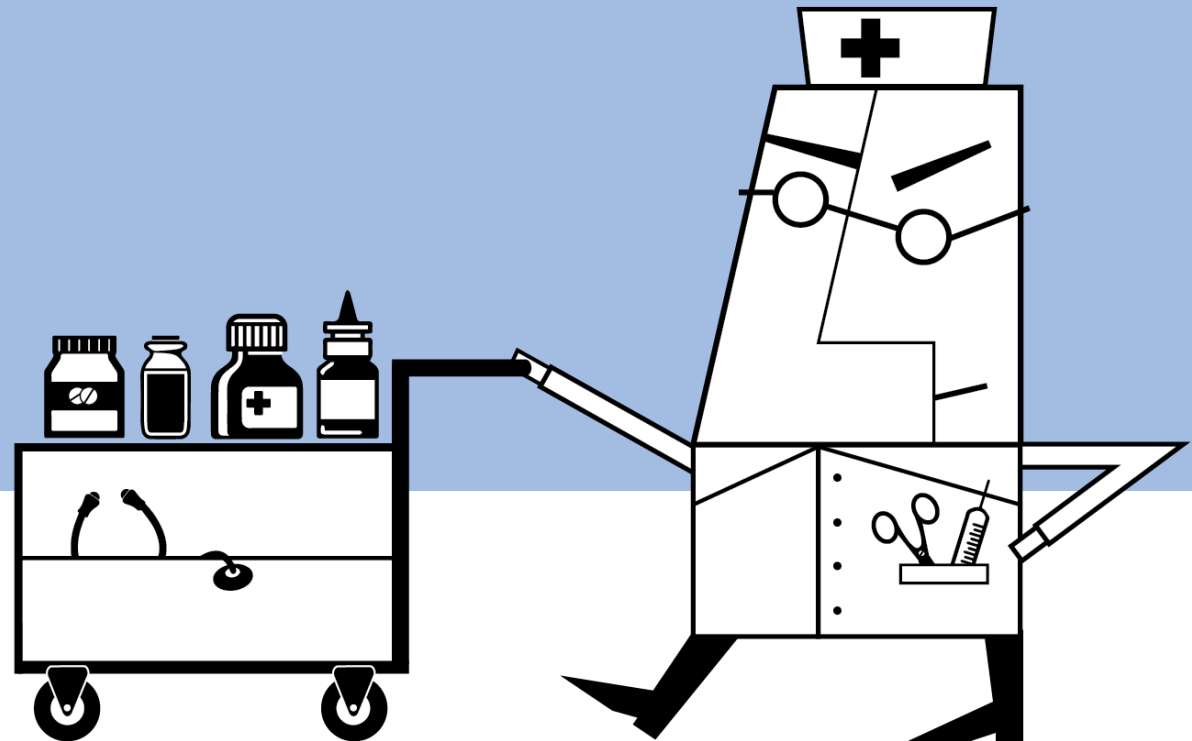




LIFE SCIENCES



About the practice



Life Sciences is one of the key divisions with Pepeliaev Group



Our lawyers have been working for many years with producers, distributors, professional associations and sector regulatory authorities, and are ready to provide comprehensive legal support with regard to regulation in the industry



The Life Sciences practice of Pepeliaev Group has been acknowledged in the ratings compiled by international and Russian independent legal directories

**CHAMBERS
EUROPE**

Chambers Europe
Band 3, 2021



PRAVO-300
– Tier 2, 2023



Konstantin Sharlovskiy, Head of Life Sciences Practice, has been included in the individual **Pravo.ru-300 (2023)** ranking in the life sciences category

300

projects
in the last
3 years

>100

clients from the top 10 largest
pharmaceutical companies
of the world

THE PRACTICE WAS ASSESSED
AS FOLLOWS: "VERY GOOD
UNDERSTANDING OF THE PRACTICE
AND OUR BUSINESS".

CHAMBERS EUROPE

Competitive advantages



The lawyers **solve a wide range of issues in pharmaceuticals and associated industries**, from providing routine advice to supporting major investment contracts and transactions with assets.



Each lawyer of the team has an average experience of **8-10 years** in life sciences, including working for pharmaceutical companies **(in-house)**. This allows us to understand clients' business demands and provide practical advice.



