

THE PHARMA LEGAL HANDBOOK



UKRAINE

THE PHARMA LEGAL HANDBOOK ANSWERS ESSENTIAL QUESTIONS ABOUT THE LEGAL AND REGULATORY 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.

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**MARKETING, MANUFACTURING,
PACKAGING & LABELING,
ADVERTISING**

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03 MARKETING, MANUFACTURING, PACKAGING & LABELING, ADVERTISING

 (Questions 1-11: Oleg Klymchuk, Volodymyr Smelik, Pavlo Kovalchuk, Yelyzaveta Semenovykh; questions 12-22: Anzhela Makhinova, Ivan Baranenko)

22. What is the authorization process for the marketing of new drugs, biologics, medical devices, over-the-counter medications, and other medicinal products?

With respect to the authorization process for the marketing of new drugs, biologics, medical devices, over-the-counter medications, and other medicinal products, please refer to question 3 in Regulatory, Pricing, and Reimbursement Overview.

23. What is the authorization process for the marketing of generic versions of these products?

Obtaining marketing authorization for generic versions of innovator medicinal products has certain peculiarities. In particular, an applicant must prove that the generic product is equivalent to the innovator/reference product. The applicant shall provide, inter alia,

- Brief information on the generic medicinal product (quantitative and qualitative indicators of active substances, dosage form, security and safety profile of its active substances in comparison with active substances of the reference product, information on bioavailability and bioequivalence of the generic product);
- Evaluation of bioequivalence investigations or justification of the absence of such either according to the EMA Guideline on the Investigation of the Bioequivalence (CPMP/QWP/EWP/1401/98 Rev. 1) or Regulation CT-H MO3Y 42-7.1:2014; and
- Results of the respective bioequivalence investigations.

The applicant must not violate the exclusivity and intellectual property rights related to the innovator/reference medicinal product.

24. What are the typical fees for marketing approval?

Ukrainian Healthcare Laws provide for the following state duties for state registration (re-registration) of medicinal products:

1. For state registration (re-registration) of medicinal products (except for radioactive medicinal products, diagnostic products, simple or complex (galenicals) products of herbal materials) — EUR 100 for each pharmaceutical form; EUR 10 for each subsequent strength; EUR 10 for each subsequent package of a medicinal product;
2. For state registration (re-registration) of radioactive medicinal products, diagnostic products, simple and complex (galenicals) products of herbal

materials, preparations of limited use and those produced according to the specifications approved by the Ministry (information on composition, production technology (manufacture), quality control and use of a medicinal product) and donor blood or plasma products — EUR 25 for each item; EUR 5 for each subsequent strength; EUR 5 for each subsequent package of a medicinal product.

(The above state duties can be also paid in Ukrainian hryvnia currency.)

In addition to the above state duties, the applicant shall also pay official fees for examination of the registration materials by the Center. The fee depends on the type of application for marketing authorization and the type of medicinal product or materials to be assessed and may range from UAH 14,250 (approximately US\$ 540) to UAH 117,900 (approximately US\$ 4,530

25. What is the period of authorization and the renewal process?

Pursuant to the Law of Ukraine “On Medicinal Products”, marketing authorization is granted for a five-year term. This initial term can be renewed (re-registration of the medicinal product). As soon as marketing authorization is promptly renewed, the period of respective marketing authorization becomes generally unlimited (with a few exceptions).

For the purpose of said renewal, an applicant must submit a respective application to the Ministry. The application must be filed not earlier than a year but not later than 90 calendar days prior to the expiry date of the medicinal product registration certificate. In addition to the application, the applicant must submit a set of required supporting documents including, inter alia, updates on clinical data overview focusing on critical analysis of medicinal product risk/benefit ratio. On the basis of the Center’s examination of the provided documents and conclusion of the latter, the Ministry may either re-register the medicinal product or refuse to renew the marketing authorization.

26. What are the requirements, if any, for post-approval pharmacovigilance?

The pharmacovigilance system in Ukraine involves both manufacturers of medicinal products (applicants) and regulatory authorities (e.g. the Ministry, the Center). The existing pharmacovigilance system is mainly focused on ensuring the safety of medicinal products, detecting any changes in their risk/benefit ratio, and developing measures to minimize or prevent risks associated with the medicinal products.

