



Local Knowledge
for Global Business

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Фармацевтика і охорона здоров'я

Healthcare system is one of the world's largest and fast-growing domains, and due to its vital importance for humankind, in pursuit of solutions, it is subject to changing regulations.

With our capabilities at GRATA International, we understand the business and legal specialties that pharmaceutical and healthcare companies face daily, such as adherence to government regulations, consideration of local and international tax and customs regulations, all types of commercial issues including antitrust compliance, parallel importation practice, labor matters, intellectual property and data protection, and other key issues.

Our knowledge of the local business environment and clear understanding of practical challenges and needs help us to be truly adding value for our clients at all stages of the projects, providing them with viable and legally robust solutions.

- ▶ Ethical promotion of the medicines;
- ▶ IP rights protection;
- ▶ Antitrust and Competition;
- ▶ Pricing;
- ▶ Localization of manufacturing;
- ▶ Investments negotiations;
- ▶ PPP structuring;
- ▶ Personal data protection;
- ▶ Employment relations;
- ▶ Taxation;
- ▶ Customs regulations;
- ▶ Dispute resolution.





Індустріальні нагороди та рейтинги

Росія

Коммерсантъ®

Kommersant

Досвід

Azerbaijan

- ▶ Assisted a major global pharmaceutical company, in litigation concerning debt recovery. Judgment in favour of the Client - USD 712 000;
- ▶ Advising global pharmaceutical companies on COVID-19 vaccine issues;
- ▶ Advised a global American pharmaceutical company on drug distribution issues in the Republic of Azerbaijan;
- ▶ Legal support for the registration of medical equipment in the Republic of Azerbaijan for a large international company producing a wide range of diagnostic and treatment equipment;
- ▶ Legal support of the Russian pharmaceutical company in matters of import of medicines into Azerbaijan and their registration;
- ▶ Advised a global European firm on the promotion of prescription and over-the-counter medicines;
- ▶ Advised a multinational pharmaceutical company on the issue of making manufactured drugs in the state register;
- ▶ Assisted a leading pharmaceutical company in litigation concerning employment disputes. Judgment in favour of the Client;
- ▶ Consulting a pharmaceutical company on advertisement of medical products;
- ▶ Advised a large American pharmaceutical company on various aspects of labor legislation in the Republic of Azerbaijan;
- ▶ Advised a major European pharmaceutical company regarding migration legislation and obtaining permits to attract foreign personnel.

Belarus

- ▶ Advising members of the Association of International Drug Manufacturers of Belarus on drug pricing;
- ▶ Providing comprehensive legal support to “Tahat” – company which develops, manufactures and supplies medical tools, medical equipment and medical products in the Republic of Belarus;
- ▶ Legal support of a US-based company (clinical studies) in reorganization of the legal entity and advising on implementation of the clinical studies project;
- ▶ Advising a Swiss pharmaceutical company on various legal issues of doing business in the pharmaceutical sphere in Belarus (investment and employment law, requirements of anti-corruption law etc.);
- ▶ Advising an English supplier on participation in public procurement of medical equipment. Representing interests of the Client in the dispute in the International Arbitration Court at the Belarusian Chamber of Commerce and Industry. Signing an amicable agreement with our assistance;
- ▶ Representing interests of the largest state-owned pharmaceutical company in Belarus, in the dispute with the buyer, resident of the USA, which refused to pay for the drug products supplied by the Client;
- ▶ Legal support of the deal on sale of a network of pharmacies (representing the seller). Due to the proposed structure of the deal, the buyer received the required guarantees, and the seller received the complete payment sooner;
- ▶ Advising a Slovenian pharmaceutical company on the issues of labor law and representing interests of this company in the process of recovering debts;
- ▶ Legal support of construction of medical centers, obtaining licenses and permits;
- ▶ Advising a major international drug manufacturer on the consequences of reorganization of the company, in particular, the need to obtain the consent of the antitrust authorities, as well as amending the drug master file;
- ▶ Comprehensive advising of the Client on the issues of regulating of manufacturing, registration, disposal, distribution of medical devices for diabetic patients;
- ▶ Advising a major Belarusian dental clinic named Del Company on the issues of reconstruction of the building, which is a joint property, to create additional facilities for medical activities;
- ▶ Advising a Slovak medical company-manufacturer of lung ventilators on the registration of such lung ventilators, obtaining a EAEU declaration of conformity and their import into Belarus.

