The Pharma Legal Handbook

Bulgaria

Regulatory, Pricing and Reimbursement Overview · Preclinical and Clinical Trial Requirements · Marketing, Manufacturing, Packaging and Labeling Advertising · Traditional Medicines and OTC Products · Product Liability · Patents and Trademarks · Regulatory Reforms

PHARMA BOARDROOM

Bulgaria

**The Pharma Legal Handbook answers essential questions about this 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 Kinstellars, it should answer any questions linked to Regulation, Pricing, Clinical and Preclinical Trials, Marketing, Manufacturing, Trademarks and Patents.

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PharmDedict

Established in 2007 as a local regulatory services provider, PharmDedict have excelled in providing product life-cycle services to manufacturers and marketers of pharmaceuticals, medical devices, food supplements and cosmetics. We responsibly expanded internationally via a trusted network of partners to cover all EU and the non-EU Balkan countries. We offer wide scope of regulatory, pharmacovigilance, market access and quality assurance services. We dedicate all our efforts to maintain high quality standards and professionalism in the regulatory consultancy business.

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KINSTELLAR

Kinstellar is a leading independent law firm in Emerging Europe, Turkey and Central Asia, with offices in Almaty and Nur-Sultan (formerly Astana) (Kazakhstan), Belgrade (Serbia), Bratislava (Slovakia), Bucharest (Romania), Budapest (Hungary), Istanbul (Turkey), Kyiv (Ukraine), Prague (Czech Republic), Sofia (Bulgaria) and Tashkent (Uzbekistan). Operating as a single fully integrated firm, Kinstellar delivers consistently high-quality services across all jurisdictions in a joined-up and seamless manner. We are particularly well suited to servicing complex transactions and advisory requirements spanning several jurisdictions. Kinstellar's Sofia office opened on 1 November 2014 and enhances our coverage, enabling us to provide comprehensive support for cross-border transactions and commercial needs across the region.

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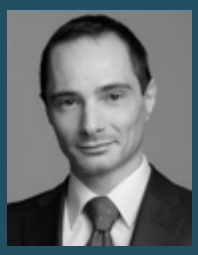

PETKO KONAKCHIEV

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 Issaev is a Counsel at Kinstellar's Sofia office specialising in life sciences and healthcare, as well as banking and finance. He has over fourteen years of post-qualification experience.

Svilen earned Master's degrees in Law and Economics from Sofia University. He also holds an academic specialisation in the "Organisation and Economy of Pharmaceutical Manufacturing" from the Medical University of Varna. He is currently a PhD candidate in social medicine at the Medical University, Sofia.

Svilen advises, among others, some of the largest international pharmaceutical companies on various regulatory and compliance matters realting 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.

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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01

REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

1. What are the regulatory authorities with jurisdiction over drugs, biologicals, and medical devices in your country?

2. What is the regulatory framework for the authorization, pricing, and reimbursement of drugs, biologicals, and medical devices?

3. What are the steps to obtaining authorization to develop, test, and market a product?

4. What are the approximate fees for each authorization?

5. For how long are marketing authorizations/registrations valid? How are marketing authorizations/registrations renewed?

6. How does the authorization process differ between brand-name products and generic products? Are there differences for local manufacturers versus foreign-owned manufacturers?

7. How are combination products (drug + drug, drug + biologic, drug + device, biologic + device, drug + biologic + device) regulated?

8. How is compliance with regulation monitored and evaluated? Is the regulatory regime comparable with the U.S. Food and Drug Administration or the European Medicines Agency expectations and requirements?

9. What is the potential range of penalties for noncompliance?

10. Is there a national healthcare system? If so, how is it administered and funded?

11. How does the government (or public) healthcare system function with private sector healthcare?

12. Are prices of drugs and devices regulated and, if so, how?

13. How are drugs and devices used by patients paid for? What roles do public and private payers play?

14. Who dispenses drugs and devices to patients and how are those dispensers compensated?

15. What are the professional and legal responsibilities of those who dispense drugs and devices? What role do they play in providing patient care, information, and safety?