The obligations of the applicant include, inter alia, (i) appointment of a person responsible for pharmacovigilance matters; (ii) reporting to the Center on all recorded and proven cases of serious adverse reactions as well as any cases of unexpected non-serious adverse reactions to medicinal products; (iii) submitting a periodic safety report regarding the medicinal product to the Center.

Post-registration Surveillance Board of the Center (“Board”) and the Board’s regional divisions acting in all regions of Ukraine play the key role in

pharmacovigilance system. According to the Procedure for Surveillance over Adverse Reactions to Medicinal Products Permitted for Medical Use approved by Order No. 898 of the Ministry dated 27 December 2006, the Center collects information on adverse reactions to medicinal products by means of unscheduled reporting, active hospital-based monitoring, monitoring of prescriptions, meta-analysis and other methods such as involving of applicants, medical officers, legal and natural persons, performing medical practice, as well as patients and/or their representatives.

Based on analysis of the safety and efficacy of medicinal products as well as information on safety studies conducted by the parties engaged in pharmacovigilance in the post-registration period, the Center may propose the Ministry to prohibit in full or temporarily the medical use of the medicinal product.

27. Are foreign marketing authorizations recognized?

Foreign marketing authorizations are not valid in Ukraine and local authorization is required.

However, obtaining marketing authorization (state registration) for those medicinal products which are already authorized by competent authorities of the United States, Switzerland, Japan, Australia, Canada and the European Union is subject to special rules. In particular, instead of submitting the materials from preclinical and clinical studies to the Center, an applicant shall attach the materials of the foreign registration dossier to the application and such materials are not subject to expert examination by the Center.

28. Are parallel imports of medicines or devices allowed?

Medicinal products can only be imported to Ukraine after their registration save for the cases when they are imported for the purpose of conducting preclinical or clinical trials, obtaining market authorization, etc.

In addition to proper local registration, an import license should be issued by the State Service of Ukraine on Medicines and Drugs Control (“SSM”) for the purpose of importing medicinal products which are manufactured outside Ukraine.

When it comes to prohibition or allowance of parallel import, no clear-cut statutory regulation is in place.

However, in relation to intellectual property, relevant provisions of Ukrainian laws may be interpreted as such that establish the principle of international exhaustion of intellectual property rights in copyright, trademarks as well as patented designs, utility models, and inventions. International exhaustion means that, once a medicinal product is legally brought to market anywhere in the world, a trademark or patent owner/licensor may not prohibit the further import of such medicines into Ukraine.

29. What are the restrictions on marketing practices such as gifts, sponsorships, consultancy agreements, travel and entertainment, or other incentives for healthcare organizations and individual medical practitioners?

Ukrainian Healthcare Laws envisage prohibition for HCPs to:

- Obtain unjustified benefits from producers of medicines/medical devices and/or their distributors within their professional activity;
- Obtain samples of medicines/medical devices from producers of medicines/medical devices and/or their distributors for use in professional activity, unless to be used for clinical trials with respect to medicines/medical devices;
- Advertise medicines/medical devices within their professional activity, including by way of writing prescriptions on the papers which contain information of an advertising nature or specify producers of medicines/medical devices (trademarks).

In addition to healthcare law restrictions, HCPs are also bound by prohibitions prescribed by anticorruption regulations if they serve as officials at healthcare organizations.

As a matter of practice, certain limitations for HCPs - which mainly duplicates the described statutory prohibitions - might be included in the internal regulations (policies) of the healthcare organization.

30. How is the manufacturing of medicines and devices regulated and by which agencies?

Ukrainian regulations pertaining to manufacturing and distribution of medicinal products and medical devices consist of a number of legal acts issued by state authorities of different levels.

The Law of Ukraine “On Medicinal Products” provides for general regulation for medicinal products. Foregoing regulation is further developed and extended in the Licensing Terms for Manufacturing, Wholesale and Retail, Import of the Medicinal Products, Regulations approved by the Ministry (e.g. GMP Regulation No. 42-4.0:2016, Operation Area Dossier Regulation No. 42-4.1:2011); regulations approved by the Ministry, the SSM, and other local regulators.