The firm has tax, antitrust and IP practices, among others, and therefore can implement **integrated** legal projects for clients.



Clients choose our team when they need **legal support for research and development projects** which include pre-clinical and clinical trials, localisation of production, an assignment of rights to technologies, the launching of new products in the Russian / EAEU market and building a model of work with distributors / pharmacy chains.



The clients **praise the lawyers of the practice for resolving complex regulatory issues**.



The practice is specifically acclaimed for its **experience of conducting projects relating to the regulation of the production and circulation of medical products**.



Clinical research and trials

- Advising on the implementation of the results of clinical trials that were obtained abroad for registration in Russia and the EAEU; legal nuances of their cross-border transfer, ethical aspects of research and other issues
- Providing legal assistance with the conclusion of contracts with medical institutions and organisations involved in clinical trials (CROs)
- Providing support for clinical trials of complex medical products the use of which is connected with a medical device
- Structuring and providing legal support for communication within a group of companies within the framework of multicentre clinical trials
- Advising on trials of medical devices, studies of food supplements and cosmetic products



Localising manufacturing

- Drafting and concluding agreements on contract manufacturing and on the transfer of the production technology to new manufacturing sites
- Advising on a wide range of conditions and measures for supporting domestic manufacturers and foreign investors (preferences, benefits, special investment contracts (SPICs) and offsets)
- Providing legal support with regard to all aspects of the construction and the equipping of new manufacturing facilities
- Providing legal support for the import of equipment, reagents, samples of medicines and medical devices; representing the client in disputes with customs authorities



Wholesale and retail trading

- Providing comprehensive legal support when selecting, building and changing the distribution model in Russia
- Drafting and analysing existing contracts, commercial policies, and rules for selecting distributors; communicating with the latter, as well as with pharmacy chains and aggregators
- Advising on issues relating to the distance selling of medicines and medical devices, food supplements, perfumes and cosmetics; providing legal support for the entry into and performance of agreements with aggregators, marketplaces and e-pharmacies



Transactions with assets

- Performing due diligence of companies and assets (the rights to medicines, medical devices, food supplements, perfumes and cosmetics, pharmaceutical substances and so on)
- Providing support for the purchase of exclusive rights to intellectual property items (new developments and products circulating in the market) including preparing agreements and other transaction documents, participating in negotiations on the client's part and so on
- Structuring transactions taking into account the specifics of the regulatory regime and the best business practices in the pharmaceutical and medtech industries



Advertising and liaising with the professional community

- Advising on all issues connected with promoting prescription and OTC medicines, medical devices and food supplements, including checking the content of specific advertising materials
- Advising on how to interact with employees of medical institutions and pharmacies, including checking or drafting the relevant contracts, supporting documents, internal policies and due diligence and support of compliance procedures
- Assisting in communication with non-profit patient and medical organisations: analysing and drafting donation and service agreements, as well as internal policies



Legal support with regard to other aspects

- Advising on issues arising:
 - In the context of registering a medicine, medical devices, food supplements and cosmetics, including when (re)registering the maximum selling prices of medicines included in the List of Vital and Essential Medicines;
 - In the context of devising a strategy for launching a medicine/medical device on the Russian/EAEU market, including in relation to issues connected with patent protection and the exclusivity of data pertaining to the medicine;
 - In connection with participation in state procurement procedures (including with regard to issues of entering into contracts using lifecycle-contract models and long-term contracts)
- Providing legal support during inspections by supervisory authorities, as well as when such authorities' actions and decisions based on the results of such inspections are subsequently challenged
- Providing legal support to pharmaceutical and medical technology companies regarding customs, tax and currency issues connected with their activities

Selected projects

Assessed and mitigated risks arising during an advertising campaign

For the purposes of assessing and minimising the client's potential risks arising during an advertising campaign which included putting into circulation batches of goods with changed packaging (labels) and placing advertising materials in retail chains and on the Internet, the client had requested us to prepare a legal opinion on the materials of the advertising campaign and to provide practical recommendations as to how the identified risks could be mitigated.