Georgia

- ▶ Advising on marketing, promotion and placement of pharmaceutical products and medical devices;
- ▶ Representing the Client in the local regulatory authority for purposes of approving advertising materials of pharmaceutical products;
- ▶ Advising on personal data protection requirements;
- ▶ Advising on competition and compliance;
- ▶ Tax advising services;
- ▶ Review of distribution agreements on their compliance with mandatory rules under the Laws of Georgia.

Kazakhstan

Advertising, Promotion and Sales of Medicines and Medical Products

- ▶ Advising on interaction with pharmacies, healthcare and pharmaceutical professionals on motivation and applicable restrictions;
- ▶ Advising on advertising of medicines and product branding;
- ▶ Developing detailed marketing guidelines for a multinational pharmaceutical company and advising on legal and tax regulation of the pharmaceutical activity in Kazakhstan;
- ▶ Advising on advertising and free distribution of samples of prescription medicines;
- ▶ Review of marketing materials for compliance with local regulations;
- ▶ Advising on import and distribution of medicines aimed to obtain clinical practice with the patients;
- ▶ Drafting model agency agreements for use in Kazakhstan and other CIS countries;
- ▶ Advising on import of non-registered medicines to Kazakhstan;
- ▶ Advising on one-time imports of medical products not registered in Kazakhstan;
- ▶ Advising on the conclusion of agreements with pharmacies;
- ▶ Legal support for the activities of a large international company on matters related to distribution and advertising of medical devices;
- ▶ Advising on possibility of distributing information about non-registered medicines during events for healthcare officials;
- ▶ Advising on marking of medical products;
- ▶ Advising a large medical equipment manufacturer company on consumer rights protection matters.

Registration and Permits

- ▶ Advising on interpretation and application of pricing rules and analyzing the implications;
- ▶ Overview of the development of pricing rules in Kazakhstan and an assessment of the compliance of decisions and actions of an international pharmaceutical company with legislation, as well as the development of key risk assessment indicators;
- ▶ Legal support for a pharmaceutical company in the framework of an anti-corruption investigation against third parties;
- ▶ Advising on the formation of lists of limit purchases for medicines in public procurement;
- ▶ Localization of medicine production;
- ▶ Analysis of investment preferences, foreign investors in the field of pharmaceuticals;
- ▶ Analysis of the phased localization of the production of medicines to match the criteria for recognizing products as locally produced goods;
- ▶ Assessment of potential risks for the project of localization of the production of medicines and development of drafts of relevant amendments to the legislation in the field of healthcare;
- ▶ Analysis of the perspectives and risks of the emergence of the production of medicines related to the membership of the Republic of Kazakhstan in the Eurasian Economic Union;
- ▶ Participation in negotiations with the participation of the ministry and state bodies on the medicine allocation project,

as well as the possibility of providing investment incentives.

Intellectual Property

- ▶ Advising and legal support for an international pharmaceutical company in negotiations with a Single distributor on the supply of a medicinal product in the framework of public procurement;
- ▶ Advising on the conclusion of long-term supply agreements;
- ▶ Drafting model agency agreements for use in Kazakhstan and other CIS countries;
- ▶ Advising on various commercial issues in relations with distributors;
- ▶ Advising on the supply of equipment to a medical facility;
- ▶ Advising on issues on possible ways of importing unregistered medicines;
- ▶ Advising an international pharmaceutical company on preferences granted to local pharmaceutical companies under a drug supply agreement;
- ▶ Advising on the proposal for the implementation of the project of cooperation with the state on the principle of sharing costs and risks.

Safety of Medicines and Medical Product

- ▶ Advising major international manufacturers of medical devices on safety regulations;
- ▶ Advising on clinical trials regulations;
- ▶ Advising on import and distribution of medicines for clinical practice in Kazakhstan;
- ▶ Advising an international pharmaceutical company on obtaining a permit from state authority to set up a register of patients;
- ▶ Advising on the competence of the parties involved in the suspension of the marketing authorization;
- ▶ Advice on post-registration monitoring of the medicine use.

Sponsorship and Trainings

- ▶ Advising an international pharmaceutical company on the distribution of medical educational and promotional materials;
- ▶ Advising on regulations concerning educational grants and donations;
- ▶ Advising on collecting fees for patients' training classes, as well as on paying patients for participation in surveys;
- ▶ Advising a medical equipment manufacturer on receiving and allocation of sponsorship aid by the public healthcare authorities;
- ▶ Advising on legal aspects of scientific research funding;
- ▶ Advising a major producer of medical equipment and medicines on feasibility of a public-private partnership project for better social reintegration of patients with mental disorders;
- ▶ Advising on use of fees received from medical services for participation in the project of online coordination between healthcare organizations and patients.

