

# THE PHARMA LEGAL HANDBOOK

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# BULGARIA

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 PHARMA  
BOARDROOM

**THE PHARMA LEGAL HANDBOOK ANSWERS ESSENTIAL QUESTIONS ABOUT THE LEGAL AND REGULATORY ENVIRONMENT FOR PHARMACEUTICALS IN BULGARIA. IT IS A MUST-HAVE FOR ANY COMPANY OPERATING IN THE COUNTRY OR LOOKING TO ENTER THE MARKET.**

**PREPARED IN ASSOCIATION WITH PHARMDEDICT AND KINSELLAR, IT SHOULD ANSWER ANY QUESTIONS LINKED TO REGULATION, PRICING, CLINICAL AND PRECLINICAL TRIALS, MARKETING, MANUFACTURING, TRADEMARKS AND PATENTS.**

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Petko was one of the founders of PharmDedict back in 2007. He is among the few Bulgarian professionals with legal background focused on healthcare and pharmaceutical business. He has 16 years of experience in the field: starting as an in-house counsel for one of the major local pharmaceutical manufacturers and wholesaler and then working in the consultancy business for more than 10 years. Thus, Petko knows the pharmaceutical and pharma-related industries from various perspectives, which allows him also to understand the business processes beyond the regulatory framework. This is especially useful in the market entry process. Petko is experienced in leading negotiations in the international environment which include legal issues, as well as commercial terms and conditions. Project management and strategic planning have also been part of his work.

He has knowledge of the regulatory framework, at national and EU level, and the contractual relations concerning medicinal products in the areas of product licensing, contract manufacturing, pre-wholesale and wholesale distribution, marketing and advertising of RX products, market access (including pricing & reimbursement), regulatory and pharmacovigilance issues, legal and trade representation.



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Svilen advises, among others, some of the largest international pharmaceutical companies on various regulatory and compliance matters relating to their operations in Bulgaria. His expertise includes marketing authorisation, production, distribution, pricing and reimbursement, pharmacovigilance, advertising and clinical trials of pharmaceutical products and medical devices.

Svilen's experience also includes participation as a member of ethics committees in clinical trials and as a member of committees responsible for health technology assessments of medicinal products. He is an associated member of the Bulgarian Industrial Pharmacists Association.

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Enjoying successful market entry and presence in a complex regulatory environment is more than complying with the legislation...

We know the pharmaceutical law from every angle of its complexity and we are ready to guide you to your Success.

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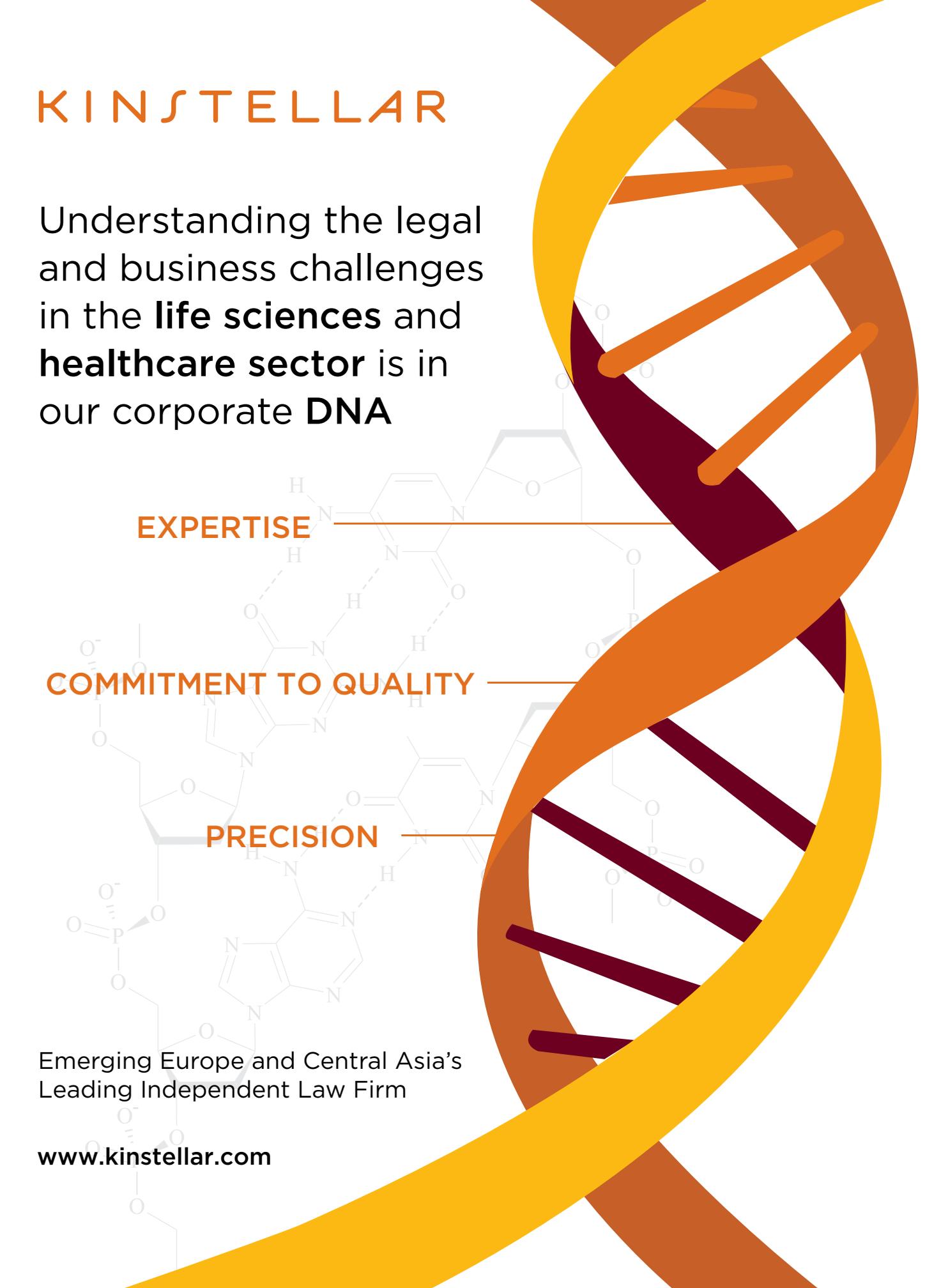
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