



GRATA
INTERNATIONAL

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PHARMACEUTICALS &
HEALTHCARE

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



EXPERIENCE

- Assisted a major global pharmaceutical company, in litigation concerning debt recovery. Judgment in favor of the Client - USD 712 000;
- Advised a global American pharmaceutical company on drug distribution issues in the Republic of Azerbaijan;
- 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 large American pharmaceutical company on various aspects of labor legislation in the Republic of Azerbaijan;
- 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.);
- Comprehensive advising of the Client on the issues of regulating of manufacturing, registration, disposal, distribution of medical devices for diabetic patients;
- 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;
- 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;
- Review of distribution agreements on their compliance with mandatory rules under the Laws of Georgia;
- Advising in Kazakhstan a number of BigPharma corporations and other large international pharmaceutical company on pricing, advertising and promotion of medicines, as well as evaluating various business issues in the course of commercial activities;
- Due Diligence of a large international pharmaceutical company in Kazakhstan with recommendations to reduce corporate and commercial risks;
- Legal support within the anti-corruption investigation against third parties;
- Legal and tax analysis of the perspectives and risks within the EAEU when localizing production in Kazakhstan;
- Development of a single model of a distribution agreement to conclude with distributors in the CIS countries;
- Protecting the interests of intellectual property rights holders in Kazakhstan;
- Advising on clinical trials in Kazakhstan; on the safety of medical products;
- Advising on legal requirements for the provision of educational grants and donations, sponsorship, research funding in Kazakhstan;
- 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;



EXPERIENCE

- Comprehensive advice on collection, processing and protection of personal data in Kazakhstan;
- Development and checking of various consent forms for owners of personal data, including employees, their families, healthcare professionals, patients, participants of other events organized by pharmaceutical companies in Kazakhstan;
- Advising on applicability of the General Data Protection Regulation of the European Union in Kazakhstan;
- Legal support of corporate restructuring and transfer of personnel between affiliated offices of a single group of companies;
- Audit of HR related documentation of a large pharmaceutical company represented in Kazakhstan;
- Assistance with development of internal labor and workplace safety policies for the local office of a medical equipment manufacturer;
- Advising on Kazakhstani antitrust legislation in relation to distribution agreements;
- Advising international manufacturers of origin medicines on a strategy for protecting the rights and interests within framework of compliance with the requirements of competition law;
- Audit of the activities of an international pharmaceutical company in terms of antitrust risks in the CIS countries;
- Advising on issues related to customs clearance under various distribution schemes in Kazakhstan;
- Representing and protecting interests of a manufacturer of medical equipment when appealing the results of customs inspection in Kazakhstan, as a result of which the FEACN codes of imported medical products were changed and additional amounts of customs duties were charged;
- Advising and legal support in communication with tax authorities over the taxability of funds received by a representative office in Kazakhstan from its parent company overseas;
- 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 in Kazakhstan;
- Advising a European pharmaceutical company on inclusion in the register of creditors under the debtor rehabilitation procedures in Kazakhstan;
- 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 in Kazakhstan;
- 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 in Kazakhstan;
- Legal support of pre-trial settlement of labor disputes in Kazakhstan;



EXPERIENCE

- 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 etc.;
- Advising a leading American 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 US pharmaceutical company on requirements of the Kyrgyz Law to notification of the authorized state agency on adverse reaction of a drug;
- Advising a local pharmaceutical company on import requirements of pharmaceutical products, participation in tenders and lifesaving medicines;
- 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;
- 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 on anti-corruption policy, privacy policy and personal data procedure;
- Advised a multinational pharmaceutical company on execution donation and sponsorship agreements with state hospitals professionals;
- 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;
- Advising a group of pharmaceutical companies on the import of pharmaceutical products, medical products, equipment;
- Consulting on the possibility of paying remuneration to medical workers for conducting statistical research;
- Advising a large Kazakh pharmaceutical company on labor law issues;
- Advising a major pharmaceutical manufacturer on drug advertising regulation;
- 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;



EXPERIENCE

- 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;
- 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 reorganization of business in Russia and a joint venture with a Russian partner;
- 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;
- Legal support for the reorganization 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 reorganization, preparation of the charter of the reorganized entity, support for state registration and its exclusion from the register of affiliated organizations;
- Support of an investment project for the construction of a medical center;
- Representing a major regional supplier of medical equipment, Labmedconsult LLC, in a labor dispute with an employee who misuses disability certificates;
- 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 provisions of the Tajik laws on drug advertisement;
- Advising RP Canon Medical Systems on licensing for training, service and repair of medical equipment (Tajikistan);
- 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.

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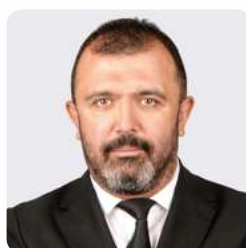
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About GRATA International

GRATA International is a dynamically developing international law firm which provides services for projects in the countries of the former Soviet Union and Eastern Europe: full coverage of the entire region with network of offices, highly qualified team of professionals suited for cross-border projects. Firm's reputation and expertise are confirmed by testimonials from transnational clients and leading international ratings.

A wide network of offices operating under one system and platform delivers great convenience for our clients. Any office can act as a "one-stop-shop" for its clients and provide them with access to services in other cities and countries. If necessary, inter-office teams with relevant experience are assembled to provide solutions to complex tasks. Service quality is assured by a clear system of organisation of this process.