Personal Data Protection

- ▶ Advising on collection, processing and protection of personal data;
- ▶ Development and checking of various consent forms for owners of personal data, including employees, their families, healthcare professionals, patients, participants of events organized by pharmaceutical companies;
- ▶ Advising on company's approaches to interaction with owners of personal data for the compliance with the regulations of Kazakhstan and other CIS countries;
- ▶ Advising on applicability of the General Data Protection Regulation of the European Union in Kazakhstan.

Corporate and Labour Matters

- ▶ Providing assistance on corporate and labor matters to a large international pharmaceutical company;
- ▶ Conducting due diligence of a subsidiary of a major international manufacturer of generic drugs;
- ▶ Legal support of corporate restructuring and transfer of personnel between affiliated offices of a single group of companies;
- ▶ Advising a large pharmaceutical company on the aspects of labor law, specifically, on payment for overtime, as well as advising on failure to perform job responsibilities by an employee;
- ▶ Audit of HR related documentation for compliance with the labor regulations of Kazakhstan;
- ▶ Developing a policy for the conciliation commission;
- ▶ Advising various international pharmaceutical companies on termination of employment with the management and other employees;
- ▶ Registration of a subsidiary of international pharmaceutical company in Kazakhstan and advising on labor law matters;
- ▶ Legal assistance with development of internal labor and workplace safety policies for the local office of a medical equipment manufacturer;
- ▶ Advocacy support to foreign staff / secondees in dealings with the migration police of Kazakhstan.

Competition and compliance

- ▶ Advising on the compliance of the distribution agreement with the provisions of the antimonopoly law and developing proposals to eliminate potential risks;
- ▶ Representing the interests of an international pharmaceutical manufacturer in the course of proceedings on a claim against a competitor regarding a comparison given in the instructions for a medicinal product;
- ▶ Advising an international manufacturer of an original medicinal product on a strategy for protecting the rights and interests in relation to actions taken by a competitor;
- ▶ Audit of the activities of an international pharmaceutical company in terms of antitrust risks and the risk of prosecution of officials as part of a criminal investigation;
- ▶ Advising an international pharmaceutical company on the protection of rights and interests in the framework of compliance with competition law requirements.

Taxation and Customs

- ▶ Advising a pharmaceutical company on taxation of non-residents' income generated in Kazakhstan;
- ▶ Advising on corporate and tax matters related to the operations of representative offices and branches of international pharmaceutical manufacturers in Kazakhstan;
- ▶ Advising on regulatory compliance of representative offices of foreign companies which do not form a permanent establishment under the legislation of the Republic of Kazakhstan;
- ▶ Representing and protecting interests in the appeal over the results of customs inspection which resulted in changes of the Foreign Economic Activity Commodity Nomenclature codes of imported medical products and additional customs duties charges;
- ▶ Advising and legal assistance in communication with tax authorities over the taxability of funds received by a representative office in Kazakhstan from its parent company overseas;
- ▶ Advising on possibility of including a local office of an international pharmaceutical company in the corporate system of internal settlement payments and funding;
- ▶ Advising on taxation and customs procedures in delegated distribution arrangement cases involving a single authorized distributor.

Litigation and Pre-trial Settlement

- ▶ Successful representation of a subsidiary of one of the world's leading pharmaceutical companies in court proceedings over the application of a rehabilitation procedure to a debtor;
- ▶ Advising a European pharmaceutical company on inclusion in the register of creditors under the debtor rehabilitation procedures;
- ▶ Representing the interests of an international pharmaceutical company in the framework of an appeal against an act of a state body on the refusal to register a medicine;
- ▶ Representing the interests of a large pharmaceutical company in litigation on the cancellation of decisions of the Appeal Board of the Committee on Intellectual Property Rights on the cancellation of trademark registrations for medicines;
- ▶ Legal support of pre-trial settlement of labor disputes

Kyrgyzstan

- ▶ Advising Fresenius Medical Care Deutschland GmbH on the first PPP project in the Kyrgyz Republic "Organization and provision of hemodialysis services in Bishkek, Osh and Jalal-Abad" (Public partner – Ministry of Health of the Kyrgyz Republic). Assisting the Client with realization of the PPP project, construction of four clinics and provision of hemodialysis services in the Kyrgyz Republic, including, but not limited to: all questions related to realization of the project, labor, customs, licensing, healthcare regulation;
- ▶ Advising a leading US pharmaceutical corporation on advertising and promotion requirements of Non-Rx (OTC) drugs, conducting and sponsoring conferences and symposiums. Advising on provision of grants for research purposes;

