

Promoting Medical Products Globally

Handbook of Pharma and MedTech Compliance



UKRAINE

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Ukraine

Introduction

The Ukrainian pharmaceuticals market is growing constantly and offers a larger scope of medications to both health professionals and consumers each year. At the same time, the regulation of activities in the Ukrainian pharma market, including such a sensitive matter as promotion of medical products, is sometimes ambiguous and has specifics to be considered. Thus, below is a summary covering basic concepts of the regulatory framework, the allowed and the prohibited practices related to the promotion of medical products, the attached risks and the possible negative consequences, as foreseen by the applicable Ukrainian legislation.

The Regulatory Framework

The principal legislative acts governing the promotion of medications in Ukraine are the Law of Ukraine On Medicines of 4 April 1996 (the “Law on Medicines”) and the Law of Ukraine On Advertising of 3 July 1996 (the “Advertising Law”).

The Law on Medicines regulates research and development activities with respect to medications. In particular, it regulates the performance of clinical trials as well as the registration, production and sale of medicines in Ukraine. However, the Law on Medicines provides that the promotion of medications in Ukraine is governed by the Advertising Law.

The Advertising Law provides for both general advertising rules and rules specific for the promotion of medical products. All types of medications, medical devices, preventive measures and any methods of diagnosis, treatment and rehabilitation that are authorized in Ukraine fall under the scope of the Advertising Law. The provisions of the Advertising Law also apply to the promotion of cosmetics, food, vitamins and other types of food additives that have a certified medical effect.

The Law of Ukraine On Protection from Unfair Competition of 7 June 1996 (“Unfair Competition Law”), together with the Advertising Law, specifies general requirements to comparative advertising.

The promotion of medications to medical institutions and health professionals, as well as rules for advertisement of medicine for treatment of children, is also regulated by Order No. 177 of the Ministry of Health of Ukraine On Approval of Legislative Acts Governing Promotion of Medical Products of 10 June 1997 (“Order No. 177”).

Permitted and Prohibited Practices

The abovementioned legislative acts define the scope of permitted and prohibited practices relating to the promotion of medical products in Ukraine. At the same time, the recently amended Law of Ukraine On Fundamentals of Legislation of Ukraine on Health Protection (the “Law on Health Protection”) provides, although rather unclearly, for some restrictions that can apply regarding the provision of gifts, seminars, hospitality and entertainment to health professionals. Additionally, the general provisions of Ukrainian law, as well as provisions of Ukrainian legislation aimed at combating corruption in Ukraine, will be applicable.

Gifts, Seminars, Hospitality and Entertainment

Ukrainian law specifically addresses the issue of providing gifts to public servants or officials of public legal entities¹ in Ukraine, including health professionals. In addition, the Law on Health Protection prohibits health professionals and pharmacists from receiving unlawful benefits while performing their professional duties; however, such unlawful benefits are not clearly determined in law.

¹ Part 2 of Article 81 Civil Code of Ukraine foresees that the public legal entity is a legal entity established by the administrative act of the president of Ukraine, of the state authority, of the authority of the Autonomous Republic of Crimea or by the local self-government authority, which means that generally, medical institutions are considered public legal entities.



The Ukrainian law On Public Service applies to those health professionals who qualify as public servants or officials of public legal entities. Officials of the Ministry of Health of Ukraine, as well as of its branches at various local levels, qualify as public servants. The new Law of Ukraine On Prevention of and Counteraction Against Corrupt Practices of 14 October 2014 (the “Anti-Corruption Law”), applies both to public servants and to company officers. Thus, restrictions on value of gifts and hospitality apply to health professionals both in the public and private sectors.

Foreign public servants and officials of international organizations are also covered by the restrictions in the Anti-Corruption Law.

According to the rules of the Anti-Corruption Law, public servants and officials of public legal entities are explicitly prohibited from receiving gifts (donations) from legal entities or individuals in exchange for decisions, actions or inactivity, performed directly or by other officials in the interests of the presenter. They are also explicitly prohibited from receiving such gifts from any subordinated person.

