

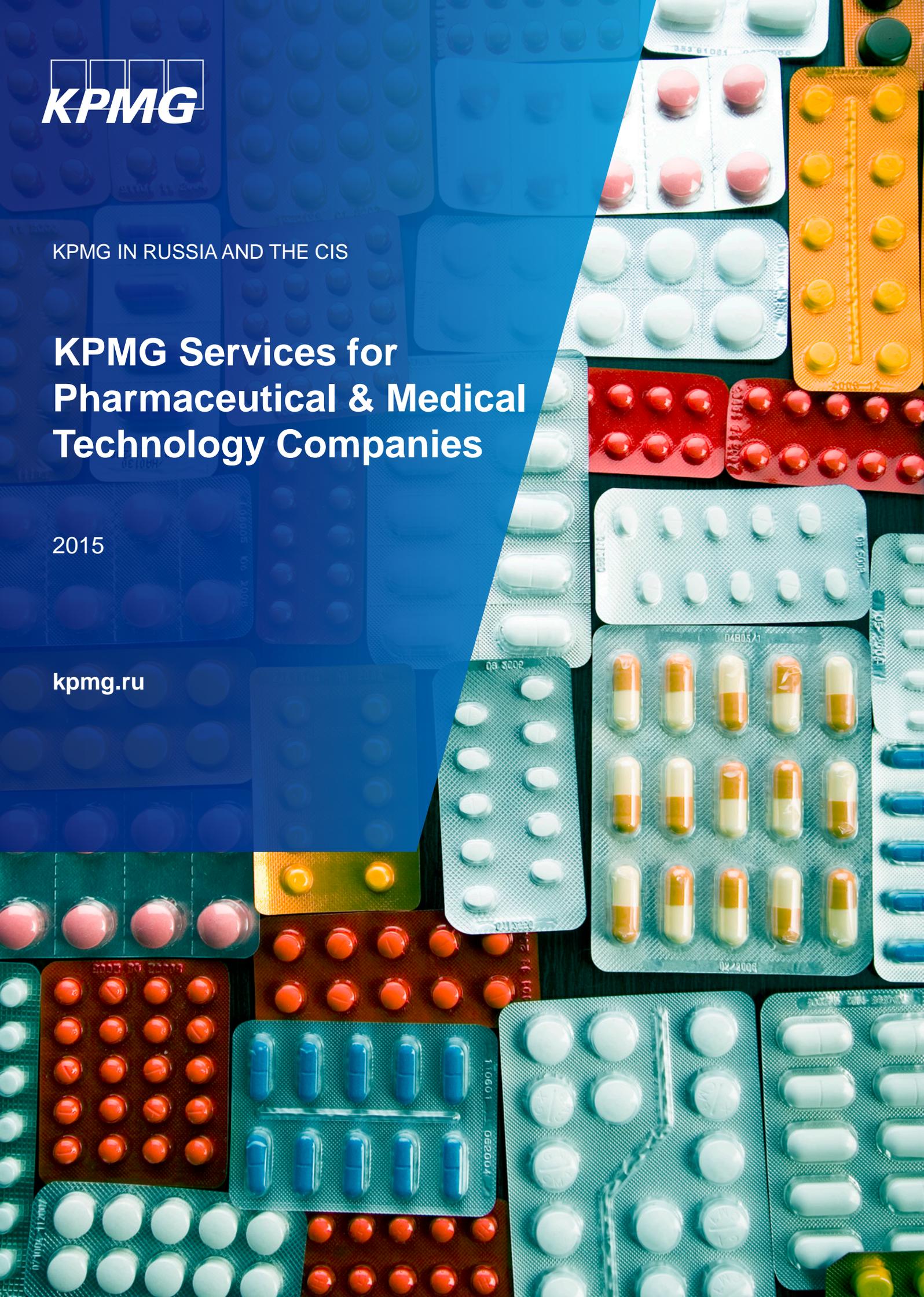


KPMG IN RUSSIA AND THE CIS

KPMG Services for Pharmaceutical & Medical Technology Companies

2015

kpmg.ru





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& Pharmaceuticals,
Russia and the CIS

Introduction

KPMG's Pharmaceuticals & Medical Technology Practice assists companies specializing in pharmaceuticals and medical devices production and biotechnologies development in Russia and the CIS.