Clinical trials in Russia

Provided legal support to one of the world's largest pharmaceutical companies performing clinical trials in Russia: we devised legal recommendations for patients to participate in the trials as well as mechanisms of conducting clinical studies in relation to a medicine the use of which closely relates to a medical product.

Provided comprehensive support to the client during the change of the distribution model

The client was considering changing the form of its presence in Russia including changing how medicines were to be supplied to Russia. In this regard, the client needed comprehensive legal support during the process of changing the distribution channel. In particular, we needed to assess different options for restructuring contractual and corporate relationships from the standpoint of the legal and transactional risks, to prepare a commercial policy that would be in line with the client's interests and be compliant with Russian legislation, relevant case law and business practice, to draft intra-group agreements (for the supply of medicines, for registration services and an agency agreement) and to prepare a template of a supply agreement with Russian distributors.

Selected projects

Prepared overviews of counter-sanctions for pharmaceutical companies

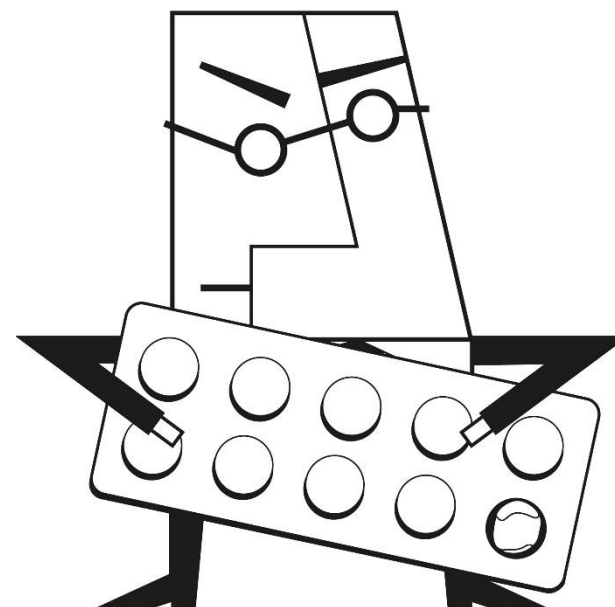
Prepared daily, weekly and monthly reviews of counter-sanctions and support measures with a brief description of each amendment, its status and potential effect on business, as well as how it is connected with other laws. In addition to regulatory and legal acts, the review included relevant judicial cases demonstrating how courts and administrative bodies were applying counter-sanctions and support measures, as well as certain non-regulatory legal acts, clarifications, letters and guidelines by authorised bodies.

Provided legal support to a major pharmaceutical company in its day-to-day operations

In the framework of legal support of the client's day-to-day operations we were preparing legal opinions and drafting contractual documents in different areas including employment law and currency regulation, as well as regulatory (such as conducting clinical trials) and commercial matters (including adjusting commercial policies and considering specific situations in which they were applied).

Expanding geographical coverage

In order to identify the most effective model of business coverage in Kazakhstan for a major Russian pharmaceutical company, it was necessary to consider different options for forming the marketing function in Kazakhstan, taking into account local risks, as well as the regulatory, commercial, tax and employment risks of the parent company, which is a resident of Russia.



Selected projects

Localisation of the manufacturing of vital and essential medicines in Russia

Provided legal support in a project involving the localisation in Russia of the manufacturing of a medicine which is on the List of Vital and Essential Medicines, which included preparing an opinion regarding the legal and tax risks connected with different contractual models, analysing agreements for the purchase of rights to a product, developing a template agreement for contract manufacturing (including all necessary appendices) and providing additional advice regarding the use of the agreement when a specific transaction is formalised.

Tax support

Provided tax support for a medicine of Russian origin to be launched on international markets, including with regard to its export out of Russia, manufacturing abroad to be subsequently sold on foreign markets, or licences being granted to foreign manufacturers.

The manufacturing and sale of a medicine

Advised the client regarding the tax consequences and risks arising from the terms and conditions of an agreement for the production and sale of a medicine within a group of affiliated companies, taking into account the actual distribution of functions and pharmaceutical licences. Based on the results of this work, we proposed an option for structuring the relationships with the minimum of tax risks, which did not violate the requirements of legislation on the circulation of medicines.