Gifts and donations that meet the generally accepted criteria of hospitality are allowed, but the value of such gifts and donations is limited. In particular, the value of a gift or donation cannot exceed one statutory minimum monthly salary, effective as of the date of the acceptance of such gift (donation). Additionally, the aggregate value of such gifts (donations) accepted from a single source during one calendar year cannot exceed two times the statutory subsistence amount for a working person, set as of 1 January of the respective year.

As of November 2015, the value of a single gift cannot exceed approximately USD58 and the total value of gifts during one year cannot exceed approximately USD116.

Therefore, those health professionals who have the status of public servants or officials of public legal entities under the applicable Ukrainian legislation can receive gifts or donations, bearing in mind

the abovementioned restrictions regarding the value of such gifts (donations).

Ukrainian legislation fails to provide for any specific rules governing hospitality or entertainment to health professionals. Therefore, one may conclude that any such hospitality or entertainment may be extended to those health professionals who do not qualify as public servants or officials of public legal entities, bearing in mind, however, the restrictions regarding obtaining unlawful benefit under the Law on Health Protection and the value thresholds and other restrictions established in the Anti-Corruption Law. If a hospitality or an entertainment offer is extended to and/or accepted by a public servant or official of a public legal entity, it may qualify as corrupt practice if the value of such hospitality or entertainment exceeds the allowed gifts value, according to the applicable legislation. Moreover, any act of such healthcare professional that provides a competitive advantage or other benefit to the gift provider may be cancelled or recognized as void.

As regards the participation in scientific seminars, as well as receiving relevant financing (sponsorship) for such participation, health professionals who qualify as public servants or officials of public legal entities in Ukraine may lawfully participate in scientific seminars only if their participation is paid for either by themselves or by their employer, or if such attendance is due to a business trip authorized by their employer (if the costs are paid by the host).

In turn, health professionals who do not have the status of public servants or officials of public legal entities under the applicable Ukrainian legislation are authorized to take part in scientific seminars or conferences, and they may be paid for such participation as long as there is no corrupt intent.

Promotional Activities

Under the Advertising Law, the promotion of medical products qualifies as ‘advertising,’ which is defined as “information about a person or a product disseminated in any form and by any method,



which purports to form or to maintain the awareness of the consumers and their interest in such person or products.”

An advertisement should be directed at an indefinite number of persons. The Advertising Law lists advertising practices which are prohibited in Ukraine.

Under the general rules applicable to advertising of any products in Ukraine, including medications, such advertising should:

- be lawful, accurate, true, and harmless to its consumers;
- comply with the principles of fair competition;
- not include information or images that contradict the principles of morality and humanity; and
- consider particular sensitiveness of children and avoid inflicting damage.

The Advertising Law makes a precise distinction between promoting medications to the general public and promoting them to health professionals. This distinction primarily concerns the promotion of prescription and non- prescription medications in Ukraine. Only non-prescription medications, which are not entered into the special list of medications prohibited from advertising, may be advertised to the general public in Ukraine.

The following information cannot be included in advertisements of medications, medical devices, etc.:

- Information regarding the guaranteed curative effect of the advertised product
- References to actual cases of the successful application of the advertised product

- Comparisons to other products, intended to increase the impact of the advertised product
- Information stipulating that use of the advertised medications or medical technologies does not require consultation with a doctor
- 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 equipment, methods of prevention, diagnostics, treatment and rehabilitation as the most effective, most secure and exclusive because of lack of side effects
- References to separate cases of successful use of medications, medical equipment, methods of prevention, diagnostics, treatment and rehabilitation
- Recommendations or references to recommendations of the advertised product or service by medical professionals, scientists, medical institutions and organizations
- Special expressions of gratitude, the letters or extracts therefrom 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 that may mislead the consumer regarding the composition, origin, production, effectiveness or patent protection of the product
- References to the therapeutic effect of advertised products on incurable illnesses or illnesses that do not respond well to treatment

Advertisements of medications and medical devices must include the following:

- True information on the advertised product, with the clear statement of such information being an advertisement and the advertised product being a medical product
- Requirement of the mandatory consultation with a doctor before use of the product
- Recommendation on the mandatory review of the instruction on use of the advertised product
- The warning: “Self-treatment can damage your health” which must take up at least 15 percent of the advertisement’s area.

