informational materials and instructions for the medical use of registered medicinal products and medical devices. This also includes medicinal products and medical devices *not registered* in Kazakhstan, provided they are used to deliver medical care based on life-threatening indications for a specific patient or to provide medical care to a limited group of patients with rare (orphan) diseases and/or conditions.

At the same time, providing this type of information is not mandatory and will not be included in the planned procedures for budget formation for procurement (for which special procedures are provided and information exchange may occur).

2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?

The Promotion Ethics Rules provide for the possibility of conducting marketing research among pharmaceutical professionals, aimed at studying and analysing various aspects of the functioning of the pharmaceutical industry and market. It is also possible to conclude agreements with medical organisations and healthcare professionals for participation in marketing research. However, there are various restrictions regarding which persons such agreements may be concluded with and under what circumstances. Please also refer to the additional information provided in the responses to the following questions.

3 Advertisements to Healthcare Professionals

3.1 What information must appear in advertisements directed to healthcare professionals?

According to the Advertising Rules (Clause 7), advertising of medicinal products must contain the following information:

1) Trade name.
2) International nonproprietary name or information on the active ingredients.
3) Main indications for use.
4) Method of administration and dosage.
5) Main side effects.
6) Main contraindications.
7) Special instructions regarding use in children, pregnant women and during breastfeeding (if applicable).
8) Conditions of dispensing.
9) A clear and understandable recommendation to carefully read the instructions for medical use and the following warning before prescription and use: "Self-medication may be harmful to your health".
10) Name and address of the manufacturer and/or trade representative in Kazakhstan.
11) Number and date of issuance of the registration certificate.
12) Expiration date of the registration.

In some cases, the Advertising Rules provide for a shortened list of information (e.g., for TV channels and internet resources). The Advertising Law also requires including information on the licence, which is not provided for in the Advertising Rules.

The Health Code also establishes general requirements for advertising, according to which it must be truthful, clearly recognisable without specialised knowledge or tools, avoid comparisons with other medicinal products and medical devices, and not mislead consumers by exploiting their trust. This includes claims regarding characteristics, composition, consumer properties, cost (price), expected outcomes, and results of studies and trials.

Advertising of medicinal products must provide complete and accurate information, including any relevant usage restrictions, since omission could lead to inappropriate use of the product or unjustified risk to the consumer. Additional requirements and restrictions for advertising also apply.

The Advertising Rules do not establish special requirements for advertising addressed specifically to healthcare professionals. In Kazakhstan, only limited methods of advertising placement are permitted. Moreover, placement may be carried out only in the manner specified in the opinion of the expert organisation and cannot be disseminated by other means (e.g., direct advertising mailings to healthcare professionals).

3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to: (a) studies not mentioned in the SmPC; or (b) studies which have not been published either in peer-reviewed journals or at all ("data on file")?

Under the Advertising Rules, advertising must correspond to the approved instructions for use and must be accurate and non-misleading.

References to studies outside the approved label carry significant risk of being classified as off-label promotion. Unpublished data and data on file are not specifically addressed under Kazakhstan law and may not be used for advertising.

The Health Code, the Advertising Rules, the Advertising Law and the Entrepreneurial Code, as well as other regulatory rules, also contain additional restrictions regarding the content and format of advertising.

3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?

The Health Code explicitly prohibits referencing in advertising the recommendations of scientists, healthcare professionals or officials of state authorities, who may encourage the use and/or prescription of medicinal products and medical devices.

3.4 What rules govern comparative advertisements? Is there a requirement for "head to head" clinical trial data? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?

Under the Advertising Rules and the Advertising Law, all and any comparisons with other medicines in pharmaceutical advertising are prohibited.

3.5 What rules apply to environmental "green" claims made in relation to specific products in promotional material?

The Health Code prohibits including in advertising any information that is not directly related to the advertised service, medicinal product or medical device, and also imposes requirements regarding the accuracy and reliability of statements used. Accordingly, information on environmental issues may (depending on the context of use) fall outside the permissible scope of content for advertising.

3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?

For this question, the Promotion Ethics Rules, the Anti-Corruption Law and the Health Code apply. The main regulations governing the dissemination of information are outlined in the answers to the previous questions. It should be noted that not all materials may be considered scientific, as there are specific regulations governing scientific activities.

3.7 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?

Since all advertising materials for medicines must be pre-approved and must contain the full mandatory information set out in the Advertising Rules, a teaser advertisement containing some information about medicinal products that omits mandatory content is not allowed.

3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?

Under the Advertising Rules, advertising must correspond to the approved instructions for medical use of the specific product being promoted. Advertisement of Products A and B may not include methods of use that are not specified in the medical instructions.

4 Gifts and Financial Incentives

4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?

Under Article 56.3.3 of the Health Code, distributing samples of Rx medicines for the purpose of advertising and promotion is explicitly prohibited.

The Promotion Ethics Rules prohibit providing samples of medicinal products and medical devices to patients, except in cases not prohibited by the legislation of Kazakhstan. Such permissive cases are not established in the legislation; therefore, providing over-the-counter (OTC) products as samples may also be considered unacceptable.

In addition, the Promotion Ethics Rules prohibit giving gifts to healthcare professionals in connection with their professional functions. It should also be noted that the sale of medicinal products by healthcare professionals at the workplace (including free-of-charge distribution) constitutes an administrative offence (Article 424.5 of the Code of Administrative Offences). Consequently, neither OTC nor Rx product samples may be provided to healthcare professionals.

4.2 Are there any restrictions on the value of payments or benefits that may be provided to healthcare professionals or healthcare organisations for consultancy services? Is it necessary to obtain advance approval from the authorities for the arrangements?

Healthcare professionals are divided into two categories: (1) those with whom a consultancy agreement can be concluded; and (2) those with whom such an agreement cannot be concluded due to anti-corruption or other applicable prohibitions.

For the first group, no payment limits are established by the law. However, in all cases, general ethical and anti-corruption rules apply, prohibiting the giving of gifts or other benefits in connection with the performance of professional duties.

Therefore, any payments must be justified by fair market value, the actual business value of the agreement's outcome, and must not constitute hidden incentives for the promotion of medicinal products.

It is important to note that pharmaceutical legislation does not directly regulate interactions with healthcare professionals in the form of general consultancy or expert service agreements (except for specific regulatory cases, such as agreements concluded within the framework of official research studies). Therefore, it is not possible to completely eliminate compliance risks in all cases of interaction. Nevertheless, in practice, such agreements are widely used.

It is recommended that the company maintain an interaction policy and an anti-corruption policy, which should establish clear and transparent rules for ordering and paying for relevant services to avoid compliance violations and associated risks.

It should also be noted that in the case of an absolute anti-corruption prohibition on concluding a paid agreement with a healthcare professional under the Anti-Corruption Law, such a prohibition cannot be circumvented by obtaining consent from a higher authority. However, in certain cases, requesting consent from a superior official or authority is recommended to confirm the absence of compliance obstacles and conflicts of interest before entering into an agreement.