Contract manufacturing of active pharmaceutical ingredients and biological substances

Pepeliaev Group's lawyers have provided legal support to a client within the framework of organising the contract manufacturing of active pharmaceutical ingredients and biological substances jointly with a Russian pharmaceutical company.

Selected projects

Antitrust audits

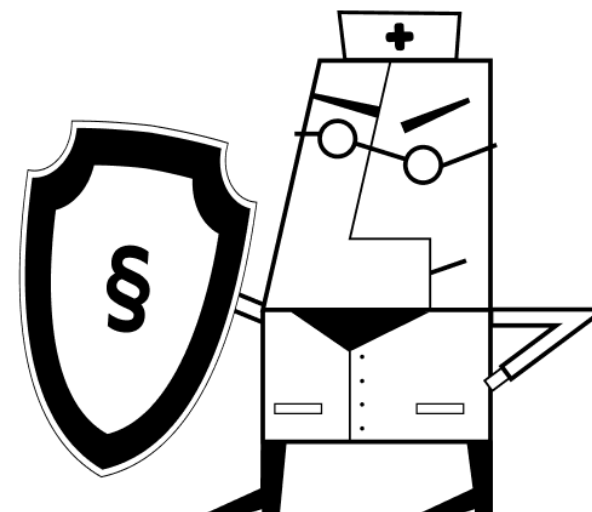
The experts of our antitrust practice have conducted a considerable number of antitrust audits in relation to the activities of pharmaceutical companies, thus accumulating a wealth of knowledge concerning the specifics of business in this industry in the Russian market. As a result, our lawyers successfully implement their knowledge of the main antitrust risks and ways to prevent them when providing support during a range of audits conducted by the Russian Federal Antimonopoly Service in relation to pharmaceutical companies, and, subsequently, when the regulator's decisions are contested in courts.

Investing in the production and acquisition of new assets

Pepeliaev Group's services also encompass legal support for Russian and global companies in relation to the legal aspects of business development, namely, investing in the production and acquisition of new assets (including rights to medicines). For instance, our lawyers have assisted a major investment fund and one of its portfolio companies, a Russian manufacturer of medicines that was acquiring rights to several brands of premium generic medicines for subsequent in-house manufacturing.

Transfer and use of patients' data

Drafted a legal opinion on whether patients' data can be transferred and used for researching routine clinical practice. Within the framework of the project we analysed the relevant legislation, court and administrative decisions, positions of state authorities, the trends in the legal regulation, and provided an assessment of data being transferred (personal or depersonalised, or anonymous and aggregated data). We prepared a position on whether the transfer of data was lawful and assessed the corresponding risks.



The team



Ilya Bolotnov

Partner

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Ilya specialises in corporate and contract law. For over 25 years, he has advised Russian and non-Russian clients on investments in Russia, M&A transactions, commercial and contract law and on antimonopoly regulation (including asset acquisitions, restructurings, the formation of joint ventures, and the integrated structuring of contractual relationships in Russia), including when working with Life Science companies. A significant part of Ilya's practice is dedicated to work with Life Science and FMCG companies.

WHAT THEY SAY

Large corporate practice now raising its reputation in the area of M&A transactions (Chambers Europe).

Lawyers of the corporate practice "provide pragmatic recommendations based on their knowledge of the local specifics" (Chambers Europe).



Maria Nikonova

Partner

m.nikonova@pgplaw.ru



Maria specialises in taxation in the pharmaceutical industry and FMCG. She advises on tax risks in sales of medicines, the conduct of clinical trials, the promotion of medicines and food supplements, as well as on other issues of pharmaceutical companies' business. She has a track record of providing legal support to large international and Russian companies when analysing and structuring their operations with a view to maximising their efficiency and minimising risk exposure.

Maria has frequently litigated on behalf of various companies on tax issues in courts of all levels and before other state bodies.

WHAT THEY SAY

"An impressive track record in resolving tax disputes and outstanding experience of handling large-scale tax disputes, including representation at the level of the Russian Supreme Court" (Chambers Europe).

The team



Konstantin Sharlovskiy

Partner

k.sharlovskiy@pgplaw.ru



Konstantin has more than 13 years of experience in law, for nine of which he has been providing legal assistance to pharmaceutical companies in Russia and the CIS. He specialises in transactions with assets in the area of pharmaceuticals, solving complex regulatory issues, including those connected with intellectual property of pharmaceutical companies, with the localisation of manufacturing in Russia, and with contractual regulation of relationships between those involved in the circulation of medicines and medical products in Russia.