The regulatory framework described above involves requirements for the manufacturing process and distribution in relation to:

- Production facilities;
- Workforce engaged;
- Safety rules;
- Equipment;
- Packaging; and
- Labelling.

The manufacturing and distribution of medical devices is mainly regulated by the Law of Ukraine “On General Safety of Non-Food Products”, the Law of Ukraine “On State Market Supervision and Control over Non-Food Products”, and the Law of Ukraine “On Technical Requirements for Products and Conformity Assessment”. The respective legal landscape is amplified in technical regulations (e.g. Technical Regulation for Medical Devices of 2013 and Technical Regulation for In-Vitro Diagnostics Medical Devices of 2013) and various state standards.

The Ministry is a governmental body that develops and establishes the general regulatory framework for medicinal products and medical devices, while the SSM is responsible for implementation and enforcement of the established framework. In particular, the SSM grants licenses for the manufacture of medicinal products; conducts checks of manufacturers for compliance with licensing terms; confirms compliance of the manufacturing to GMP standards; and observes compliance to GMP standards.

31. Are local manufacturing requirements compatible with Good Manufacturing Practices (GMPs) as defined by the US Food & Drug Administration (US FDA) and/or the European Medicines Agency (EMA)?

Ukrainian manufacturing requirements are compatible with the GMPs established by the European Medicines Agency. Ukraine recognizes and accepts GMP certificates issued by authorities of the Pharmaceutical Inspection Co-operation Scheme (PIC/S) members.

32. What is the inspection regime for manufacturing facilities?

33. Are manufacturing facilities open for inspection by foreign inspectors or third-party inspectors as authorized by the FDA/EMA?

The SSM is authorized to perform inspections of manufacturing facilities to observe compliance with the respective licensing terms. Such inspections can be both scheduled and unscheduled. The manufacturer is included in the inspection schedule on the basis of risk ratings assigned to the manufacturer.

An unscheduled inspection may be conducted at the request of the manufacturer or on the basis of specific grounds, such as:

- Detection of discrepancies in manufacturer's reports;
- Checking on whether previously discovered violations were cured;
- Respective order (assignment) of the Prime Minister of Ukraine;
- Complaints of individuals as regards to violations of their rights by the manufacturer;
- Failure to submit reporting documents for two consecutive reporting periods; and
- Individual's personal injury or death related to manufacturing of the producer.

The SMM may also decide on revocation of the manufacturing license.

34. What are the requirements for storage, packaging, and handling of medicines and devices and their constituent components?

Storage, packaging and handling of medicines is comprehensively regulated by special requirements of *Licensing Terms*¹, *Good Distribution Practice* and *Good Storage Practice*.²

Among others, warehouse **storage requirements** include:

- the size of pharmaceutical warehouse shall not be less than 250 sq. meters
- pharmaceutical warehouses shall consist of manufacturing premises, personnel facilities, household and additional premises;
- the walls, ceiling and floor of manufacturing premises of pharmaceutical warehouses shall be made of materials resistant to disinfection;
- access to manufacturing pharmaceutical premises shall be restricted, etc.

In the retail trade the size of pharmaceutical warehouse shall not be less than 10 sq. meters. Retailers shall comply with the specific requirements for storage of medicines and the *Good Storage Practice*.

Transportation of medicines shall be made in packages protected from spilling, polluting and mixing with other medicines or substances. If certain medicine requires certain temperature conditions, transportation facilities for such medicine shall be equipped with the corresponding refrigerator and temperature monitoring system.

Medicines **shall not be transported:**

- with other products, except for related products;
- by means of public transportation, post or in luggage compartments.³

Requirements for packaging of medicines include the requirements for its labelling, as described below. Packaging of medicine is submitted for approval in the process of medicine registration. The manufacturer is obliged to pack medicinal products in packaging approved during state registration. Detailed requirements for packaging are contained in the GMP.