4.3 Is it possible to give gifts, donations or grants to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.

Questions regarding the giving of gifts (including donations and grants) are governed by a range of regulatory acts, including the Anti-Corruption Law, the Promotion Ethics Rules, the Code of Honor, the Criminal Code, the Health Code and the Administrative Code. In general, giving gifts to medical and pharmaceutical professionals is not permitted regardless of value, as such gifts are typically related to the professional functions performed by these individuals. Consequently, both symbolic gifts and high-value incentives are equally prohibited.

It should be noted that, in practice, it is often assumed that certain limits or criteria exist for the permissibility of giving gifts to healthcare professionals. However, since such gifts are frequently directly related to the professional role of the recipient, which may involve prescribing or dispensing specific medicinal products, we consider that the legislation effectively prohibits giving such gifts to healthcare professionals.

4.4 Is it possible to give gifts, donations or grants to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply? If monetary limits apply, please specify.

For the purposes of answering this question, medical organisations should be divided into two groups: 1) public; and 2) private.

For private clinics, giving gifts and reimbursing expenses does not require approval from any state authorities.

For public hospitals, the situation is more complex, as a simple gift would require undergoing a special approval procedure with the competent state authorities. Moreover, there is no guarantee that the gift will be approved specifically for the chosen clinic, since such gifts become state property. However, if structured as a donation agreement under Article 516 of the Civil Code for general public benefit, it may be possible to avoid such approvals. A special legal regime and specific rules apply to donations for public-use purposes.

In all cases, no cost limits are in place for gifts in favour of legal entities. However, such gifts must not be linked to obligations

of the recipient organisations to promote specific medicinal products or otherwise distort ethics and competition.

For tax purposes, gifts provided free of charge for promotional purposes are not considered income if the value of a single unit does not exceed five times the monthly calculation index in effect on the date received.

4.5 Is it possible to provide donations or grants to healthcare professionals or healthcare organisations that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?

Under the Ethics Rules, any arrangement whereby a healthcare professional is expected to prescribe or in any manner promote the sponsor's products in return for a donation or grant (or other incentives) constitutes a prohibited inducement and is not allowed.

4.6 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?

No specific prohibition or permission exists in the Advertising Rules, and such discounts are also widely used in the market. However, regarding discounts, the competition protection rules established by the Entrepreneurial Code shall apply. In particular, such discounts must be offered on equal terms, must not discriminate between buyers, and must not result in a price so low as to create a monopoly advantage aimed at driving out competitors through aggressive price reductions, in accordance with the criteria set out in the legislation. Price reductions in the market may also, in some cases, lead to a decrease in the registered prices of products.

4.7 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable? If so, what rules apply?

In general, such types of transactions are possible. The civil law provisions of Kazakhstan will apply, and it is then necessary to assess tax and antitrust risks. In particular, it must be determined whether the provision of such goods or services is gratuitous or sold at a nominal price, whether it could result in discrimination against other comparable buyers, and how the transaction will affect the tax obligations of both parties, etc.

In addition, the Promotion Ethics Rules and anti-corruption regulations should be taken into account, as they do not permit the unlawful provision of benefits. As regards the transfer of equipment to state recipients, separate rules and restrictions apply.

4.8 Are more complex patient access schemes or managed access agreements, whereby pharmaceutical companies offer special financial terms for supply of medicinal products (e.g. rebates, dose or cost caps, risk share arrangements, outcomes-based schemes), permitted in your country? If so, what rules apply and does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?

Kazakhstan legislation primarily regulates pricing, circulation, promotion and procurement of medicinal products, including the provision of medicinal products and medical care within the framework of the state healthcare system (guaranteed volume of free medical care) and the state health insurance system.

Kazakhstan has also co-payment rules under which a patient may choose another medicinal product instead of the free product and pay the difference at their own expense. The co-payment rules were approved by Order of the Minister of Healthcare of the Republic of Kazakhstan No. ҚР ДСМ-61 dated 16 July 2021. Pharmacy chains with at least 70 pharmacies in at least three regions, or consortia of pharmacies, may participate in the co-payment mechanism. Although the rules were adopted quite some time ago, in practice this mechanism has not been operational. Its implementation is planned for several medicinal products in 2026.

Complex innovative reimbursement or access models (including risk-sharing agreements or outcomes-based agreements) remain largely outside explicit statutory regulation, although not prohibited. Such schemes are regularly proposed by pharmaceutical companies for implementation; however, due to the complexity of their budgetary implementation, they have not yet been reflected in legislative provisions and are assessed under general civil, competition, anti-corruption, tax and healthcare rules.

The implementation of such additional schemes not expressly provided for by law may prove problematic in the state hospital segment; however, various patient support programmes are used in the private sector.

In all cases, a broad comprehensive analysis of various areas of legislation is required, including pharmaceutical, tax, anti-corruption and antitrust, data protection, consumer protection and other laws and regulations.

4.9 Is it acceptable for one or more pharmaceutical companies to work together with the National Health System in your country, pooling skills, experience and/or resources for the joint development and implementation of specific projects? If so, what rules apply?

In general, there are opportunities for cooperation with the state and state organisations in the fields of science, healthcare development and centralised procurement.

The state provides support through special investment and long-term contracts and incentives for localisation of production in Kazakhstan and technology transfer. There are actual agreements of this kind concluded with pharmaceutical companies to facilitate the creation of new production facilities.

There are also mechanisms for centralised procurement directly from manufacturers without intermediaries.

There are examples where pharmaceutical companies conclude memoranda with the state providing for cooperation in the areas of healthcare development, transfer of expertise and support for educational programmes.

At the same time, each such programme that is not directly established by law requires separate assessment and structuring, since its actual implementation will depend on multiple factors, including anti-corruption restrictions, the limited competence of state authorities, budgetary issues, promotion ethics requirements, as well as antitrust, regulatory and tax considerations.

4.10 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?

In this case, it is necessary to distinguish between different types of sponsorship. Under the Law of the Republic of Kazakhstan "On Charity", the concept of "sponsorship" is associated with the public promotion of goods, the sponsor's name and its trademarks. Due to this definition, *sponsorship* in the strict legal sense is generally not possible in the pharmaceutical sector, since the possibilities for promotion and advertising, as well as interactions with healthcare professionals, are significantly restricted.

At the same time, other forms of charitable assistance not involving public promotion may sometimes be possible. For example, the Promotion Ethics Rules permit interaction with a healthcare organisation for the purpose of supporting the participation of a medical professional in a specialised scientific and practical conference, provided that such support does not impose any obligations related to the promotion of pharmaceutical products.

Donations to non-profit organisations implementing educational charitable programmes may also be possible, provided that the pharmaceutical company does not influence the decisions of such organisation, does not require the promotion of its products, and does not influence the personal selection of participants or the subsequent training process, in order to avoid corrupt influence on such persons.

All such arrangements are also limited by anti-corruption regulations, gift prohibitions, and specific rules applicable to educational and scientific activities, and therefore may not be used in all cases or in relation to all medical and pharmaceutical professionals. In addition, they require careful compliance review and proper structuring and documentation.

4.11 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. Is there a specific duty placed on companies to prevent bribery and, if so, what must companies do in order to comply with the duty? What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?

