The Pharma Legal Handbook

Ukraine

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 · Cannabinoid Drugs, Medicinal Cannabis and Opioid Drugs

PHARMA BOARDROOM

Ukraine

**The Pharma Legal Handbook answers essential questions about this environment for pharmaceuticals in Ukraine.
It is a must have for any company operating in the country or looking to enter the market.**

Prepared in association with Sayenko Kharenko, a leading ukranian law firm, it should answer any questions linked to Regulation, Pricing, Clinical and Preclinical Trials, Marketing, Manufacturing, Trademarks and Patents.

*** THIS REPORT WAS ORIGINALLY PUBLISHED IN AUGUST 2018 AND THE INFORMATION CONTAINED WITHIN IS SUBJECT TO CHANGE.**
****LAST UPDATE: MARCH 2019**

SAYENKO KHARENKO
NEWLAW FIRM

Sayenko Kharenko is one of Ukraine's largest law firms offering comprehensive support in all major sectors of economy. In order to manage the rapidly evolving Ukrainian legal and business environment, the firm embraces innovation through new products, out-of-the-box thinking and creative solutions. The emphasis on innovation brings services that allow the firm's clients excel in what they do. Sayenko Kharenko has been recognized over 100 times as No. 1 law firm in key practice areas and named "Best Law Firm in Ukraine" more than 30 times by the most prestigious professional excellence awards.

Sayenko Kharenko has provided legal services to over 1200 clients from more than 60 countries around the globe and recognizes that every single client has unique business needs. The firm tailors its services to best fit individual profile of each and every client.

Sayenko Kharenko designed an innovative project Neworld Lab to anticipate developments in the new economy and place the firm and its clients at the cutting edge of the changes shaping our collective future. Sayenko Kharenko analyzes global trends in science and economics and identifies effective instruments to manage fast-evolving relationships and implement innovations. The ultimate goal is to create newlaw solutions which would drive the firm's clients' business forward.

Sayenko Kharenko developed and is constantly improving its anti-corruption program in line with Ukrainian law and taking into account the most important provisions, recommendations, and regulations of foreign jurisdictions governing the prevention of corruption and bribery.

www.sk.ua

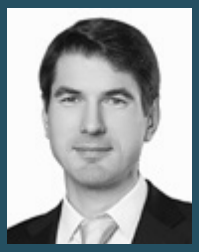
THE AUTHORS

ANZHELA MAKHINOVA

PARTNER AT SAYENKO KHARENKO LAW FIRM

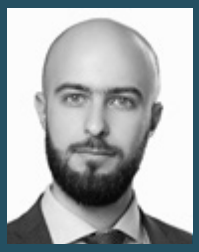
OLEG KLYMCHUK

COUNSEL AT SAYENKO KHARENKO LAW FIRM



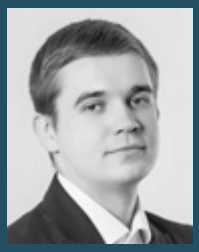
VOLODYMYR SMELIK

SENIOR ASSOCIATE AT SAYENKO KHARENKO LAW FIRM



IVAN BARANENKO

ASSOCIATE AT SAYENKO KHARENKO LAW FIRM



PAVLO KOVALCHUK

ASSOCIATE AT SAYENKO KHARENKO LAW FIRM

YELYZAVETA SEMENOVYKH

JUNIOR ASSOCIATE AT SAYENKO KHARENKO LAW FIRM

IVAN LOBODA

SENIOR TECHNICAL ADVISOR PHARMACEUTICAL FINANCE, USAID | SAFEMED

TETIANA TANCHYN

JUNIOR ASSOCIATE AT SAYENKO KHARENKO

NewLaw and Beyond

Create, Preserve, Grow

SAYENKO KHARENKO
NEW LAW FIRM

CONTENTS

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

(Ivan Loboda, Senior Technical Advisor Pharmaceutical Finance, USAID | SAFEMed)

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

- the Ministry of Health of Ukraine ("Ministry")
- the State Service of Ukraine on Medicines and Drugs Control ("SSM")
- the National Health Service of Ukraine ("NHSU")
- Quality control authorities accredited by the Ministry of Economic Development and Trade of Ukraine

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

The authorization, pricing, and reimbursement of drugs, biologicals, and medical devices is regulated by the following laws and regulations:

1. LAWS OF UKRAINE:

- On Medicinal Products
- On Licensing of Certain Types of Economic Activity
- On Technical Requirements for Products and Conformity Assessment
- On Price and Pricing
- On the Basis of the State Regulation of Economic Activity