Pharmaceuticals and medical technology are rapidly growing and innovative sectors, with a significant development potential in Russia and the CIS.

The sector development prospects in the region appear optimistic. However, we should bear in mind the risks characteristic of this business that are *inter alia* driven by structural reforms of healthcare systems and numerous amendments to legislation. In order to overcome all the challenges the business community needs a comprehensive view of the issues and a proactive approach to resolving them.

We assist our clients, both small and medium enterprises and major multinationals, in developing turnkey solutions that contribute to organic business growth and enable them to deal with market turbulence.

We are confident that our extensive project experience, in-depth sector insights and technical expertise will contribute to your business success under any circumstances.

... KPMG clients point out the outstanding level of "expertise in pharmaceutical sector issues". The firm was also highly rated for its "proactive approach, high professionalism in such areas as taxation, antimonopoly legislation, pharmaceutical sector regulation, transfer pricing and taxation issues of permanent representative offices".

– *International Tax Review, 2014*

KPMG's Global Pharmaceuticals & Medical Technology Practice

KPMG Strategy

KPMG services are aimed at providing applicable and practical solutions taking into account legislative requirements and changing needs of the sector companies.

KPMG specialists from various countries of the world assist clients in implementing such tasks as changing the management structure, ensuring compliance of companies' activities with local legislative requirements, supply structure optimization, undertaking mergers and acquisitions, information systems implementation and optimization.

KPMG's Pharmaceuticals & Medical Technology team with its extensive experience and sector specific insights is constantly raising its professional level by following key trends in the sector development and legislative changes and by exchanging experience. This ensures a high quality of KPMG services regardless of our clients' location and complexity of the challenges we are facing.

Examples of pharmaceutical and medical technology companies that are KPMG clients in Russia and the CIS

Audit

- Biocad
- Martin Bauer
- Merck
- Pfizer
- Roche
- Takeda

Advisory services

- Bayer
- Fresenius Kabi
- NovaMedica
- Novartis
- Sanofi-Aventis
- Teva

Tax advisory services

- Astellas Pharma
- GlaxoSmithKline
- Glenmark
- Johnson & Johnson
- STADA
- Private joint stock company Biofarma



KPMG in Russia and the CIS

- 25 years in Russia
- CIS: 7 countries, 18 offices
- More than 4,000 specialists



KPMG services for various lines of business

Audit

- Audit of financial statements prepared in accordance with international standards (IFRS, US GAAP)
- Audit of financial statements prepared in accordance with the Russian accounting standards (RAS)
- Audit-related services
- Accounting and reporting services
- Corporate governance and sustainable development services
- Internal audit and risk management services

Tax and Legal

Taxation

- Corporate & business tax
- Tax dispute resolution
- Advisory services related to legal regulation of the pharmaceuticals and healthcare sectors
- Accounting, financial and tax reports
- Taxation of individuals and HR management
- Customs advisory
- Mergers & Acquisitions
- International taxation
- Transfer pricing
- Indirect taxation

Legal advisory services

- Legal support of transactions
- Advisory services on Russian and international law matters
- Dispute resolution

Advisory

Deal Advisory

- Corporate finance
- Business restructuring
- Transactional support
- Debt management

Risk management advisory services

- Financial risk management
- Fraud and corruption risk management (forensic)
- Big data analysis and technologies

Management consulting

- Strategic consulting
- Increasing operational efficiency
- Financial management
- Finance and treasury management
- IT strategic management

For the purpose of enhancing the efficiency of services for international clients, KPMG created National Desks (Japanese, Korean, Italian, German and Turkish Desks) where both local and foreign experts work.

Audit

An independent audit of financial statements increases reliability of information prepared by organizations for their investors, lenders and other interested parties pursuant to the applicable laws.