Participation of doctors, or other health professionals or persons whose appearance imitates appearance of doctors, is prohibited in the advertising of medical products. In addition, health professionals are prohibited from using prescription forms bearing any information of an advertising nature. The advertisement of medications cannot contain statements suggesting that the medication is food, a cosmetic product or any other consumer product, or that the effectiveness of such product is caused by its natural origin.

The Advertising Law also prohibits advertisement, *inter alia*, of prescription-only medications, doping and methods of its use in sport, etc.

With regards to the promotion of medications to health professionals, both prescription and non-prescription medications may be lawfully advertised. However, the advertisement of prescription medications must be published in specialized editions exclusively targeting medical institutions and health professionals, or that they are disseminated during scientific medical conferences. Furthermore, only authorized medical products may be promoted to health professionals in Ukraine.

According to Order No. 177, information in promotional materials of any kind intended for health professionals must be based on scientific evidence and must include full, precise and clear information, which may not exceed the scope of information specified in the instructions for the use of the advertised medical products.

The Ukrainian law also defines the scope of permitted and restricted practices with regard to comparative advertising of medications and medical devices. Further to the explicit prohibition in the Advertising Law, comparative advertising is governed by the Unfair Competition Law.

The Unfair Competition Law defines comparative advertising as advertising containing comparison between particular products, works, services or activities of one business entity to another. It establishes that such comparison is not unlawful as long as it provides accurate and objective information that is based on fact and is useful for consumers.

Notwithstanding the abovementioned general rule, no advertising of a medical product may contain comparison to another medical product if such comparison is intended to increase the impact of the advertisement.

The Antimonopoly Committee of Ukraine is the Ukrainian authority responsible for determining whether a particular comparative advertisement is accurate, objective and useful for consumers.



Samples

The Law on Health Protection prohibits health professionals and pharmacists from accepting samples of medications or medical devices for use in the course of performing professional duties, except for such samples being used in authorized clinical trials.

Consequences of Breach of Legislation

In accordance with Article 27 of the Advertising Law, violations of Ukrainian legislation on advertising are subject to civil, criminal and disciplinary liability. In addition, the applicable legislation provides for the imposition of administrative economic sanctions for violations in the rules of advertising medical products.

Civil Liability

Civil liability, which may be imposed for violations of the applicable rules on promoting medical products in Ukraine, generally amounts to the compensation of damages by the liable party.

Civil liability may be imposed if the promotion of medical products inflicted damages on any legal entity and/or individual.

In particular, damages can be inflicted by violating the provisions of the Advertising Law regulating both the general procedures of advertising and the special legal requirements on advertising medical products. Damages can also be awarded as a result of the violation of the Unfair Competition Law.

Under the Civil Code of Ukraine, damages may be awarded if the competent court establishes:

- the fact that the damage had been caused;
- the fact of the unlawful activities of the infringer; and
- the link between the unlawful activities and the damage caused.

Economic Sanctions

According to the applicable Ukrainian legislation, economic sanctions can also be imposed on individuals and/or legal entities performing promotional activities contravening the applicable Ukrainian advertising legislation.

In particular, economic liability can be imposed for advertising medical products that are prohibited from being advertised in Ukraine (e.g., unauthorized medications and prescription-only medications.).

Penalties may also be imposed for failure to comply with the legal requirements on the content of advertising (e.g., the name of the producer of the medical product in the advertising; thank-you letters with regard to the curative effect of the advertised product; if advertising supports the idea that the involvement of a health professional is not and/or will not be required if the advertised product is consumed; and that the advertised medical product is a food or cosmetic product, or any other consumable product not having curative effect).

The economic liability for violation of Ukrainian legislation on advertising is imposed in accordance with Resolution of the Cabinet of Ministers of Ukraine No. 693 On Adoption of Order on Imposing of Penalties for Violation of Legislation on Advertising of 26 May 2004.

A fine in the amount of five times the value of the placed advertisement may be imposed for the violation of the applicable Ukrainian advertising rules.

Also, publication of the information clarifying or supplementing the non-compliant advertising may be required.