In Kazakhstan, interactions between pharmaceutical companies, medical professionals and healthcare organisations are regulated simultaneously by several areas of legislation, including anti-corruption, criminal, administrative, healthcare, advertising and antitrust laws, as well as labour and corporate compliance requirements and other applicable legal frameworks.

General anti-corruption and commercial bribery rules apply to the pharmaceutical sector and, in practice, are of very significant importance, alongside specialised pharmaceutical regulations.

The principal restrictions are contained, *inter alia*, in the Anti-Corruption Law, the Criminal Code, the Code of Administrative Offences, the Health Code, the Code of Honor, the Promotion Ethics Rules, advertising legislation, as well as legislation on public procurement and healthcare procurement.

In Kazakhstan, a particularly sensitive aspect is that many healthcare organisations belong to the state or quasi-state sector, while many medical professionals may be regarded as persons equated to public officials. Accordingly, interactions with them are often subject to enhanced anti-corruption restrictions.

In addition, specific restrictions are in place for executives of medical and pharmacy organisations.

In general terms, the following are prohibited: giving and receiving bribes; commercial bribery; the provision of unlawful material advantages or gifts; hidden incentives for prescribing or procuring medicinal products; payments for prescriptions; remuneration for inclusion of products in formularies, tender lists and similar mechanisms; conflicts of interest; and other violations of the rules. In certain cases, consultancy and other personal service agreements with healthcare professionals may also be prohibited or considered high risk.

Risk areas may include, *inter alia*, cash payments, expensive or even low-value gifts, certain forms of hospitality, sponsorship arrangements, sham consultancy agreements, excessive speaker fees, travel without a genuine scientific purpose, hidden rebates and grants to healthcare organisations without a legitimate scientific purpose.

From the perspective of corporate obligations to prevent corruption, the Anti-Corruption Law imposes general compliance duties. Business entities are required, in the course of their activities, to take measures aimed at preventing corruption, including minimising the causes and conditions facilitating corruption offences, by means of:

1) establishing organisational and legal mechanisms ensuring accountability, oversight and transparency of decision-making procedures;
2) observing the principles of fair competition;
3) preventing conflicts of interest;
4) adopting and complying with business ethics standards;
5) implementing measures aimed at fostering an anti-corruption culture; and
6) cooperating with state authorities and other organisations on corruption prevention matters.

Anti-corruption standards for business entities may also be developed and adopted by business associations, unions and other industry organisations.

In practice, these requirements are usually implemented by pharmaceutical companies through the adoption of internal procedural documents governing interactions with parties in the healthcare sector, approval procedures, standard document templates, questionnaires, due diligence mechanisms and anti-corruption measures.

Violations in the anti-corruption sphere may result in criminal liability, administrative fines, reputational damage, claims and investigations by state authorities and antitrust regulators, as well as other adverse consequences.

As regards the relationship between pharmaceutical regulators and anti-corruption authorities, their powers in Kazakhstan may overlap. Issues relating to advertising of medicinal products, promotion practices and compliance with healthcare legislation are generally supervised by the Ministry

of Healthcare, the Committee for Medical and Pharmaceutical Control and its territorial subdivisions, and in certain cases by competition and consumer protection authorities.

Anti-corruption and criminal matters fall within the competence of the Anti-Corruption Service, prosecution authorities, financial monitoring authorities, police and other law enforcement bodies.

The same conduct depending on the circumstances and the nature of the event may give rise to multiple legal considerations, such as potential violations of advertising restrictions, ethical rules, procurement legislation, anti-corruption provisions or commercial bribery.

In practice, anti-corruption authorities are entitled to conduct independent investigations even where the matter has already been reviewed by a medical regulator.

Accordingly, interactions between pharmaceutical companies and healthcare professionals and healthcare organisations in Kazakhstan require a comprehensive compliance approach simultaneously addressing anti-corruption requirements, healthcare regulation, advertising rules, procurement law, competition law, tax compliance, as well as documentation and transparency requirements.

5 Hospitality and Related Payments

5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?

Hospitality and related payments for healthcare professionals do not have direct and detailed regulation in Kazakhstan. However, these areas are significantly restricted by the general prohibition on gifts and benefits to healthcare professionals, prohibitions on payment for entertainment, leisure activities and travel to places of recreation, as well as anti-corruption regulations.

Accordingly, expenses for travel, accommodation and related hospitality may either be prohibited in principle or, depending on the specific circumstances and accompanying conditions, may be permissible only subject to significant restrictions and substantial compliance risks.

Since anti-corruption legislation also applies to trips of relevant persons abroad, travelling to another country does not allow such restrictions to be circumvented. On the contrary, such trips may create additional risks both under the laws of Kazakhstan and under the laws of the foreign jurisdiction concerned.

5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?

The issue of financing participation in scientific events lies at the intersection of the strict prohibition on gifts and inducements for prescribing, anti-corruption prohibitions and the limited possibility of supporting participation, provided that no obligations relating to the promotion of pharmaceutical products are imposed.

A comprehensive interpretation of the applicable legislation leads to the conclusion that payment merely for attendance at an event (payment for time), as a form of participation benefit or gift, is prohibited. In certain cases, and not in relation to all healthcare professionals, participation in an event may be financed by a pharmaceutical company, provided that such financing does not constitute a gift, payment for leisure or entertainment, hidden inducement, or remuneration for past or future prescriptions, etc.

A more compliant approach would be where financing of participation in the event is not provided as such, but rather occurs within the framework of legitimate personal services rendered by the healthcare professional in connection with a lawful business need of the pharmaceutical company (for example, speaking services, expert participation, moderation of a session or similar real activities).

Under the AIPM 2024 Code of Ethics in Kazakhstan, speaker fees and reimbursement of expenses are permitted for healthcare professionals participating in professional events, provided that fees reflect fair market value. Reimbursable expenses include registration fees, travel, visa support, medical insurance and accommodation for speakers. Hospitality must not include entertainment or leisure activities, and reimbursement for accompanying persons is prohibited except for medical reasons. Invitations must never be used to incentivise healthcare professionals to prescribe, supply, recommend or sell pharmaceutical products, and expenses must not serve as any form of inducement or hidden compensation.

Since such payments are not explicitly addressed by state ethical standards and are considered to fall within a "grey legal zone", pharmaceutical companies are recommended to implement internal policies with clear criteria and limits. This ensures transparency and provides evidence of the absence of any unlawful inducements to healthcare professionals.

It should be emphasised that such services must not constitute a form of promotion of medicinal products or a disguised bribe to healthcare professionals. In addition, certain employees of private and quasi-state organisations cannot legally be engaged to provide such services, and financing of their participation and reimbursement of expenses is not permissible.

In general, please note that the provision of personal services by healthcare professionals is not directly regulated under Kazakhstan pharmaceutical law and therefore remains in a legal grey area associated with significant compliance risks.

5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?

Unlawful payments may give rise to criminal and/or administrative liability. Violations of the Promotion Ethics Rules and the Code of Honor may negatively affect the company's reputation, lead to inspections and result in orders issued by the competent authority requiring elimination of the identified violations.

5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?

