



Life sciences

Legal services for the pharmaceutical
and med-tech industry

2020



Contents



- 01
- 02 **Our credentials** 7
- 03 **Why Deloitte** 10
- 04 **Our team** 13



- Advisory services and solutions
- Our credentials
- Why Deloitte
- Our team

Advisory services and solutions



Advisory services
and solutions

Our credentials

Why Deloitte

Our team



Deloitte CIS professionals strive to define and deliver integrated solutions for companies engaged in the production and circulation of medicines, biological supplements and medical devices and offer legal services relating to the usage of biological materials, utilisation of medical waste, and circulation of cosmetics and household chemicals

Advisory services
and solutions

Our credentials

Why Deloitte

Our team

Advisory services and solutions



Our lawyers offer comprehensive advice to producers, distributors, and sellers on an array of corporate, commercial and regulatory aspects:

- Assistance with the registration of medicines and medical devices:
 - Analysis of market entry and circulation risks, including tax, customs, regulatory, currency, and other implications
 - Support at the preparatory stage of the product registration process
- Assistance with the development and compliance assessment of internal policies of pharma and medical devices producers:
 - Review of internal processes, involving liaising with medical and pharmaceutical experts, and assessment of risks
 - Review of internal policies for compliance with the statutory requirements and provisions of AIPM and IMEDA codes of ethics
- Legal support with product importation, labelling, and packaging
 - Development of contractual framework and distributor arrangements
 - Assessment of compliance with labelling/packaging requirements by product; exposure analysis
- Legal support of public-private partnerships and medical construction projects:
 - Drafting concession agreements
 - Development of special investment contracts
 - Development and analysis of EPC and design contracts
 - Provision of services necessary for the implementation of investment projects
- Legal support of companies at the stage of medicine development and production, pre-clinical and clinical trials, quality, efficiency and safety controls, and circulation:
 - Structuring of contractual arrangements between stakeholders
 - Analysing patient sheets in clinical trials
 - Drafting consents to processing and disclosure of personal data and medical secrecy
- Advising on marketing activities:
 - Developing and analysing marketing materials (advertising materials, brochures, videos and slogans) for compliance with the specific statutory requirements
 - Reviewing marketing materials for potential competition violations
- Advising on the use, commercialisation and circulation of mobile apps and other electronic products

Advisory services
and solutions

Our credentials

Why Deloitte

Our team

Advisory services and solutions

Continue

- Developing contractual arrangements with pharmacies, including marketing and bonus agreements
- Support with public procurement and pricing issues, including structuring of contractual arrangements
- Legal support with regulatory audits, analysis of specifications from the regulatory authorities position perspective
- Analysing the risks and structure of telemedicine projects
- Tackling of antimonopoly issues, including the development of vendor management policies
- Intellectual property services:
 - Protection of intellectual property rights, commercially valuable information and clinical trial results
 - Brand, copyright and trade name protection, including against unfair competition practices; monitoring of breaches and implementation of respective remedial actions
 - Structuring and supporting technology (patent, trademark, registration dossier, know-how, software, database, etc.), licensing on the basis of best practices
 - Structuring of cross-border transactions, including to meet the production localisation requirements in Russia and the Eurasian Economic Union
 - Preparing paperwork for intellectual property licensing
 - Handling product developer relations, including the formalisation of exclusive rights

- Reviewing and ensuring compliance with the data privacy laws
- Performing independent copyright verification in technology, registration dossier, and trade name acquisition transactions
- Protection against parallel imports
- Settlement of and support in the litigation of intellectual property (confidential information, technology, registration dossier) and unfair competition disputes
- Automation of intellectual property management and routine contract drafting



Advisory services
and solutions

Our credentials

Why Deloitte

Our team

Our credentials



Advisory services
and solutions

Our credentials

Why Deloitte

Our team

Our credentials

Deloitte's dedicated industry practitioners work with clients to address the challenges and opportunities of the evolving life sciences, cosmetics, and household chemicals industry.

We deliver innovative robust solutions, aiming to help businesses in achieving their business targets

- Participation in the launch of a Russian website of a European pharma producer, including the development and analysis of website materials.
- Advisory and legal clinical trial services to a US pharma producer: analysis of patients' sheets and sponsorship contracts; development of patient consent templates.
- Analysis of international policies of a US pharma producer for compliance with the Russian statutory requirements and codes of ethics.
- Structuring of defective spare parts return arrangements between Russian users and a European producer of medical devices.
- Development of a special investment contract, risk analysis, legal support of a major Russian pharma producer.
- Development of a policy and transformation of internal processes of a major international pharma producer relating to the company liaising with the medical and pharmaceutical community.
- Legal support of a launch of a telemedicine service, including the structuring of user - clinic arrangements.
- Comprehensive legal services and participation in the structuring and launching of an online medical devices store of an international producer.
- Legal assistance with the development of an Internet bot for a group of Russian companies allowing to select a relevant medical specialist based on the patient's symptoms, drafting contracts and obtaining certificates of title.
- Legal assistance to a major Russian company with the formalisation of foreign doctors' participation in video conferences and issue of medical reports for Russian patients, in particular, development of contracts between foreign clinics and Russian patients, including for the disclosure of personal data, medical secrecy, and other issues.



