

# COMPLIANCE SERVICES FOR COMPANIES IN THE HEALTHCARE SECTOR



## Our services





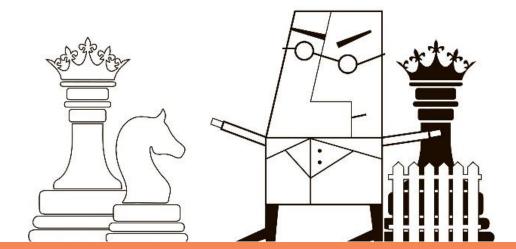
## **Developing and implementing compliance procedures**

- Developing an individual compliance system from scratch / adapting the current system to the processes, resources and needs of the specific company
- Identifying the necessary controlling points in the company's business processes
- Identifying and classifying the key compliance risks for the company's activity
- Creating algorithms of compliance procedures, implementing a compliance operations system
- Developing and implementing an SOP based compliance system / a principle based compliance system
- Implementing a compliance benchmarking system
- Analysing the current anticorruption standards and compliance procedures of the company, developing and subsequently implementing recommendations with regard to enhancing the company's anticorruption policy



#### **Dealing with contracting parties**

- Third party compliance oversee system
- Due diligence of contracting parties, including to ensure that they comply with the requirements of FCPA and UKBA
- Sanctions compliance (SSI/SDN)
- Automating algorithms to monitor bonuses and discounts for distributors



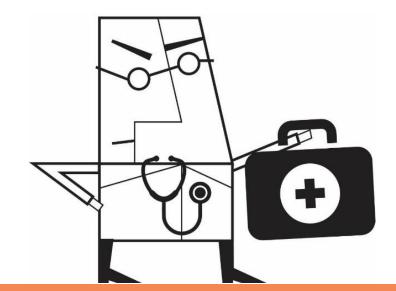
#### Our services





#### **Conducting investigations**

- Comprehensive internal investigations (involving HR, the security service, etc.)
- Investigations under FCPA, UKBA, and SAPIN II
- Forensics, searching for assets
- Providing criminal law support in an investigation





# Checking whether the company's internal documents are in line with legislation and the best healthcare practices

- Developing and updating KOL grading processes, mitigating anticorruption risks
- Developing legal relationship models with patient community and stakeholders groups
- Reports under AIPM / FCPA / SOX
- Customising and delivering training for field sales forces depending on the company's risks and needs that have been identified
- A system for notifying events (the Federal Service for Surveillance in Healthcare (in Russian abbreviated as 'Roszdravnadzor'))
- Checking events for HCP (dawn raid, 'simulated doctor')
- Organising a 'hot line'

## Our services





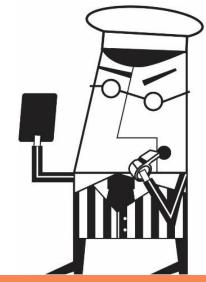
#### **Antitrust compliance**

- Analysing the company's current position on the market
- Identifying existing and potential risk areas
- Decreasing the likelihood of a violation of antitrust law, which includes assessing, forecasting and minimising potential negative implications, including financial implications (turnover-based fines)
- Enhancing the system of internal regulations
- Training employees and developing an antitrust culture
- Preparing senior management and employees to deal with the Russian Federal Antimonopoly Service (the FAS of Russia)



## Legal GR. Liaising with institutions for the protection of business

- Selecting the most effective tools for the protection of rights
- Drafting appeals, personalised letters and other documents
- Providing legal support when an appeal is considered
- Organising an expert review and public support
- Liaising with the competent state authorities to develop measures to respond to an appeal and for a favourable resolution of the situation



## Sample projects

## Integrating compliance systems when creating JV pharmaceutical companies

Pepeliaev Group's experts integrated the compliance systems of a Russian and a foreign pharmaceutical companies when creating a joint venture. In the course of integration our experts conducted a compliance audit, identified and classified the main risks, prepared a plan for corrective and prevention action (CAPA), and closed the deal in terms of compliance.

## **Investigating the consequences** of a serious adverse phenomenon

Provided support in a case connected with the consequences of a serious adverse phenomenon for a producer of medical devices. Held an actual investigation and collected the evidence base. As a result the company's senior management eliminated the risks of criminal and administrative prosecution.

#### **Creating a compliance system from scratch**

Pepeliaev Group's lawyers created a compliance system for a pharmaceutical company taking into account all specifics of its business processes. The practice's experts were supporting current compliance processes of the company, but in doing so they reached a balance between the business need and the control function.

## Conducting an anticorruption audit of a pharmaceutical company

Conducted an anticorruption audit of a pharmaceutical company, which involved: checking documents, actions of field sales forces and SOX reports, and developing a training programme for employees.