GRATA International is present in the following jurisdictions: Azerbaijan (Baku), Armenia (Yerevan), Belarus (Minsk), Georgia (Tbilisi), Cyprus (Limassol), Kazakhstan (Aktau, Almaty, Astana, Atyrau, and other cities), Kyrgyz Republic (Bishkek), Moldova (Chisinau), Mongolia (Ulaanbaatar), Russia (Moscow, St. Petersburg, Rostov-on-Don, Samara), Tajikistan (Dushanbe), Turkey (Istanbul), Ukraine (Kyiv) and Uzbekistan (Tashkent).

In addition to its offices, GRATA International has representatives in China (Beijing, Hong Kong), Germany (Frankfurt), the Malaysia (Kuala Lumpur) Russia (Kazan), Switzerland (Zurich), Turkmenistan (Ashgabat), UAE (Dubai), the UK (London), USA (New York).

GRATA International is regularly acclaimed by leading international rankings: Chambers Global, Chambers Asia-Pacific, Legal 500, IFLR1000, WWL, Asialaw Profiles, and is featured in Deals of the Year Awards by China Business Law Journal.

Key Industry Sectors:

- Banking & Finance
- Construction & Infrastructure
- Industry & Trade
- Mining
- Oil & Gas
- Pharmaceuticals & Healthcare
- Technology, Media & Telecommunications
- Transport



250+
professionals



22
countries of presence

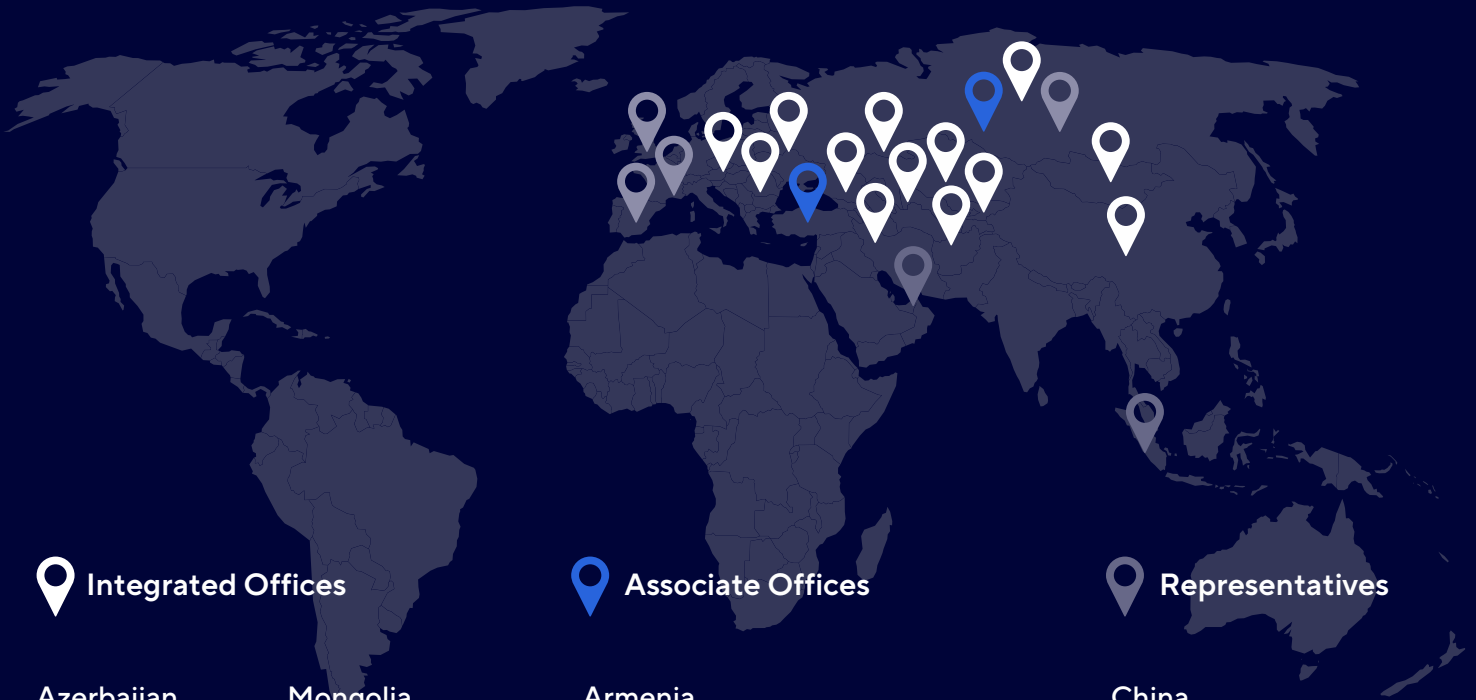


6000+
clients



11000+
projects

Global Presence



Integrated Offices

Azerbaijan
Baku

Belarus
Minsk

Georgia
Tbilisi

Kazakhstan
Aktau
Almaty
Astana
Atyrau, etc.

Kyrgyzstan
Bishkek

Moldova
Chisinau

Mongolia
Ulaanbaatar

Russia
Moscow
Rostov-on-Don
St. Petersburg

Tajikistan
Dushanbe

Ukraine
Kyiv

Uzbekistan
Tashkent

Associate Offices

Armenia
Yerevan

Cyprus
Limassol

Russia
Samara

Turkey
Istanbul

Representatives

China
Hong Kong
Beijing

Germany
Frankfurt

Malaysia
Kuala Lumpur

Switzerland
Zurich

Turkmenistan
Ashgabat

UAE
Dubai

UK
London

USA
New York