Requirements for storage, packaging and handling of medical devices are envisaged by the respective technical regulations. In particular, medical devices shall be stored and transported in a way not to hamper their characteristics. Packaging of sterile medical devices shall ensure their sterility and packaging of non-sterile medical devices shall keep them clean. Packaging of medical devices shall contain information, the full list of which is envisaged by the technical regulations.

35. What information must be included in medicine and device labelling?

The labelling of medicine or medical devices shall be provided in Ukrainian.

1. The labelling of any medicine on its packaging shall include the following information:

- Barcode of the medicine;

¹ Licensing Terms for Manufacturing, Wholesale and Retail, Import of the Medicinal Products approved by the CMU Resolution No.929 of 30 November 2016 (“Licensing Terms”)

² Approved by the Order of the Ministry No. 95 of 16 February 2009 “On the approval of documents on procuring medicinal products quality”.

³ Para. 135-139 of Licensing Terms

- Name of the product;
- Name and address of the manufacturer;
- Number of registration certificate;
- Batch number;
- Method of application;
- Dose of active substance in each item and its number on the package;
- Pharmaceutical form;
- List of supplementary substances that the product contains;
- Shelf life (expiry date);
- Storage conditions;
- Precaution for storage of the medicine away from children reach;
- Precautions when taking.

The name of the product, mass, concentration, batch number, expiry date, manufacturer's name shall be indicated as well on the inner packaging of the medicine. The name of the product, the dose of the active substance and the pharmaceutical form must also be inscribed with braille characters on the outer packaging of the product.

There are some exceptions to labelling of special kinds of medicines, namely *medicines containing radionuclides, homeopathic medicines, traditional and herbal medicines, medicines containing one or more narcotic and/or psychotropic substances.*

Medicines shall additionally include instructions which provide detailed information regarding the medicine, its application, etc.

2. Marketing and labelling of medical devices is governed by different legislation as applied to medicines. Medical devices are subject to conformity assessment procedure according to technical regulations applied to medical devices, active implantable medical devices and medical devices for in vitro diagnostics. Three technical regulations establish separate rules for labelling of each of the three above types of medical devices. In any case, the labelling of all types of medical devices must include the mark of conformity with the technical regulation placed after completion of the procedure of conformity assessment. This conformity mark shall be applied either directly on the medical device, or on its packaging and instructions for use.

The labelling of medical devices shall include the following items:

- Name or trademark and address of the manufacturer and authorized representative;
- Information necessary for consumer to identify medical device and packaging contents;
- If necessary – word “sterile”;
- If necessary – batch number;
- If necessary – shelf-life (date, month and if necessary - day);
- If necessary – single-use mark;
- For medical devices manufactured on a by-order basis – words “medical device manufactured on a by-order basis”
- For medical devices designed for clinical trials – words “medical device designed for clinical trials”
- information on any special conditions for storage and/or use;
- information on any special instructions for exploitation;
- information on any precautions;
- date of manufacturing (unless it has a limited shelf-life);
- if necessary – information on sterilisation method;

- if the medical device contains inseparable human blood derivatives – the corresponding information.⁴

The labelling of medical devices for in vitro diagnosis or active implantable medical devices shall comply with the requirements of the respective technical regulations which might require labelling of additional information.

36. What additional information may be included in labelling and packaging?

The labelling of medicine may additionally include the following items:

- other manufacturer's name (involved in product's manufacturing)
- symbols or icons that easily explain mandatory information to the consumer;
- other information which corresponds with the short characteristics of the medicine and is useful for the consumer, except advertisement;
- information translated in the regional language or the minority language, provided that it does not contradict the information in Ukrainian.

37. What items may not be included in labelling and packaging?

Labelling or packaging shall not include advertisement of the product and information which misleads the consumer.

38. What are the restrictions and requirements for the marketing and advertising of medicines and devices?

Advertisement of medicines and medical devices shall be in line with the general requirements for advertisement (prohibition of discriminatory, hidden or violent advertisement, prohibition of unfair commercial practices, etc.).