The responsibility for enforcing the applicable advertising legislation and the right to impose the respective penalties are vested with the State Inspection for Consumer Rights Protection of Ukraine.



The Antimonopoly Committee of Ukraine is also authorized to impose penalties for violations of the applicable competition legislation rules with regard to pharmaceutical advertising, particularly in the case of comparative advertising and the achievement of unfair advantage in competition.

Criminal Liability

Under the applicable Ukrainian criminal legislation, only individuals may be subject to criminal liability. Thus, individuals unlawfully proposing or providing, among others, gifts or hospitality offers that exceed the determined value (as discussed earlier) in exchange for receiving competitive advantage, as well as health professionals receiving such gifts or hospitality offers if such persons qualify as public servants or officials of public legal entities in Ukraine, may be subject to criminal liability.

In particular, there is a risk that any such benefit, gift or hospitality offer to public servants or officials of public legal entities in Ukraine, with the value exceeding the established one, can be considered a bribe if it was provided in exchange for receiving a competitive advantage.

In such case, the provisions of Article 368 “Acceptance of Unlawful Benefit” and Article 369 “Proposal or Giving of Unlawful Benefit” of the Criminal Code of Ukraine (the “Criminal Code”) will apply.

In particular, the liability of the public servants or officials of public legal entities for acceptance of an unlawful benefit may result in the imposition of a fine in the amount between 500 and 750 non-taxable minimal incomes (i.e., approximately between USD354 and USD531), corrective labor for up to one year or imprisonment for up to six months, with the prohibition from holding certain positions for a term of up to three years.

However, the amount of such penalties and liabilities may be significantly increased, including imprisonment for a term of up to 12 years, prohibition from engaging in certain activities for up to three

years and confiscation of property, subject to the occurrence of aggravating circumstances (e.g., depending on the amount of the unlawful benefit or if the bribery was committed as a result of collusion among a group of persons).

The proposal, promise or provision of unlawful benefits is punishable by a fine amounting from 500 to 750 non-taxable minimal incomes (i.e., approximately between USD354 to USD531) or by limitation of freedom for up to four years (up to 12 years if aggravating circumstances are present) and confiscation of property.

Disciplinary Liability

According to the applicable Ukrainian legislation, disciplinary liability can be imposed by the employer on the employee for his or her failure to fulfil or to properly fulfil his or her professional duties. The disciplinary liability can be applied by the issuance of a reprimand or the dismissal of the employee. Thus, the disciplinary liability for the violation of the applicable Ukrainian legislation on promotion of medication and medical devices can be imposed by the employer on the employee in the course of the latter's performance of his or her labor duties.

Professional Codes of Conduct

In 1999, a group of companies established the European Business Association (EBA) in Ukraine. The EBA is the premier organization of foreign businesses in Ukraine, currently representing the interests of 900 European (both national and international) companies operating within the country.

Due to the efforts of its medical committee, the EBA adopted the Code of the Marketing Practice of Manufacturers of Medical Products and Their Representative Offices (the "Code").

The Code was developed for purposes of assisting the respective EBA member-companies in their development and the application of standards based on fair and responsible marketing practices. The Code



expressly provides that Ukrainian laws shall, at all times, have the highest priority and that all EBA member-companies shall undertake not to publish any advertising materials that contradict the principles established by Ukrainian laws, as well as those set out in the Code.

The Code establishes the standards of advertising of prescription as well as non-prescription medical products. With respect to prescription medical products, the Code provides that “advertising materials pertaining to medical products should be precise, comprehensible, objective and set out in the form which complies both with the requirements of applicable laws and ethical standards. Claims contained in the advertising materials, pertaining to effect of the treatment based on the specific medical products should not exceed the respective effect confirmed by scientific evidence. Companies should undertake maximum efforts aimed at avoiding any misunderstandings in providing information about medical products.”

As regards the provision of samples of medical products to health professionals, the Code establishes that “samples of medical products which are expressly determined as such (they should necessarily be marked in order to prevent any abuse) may be provided to health professionals who were granted the right to prescribe respective medical product, for the purpose of finding out more about such medical product and gaining practical experience.”