Advisory services
and solutions

Our credentials

Why Deloitte

Our team

Our credentials

Continue

- Development of a distributor management policy and a code of professional conduct for a major Russian producer of medical devices.
- Court representation of a Russian producer of medical devices in a customs value adjustment dispute.
- Organisation of a workshop for a Russian pharma producer on liaising with medical specialists, including on the tax aspects, payment of distribution bonuses, intellectual property issues and tax risks related to the transfer of samples of medicines and dietary supplements to third parties.
- Legal consulting on the provision of medical grants by a non-for-profit entity and structuring of the “grant provider — clinic” arrangement.
- Drafting internal regulations, vendor selection and other policies, including a public-private partnership agreement in a regional perinatal centre project worth up to RUB 11 billion.
- Business structuring, preparation of a feasibility report and drafting of key provisions of a concession agreement for a regional hospital project worth up to RUB 7.5 billion.
- Development of business process automation guidelines; standardisation, optimisation, and unification of automated contracts for a major pharma producer.
- Representation of a major pharma producer in a trademark infringement dispute, out-of-court settlement, and its further enforcement.
- Legal support of the localisation of production to a major German pharma producer, including the cross-border transfer of intellectual property rights.
- Advising a major German pharma producer on the transfer of a registration dossier rights.



Advisory services
and solutions

Our credentials

Why Deloitte

Our team



Why Deloitte



Advisory services
and solutions

Our credentials

Why Deloitte

Our team

Why Deloitte



Deloitte team's breadth of competence and industry knowledge allows delivering an integrated service offering to life sciences and healthcare companies around the globe.



In Russia and CIS, we serve a majority of industry leaders. We would be happy to assist you regardless of what you produce or sell — medicines, medical devices, cosmetics or household chemicals.



A collaborative approach brings the customers our consulting capabilities in compliance, tax, customs, and antimonopoly regulation along with the access to the resources of a global network.



Deloitte's 2019 revenue topped

\$46,2 billion,

which makes us the largest professional services firm in the world for the second year in a row



Advisory services and solutions

Our credentials

Why Deloitte

Our team

About Deloitte

With a globally connected network of member firms in more than 150 countries, Deloitte brings world-class capabilities and deep local expertise to help clients succeed wherever they operate. Deloitte's professionals are committed to becoming the standard of excellence.

Deloitte in Russia is part of the CIS practice, a member firm of Deloitte Touche Tohmatsu Limited (DTTL).

We provide audit, tax, consulting, and financial advisory services to public and private clients spanning multiple industries through over 3,700 people working across 9 CIS countries, Georgia and Ukraine.

Deloitte CIS is represented in Russia (Moscow, St. Petersburg, Ufa, Ekaterinburg, Novosibirsk, Vladivostok and Yuzhno-Sakhalinsk), Ukraine (Kyiv), Belarus (Minsk), Georgia (Tbilisi), Armenia (Yerevan), Azerbaijan (Baku), Kazakhstan (Aktau, Almaty, Astana, Atyrau), Kyrgyzstan (Bishkek), Uzbekistan (Tashkent), Tajikistan (Dushanbe)



Advisory services
and solutions

Our credentials

Why Deloitte

Our team

Our team



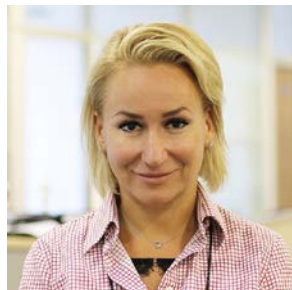
Advisory services
and solutions

Our credentials

Why Deloitte

Our team

Our team



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Anna has more than 20 years of experience in representing clients in commercial and arbitration courts.

She has strong competence in IP/IT projects, including the development of defence strategy and tactics. Anna also has recognised experience in developing litigation strategies and defenses.

Anna was ranked by Best Lawyers as one of the leading experts in Litigation



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Yuriy's experience includes advising and supporting companies across industries, including automotive, healthcare and retail.

Yuriy has an extensive track record of M&A and real estate transactions, as well as integrated support of public-private partnerships. He specialises in projects relating to the operation of major hazard facilities and environment protection and supports clients during litigations.

Advisory services
and solutions

Our credentials

Why Deloitte

Our team

Our team



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Artemy specialises in protection and commercialisation of intellectual property (IP). Over eight years in profession, he has worked with Russian and international companies from the IT, pharmaceutical, manufacturing, retail, and consumer goods sectors.

His portfolio includes projects on IP rights review, development of IP management systems, legal protection of brand at court and before the antimonopoly regulator, and support of tax benefit implementation in R&D and IT companies.

Artemy earned his LLM from the Saint Petersburg State University. He contributes to legal journals and has an extensive experience of lecturing and presenting at conferences and workshops, including the International Legal Forum in Saint Petersburg.



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Daria specialises in providing legal services to pharmaceutical companies and representing producers and distributors of medical devices, cosmetics and household chemical products.

She handles a wide scope of regulatory and commercial issues, including the circulation of medicines, medical devices and cosmetics, clinical trials/investigations, and code of ethics compliance.

Advisory services
and solutions

Our credentials

Why Deloitte

Our team



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