01 REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

1. What are the regulatory authorities with jurisdiction over drugs, biologicals, and medical devices in your country?

The following authorities are responsible for applying and enforcing the regulatory framework pertaining to drugs (including biologicals) and medical devices in Bulgaria:

- The Bulgarian Drug Agency (BDA) is a specialized State regulatory authority established to the Minister of Health, which exercises supervision over the quality, safety and efficacy of drugs (including biologicals), and of medical devices. The BDA is responsible for authorizing and registering drugs and medical devices to be placed on the market, as well as for issuing of permits, authorisations and certificates for various activities, including without limitation import/export, wholesale distribution and retail trading, manufacturing and brokering activities. It assesses and confirms the conformity with the law of manufacturers, marketing authorisation holders, wholesalers, retailers, of both drugs and medical devices. It has a role in initiation and carrying out of clinical trials and supervises the trial procedures. The BDA has also control functions related to pharmacovigilance. In addition, the BDA performs supervision over promotional activities pertaining to drugs. In its activities, the BDA correlates with the State customs authorities, revenue authorities, the National Health Insurance Fund (NHIF), the National Council for Prices and Reimbursement of Medicinal Products (NCPRMP), as well as with the Ministry of Health (MoH).
- The NCPRMP is a specialized administrative body established to the Minister of Health and responsible for inclusion and exclusion of drugs from the Bulgarian Positive Drug List (PDL), as well as for determining, registering and controlling the prices of drugs, including reimbursed products, and of maintaining their reimbursement status. The NCPRMP performs health technology assessment of drugs and issues pharmaco-therapeutic guidelines.
- The NHIF is a State authority responsible for the reimbursement of drugs and medical devices and is one of payers with public funds.

2. What is the regulatory framework for the authorization, pricing, and reimbursement of drugs, biologicals, and medical devices?

The main local statutory act pertaining to the authorisation, pricing, and reimbursement of drugs (including biologicals) is the Law on Medicinal Products in Human Medicine (LMPHM), and the secondary legislation on its implementation. The main local statutory act pertaining to the registration, pricing, and reimbursement of medical devices is the Law on Medical Devices (LMD), and the secondary legislation on its implementation. Depending on the type of the statutory act, secondary legislation is issued by the Council of Ministers or by the Minister of Health. Relevant guidelines and authority practice are also deemed of relevance. In addition, Bulgarian pharmaceutical

legislation is, for the most part, harmonized with the EU Directives and Regulations (the latter, being directly applicable in Bulgaria), e.g. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as amended and Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, as amended.

3. What are the steps to obtaining authorization to develop, test, and market a product?

A) Medicinal Products

In order to develop and test medicinal products (drugs) in Bulgaria, it is necessary to obtain an authorisation for manufacturing of medicinal products. This is so, insofar as both the development and the testing activities would qualify as "manufacturing of medicinal products", as such term is defined in the LMPHM. The manufacturing authorisation is issued by the Director of the BDA. Applicants must comply with certain requirements set forth in the law. Manufacturing sites are subject to inspections by the competent authorities for compliance with the applicable Good Manufacturing Practices. The manufacturing authorisation is issued only for the manufacturing activities, the pharmaceutical forms and the premises, which have been applied for by the applicant. Changes to the circumstances subject to authorisation (including – with respect to manufacturing activities, manufacturing sites/premises, pharmaceutical forms, the qualified person, and other significant personnel, etc.) are subject to additional manufacturing authorisation for the change.

A medicinal product may be placed on the market in Bulgaria based on a marketing authorisation, issued under one of the following procedures: (i) National Procedure; (ii) Mutual Recognition Procedure; (iii) Decentralised procedure or (iv) Centralized Procedure at the European Medicines Agency.

Homeopathic and traditional herbal medicinal products may be placed on the market in Bulgaria based on registration certificate.

B) Medical Devices

There is no specific authorisation for manufacture of medical devices required; however, manufacture of medical devices may, depending on the circumstances, include activities for which authorisation is required (e.g. handling of chemicals, usage of radiation, etc.).

There is no marketing authorisation for medical devices. However, depending on the medical devices class, certain requirements have to be met. Medical devices shall bear CE marking indicating that they have been the subject of an assessment of their conformity (there are certain exceptions, e.g. for custom-made devices not bearing CE marking).

In case the manufacturer or its EU-based authorised representative are established in Bulgaria, there is a special registration procedure at the BDA depending on the medical device type and class.

For certain types of medical devices there is a notification procedure at the BDA.