## Sample projects

#### **Implementing anti-corruption standards**

Pepeliaev Group's experts used the best anticorruption practices of world-leading international companies to update and form a modern set of internal anticorruption regulations in a large Russian asset-holding company, so that these regulations complied with the corresponding provisions, rules and requirements defining anticorruption standards of international commercial transactions and GR.

#### Implementing an antitrust compliance system

Conducted an antitrust audit in a pharmaceutical company which resulted in the implementation of a comprehensive antitrust compliance system aimed at adhering to the requirements of antitrust legislation and preventing violations of it.

## Assessing whether the compliance procedures implemented in a company are in line with accepted standards and the best international compliance practices

Pepeliaev Group's lawyers supported a compliance audit and a stresstest when the company was implementing anticorruption rules and obtaining a 'compliance certificate' of an authoritative nongovernmental anticorruption organisation.

## Successful appeal against an unlawful refusal of the commissioning of residential buildings

As result of our integrated work involving institutions for the protection of business, we had administrative barriers for city municipal unitary enterprises eliminated and the problem with commissioning residential buildings was solved. Criminal liability was imposed on the officers who were guilty of the violations committed.

## Sample projects



## Assisting in the termination of a tax case against a company's officers

The company's officers were accused of knowingly filing a false VAT tax return. As a result of our joint work with the office of the Presidential Commissioner for Entrepreneurs' Rights, the criminal cases against the company's officers were terminated. In addition, the dispute in a state commercial court was resolved in favour of the company.

WHAT THE TEAM IS KNOWN FOR LARGE DOMESTIC PLAYER FOCUSED ON BEHAVIOURAL AND COMPLIANCE ISSUES

**CHAMBERS EUROPE** 



#### The team





**Sergey Taut**Expert, Attorney-at-Law

s.taut@pgplaw.ru

Sergey specialises in anti-corruption compliance.

He has particularly sound credentials in the field of expert support in legislative drafting activities and changing the regulatory environment for the client's benefit.

He provides advice on matters that relate to safeguarding entrepreneurs' rights from unlawful administrative and criminal prosecution, applying tools of social and state agencies for the protection of the rights of business.

#### **WHAT THEY SAY**

Sergey has been awarded: a certificate of honour from the Russian President's Business Ombudsman For Contributing to the Development of Institutions for the Protection of Entrepreneurs' Rights; a certificate of honour of the Council of Europe Programme Office in Russia For a Personal Contribution; and an acknowledgement from the Law Department of the Higher School of Economics For Legislative Initiatives Aimed at Securing Entrepreneurs' Rights.

Pepeliaev Group's compliance practice featured in Tier 1 of the Pravo-300 ratings in 2019-2023.

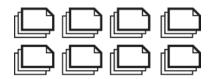
## About the firm



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

#### Lawyers

160



Our lawyers include 2 Doctors of Laws and 18 PhDs in Law.









#### Clients

2000



#### Office

6

Moscow

St Petersburg

Nizhnekamsk

Krasnoyarsk

Vladivostok

Dubai

#### **Developing Eastwards**

- Chinese Desk
- Korean Desk
- Middle East Desk

#### **Ratings**



**CHAMBERS EUROPE** 

**CHAMBERS GLOBAL** 

IFLR1000

Best Lawyers







**Expert** 

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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



Intellectual property and trademarks



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



Bankruptcy



Environment



Telecommunications, media and IT



Digital group



Life sciences

## Geographical coverage



#### **Chinese Desk**

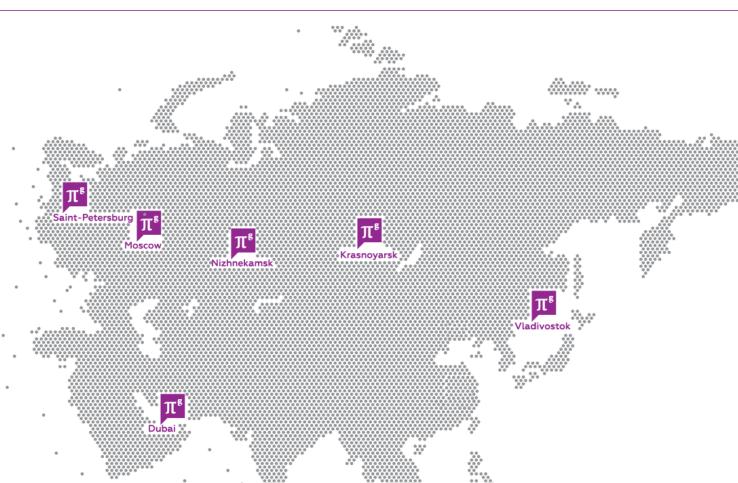
- Support for Chinese investors in Russia and for Russian investors in China.
- We have strategic partners on the Chinese market.
- Comprehensive legal support.

#### **Korean Desk**

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

#### **Middle East Desk**

 Providing services that involve tax structuring and tax advice in the UAE and in Persian Gulf countries.



## Contacts



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