Konstantin has vast experience of representing clients in negotiations, within the framework of complaint proceedings and in litigation, including disputes with supervisory authorities.

WHAT THEY SAY

Pepeliaev Group's team exhibits "excellent value for money and a result-oriented approach" (Legal 500).



Taisia Kubrina

Senior Associate

t.kubrina@pgplaw.ru

For more than ten years, Taisia has been involved in the legal support of the activities of medical and pharmaceutical institutions.

She has a wealth of practical experience of work, including the position of an inspector in a local office of Roszdravnadzor and also the position of a lawyer in one of the largest domestic pharmaceutical companies. Taisia specialises in solving complicated issues of legislation in the field of the circulation of medicines, including preventing the illegal circulation of medicines and their theft, while she has experience of conducting an audit of pharmaceutical activity, of providing legal support in inspections and licensing, and providing support for contractual relationships.

WHAT THEY SAY

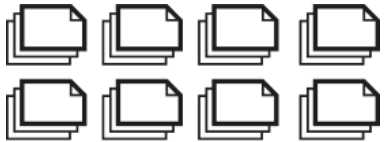
A client notes: "They are very good at making a thorough analysis," adding: "They are always able to answer complex questions". (Chambers Europe).

About the firm

A leading Russian law firm offering the full range of legal services.

Lawyers

160

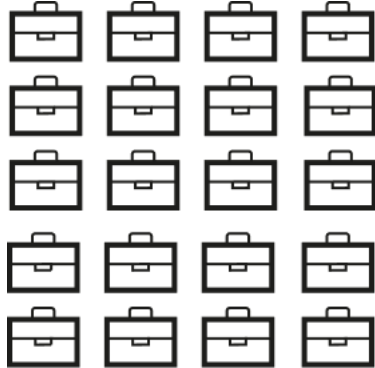


Our lawyers include 3 Doctors of Laws and 19 PhDs in Law.



Clients

2000



Office

8

Moscow
St Petersburg
Nizhnekamsk
Krasnoyarsk
Vladivostok
Beijing
Shanghai
Dubai

Ratings



CHAMBERS EUROPE

CHAMBERS GLOBAL

IFLR1000

World
Trademark
Review.

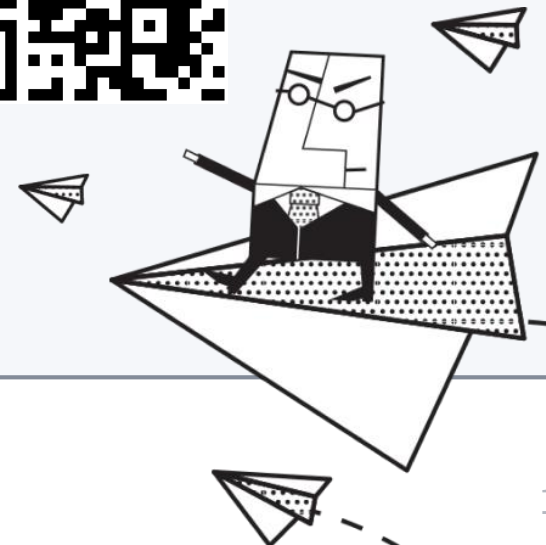
INTERNATIONAL
TAX REVIEW



Best Lawyers

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News of the firm, themed overviews of legislation and administrative and judicial practice, and expert commentary



