This country-specific Q&A provides an overview of pharmaceutical advertising laws and regulations applicable in Ukraine. For a full list of jurisdictional Q&As visit legal500.com/guides
1. What laws are used to regulate advertising on medicines in your jurisdiction?

Advertising on medicines in Ukraine is regulated by a number of legal acts, inter alia:

- The Law of Ukraine “On Advertising”,
- The Law of Ukraine “On Medicinal Products”,
- The Law of Ukraine “On Protection against Unfair Competition”,
- The Law of Ukraine “On Consumers’ Rights Protection”,
- The Civil Code of Ukraine,
- The Law of Ukraine “On Ensuring the Functioning of the Ukrainian Language as the State Language”,
- The Law of Ukraine “On Copyright and Related Rights”.

2. Are there any self-regulatory or other codes of practice which apply to the advertising of medicines? a) If there are any such codes, to whom do they apply (companies, or healthcare professionals, for example)? b) What is the legal status of the self-regulatory codes?

Yes, there are self-regulatory codes of practice which apply to the advertising of medicines in Ukraine.

In particular, the Code of Pharmaceutical Marketing Practices of Association of Pharmaceutical Research and Development (so called “the APRaD Code of Ethics”) regulates promotion of prescription-only medicines. By the way, the APRaD is a Member of the European Federation of Pharmaceutical Industries and Associations (the EFPIA). Thus, the APRaD Code of Ethics implements the main principles and approaches outlined in the EFPIA Code of Practice.

Moreover, the Ethical Code of Ukrainian Doctor was adopted at the National Congress of Healthcare Organizations and the Congress of the Ukrainian Medical Association on September 27, 2009. For instance, under the abovementioned the Ethical Code of Ukrainian Doctor:

1. The doctors shall not:
   - engage in unfair advertising and allow to use his / her name and statements for the purpose of blurb of misleading medical information;
   - participate in collusion with other physicians, pharmacists, agents of medical and pharmaceutical industry and other individuals or legal entities in order to obtain illegal profit;
2. The publication of medical nature, doctor’s speeches at scientific meetings, educational activities through the media should be flawless in ethical way, limited to objective scientific and practical information and do not contain elements of unfair competition, advertising and self-promotion.

a) If there are any such codes, to whom do they apply (companies, or healthcare professionals, for example)?

The APRaD Code of Ethics applies to pharmaceutical companies which are member companies of the Association of Pharmaceutical Research and Development (APRaD), - employees of such member companies, inter alia medical sales representatives (i.e. personnel employed by member companies or retained by way of contract with third parties, who interact with Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs), in connection with the promotion of prescription-only medicines).

In particular, the APRaD Code of Ethics regulates:

- Promotion of prescription-only medicines to
HCPs (inter alia, all methods of promotion including, but not limited to, oral and written promotional activities and communications, journal and direct mail promotions, the activities of medical sales representatives, the use of digital communications and channels, such as websites and social media, the use of audio-visual systems such as films, video recordings, data storage services and the like, as well as the provision of informational and educational materials, items of medical utility, hospitality in relation to events and medical samples),
- Interaction between member companies and HCPs, HCOs and Patient Organisations (POs),
- Disclosure of transfers of value from member companies to HCPs, HCOs and POs.

The Ethical Code of Ukrainian Doctor applies to physicians, administrative staff and researchers, which are directly related to the treatment and prophylactic, as well as research activities in the field of healthcare.

b) What is the legal status of the self-regulatory codes?

The APRaD Code of Ethics is binding only for the member companies which voluntarily joined the Association of Pharmaceutical Research and Development (the APRaD). Besides, those companies, which did not join the APRaD, are not obliged to adhere to provisions stipulated in the APRaD Code of Ethics.

According to the Law of Ukraine “On Protection against Unfair Competition” (Article 33) business entities shall obtain approval of the Ukrainian antitrust & competition authority - Antimonopoly Committee of Ukraine (hereinafter - the “AMCU”) for the industry codes of conduct (i.e. so called “rules of professional ethics”) developed by them. In 2019 the AMCU developed a special procedure for approval of the rules of professional ethics in competition. However, according to publicly available information, the APRaD Code of Ethics was not submitted to the AMCU for approval.

The current Ukrainian legislation does not provide for liability for the very fact of developing and applying codes of conduct, which are not approved by the AMCU. However, the AMCU’s approval would strengthen the status of the APRaD Code of Ethics as commercial customs which could be unquestioningly used in Ukrainian public authorities, including the AMCU and the courts, in order to defend the companies’ interests from unfair competition, e.g. if other companies do not comply with the APRaD Code of Ethics.