KPMG Audit department not only gives its clients reasonable assurance that their financial statements contain no material misstatements but also provides its opinion on certain matters that fall outside the scope of an ordinary auditor's report.

At present IFRS financial statements audited by KPMG are a must-have for efficient communication with international and Russian partners and for discussing various forms of financing current or future projects.

KPMG services include:

- **Audit**
 - Audit of financial statements
- **Internal audit:**
 - Independent assessment of the internal audit function
 - Creation of an efficient internal audit function
- **Accounting and reporting services:**
 - Support in the implementation of “turnkey” information systems or management of implementation projects
 - Ensuring preparation of IFRS financial statements
 - Improving the quality of accounting and reporting
- **Corporate governance:**
 - Improving the management system by introducing optimization measures in sustainable development, corporate social responsibility and environmental protection
 - Improving the corporate system of risk management
 - Increasing the efficiency of investor relations and upgrading the credit rating
 - Preparation of annual reports and sustainable development reports

Selected projects



Pfizer

RAS and US GAAP
audit

2010–2015



Roche

RAS Audit

2005–2015



Terumo Corporation

RAS Audit

2013–2015



NPK Katren

RAS and IFRS audit

2010–2015



NovaMedica

IFRS audit

2012–2015



Merck

RAS and IFRS audit

2010–2015



Martin Bauer

IFRS audit

2005–2015



GE Healthcare

RAPS and IFRS audit

2009–2015

Tax advisory services

KPMG services include:

- Corporate & business tax
- Developing and implementing tax accounting systems
- Tax dispute resolution
- Customs regulation
- HR management and taxation of individuals
- Indirect taxation
- M&A tax advisory services
- Transfer pricing

KPMG provides its clients with services related to the development of business structures and strategies while optimizing tax expenses, including:

- development and implementation of tax-effective operational, contractual and financial structures;
- support in receiving tax privileges in the process of investment projects implementation;
- identification and assessment of tax risks (due diligence);
- support during tax audits, development of a defense position and representation of clients in tax disputes on pre-trial and trial phases;
- analysis of compliance with regulatory requirements and development of appropriate policies and rules (interaction with medical staff, advertising and promotion of pharmaceuticals, essential drugs pricing regulation);
- analysis and preparation of transfer pricing documentation.

Selected projects

 GlaxoSmithKline Verification of tax liabilities assessment and advice on tax risks mitigation in Russia, Kazakhstan, Ukraine, Armenia 2011–2015	 Roche Diagnostics Preparing a legal opinion regarding new provisions for regulating the public procurement process in the RF 2014	 Besins Healthcare Analysis of transfer pricing and financial modeling of a new operational structure in Russia 2014	 Astellas Pharma Advisory services on taxation and sector regulation 2013–2015	 Smith & Nephew Advisory services on a wide range of issues related to expanding the operational structure in Russia 2013–2014
 Aspen Pharmacare Advice on tax and regulatory aspects of commercial activities in Russia 2014–2015	 Paul Hartmann Preparation of objections to a tax audit report, representation and successful defense of the client's interests at the pre-trial stage 2015	 Akrihin Development of internal policies and rules on the company's interaction with medical staff 2015	 Confidential Advice on tax aspects of changing the operational structure of a Russian business 2015	 A Russian producer of biopharmaceutical products Development of holding and financial structures to mitigate risks related to deoffshorization legislation 2015

Legal advisory services

Experience of the KPMG legal team in implementing pharmaceutical and medical technology projects ensures high efficiency of business management, mitigation of any risks related to acquisition of assets and application of legally appropriate methods for investor protection.

Our legal experience includes:

- legal structuring of transactions, contractual relations, joint ventures and production projects;
- developing a corporate governance structure;
- advice on anti-monopoly legislation issues;
- legal due diligence;
- support during participation in public procurement;
- structuring and legal support of PPP projects;
- registration of Russian companies, branches and representative offices of foreign companies.