In general, the provision of personal services by healthcare professionals is not directly regulated under Kazakhstan pharmaceutical law and therefore remains in a legal grey area associated with significant compliance risks.

However, in practice, healthcare professionals may be engaged and compensated for *bona fide* expert and professional services, including participation in advisory boards, speaking engagements, expert consultations, moderation of scientific sessions and similar activities. In practice, pharmaceutical companies frequently use such forms of engagement and cooperation.

However, such arrangements are subject to significant legal, anti-corruption and compliance restrictions in Kazakhstan. Interactions between pharmaceutical companies and healthcare professionals are regulated by anti-corruption, criminal, administrative, labour, healthcare, advertising and procurement legislation, including the Health Code, the Code of Honor, the Promotion Ethics Rules and anti-corruption legislation.

The key principle is that such engagements must pursue a legitimate business purpose and must not constitute hidden promotion, unlawful benefits, inducement to prescribe or procure medicinal products, commercial bribery or a conflict of interest. In practice, the services must be genuine, necessary and properly documented, while compensation must correspond to the fair market value of the services rendered and must not be excessive. Payments must not be linked directly or indirectly to prescriptions, recommendations, procurement decisions, inclusion in formularies or tender lists. Sham consultancy agreements, fictitious advisory boards and excessive speaker fees create substantial anti-corruption and compliance risks.

Particular caution is required because many healthcare professionals in Kazakhstan may be regarded as persons equated to public officials, especially within state and quasi-state healthcare organisations. Accordingly, certain healthcare professionals may be prohibited from providing such services altogether or may be subject to enhanced restrictions.

As a practical example, under the Anti-Corruption Law, it is not permissible to enter into a paid consultancy or other agreement with a physician employed by a state hospital if the physician holds organisational, administrative or managerial functions and any of the following conditions are met: (1) the contracted activity interferes with the performance of official duties (e.g., a lecture or participation as a speaker at a conference occurs during working hours rather than during lawful leave); (2) the activity involves the use of official property (e.g., an online lecture conducted using the physician's work computer, or a presentation prepared at the physician's workplace); (3) a conflict of interest exists (e.g., to execute the agreement, the physician would need to conceal information regarding safety or prescribe certain medicines in excessive quantities in the interests of collecting materials for the lecture, and not in the interests of the patient); (4) the physician uses official authority in the interests of the pharmaceutical company (e.g., access to hospital patient databases, advertising the event including the physician's position and status); (5) official or other non-public information is used to obtain or extract material or non-material benefits (e.g., clinical practice data, hospital procurement information, patient personal data); and (6) the physician receives financial compensation, gifts or services in exchange for actions benefitting the pharmaceutical company.

In addition, agreements with pharmaceutical companies are explicitly prohibited in cases where such agreements must be concluded by an expert organisation (for example, within the framework of clinical trials).

Such arrangements would generally be considered unlawful under Kazakhstan's anti-corruption framework.

Improper payments or unjustified consultancy arrangements may result in criminal and/or administrative liability, inspections by the competent authorities, reputational damage and other adverse consequences. Therefore, such arrangements generally require careful case-by-case legal and compliance assessment, proper contracts, internal approvals, due diligence and robust documentation and transparency measures.

5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?

Kazakhstan's pharmacovigilance regulations (Order of the Minister of Healthcare of the Republic of Kazakhstan No. ҚР ДСМ-320/2020 dated 23 December 2020) establish the fundamental framework for regulating *post-marketing safety studies*. Specifically, post-marketing safety studies of medicinal products are conducted to collect additional scientific data on the safety of a medicinal product that may have potential clinical significance or importance for public health. These studies are carried out by the marketing authorisation holder in Kazakhstan either voluntarily or pursuant to a decision of the state authority if potential risks associated with a registered medicinal product require further investigation through a study.

Such studies are conducted in accordance with the procedure established by Article 238.6 of the Health Code, which covers clinical trials of medicinal products and medical devices, *in vitro* clinical laboratory testing of medical devices for diagnostic purposes, and requirements for clinical sites. The protocol for a post-marketing safety study is developed by the marketing authorisation holder in accordance with Kazakhstan legislation and must be agreed with the expert organisation. The marketing authorisation holder must submit the final report of the post-marketing safety study to the expert organisation no later than 12 months from the completion of data collection. Consequently, post-marketing safety studies are organised and conducted according to the procedures established for clinical trials, including obtaining ethics approval, site authorisations and investigator agreements.

In addition to the stated pharmacovigilance and clinical trial rules, post-marketing safety studies are also subject to the GVP and GCP standards of Kazakhstan and the EAEU. Within this framework, the study sponsor enters into an agreement with the clinical site and may additionally conclude an agreement directly with the investigator to ensure proper performance of their responsibilities. Such agreements must clearly define the scope of responsibilities, remuneration and compliance obligations, and must not provide any inducement for prescribing or purchasing the study product.

Pharmacovigilance standards also take into account other types of studies that are not classified as clinical trials. The Promotion Ethics Rules permit, in interactions with healthcare organisations and members of professional associations, the conclusion of agreements for conducting clinical trials, pharmacoeconomic studies, epidemiological studies and other types of research not prohibited by the legislation of Kazakhstan (the results of pharmacoeconomic and epidemiological studies must contribute to the rational use of medicinal products).

These types of services can be subject to specific regulation and are generally provided by legal entities or individual professionals holding the necessary permits and authorisations. It should be noted that any direct payment to an individual investigator who holds a position subject to the Anti-Corruption Law is prohibited.

Pursuant to Order of the Minister of Healthcare of the Republic of Kazakhstan No. ҚР ДСМ-248/2020 dated 11 December 2020, external specialised experts may also engage with expert bodies. Conducting a sanitary and epidemiological audit falls within the scope of the Law of the Republic of Kazakhstan No. 202-V dated 16 May 2014 "On Permits and Notifications".

Other informal studies do not have official status and carry a higher potential for compliance risks. In particular, physicians are not permitted to use clinical practice data from clinics or personal medical data of patients without consent or hidden from their employer. The subject and methodology of such studies must be critically assessed from the perspective of regulatory requirements and compliance obligations.

Personal services provided by healthcare professionals in the field of post-marketing surveillance (PMS) with direct personal remuneration from a pharmaceutical company should be considered from the perspective of a number of legal requirements, including licensing and authorisation requirements, medical data protection rules, professional ethics obligations, personal employment duties and anti-corruption regulations. Such requirements must be carefully analysed in relation to the specific services contemplated.

It is also important to ensure that payments are not made for activities that are already part of the healthcare professional's official duties, such as reporting adverse drug reactions. Providing additional remuneration for these statutory duties may constitute an anti-corruption risk.

5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?

Unlike *bona fide* PMS studies, marketing research involving healthcare professionals is generally not subject to the same level of specific scientific and pharmacovigilance regulation, although it remains subject to significant anti-corruption, advertising and ethical restrictions.

The Promotion Ethics Rules permit the conduct of marketing research among pharmaceutical professionals aimed at studying and analysing various aspects of the functioning of the pharmaceutical industry and market, as well as the participation of healthcare professionals in marketing research activities.