2. DECREES OF THE CABINET OF MINISTERS OF UKRAINE:

- "On Approval of the Procedure for State Registration (Re-registration) of Medicinal Products and Amounts of Fees for Their State Registration (Re-Registration)" No. 376 dated 26.05.2005
- "On the State Register of Medicinal Products" No. 411 dated 31.03.2004
- "On Approval of License Conditions for Conducting Business Activity of Medicinal Products Production, Wholesale and Retail Trade, Import (except active pharmaceutical ingredients)" No. 929 dated 30.11.2016
- "On Approval of the Technical Regulation for Medical Devices", "On Approval of the Technical Regulation for in vitro Diagnostic Medical Devices", "On Approval of the Technical Regulation for Active Implantable Medical Devices" No. 753, 754, 755 dated 02.10.2013
- "On Reference Pricing for Medicines and Medical Products, Purchased with Funds of the State and Local Budgets" No. 240 dated 02.07.2014
- "On State Regulation of Prices on Medicines" No. 862 dated 09.11.2016
- "On Introduction Reimbursement of Medicines" No. 863 dated 09.11.2016
- "On Ensuring Access to Medicinal Products" No. 152 dated 17.03.2017
- "On Some Issues of State Regulation of Prices for Medicines and Medicinal Products" (National List of Essential Medicines) No. 333 dated 25.03.2009
- "On the Implementation of Pilot Project on State Regulation of Insulin Products Prices" No 73 dated 05.03.2014
- "On Certain Issues of Insulin Products Costs Reimbursement" No. 239 dated 23.03.2016

3. A NUMBER OF ORDERS OF THE MINISTRY OF HEALTH OF UKRAINE:

- "On Approval of the Procedure for State Registration (Re-registration) of Medicinal Products" No. 426 dated 26.08.2005
- "On Approval of the Procedure of Maintaining the Register of Persons Responsible for the Introduction of Medical Devices, Active Implanted Medical Devices, and Medical Devices for in vitro Diagnostics in Turnover, Forms of Communication and List of Data Stored therein and Access to Them" No. 122 dated 10.02.2017
- "On Approval of the Register of Margin Wholesale and Trade Prices for Medicinal Products"No. 2 dated 02.01.2018
- "On Approval the Procedure for Calculation of the maximum Wholesale Prices for Medicinal Products Based on Reference Prices" No. 1423 dated 29.12.2016
- "On Approval of Form of the Register of Medicinal Products Subject to Reimbursement" No. 298 dated 21.03.2017
- "On Approval of Regulation on Register of Reference (Reimbursement) Prices for Insulin Products and the Procedure for Calculation of Reference (Reimbursement) Price for Insulin" No. 453 dated 07.03.2018
- "On Approval of Rules of Writing Prescriptions for Medicines and Medicinal Products, the Procedure for the Dispatch of Medicines and Medicinal Products from Pharmacies and their Structural Subdivisions, Rules on Storage, Recording and Disposal of Prescription Forms" No. 360 dated 19.07.2005, etc.

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

In cases relating to a finished medicinal product:

Production, market access and distribution:

1. Undergo the procedure of state registration of medicines (for registration of medical devices, the applicant should submit the necessary documents based on the requirements of the Ministry)
2. Obtain a state registration certificate for medicinal products (issued by the Ministry)
3. Obtain a license for economic activity on import of medicines/manufacturing of medicines (issued by the SSM)
4. Receive confirmation of GMP compliance (issued by the SSM)
5. Complete the quality control procedure (controlled by the SSM)
6. Receive a license for wholesale trade of medicinal products (issued by the SSM)
7. Conclude agreement with drug manufacturer (for procurement)
8. Conclude agreement with pharmacy (for sale)

Retail

1. Obtain a license for retail trade in medicinal products (for direct sale to patients)
2. Conclude a medicine supply agreement with a distributor

Economic entities must subsequently undergo, in the terms set by the legislation, a check for the observance of the licensing conditions for medicinal product manufacturing, wholesale and retail trade in medicinal products (carried out by the SSM)

4. What are the approximate fees for each authorization?

Medicine state registration:

State registration (re-registration) fee:

1. for state registration (re-registration) of medicinal products, including medical immunobiological drugs, in addition to radioactive drugs, diagnostic agents, simple or complex (galenical) herbal medicinal products, in the amount equivalent to EUR 100 for each dosage form, EUR 10 for each subsequent dose, and EUR 10 for each subsequent package of a medicinal product.
2. for state registration (re-registration) of radioactive drugs, diagnostic agents, simple or complex (galenical) herbal medicinal products, active restricted drugs and those produced in accordance with the regulations approved by the Ministry (information about the composition, formulation (manufacturing technique), quality control, and application of a medicinal product), and donated blood or plasma products equivalent to EUR 25 per item, EUR 5 for each subsequent dose, EUR 5 for each subsequent package of the medicinal product

The registration fee does not include the cost of medicinal product expertise as well as additional expertise.

Information on the cost of expertise procedures for the state registration of medicinal products submitted for state registration (re-registration) is available on the website of the State Expert Center ("Center") at **www.dec.gov.ua/index.php/ua/1**

Licensing of economic activities:

The license fee is payable once at one minimum subsistence income, based on the minimum subsistence income of able-bodied persons valid on the day the licensing body takes the decision to issue the license.

The procedure for assessing the conformity of medical products/confirmation of conformity of the production conditions of medicinal products with the GMP requirements:

The cost of the specified procedures is specified in the contract between the applicant and the appropriate body depending on the performed works (to determine an estimated cost of the procedures, the applicant must consult the appropriate body).

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

The registration certificate for a medicinal product is valid for five years; after re-registration, the validity is unlimited.

The validity of the conformity assessment certificate for medical products according to the decision of the relevant body that assesses for conformity