With regard to the organization of symposia and congresses of health professionals, the Code establishes that “symposia, congresses and similar events are to be held in order to disseminate knowledge and experience. Objectives for holding such events should be associated with science. Entertainment and exercise of hospitality should not go against such scientific objective.”

The Code also establishes the following rules as to the offering of gifts and hospitality to health professionals:

- “No gifts, remuneration or incentives whatsoever shall be offered or promised to be granted to health professionals,

except for the instances when such gifts are inexpensive and comply with the practice acceptable in the fields of medicine and pharmacology.”

- “Hospitality should be offered at the professional and scientific events within reasonable limits and be of auxiliary/supplementary nature in comparison with the main objective of such event.”

Also, certain multinational companies have established the Association of Pharmaceuticals Research and Development (APRaD). In 2015, the Ukrainian office of APraD implemented the EFPIA Code of Pharmaceutical Marketing Practices in Ukraine.

Contracts with Healthcare Professionals and Medical Institutions

The general rules of Ukrainian contractual law are applicable for entering into agreements with health professionals and medical institutions. However, the principles and limitations in respect of the health professionals having the status of public servants should be considered with regard to such contracts.

The main types of contracts entered into by health professionals and medical institutions are clinical trials contracts and contracts regarding the provision of expert services (consulting contracts).

Clinical trial contracts are usually entered into by the companies (mainly pharmaceutical research and development (R&D) companies or clinical research organizations) and authorized Ukrainian medical institutions. However, a company may also enter into a separate contract with the chief investigator (an individual) who heads a group of health professionals conducting clinical trials in Ukraine. The essential provisions of such contracts are provided for by Ukrainian legislation on conducting clinical trials. In particular, the functions of the chief investigator under its contract with the sponsor or the clinical



research organization should not overlap with the employment duties owed to the clinic in which the clinical trial is run.

Generally, no restrictions apply to consulting contracts with health professionals under the applicable Ukrainian legislation. At the same time, the restrictions imposed by Ukrainian law on health professionals who qualify as public servants should be considered. In particular, certain highly positioned public servants are prohibited from receiving remuneration from third parties other than in connection with teaching, medical practice, or artistic or scientific work. Applicability of such restrictions to a particular healthcare professional needs to be evaluated before a consulting contract is signed with such health professional.

Medical institutions and health professionals may also be involved in market research contracts. Neither party is subject to any restrictions other than those generally applied to public servants and those relating to unfair advantage rules, which are described in the section of “Permitted and Prohibited Practices.”

Recommendations

In promoting medical products in Ukraine, the limitations established by the applicable law must be considered to avoid allegations of corrupt practices, which may involve criminal liability. Providing gifts (donations), hospitality and entertainment to healthcare professionals should also be evaluated for compliance with the restrictions imposed by law. Restrictions on contracts with chief investigators must be taken into account when entering into clinical trial contracts with the clinics and the respective health professionals.

It is also important to strictly follow the requirement of the Advertising Law, especially in terms of distinguishing advertising of non-prescription and prescription-only medications. The limitations in respect of the advertising content, established by the Advertising Law, must be considered and complied with as well.

Finally, further to the mandatory compliance with the applicable Ukrainian legal rules, it is also recommended to follow the EBA's Code of the Marketing Practice of Manufacturers of Medical Products and their Representative Offices as well as APRaD's Code of Pharmaceutical Marketing Practices in Ukraine.



This third edition of "Promoting Medical Products Globally. Handbook of Pharma and MedTech Compliance" is intended to provide an overview of the applicable compliance laws governing the cooperation between the medical industry and physicians in Europe, North America, Latin America and the Asia Pacific region. It highlights the legal framework within which medical device and pharmaceutical companies cooperate with health care professionals. It deals with common sponsoring practices such as invitations, conferences and financial grants for research, personnel and equipment as well as other promotional activities such as the giving of gifts, samples and other items and services which are of interest to health professionals. We trust that the third edition is a useful resource for lawyers, compliance officers, managing directors and managers in marketing and medical departments of the medical industry to assess the legal impact on their promotion and marketing activities involving healthcare professionals or medical institutions.

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