At the same time, such activities must not constitute disguised promotion of medicinal products or improper inducement to prescribe, recommend, purchase or procure specific medicines. Participation criteria should not be linked to prescribing volumes, purchasing behaviour or other commercial performance indicators. The Health Code (Article 265.4) explicitly prohibits the promotion of medicinal products and medical devices by representatives of manufacturers and/or distributors within healthcare organisations and healthcare educational institutions, except in the context of routine medical conferences, scientific and practical conferences, and/or specialised seminars.

In such cases, it is also necessary to take into account anti-corruption restrictions applicable under certain circumstances to paid activities of managerial persons in the quasi-state sector. In addition, internal policies of healthcare organisations, employment obligations and restrictions applicable to contacts with healthcare professionals during working hours and at the workplace may also be relevant.

Furthermore, prohibitions on gifts and inducements for prescribing impose enhanced requirements regarding transparency, the actual substance of the research and confirmation of its results.

It should be noted that market research arrangements are generally considered lower risk where concluded with healthcare organisations rather than directly with individual physicians or pharmacists. This approach allows for a group-based research structure and clearer documentary evidence for compliance, accounting and tax purposes. By contrast, individual agreements with physicians or pharmacists may be questioned as lacking genuine justification and may raise suspicions that they conceal unlawful payments under the guise of marketing research.

In addition, where physicians or pharmacists are engaged in conducting such research using patient interactions arising from their ordinary clinical practice, the associated risks include potential conflicts of interest, interference with official duties, breaches of medical confidentiality, personal data protection obligations and anti-corruption requirements.

The AIPM 2024 Code of Ethics prohibits for the members of this association the use of marketing research for the promotion of products and the payment to healthcare professionals for such activities. Compensation is permitted only in certain cases, where the healthcare professional does not know on behalf of which company the research is being conducted and a number of other criteria are met, including the absence of influence and the pharmaceutical company's lack of knowledge regarding the selection of specific healthcare professionals.

6 Advertising to the General Public

6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?

According to Article 56.4 of the Health Code, dissemination and placement of advertising of medical services, medicinal products and medical devices are permitted in media outlets and electronic information resources within healthcare organisations. Advertising is carried out in accordance with the Advertising Rules, which require obtaining a positive expert opinion prior to dissemination. Such expert review is conducted by the NSCHD.

It should be noted that the expert organisation has its own interpretation and administrative practice regarding the Advertising Rules and the Health Code. Accordingly, the practical approach of the expert body in some issues differs from the literal wording of Article 56.4 of the Health Code.

As stated above, the Health Code permits advertising through "media outlets". However, under Kazakhstan law, the term "media outlets" is not equivalent to the broader concept of "mass media", but refers specifically to registered relevant media outlets/mass media (including internet media outlets). Internet resources of pharmaceutical companies are generally not registered as media outlets within the meaning of Kazakhstan legislation, and therefore the possibility of placing advertising on such resources is either unavailable or legally questionable.

At the same time, the NSCHD issues positive expert opinions for placement of advertising on internet resources, which

in practice effectively legitimises such placement for as long as this administrative practice of the expert body continues.

It should also be noted that the interpretation of legislation by the NSCHD sometimes differs from the position of the Ministry of Healthcare. In certain cases, the Ministry of Healthcare does not provide direct answers to interpretation requests and instead recommends contacting the NSCHD.

As regards the substantive requirements applicable to advertising, they are established by the Health Code and the Advertising Rules. In addition, general requirements under the Advertising Law and the Entrepreneurial Code also apply.

6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?

Advertising of Rx medicines in media outlets aimed at the general public is explicitly prohibited under the Health Code.

It should also be noted that, according to the information available to us, the NSCHD has adhered to the position that advertising of Rx medicinal products is generally impermissible and, accordingly, has not issued expert opinions for such advertising. Although this position may be considered debatable with respect to advertising outside registered media outlets, in practice it means that advertising of Rx medicinal products is generally not feasible in Kazakhstan.

We note that some time ago we submitted requests to the Ministry of Healthcare and NSCHD seeking clarification of this position, and differences in the approaches of these authorities were identified. Nevertheless, to date, our clients have not reported to us any instances where the NSCHD has accepted advertising materials for Rx medicinal products for review.

6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?

According to the Advertising Rules, information relating to human health or diseases does not qualify as advertising of medicinal products. Accordingly, such information may in principle be disseminated; however, the following restrictions should be taken into account.

Under the Health Code, advertising addressed to the general public may not contain references to methods of treatment for sexually transmitted diseases, oncological diseases, mental or behavioural disorders (diseases), dangerous infectious diseases, HIV infection, tuberculosis or diabetes mellitus.

In addition, Article 428 of the Code of Administrative Offences establishes administrative liability for dissemination by an advertiser of advertising relating to medical services, methods and means of prevention, diagnosis, treatment and medical rehabilitation by a person not holding the relevant licence for the corresponding type of activity, as well as for advertising biologically active food supplements without state registration, provided that such conduct does not contain elements of a criminal offence.

This means that a pharmaceutical company is not permitted to publish materials that could be considered advertising related to medical services, methods or means of prevention, diagnosis, treatment and medical rehabilitation, including encouraging to contact healthcare organisations or doctors, as the company does not hold a medical licence.

6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?

Under the general rules, press releases about Rx medicines directed at non-scientific media could be classified as prohibited mass media advertising under the Health Code.

At the same time, information on Rx medicinal products may be provided in specialised printed publications intended for medical and pharmaceutical professionals in accordance with Article 262 of the Health Code. In our opinion, this provision relates to *non-promotional* informational materials rather than advertising in the strict legal sense.

Non-promotional information relating to medicinal products that have not undergone state registration may also be placed in the above-mentioned sources.

The conditions and restrictions relating to off-label use were discussed in the responses to the previous questions.

As noted earlier, certain press releases exist in practice in a news-style format rather than as advertising – for example, we previously referenced the press release by the Minister of Science and Higher Education. However, press releases issued directly by pharmaceutical companies carry a higher risk of being considered advertising.

It is also important to note the GVP standards, which, in certain cases, allow for a press release or press conference when it is necessary to communicate safety information (non-promotional) to the general public, sometimes with the participation of the competent authority.

6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?

If such brochures and annual reports are prepared for internal purposes, they are generally not regulated.

However, once such materials become publicly available, advertising and promotion rules and restrictions become applicable. For example, restrictions on advertising of Rx medicinal products, the requirement to obtain a positive expert opinion from the expert organisation, and requirements relating to the form and content of advertising materials may apply.

Any information mentioning medicinal products and aimed at attracting attention to them or promoting them may be interpreted as advertising.

Again, pharmacovigilance reports and materials are mandated by legislation and must not include promotional statements, advertising content or marketing-oriented presentation of information.

6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?

According to Article 16 of the Health Code, public associations for the protection of citizens' rights in the field of healthcare are not entitled to advertise specific trade names of medicinal products, biologically active food supplements, medical devices, specialised therapeutic nutrition products or breast milk substitutes.