KPMG services include:

- Full legal support of transactions both locally and globally (acquisition of companies and assets, JV establishment, disposal of non-core assets)
- Legal support of business restructuring
- Due diligence of assets
- Development and assistance in implementing efficient corporate governance schemes
- Representation in disputes

Selected projects



Aspen Healthcare

Legal, tax and regulatory support in changing the legal structure in the RF

2013–2015



Martin Bauer

Analysis of legal and tax consequences of various options for group reorganization in the RF

2014



Paul Hartmann AG

Support in developing the defense line and calculations provision in a commercial dispute

2013



GlaxoSmithKline

Support in developing the corporate system of cash pooling

2015



Confidential

Legal due diligence related to planned acquisition of a Russian business

2015



Alliance Biomedical

Advice on legal settlement of a corporate conflict with the other participant of the limited liability company

2015



Qiagen

Legal support in establishing a joint venture (Russia-Netherlands), including contractual support

2015



PSI

Legal due diligence, assistance in changing the operational structure of the business and contractual support

2015

KPMG renders a vast range of services that are highly demanded by our clients and have a common purpose of increasing the business value and assisting shareholders and top managers in dealing with key challenges their companies face.



Selected projects



Fresenius Kabi

Development and modeling of operational and financial structures in the RF, preparation and introduction of accounting methodologies, installation and configuration of the SAP system

2012–2014



Italian pharmaceuticals producer

Installation and configuration of the SAP system for the Russian division of the company

2015



Baxter

Planning and methodological support of business separation in Russia

2015



Novartis

Increasing the accuracy of demand forecasts as part of integrated planning of sales and operations

2015

Deal Advisory

Our team is one of the biggest and most experienced ones in the field of M&A advisory (including due diligence), business valuation, raising finance and restructuring.

- ✓ A global network of deal advisory professionals: more than 7,300 specialists around the world.
- ✓ A single team in Russia and the CIS: more than 250 professionals in Moscow, St.Petersburg, Kiev, Baku, Yerevan, Tbilisi, Almaty and Astana offices.
- ✓ More than 115 deals in Russia and the CIS since the beginning of 2014 and 542 for the past 5 years.
- ✓ Significant experience in the pharmaceuticals and healthcare sectors.
- ✓ Protection of a client's interests at every stage of a deal.

KPMG services include:

- M&A support
- Assistance in raising finance
- Business plans and financial models development
- Business valuation
- Due diligence
- Business restructuring services
- Support of PPP projects

Selected projects



RB

Support in selling a non-core asset of medical goods distribution, including functions of a leading financial advisor of the deal, pre-sale due diligence and tax structuring

2015



Oriola-KD Corporation

Support in selling the Russian division of the company

2014



Major Indian pharmaceuticals producer

Support in the process of acquiring a similar Russian business

2014



Confidential

Development of business plans and financial models and support in negotiations with banks regarding projects of pharmaceuticals plants construction in Russia

2014–2015



Confidential

Due diligence of a group of companies producing medicinal cosmetics and dietary supplements

2014



Confidential

Assistance in a potential acquisition of a Russian biopharmaceutical company

2013



Confidential

Advice on planned investments related to a major pharmaceuticals producer in Russia

2013



Major international pharmaceutical company

Advice on a planned acquisition of a Russian pharmaceuticals producer

2013

Advice on fraud and corruption risk management issues

KPMG services include:

- Analysis and setting up a fraud and corruption risk management system
- Forensic investigations
- RADAR and social media analysis
- Assistance in dispute resolution in legal proceedings
- Intellectual data analysis to assess fraud risks and undertake investigations (forensic)

Fraud and corruption risk management should be smoothly incorporated into the corporate culture. However, in many companies in Russia and the CIS management standards do not get sufficient attention.

Mature corporate governance implies much more than just risk management. It also encompasses the creation of clear control systems to prevent fraudulent or corruption practices as well as compliance with the effective laws and regulations.

All these measures are advantageous for companies, as the management can receive the most complete information possible on the actual state of affairs and respond to potential threats on a timely basis.