Additionally, advertisement of medicines and medical devices shall contain:

- objective information on the medicine or medical device, provided in a manner to understand that such information is advertisement and the advertised product is a medicine or medical device;
- requirement for consultation with a doctor before use of the medicine or medical device;
- recommendation to read the instructions for the medicine;
- it should contain the warning "self-treatment might be harmful for your health", taking not less than 15 percent of the space (length) of the advertisement.

It is prohibited to place the following information in the advertising of medicines and medical devices:

⁴ According to para. 44 of Annex 1 to Technical regulation for medical devices

- references to the therapeutic effect on incurable illnesses or illnesses that do not respond well to treatment;
- information regarding the guaranteed cure;
- information stipulating that use of the advertised medications or medical technologies does not require consultation with a specialist;
- images of the effect of illness or injury to the human body or its parts;
- statements provoking fear of illness or deterioration of one's health condition as a result of failure to use the advertised products;
- statements supporting self-diagnosis and self-treatment with the use of the advertised products;
- references to medications, medical devices, methods of prevention, diagnostics, treatment and rehabilitation as the most effective, most secure and exclusive because of lack of side effects;
- comparisons to other products intended to increase the impact of the advertised product;
- references to separate cases of successful use of medications, medical equipment, methods of prevention, diagnostics, treatment and rehabilitation;
- recommendations or references to recommendations of medical professionals, scientists, medical institutions and organizations;
- special expressions of gratitude, letters or extracts with recommendations, stories about the use of the advertised goods or services and the results of such use;
- images and references to celebrities, film characters or reputable organizations;
- information which misleads consumers stating that a medicinal product is a food, cosmetic or other product of consumption or that the safety and effectiveness of the product is determined by its natural origin.

Participation of doctors, other healthcare practitioners or persons whose outlook resembles that of the doctors in advertising of medicines or medical devices is prohibited. Advertising of products which do not belong to the medical devices, medicinal products or special foods, shall not contain references to their curative effect. Sponsorship of TV or radio shows by manufacturers or sellers of medicinal products or medical devices is allowed, provided that it does not contain references to prescription-only medicines or medical devices, which use requires special knowledge. TV sales of medicines and medical devices, which use requires special knowledge, is prohibited.

It is prohibited to advertise prescription-only medicines, medicines not allowed for use in Ukraine or prohibited for advertising, doping and methods of its use in sport etc.⁵ Advertisement of medicines and medical devices shall be ordered by persons, having the license (for medicines) or conformity certificate (for medical devices).

⁵ According to para.6-14 of Art. 21 of the Law of Ukraine "On Advertising"

**39. Where can medicines and devices be sold or delivered?
Can medicines and devices be sold or delivered via post?**

Medicines shall only be sold for wholesale in pharmaceutical warehouses and for retail in pharmacies or their branches. Trade in medicines can be made exclusively through pharmaceutical establishments and shall not be made through any electronic commercial means, by post or by establishments other than pharmaceutical ones (some exclusions are envisaged for rural areas, where medicines may be sold by certain healthcare institutions).

At the same time, legislation sets no restrictions on sale of medical devices via the Internet and by post. Generally, medical devices may be sold and delivered by any means (except medical devices whose use requires special knowledge and which are prohibited for sale through TV).

40. What are the restrictions and requirements for electronic marketing and advertising via email, by internet, social media, and other channels?

General requirements and restrictions shall apply to any kind of promotion and advertising of medicines or medical devices. Dissemination of commercial information by digital means is governed by the law “On Electronic Commerce”. Commercial digital messages (e-mail) shall include:

- full name of the commercial entity, its registration place and ID or tax code;
- e-mail or domain name of the online shop;
- information on the license (if required);
- information on the delivery price and the taxes.

Sales of medical devices by electronic means shall also comply with the requirements of the Law “On Consumer Protection” for distant transactions. Such requirements include provision of full information on the seller, place, characteristics of the product, warranty obligations, etc. Failure to provide such information entitles the buyer to terminate the contract.

Personal data received and used for such types of advertising and marketing shall be processed and stored according to the requirements of the Law of Ukraine “On Personal Data Protection”.

Ukrainian legislation prohibits healthcare practitioners from receiving from manufacturers or sellers of medicines or medical devices unlawful benefits, samples of such medicines or medical devices for use in professional activity, or advertising medicines or medical devices.