- ▶ Advising a leading German pharmaceutical company in establishment of the representative office in Kyrgyzstan;
- ▶ Obtainment of registration certificate of pharmaceuticals for a Polish pharmaceutical company;
- ▶ Advising a leading US pharmaceutical company on requirements of the Kyrgyz Law to notification of the authorized state agency on adverse reaction of a drug;
- ▶ Advising a major Swiss pharmaceutical company on registration of drugs and trademarks in Kyrgyzstan;
- ▶ Advising an American pharmaceutical company on provisions of the Kyrgyz laws on drug advertisement;
- ▶ Advising a leading US pharmaceutical company on provisions of the Kyrgyz laws on execution of questionnaires and quizzes among pharmacists;
- ▶ Advising a major US pharmaceutical corporation on import of pharmaceuticals as humanitarian aid into the territory of Kyrgyzstan;
- ▶ Advising a local pharmaceutical company on import requirements of pharmaceutical products, participation in tenders and lifesaving medicines;
- ▶ Advising a leading US pharmaceutical corporation on advertising and promotion requirements of non-Rx drugs, conducting and sponsoring conferences and symposiums. Advising on provision of grants for research purposes;
- ▶ Advising a leading international law firm on localization of pharmaceutical production;
- ▶ Registration (prolongation of registration) of vinpocetine for a chemical and pharmaceutical company.

Moldova

- ▶ Representing one of the largest pharmaceutical distribution companies from Egypt in a complex fiscal litigation with the annulment of certain administrative acts for the establishment of financial obligations related to customs duties (customs taxes and VAT) in connection with some types of medicines;
- ▶ Advising a leading Dental Practice from Moldova in drafting and implementing the strategy for the restructuring of various companies within the group, assistance in acquisition of finance with Private Equity investors from EU;
- ▶ Assisting an international consortium from Germany retained by the Ministry of Health for 25 years in a Public Private Partnership (PPP) Project to provide dialysis services in Moldova, including provision of legal assistance throughout the entire bid process and performing the Project Finance Documentation for the SPV and Sponsors. The total investment exceeded EUR 15 million.

Mongolia

- ▶ Advised a multinational pharmaceutical company execution of the agreement on manufacture and supply agreement on vaccination of COVID-19 with value of 2.5 million USD;
- ▶ Advised a multinational pharmaceutical company with head office in the US on official communication letter with state registration authority of medicine with its distributor's change and execution of the distribution agreement;
- ▶ Advised a multinational pharmaceutical company on anti-corruption policy, privacy policy and personal data procedure;
- ▶ Advised a multinational pharmaceutical company on registration procedure of medicine;

- ▶ Assisted an international pharmaceutical company with head office on Netherland on registration of new director and change of registered address of the Representative office in Mongolia;
- ▶ Advised privacy policy of Herbalife International Inc in accordance with the laws of Mongolia;
- ▶ Advised a multinational and Russian pharmaceutical company on advertising legal requirements of drug and medicines;
- ▶ Prepared in-depth questionnaire on indemnification system of Mongolian on vaccination to a multinational pharmaceutical company;
- ▶ Advised a multinational pharmaceutical company on parallel importing regulation of Mongolia;
- ▶ Advised a multinational pharmaceutical company on execution donation and sponsorship agreements with state hospitals professionals;
- ▶ Advised Russian and Korean companies to register biologically active products in Mongolia;
- ▶ Advised to Czech pharmaceutical company on employment agreement with Director of Head of Representative office in Mongolia;
- ▶ Advised on promotion policy of Czech pharmaceutical company for its Representative office in Mongolia;
- ▶ Advised international pharmaceutical company on competition law of Mongolia;
- ▶ Assisted to German pharmaceutical company on incorporation of a subsidiary in Mongolia, advised on registration of Ultimate beneficial owner at commercial banks and advised on several commercial contracts.

Russia

Moscow:

- ▶ Advising a major German pharmaceutical company in connection with registration of medicines in the Eurasian Economic Union and representing its interest in the course of regulatory acts development;
- ▶ Advising a major European pharmaceutical company on the formalization of relations with representatives in the CIS and Georgia in terms of legal and tax risks;
- ▶ Advising a European manufacturer of medical equipment on the localization of production in Russia;
- ▶ Full legal support of the activities of a subsidiary of a European manufacturer of medical devices for two years, including the development and examination of various contracts and internal provisions (i.e. the processing of personal data and commercial secrets), advising on advertising, state procurement and employment matters, protection of trademarks;
- ▶ Advising a Chinese manufacturer of dietary supplements on certification, state registration and labeling of products in Russia;
- ▶ Advising an international group of companies (medical services) in connection with the reorganisation of business in Russia and a joint venture with a Russian partner.