Public associations and other non-profit organisations may engage in activities relating to prevention of socially significant diseases, diseases posing a danger to others, as well as promotion and development of a healthy lifestyle.

As non-profit organisations, they may receive charitable donations, including from pharmaceutical companies. However, such donations must not be connected with any activities involving advertising or promotion of medicinal products. In addition, such contributions must not result in violations of, or circumvention of, the Promotion Ethics Rules or anti-corruption legislation. Furthermore, as non-profit organisations, their activities generally should not consist in providing *commercial services* to pharmaceutical companies (for example, organisation of conferences or events *on behalf of or at the instruction* of pharmaceutical companies as a paid service activity).

It should also be noted that such organisations are not entitled to purchase medicinal products and distribute them to patients unless they hold the relevant licence permitting such activities.

6.7 What rules apply to consultancy arrangements with patient organisations or patient organisation representatives?

A consultancy agreement usually constitutes a remunerated service arrangement. However, patient organisations are non-profit organisations and, as a general rule, do not engage in commercial activities. Accordingly, entering into *paid* consultancy agreements under which a patient organisation provides such services may contradict its non-profit status and may also give rise to tax implications and related obligations for the organisation.

In addition, such agreements are impermissible where they are intended to conceal activities that violate other provisions of legislation (for example, activities related to unlawful promotion of medicinal products).

It should also be noted that advertising may not reference recommendations from scientists or healthcare professionals if such references could encourage the use and/or prescribing of medicinal products or medical devices. This means that if a consultative opinion from a non-profit organisation involving healthcare professionals is requested by a pharmaceutical company, that opinion cannot subsequently be used for promotional purposes.

According to the AIPM 2024 Code of Ethics, when a company collaborates with a patient organisation, all interactions, as well as the fact and nature of the collaboration, including financial and non-financial support provided to the patient organisation, must be transparent, clearly disclosed and properly documented by the company.

6.8 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?

As previously noted, the distribution of medicinal product samples to patients for advertising purposes is prohibited.

In addition, the Health Code prohibits placement of advertising information of medicines and medical devices (and some other products and services) on industrial products and prescription forms. This prohibition is general in nature and may also extend to the gifting of branded items to patients.

At the same time, the provision of non-branded gifts to patients is not expressly prohibited, provided that such gifts do not contain advertising of medical services, methods and means of prevention, diagnosis, treatment and medical rehabilitation, medicinal products, medical devices or other regulated products.

Nevertheless, such gifts may not be provided to patients having a special anti-corruption status (for example, public officials or, in certain cases, their relatives and some other individuals).

It should also be noted that not all channels for providing gifts to patients may be permissible. For example, in our opinion, the use of physicians for such purposes would not be allowed.

It may also be impermissible to provide gifts to minor patients or to those with limited legal capacity without the consent of their legal representatives.

In addition, the AIPM 2024 Code of Ethics completely prohibits the provision of donations to patients. This restriction applies directly to organisations that are members of the AIPM.

6.9 What are the rules governing company funding of patient support programmes?

This is a multifaceted area that offers opportunities for careful and compliant support of patients. It requires a comprehensive approach, taking into account relevant legal provisions such as tax legislation, anti-corruption laws, competition and consumer protection rules, pharmaceutical regulations, personal data protection requirements and other applicable areas of law to ensure that programmes are both effective and fully compliant.

7 Transparency and Disclosure

7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?

According to Order of the Minister of Healthcare of the Republic of Kazakhstan No. ҚР ДСМ-248/2020 dated 11 December 2020, all clinical trials of medicinal products conducted on the territory of Kazakhstan must be registered in the National Information System for Biomedical Research.

The description of the clinical trial must be registered in a publicly accessible database (such as the International Clinical Trials Registry Platform, EU Clinical Trials Register, ClinicalTrials.gov, etc.) prior to the enrolment of participants. The content of the registration must be kept up to date throughout the duration of the study, and the results must be registered upon completion of the trial.

In addition, the Promotion Ethics Rules require a speaker to disclose any conflicts of interest with entities operating in the field of medicinal products and medical devices when presenting the results of clinical, post-marketing or other medical research at scientific and practical conferences, congresses or symposia.

7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations, patient organisations or members of the public (including journalists)? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?

At present, Kazakhstan law does not contain a direct and

detailed requirement for mandatory public disclosure by pharmaceutical companies of all transfers of value (ToVs) provided by it to healthcare professionals, healthcare organisations, patient organisations or members of the public. In other words, there is currently no obligation in Kazakhstan for open reporting of each payment, gift or sponsorship.

However, the Promotion Ethics Rules generally require that pharmaceutical promotion be conducted in accordance with the principles of legality and transparency, with the aim of improving the quality of medical care and promoting the development of medical technologies and innovations.

This means that any payments or ToVs must be justified, lawful and properly documented. They cannot be executed outside of standard accounting records, and the company must be prepared to provide the relevant information upon request by the competent authorities.

In this context, we are focusing specifically on disclosures directly relevant to the pharmaceutical sector, while other general reporting requirements (such as notifications to tax authorities of receipts and expenditures from non-residents or public reporting by non-profit organisations) are handled separately under broader legal frameworks.

Attention should also be given to the tax obligations arising for a company providing ToVs to an individual. The company may have duties to withhold and remit the applicable taxes and other mandatory payments at the source of payment, as well as to submit the corresponding reports to the tax authorities.

7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations, patient organisations or members of the public (including journalists)? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?

The Promotion Ethics Rules require healthcare professionals to disclose their conflict of interests with pharmaceutical companies when presenting research results at scientific conferences. No other disclosure requirements apply under the self-regulatory framework.

The AIPM 2024 Code of Ethics does not impose a requirement to publish ToVs via a central platform or otherwise, but it requires the implementation of a rule of transparency and proper documentation for matters of interaction.

In particular, under the AIPM 2024 Code of Ethics, if a company or the AIPM acts as a sponsor of a symposium, congress or other similar healthcare- or education-related event, the following conditions must be observed: the sponsorship must be clearly indicated in advance; the final materials of the event (printed, audiovisual, etc.) must accurately reflect the objectives achieved, as well as the content of presentations and discussions. Companies are permitted to make publicly available information regarding the sponsorship provided (in the form of funds or their equivalent).

7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?

In this context, it is necessary to determine on whose side the relevant obligation lies. Accordingly, the individual bears responsibility for non-compliance with such obligations. In the case of healthcare professionals, there is a direct duty to disclose conflicts of interest during public presentations, as noted above. The company will not incur public liability if the individual fails to disclose a conflict. However, such failure may increase reputational risks for the company in the event of subsequent identification of inconsistencies.

Therefore, we recommend including in agreements with healthcare professionals a provision obliging them to disclose conflicts of interest and to make other relevant information public, in order to ensure transparency and to protect the company from accusations of collusion or undue influence over the presentation.

It is further recommended to include clauses specifying that the healthcare professional acts independently, expresses their own professional opinion on the matters presented and is under no obligation to promote pharmaceutical products. Such clauses should be carefully drafted to ensure maximum compliance with applicable legislation governing interactions with healthcare professionals.