Selected projects



Russian pharmaceutical company

Analysis of costs related to the construction of a pharmaceuticals plant based on similar sites

2014



International pharmaceuticals company

Analysis of costs related to the construction of sites at a packaging plant

2014



Foreign pharmaceuticals producer

Investigation of potential FCPA violations in interaction with medical staff and in conducting marketing events

2014



Foreign pharmaceuticals producer

Investigation of potential FCPA violations related to participation in public tenders

2014



Russian medical company

Introduction of the anti-corruption legislation compliance system (Russia, UKBA)

2015



Foreign producer of medical equipment

Investigation of fraudulent actions of the top management using company resources for personal purposes

2015



Russian pharmaceuticals company

Automated checks for potential affiliation of employees and counterparties using the IT-solution RADAR

2014



Foreign pharmaceuticals producers

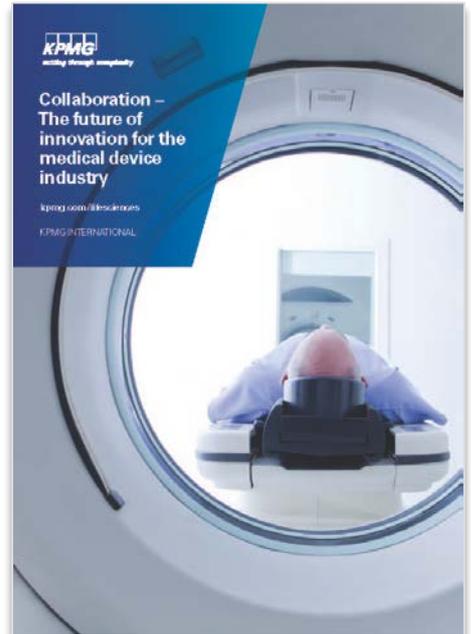
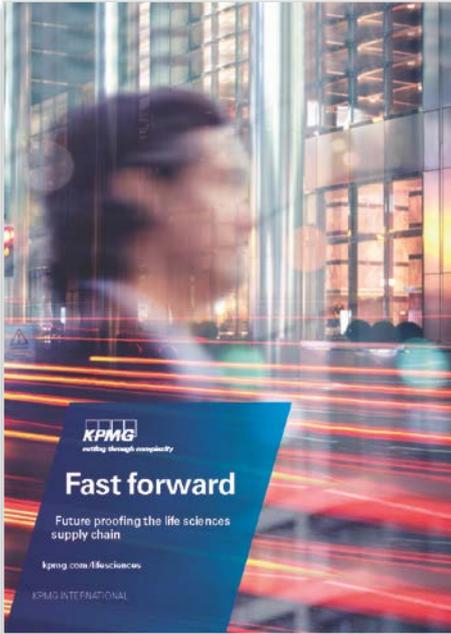
Audit of distributors' activities for potential FCPA violations

2014–2015

KPMG publications

Web-page of the Healthcare & Pharmaceuticals sector on KPMG web-site:

http://www.kpmg.com/RU/ru/industry/Healthcare_and_Pharmaceuticals/Pages/default.aspx



Deal Capsule
Transactions in Chemicals & Pharmaceuticals

2014 marked the return of the big deal. The wave of consolidation is likely to continue well into 2015.

HIGHLIGHTS

- The deal value of public M&A in the pharmaceutical sector increased by 57% in 2014 compared to 2013, with a significant increase in deal value.
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MARKET OUTLOOK

• The deal value of public M&A in the pharmaceutical sector is expected to continue to grow in 2015, driven by consolidation in the industry.

DEAL THERMOMETER

KPMG Deal Thermometer tracks deal activity across the pharmaceutical industry. The thermometer shows that deal activity is high and likely to continue in 2015.