Services



Tax advice &
tax disputes



Administrative law
defence of business



Banking and
finance practice



Bankruptcy



Family and
inheritance law



Employment and
migration law



Customs law and
foreign trade
regulation



Currency regulation
and currency control



International litigation
and arbitration



Corporate law / M&A



Antitrust regulation



Dispute resolution
and mediation



Criminal law defence
of business



Legal protection
of information



Real estate & construction



Intellectual property
and trademarks



Environment



Telecommunications,
media and IT



Digital group



Life sciences

Geographical coverage

Chinese Desk

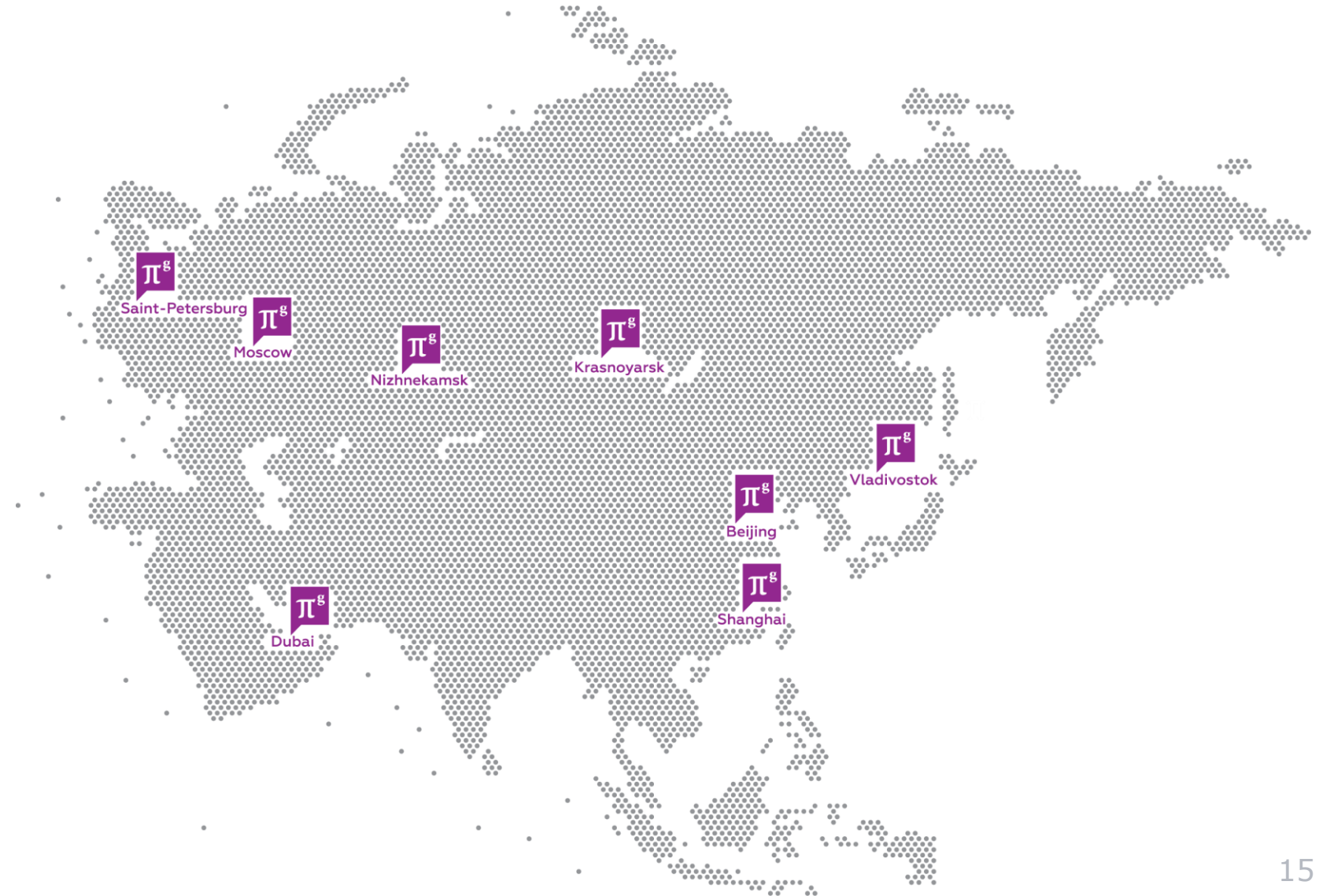
- Representative offices in Beijing and Shanghai.
- Support for Chinese investors in Russia and for Russian investors in China.
- We have strategic partners on the Chinese market.
- Comprehensive legal support.

Korean Desk

- Legal advice to Korean companies in Russia and to Russian investors in Korea.

Middle East Desk

- PG TAX Consultancy LLC provides services on tax structuring and tax consultancy in UAE and GCC.



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