It should also be noted that certain healthcare professionals employed by quasi-state organisations have a direct obligation to disclose conflicts of interest to their employer. Such healthcare professionals are generally already restricted in their interactions with pharmaceutical companies. Failure by them to disclose a conflict of interest would constitute a corruption-related violation on their part.

In this context, it is even more important to draft agreements in a manner that ensures the transaction is free of any breach of law and obstacles, and does not create conflicts of interest. We consider it fundamentally impermissible to enter into an agreement with a healthcare professional if a conflict of interest exists or could arise as a result of entering into or performing the agreement.

8 Digital Advertising and Social Media

8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?

Internet resources are considered "mass media" under the Mass Media Law. Such resources may be classified either as (1) ordinary mass media, or (2) registered media outlets (internet publications) if they are formally registered and meet the criteria for such activities.

The applicable requirements depend on the status of the internet resource. It should be noted that advertising of OTC products is permitted in registered media outlets, including internet media outlets. However, advertising on other internet resources that do not have such registration is legally questionable. In any case, advertising may only be disseminated through sources listed in a positive expert opinion issued by the competent expert organisation (NSCHD).

Internet resources can further be categorised as (1) ordinary websites, (2) online platforms, or (3) e-commerce resources. Online platforms are internet resources that, broadly speaking, allow user accounts to be created; they do not include e-commerce platforms.

Online platforms are subject to the Online Advertising Law. Such online advertising, if permitted by an expert opinion, must be clearly identified and marked in accordance with the requirements of this law and Order of the Minister of Culture and Information of the Republic of Kazakhstan No. 59-NҚ dated 16 February 2024.

In addition, restrictions on targeting will apply. In Kazakhstan, the Online Advertising Law strictly limits targeting and profiling based on sensitive data, including information about users' health status. For pharmaceutical companies, this means that data on diagnoses, visits to medical websites or treatment-related interests cannot be used to select the audience for advertising campaigns. For example, it is prohibited to target advertising for pain relievers, cold and flu medications, or vitamins specifically to individuals who have visited specialised medical portals. In addition, any online campaigns aimed at minors are prohibited, even if they comply with the general requirements of the Advertising Law and industry standards.

Notification requirements established under the AI Law will also be relevant to "synthetic" content used in internet resources. The dissemination of synthetic outputs generated by AI systems is permitted only if they are labelled in a machine-readable format and accompanied by a visual or other form of notice that allows the user to perceive the content without using methods that hinder such perception. The distribution of mass media content created using an AI system is permitted only if information about such content is provided in accordance with the AI Law.

In general, other applicable laws and rules concerning the content of advertising also apply to internet advertising. It should be noted that online advertising has been subject to increased scrutiny in recent times.

8.2 What, if any, level of security is required to ensure that members of the general public do not have access to websites or digital platforms intended for healthcare professionals?

Internet resources intended exclusively for healthcare professionals must be protected to prevent unauthorised access. These resources can be divided into two main groups: (1) informational portals that do not contain personal data; and (2) resources containing personal data, including patients' or healthcare professionals' data, medical data, personal accounts and other information requiring protection. Additionally, portals may be (a) governmental (for example, as part of the national digital healthcare system), or (b) private.

Depending on the type of portal, different access conditions and security requirements may apply. These include multi-factor user authentication, the use of electronic digital signatures, technical measures to prevent unauthorised access, special protocols for integration with the national digital infrastructure, as well as administrative, legal and other security measures.

Such classification allows for differentiated access rules and protection levels appropriate to the nature of the information, internet resources and the degree of confidentiality required.

8.3 What rules apply to the content of independent websites or digital platforms that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent sites to a company's website or platform? Will the company be held responsible for the content of the independent site in either case?

The owner of an internet resource has the right, and in some cases the obligation, to establish terms of use for that resource. These terms may include restrictions or provisions regarding links to external resources.

External resources can generally be divided into two main categories: (1) those controlled by the company or over which the company can influence the content; and (2) independent sources over which the company has no control. Links to the first category may be treated as part of a single integrated content ecosystem, including the main site, if they are interrelated. In this case, the company bears responsibility for all such linked sites.

For independent sources, the company should include appropriate disclaimers in the site's terms of use. However, this does not exempt the company from liability if the link relates to medicinal products or related content. If a pharmaceutical company places a link on its website to an independent resource containing information related to medicinal products or healthcare topics:

- The company must ensure that the link does not direct users to content that violates the Advertising Law, the Promotion Ethics Rules, anti-corruption regulations or other applicable laws.
- It is recommended to include disclaimers or notices indicating that the external site is independent and that the company is not responsible for its content.
- The link must not be used as a means of covert promotion of medicinal products or as an inducement for prescribing products.

8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?

Information about the company itself may be published. Links to official product information, such as instructions for medical use registered in the medicinal products registry, may also be included. Trade catalogues and price lists can be published, as they are not considered advertising of medicinal products.

Health-related information is often published by companies; however, extreme caution is required, since such information may be deemed advertising of medicinal products or treatment methods which cannot be distributed. As noted in the answers to the previous questions, methods of treating certain diseases generally must not be advertised to the general public. Moreover, in general, any person or entity without a medical licence may not advertise medical services, methods and means of prevention, diagnosis, treatment and medical rehabilitation regardless of the specific disease or medical condition.

At the same time, pharmacovigilance rules and standards require pharmaceutical companies (marketing authorisation holders), within the pharmacovigilance system, to develop measures to inform patients and healthcare professionals about safety and proper use, including through materials published on the internet and other information channels.

GVP specifically emphasises that a website is an important tool for informing the public, including patients and healthcare system professionals. Competent authorities, as well as marketing authorisation holders, must ensure that critical safety information posted on the websites they control is easily accessible and understandable to users. Information on these sites must be kept up to date, and any outdated information should be appropriately marked or removed. Certain materials must be approved by the competent authority and under no circumstances may they directly or indirectly include promotional or advertising content.

The content of any educational materials must be fully aligned with information on the medicinal product approved by the competent authorities (general product characteristics or the instructions for medical use). Educational materials may serve as a supplement to the officially approved information on the medicinal product. These materials must not contain promotional elements – whether direct or indirect (e.g., logos, distinctive product colour schemes or stimulating imagery), but should include information on the risks associated with the medicinal product and the management of these risks, including additional measures required to minimise them. Educational programmes must be completely separate from any promotional campaign for the medicinal product. It is not permissible to use the contact information of physicians or patients, obtained through participation in educational programmes, for advertising purposes.

8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?

Social media platforms fall within the scope of the Online Advertising Law, which was adopted specifically to regulate social networks and similar resources (although it applies more broadly) and advertising on them, including advertising conducted through bloggers.

Other applicable regulations also apply to social media platforms. A company may establish rules for employees regarding the use of official organisational accounts or personal social media accounts, specifically with respect to information that is protected, confidential or belongs to the employer or another third party.

8.6 Are there any restrictions on social media activity by company employees using their personal accounts, including interactions with third parties through "likes", "applauds", etc.?

This is not regulated under Kazakh pharmaceutical advertising law. No specific provision addresses personal social media activity by employees, including likes or endorsements. General rules on inducements and accuracy under the Promotion Ethics Rules would apply if the activity could be construed as promotion.