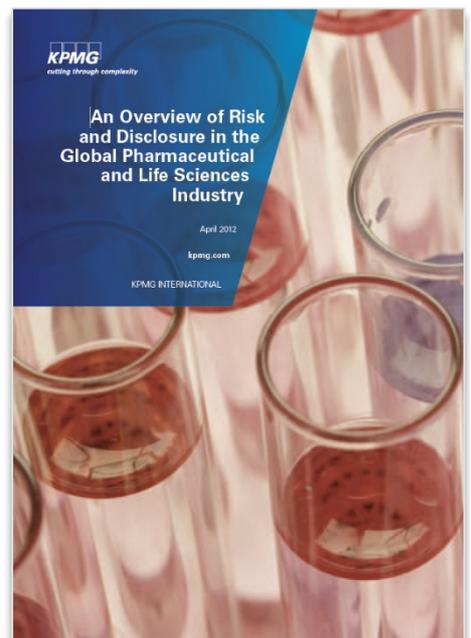
Консультационные услуги КПМГ в России и СНГ

С 1 октября 2015 года обновлен порядок регистрации и расчета предельных отпускных цен на жизненно необходимые и важнейшие лекарственные препараты

Постановлением Правительства РФ от 15 сентября 2015 г. N 979 обновлены правила расчета и регистрации предельных отпускных цен на ЖВЛП (жизненно необходимые и важнейшие лекарственные препараты).

Основные изменения:

1. Расширен перечень документов и сведений, предоставляемых при регистрации и перерегистрации лекарственных препаратов (ЛП).
2. Утверждена возможность в определенных случаях вносить изменения и регистрировать ЛП без сопоставления с ФАС РФ, при этом посылка зарегистрированных ЛП будет обязательна.
3. Утверждена обновленная Методика определения предельных отпускных цен на ЛП производства стран - членов ЕАЭС и ЛП иностранного производства.
4. Предусмотрено ограничение предельных отпускных цен на воспроизведенные ЛП и биопрепараты, не находящиеся в обращении в РФ.
5. Уточнены основания и порядок перерегистрации предельных отпускных цен на ЛП, в том числе для иностранных производителей.



Corporate social responsibility



Projects that we are proud of

KPMG is actively engaged in the field of social responsibility.

Our projects include:

- Support of programs launched by 18 socially-oriented service, institutional and environmental non-profit organizations.
- “Children in hospitals” project. In collaboration with federal clinics, we renovate playrooms and organize art therapy workshops for little patients.
- “People, not things” project. In partnership with the best service non-profit organizations, we suggest our employees make social investments into the development of professional services for vulnerable children.
- Donor's Days at KPMG. About 600 employees annually give blood for treatment of little patients of federal Moscow clinics.
- KPMG school for non-profit organizations. Professional development workshops and advice offered by the leading KPMG experts for non-profit organizations.
- Volunteer projects in partnership with the best service non-profit organizations (Center for Curative Pedagogics, Volunteers for Orphans Fund, Big Change, Artel of the Blessed Ones, Maria's Children).
- Green initiatives. Enhancement of responsible environmental conduct among our employees (visits to animal shelters, Eco Lectures and other internal projects).

“Corporate social responsibility at KPMG is the very corporate value that largely determines our corporate culture.

We follow principles of ethical conduct in our day-to-day work and recognize that business issues may be handled most efficiently only if everyone is involved and committed. Every time I pay a visit to a children's hospital or a center for children with development disorders, sit on a jury of a contest of student projects or make decisions on KPMG environmental initiatives, I feel pride in our company and our people.

At the same time I can see how much still needs doing”.

Oleg Goshchansky

*Chairman and Managing Partner,
KPMG in Russia and the CIS*

Our figures*

Volunteer hours	4,270
No. of volunteers	1,362
Employees' donations	1,089,649 roubles
Corporate donations	8,756,017 roubles

* data for Russia for the 2015 financial year

“KPMG support makes the work of 100 specialists of the Center for Curative Pedagogics possible – special education teachers, speech and language therapists, psychologists, lawyers, specialists in musical and physical therapy, alternative therapy. Thanks to these specialists' efforts, every year 1,300 children with development disorders have a real chance to get ready for school, receive education, find a job and create decent living standards. This support is a chance for a different, normal life”.

Anna Bitova

President, Center for Curative Pedagogics

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