Rostov-on-Don

- ▶ Consulting the seller of medical equipment on compliance with the legislation on the stock market and on joint-stock companies. Preparation of necessary documents and representation of interests before Federal authorities
- ▶ Preparation of constituent documents for the creation of a company by a client, a doctor in the main activity, that organises services for training courses for medical workers
- ▶ Support for the creation of a subsidiary in the South of Russia pharmaceutical company, including preparation of decisions on establishment of subsidiary companies, preparation of constituent documents, assistance in registration of company, creation of a separate division of the company
- ▶ Legal support for the reorganisation of the city hospital by joining other two city hospitals, including preparation of decisions of the city administration and hospital management bodies related to the reorganisation, preparation of the charter of the reorganised entity, support for state registration and its exclusion from the register of affiliated organisations
- ▶ Support of an investment project for the construction of a medical center
- ▶ Consulting a network of pharmacies on the risks related to the conclusion of a number of interrelated transactions for the supply and further sale of medicines

St. Petersburg:

- ▶ Representing a major regional supplier of medical equipment, Labmedconsult LLC, in a labor dispute with an employee who misuses disability certificates.

Tajikistan

- ▶ Advising of Pharmaceutical Company Roche on the registration and circulation of medical products;
- ▶ Advising Pharmaceutical Company "Astellas Pharma" on leading the seminars by foreign medical officers to local medical officers;
- ▶ Advising a leading US pharmaceutical company on requirements of the Tajik Law to notification of the authorized state agency on adverse reaction of a drug;
- ▶ Advising a leading US pharmaceutical company on provisions of the Tajik laws on drug advertisement;
- ▶ Advising a major European pharmaceutical company on the legislation of Tajikistan and the completion of a questionnaire on the restriction of interaction between pharmaceutical companies and health professionals (doctors, pharmacists).

Ukraine

- ▶ Consulting a Polish producer of medical devices on the importation of medical devices in Ukraine, their certification, and requirements regarding the registration of the wholesale prices on medical devices;
- ▶ Advising one of the biggest European radiology providers on entering the Ukrainian market, including advising on

radiology equipment importation in Ukraine, certification in Ukraine of the advanced diagnostic system (MRI, CT, Digital X-Ray, Ultrasound, etc.) and licensing requirements of the medical practice in Ukraine;

- ▶ Advising a European producer and distributor on importation of pharmaceuticals to Ukraine;
- ▶ Development of the supply/distribution contract framework in Ukraine for a European producer of medical devices; advising on the tax structuring of medical devices sales in Ukraine.

Uzbekistan




- ▶ Due diligence of local representative office activities for Indian pharmaceutical companies, advising on transfer of business issues;
- ▶ Representing a leading German pharmaceutical company at Uzbek antitrust authority and economic court against producers and retailers of counterfeit pharmaceutical products in Uzbekistan;
- ▶ Assisting a leading Serbian pharmaceutical company on trademark assignment, drafting and registration of the assignment of trademarks;
- ▶ Successfully defending a representative office of the Polish pharmaceutical company against a lawsuit brought by a former employee related to payment of damages and moral compensation for illegal termination of employment relations;
- ▶ Assisting a leading multinational manufacturer of hygiene products on trademark protection and general trademark issues;
- ▶ Advising a group of pharmaceutical companies on the import of pharmaceutical products, medical products, equipment;
- ▶ Consulting on the development of websites, platforms for pharmaceutical companies;
- ▶ Consulting on the possibility of paying remuneration to medical workers for conducting statistical research;
- ▶ Advising and supporting the registration of Chinese company vaccination information management software;
- ▶ Advising an American pharmaceutical company on indemnity issues;
- ▶ Advising a large Kazakh pharmaceutical company on labor law issues;
- ▶ Advising a major pharmaceutical manufacturer on drug advertising regulation.

Ключові контакти



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
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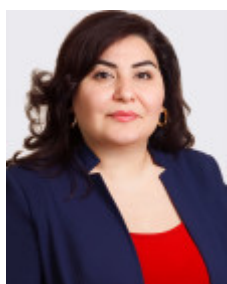
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
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
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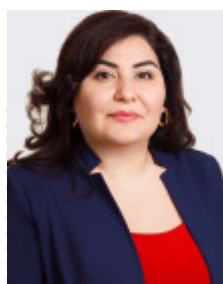
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