41. May medicines and devices be advertised or sold directly to consumers?

Under Ukrainian law medicines are allowed for sale directly to customers only in pharmacies or their branches.

As for advertising, all requirements and restrictions described in question 17 shall apply even in case of direct communications with customers. Notably, non-prescription medicines and medical devices may be sold directly to consumers. Prescription medicines may be sold directly to consumers upon provision of prescription and according to the rules of such sales.

As for medical devices, they may be advertised (subject to the above restrictions and requirements as described in answer to question 17) and sold directly to consumers.

42. How is compliance monitored?

Compliance over efficiency of medicines and potential side-effects is monitored by the system of pharmacovigilance, which is exercised by the bodies of the Ministry. Manufacturers are obliged to develop a system of pharmacovigilance and to have an employee responsible for pharmacovigilance. Manufacturers also collect information on the efficiency of the medicine, risks associated with it, and side effects. Manufacturers are obliged to submit notification on discovered side-effects of medicines or its inefficiency. Healthcare institutions submit an annual report on pharmacovigilance and extraordinary reports in case of unusual reactions to vaccination.

Quality of imported medicines is controlled by the SSM. Each lot of imported medicines requires a safety certificate issued by the SSM upon the results of compliance control. Control is performed by analysis of documents submitted by the importer, on-site inspection of the imported medicines and, if necessary, laboratory analysis. Sale of the imported medicine is only allowed after receipt of the certificate.

Monitoring over compliance of medicines placed on market is controlled by the SSM. Legislation distinguishes between several stages of non-compliance, depending on potential negative effects. Non-compliance may include mistakes in labelling of medicine and doses in the package, falsification of medicine, its contamination, insufficient information in the instructions, etc. Depending on the type of non-compliance, the SSM may impose prohibition on turnover (sale, production, importation, transportation, storage and use) of the medicine; request the Ministry to terminate registration of the medicine; or take measures on recall of the medicine. The legislation provides for criteria used for taking measures, depending on the circumstances. After elimination of the grounds for the prohibition of turnover, the turnover of the medicine may be resumed. Safety control is also performed at the stage of wholesale and retail trade. Wholesalers and retailers are obliged to inform the SSM on any identified problems with the compliance of medicines.

Compliance with requirements in the sphere of safety of medical devices, as well as compliance with the licensing requirements is monitored by the SSM. Compliance of the medical devices with safety requirements is confirmed by conformity assessment procedure and conformity certificate. The manufacturer or its authorized representative is responsible for the conformity of medical devices and any issues regarding their safety. In case of discovered non-compliance of the medical devices, the manufacturer or its authorized representative shall, depending on the risk, take measures to bring the medical devices in line with the legislation, to withdraw or to recall the medical devices.

Compliance with advertisement regulations is monitored by the State Service of Ukraine on Food Safety and Consumer Protection and the Antimonopoly Committee of Ukraine.

43. What are the potential penalties for noncompliance?

Penalties vary depending on the particular type of violation.

For example, violation of licensing requirements in the sphere of production, import, distribution of medicines entails an administrative fine of UAH 17,000 to 34,000.

Violation of the requirements regarding advertising entail a fine, which may be applied to advertisers, producers and distributors of the advertisement. The size of the fine for advertisers is five prices the produced advertisement.

If such advertisement constitutes violation of unfair competition rules, the fine may reach up to 5 percent of the legal entity's income of the sale of goods and services for the last fiscal year.

Certain offences, e.g. smuggling drugs or falsified medicines, violation of the rules of turnover of drugs, falsification and turnover of falsified medicines, violation of the rules of clinical trials or state registration of medicines, etc., may entail criminal liability.

Violation of consumer rights (e.g. sale of expired products, sale of the non-compliance (unsafe) products, sale of products prohibited for sale by state bodies, failure to provide the required information to the consumer, etc.) may entail large fines up to 500 percent of the value of the batch of product received for sale.

Separate penalties are envisaged for violation of the requirements on safety of medical devices, pricing of medicines, market placement of unsafe products, etc.



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