At the same time, the employer may impose restrictions on employees' access to social media platforms that are not used for work purposes during working hours. The company's position must be clearly distinguished from the employee's personal views, which may differ on non-work-related matters.

Employees should also sign appropriate obligations regarding non-disclosure of confidential information and proper conduct in managing social media accounts on behalf of the employer.

This is particularly relevant because likes, reposts and endorsements by employees on social media related to medicinal products can create risks for the company, as such actions may be indirectly perceived as advertising. For Rx medicines, promotion to the general public is prohibited, and any encouragement of healthcare professionals to engage with content may be considered an improper inducement and could violate anti-corruption laws. Targeting advertising to users based on medical or health-related interests (e.g., patients' likes on health-related content) is also prohibited under the Online Advertising Law.

8.7 Are there specific rules governing advertising and promotional activity conducted virtually, including online interactions with healthcare professionals, virtual meetings and participation in virtual congresses and symposia?

Pharmaceutical legislation does not establish specific rules for online interactions with healthcare professionals outside the infrastructure of digital healthcare. All the same rules previously discussed apply to online interactions.

First, there is a prohibition on individual interactions aimed at promotion of medicines during healthcare professionals' working hours, alongside anti-corruption measures – for example, a managerial employee of a state hospital is not permitted to conduct lectures on behalf of a pharmaceutical company using a work computer during working hours. Data protection legislation applies to the collection, processing and protection of personal data. Advertising prohibitions also remain applicable.

The use of healthcare professionals authorised to prescribe medicinal products and medical devices as *distributors of advertising* is prohibited, except in cases where they provide accurate information on medicinal products and medical devices for scientific or educational purposes, or for the purpose of informing patients.

It should also be noted that a pharmaceutical company is not permitted to conduct educational programmes or training, including issuing certificates, because all types of continuing education in healthcare are regulated by the Health Code and may only be conducted by specialised organisations. Conducting a specialised seminar (without issuing certificates) that is not educational in nature may potentially be permissible. Participation in conferences and congresses remains subject to the previously discussed and some other conditions and restrictions, including the prohibition on promoting medicinal products through healthcare professionals.

Such activities should be distinguished from mandatory educational measures conducted within the framework of pharmacovigilance, which focus on safety issues and must not have a promotional or advertising character, and should not be considered a form of separate educational service for continuing education.

Of course, there are additional details and requirements that must also be taken into account.

9 Developments in Pharmaceutical Advertising

9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?

Last year, the Parliament of Kazakhstan considered a proposal for a complete ban on the advertising of medicinal products, which caused significant concern among pharmaceutical companies. However, this proposal was not adopted.

In the same year, the AI Law was enacted, which came into force in 2026 and must already be applied by all entities using AI systems. At the same time, administrative liability was introduced for violations in this area, including the dissemination of unlawful content.

The personal data rules were also strengthened.

9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?

The Ministry of Healthcare regularly updates regulatory and normative documents. Currently, the agenda includes the simplification and acceleration of medicinal product registration, regulation of prices for Rx medicines, and the modernisation of the system for providing the population with medicines for outpatient treatment funded by the state. Legislative changes on these issues are planned for 2026.

Accordingly, with the acceleration of registration procedures, companies will gain the opportunity to launch advertising campaigns for OTC medicinal products.

Another important trend is the use of AI systems. In Kazakhstan, the AI Law came into force on 18 January 2026. In April 2026, the Rules for the Development, Application, and Dissemination of Machine-Readable Forms for the purpose of use and ensuring transparency in AI systems (approved by Order of the Deputy Prime Minister-Minister of Artificial Intelligence and Digital Development of the Republic of Kazakhstan No. 202/НҚ dated 15 April 2026) also came into effect.

Therefore, companies should carefully study the nuances of AI legislation and begin implementing compliance procedures related to this law immediately. These issues are highly relevant for pharmaceutical companies, as the use of AI is expanding significantly, particularly in marketing and advertising. It is anticipated that government oversight in this area will continue to increase over time.

The Healthcare Development Concept of the Republic of Kazakhstan for 2022–2029 provides for the expanded use of digital solutions to monitor the advertising of regulated products with the aim of ensuring the sustainability and safety of the healthcare system.

9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

Enforcement remains focused on compliance with mandatory pre-approval of advertising materials, accurate presentation of indications/contraindications and restrictions on Rx medicines in mass media.

9.4 Do you consider that the applicable legislation, codes and guidance in your country are keeping pace with current ways to publish and access information, particularly in digital format? If not, where do you see the most significant gaps?

A significant number of questions, including those addressed previously, that are highly relevant to the pharmaceutical market, remain in a legal grey area, are unregulated or are insufficiently defined by legislation.

Therefore, for the last several years, in international pharmaceutical forums and interviews, we have highlighted areas where the promotion and advertising regulations in Kazakhstan may benefit from further clarification and development. Certain types of interactions that are commonly used internationally with the public and the medical community are currently less explicitly regulated in Kazakhstan or even not regulated. In some cases, the existing rules may leave room for interpretation or differences in enforcement practices.

This situation requires careful consideration by pharmaceutical companies to ensure compliance and minimise legal uncertainty. In our view, further development and clarification of the rules on promotion and advertising in the pharmaceutical sector, guided by the principles of reasonableness, legality and transparency, would support all stakeholders, including patients, healthcare professionals, manufacturers and distributors, while also contributing to effective state regulation and the continued development of the healthcare industry.

Disclaimer

The responses provided in this chapter are for general informational purposes only regarding key issues and do not constitute legal advice, nor do they represent a detailed or exhaustive statement of applicable regulations. Each question requires a comprehensive analysis taking into account the specific circumstances, types of products and applicable law. For decisions in a particular situation, it is recommended to consult a qualified lawyer specialising in Kazakhstan law.

Endnotes

1 https://qazaqstanhalqyna.kz/ru/press/79-first.html

2 https://inbusiness.kz/ru/last/chetyre-kazahstanskih-rebenka-poluchili-samyj-dorogoj-v-mire-preparat

3 https://www.zakon.kz/obshestvo/6512864-pochemu-zaderzhalsya-vykhod-na-rynok-kazakhstanskogo-lekarstva-ot-raka.html

Larissa Yemelyanova successfully combines work in AEQUITAS's active areas of practice – business law, compliance, pharmaceuticals, labour and employment – with other practice areas important for clients. Larissa heads the AEQUITAS Healthcare, Medicine and Pharmaceuticals, Compliance, IP and Competition practices and advises leading international and local clients on a broad range of regulatory, commercial and compliance matters in the healthcare and pharmaceutical sectors.

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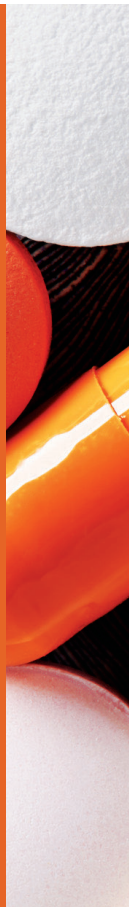

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