The Ethical Code of Ukrainian Doctor is binding for physicians, administrative staff and researchers, which are directly related to the treatment and prophylactic, as well as research activities in the field of healthcare. Recognition of this Code by physicians of healthcare institutions, scientific establishments, higher medical educational or postgraduate educational institutions, medical and scientific education establishments, associations, societies or other public organizations acting in the field of healthcare, shall be confirmed by an official statement to the Committee of Bioethics at the Ministry of Health of Ukraine. In case of breaching of this Code by physicians of medical, scientific and educational institutions, members of federations, associations, societies or other public organizations that act in the field of healthcare and recognize this Code, such physicians may be sanctioned by the ethical board or committees of these institutions and organizations. Elimination of a physician or researcher from the professional association is the outer form of public condemnation of breach of professional and ethical principles.

3. Is there a statutory or generally accepted definition of “advertising”? a) What does the definition cover? - does it include patient information leaflets, for example, catalogues, disease awareness campaigns or correspondence, for example? b) Does the definition apply equally to all target audiences?

Yes, the Law of Ukraine “On Advertising” provides for the following definition of “advertising”:

- “Advertising” is defined as “an information about a person or a product, disseminated in any form and in any way and intended to form or maintain awareness of consumers of advertising and their interest in such a person or product”.

Besides, the abovementioned Law defines “consumers of advertising” as “an indefinite circle of persons to whom advertising is addressed”.

a) What does the definition cover? - Does it include patient information leaflets, for example, catalogues, disease awareness campaigns or correspondence, for example?

The definition of the term “advertising” is quite broad, as it indicates that advertising may be disseminated in any form and in any way. However, the main criterion which shall be applied while differentiating “advertising” from other information is the audience - whether such
audience is unlimited (i.e. an indefinite circle of persons to whom advertising is addressed) or limited (i.e. a particular person or a definite circle of persons to whom the information is addressed).

Thus, a pharmaceutical company may claim that a patient information leaflet or correspondence which is addressed to a particular patient (for example, contains the patient’s name) shall not be considered as an advertising.

b) Does the definition apply equally to all target audiences?

The definition of the term “advertising” does not contain such criterion as the type of the target audience. However, a number of legislative requirements and restrictions, which are applicable to advertising of medicines, medical devices, methods of prevention, diagnosis, treatment and rehabilitation, do not apply to such advertising which is placed in specialized publications, which are intended for medical institutions and physicians or advertising which is distributed at seminars, conferences and symposia on medical topics.

Please note, on September 09, 2021 a new Draft Law of Ukraine “On Medicinal Products” (registration number 5547 dated 21.05.2021) was adopted by the Ukrainian Parliament in the first reading and is pending the second reading. This Draft Law intends to introduce a new term - "promotion of medicinal products" (except for "advertising") as well as establish special requirements for promotion of medicinal products.

Under the abovementioned Draft Law:

1. “Promotion of medicinal products” is defined as “an information about a medicinal product, disseminated in any form and in any way, intended to create or maintain the awareness of a defined circle of consumers and their interest in such medicinal product, and is directed at promotion of prescription, dispensing, sale and application of a medicinal product”;
2. Promotion of medicinal products includes, inter alia:
   - Dissemination of promotional materials on medicinal products to defined persons, in particular, to: i) doctors who are authorized to prescribe medicines, ii) persons which supply medicines, or iii) defined patients or groups of patients;
   - Visits of medical or sales representatives to doctors who are authorized to prescribe medicinal products;
   - Organizing, conducting, sponsorship of promotional events, conferences, seminars, symposia on medical topics with participation of doctors who are authorized to prescribe medicines or persons which are authorized to supply medicines.

4. Are press releases regarding medicines allowed in your jurisdictions, and if so what are the restrictions on these (bearing in mind the target audience)?

The Ukrainian legislation does not contain any special restrictions or prohibitions applicable to press releases regarding medicines. Thus, the general rules regulating advertising of medicinal products shall be applicable to press-releases (inter alia, prohibition of advertising of prescription-only medicines etc.).

5. Are there any processes prescribed (whether by law or Codes of Practice) relating to the approval of advertising of medicines within companies?

Current Ukrainian legislation does not regulate processes relating to the approval of advertising of medicines within companies. As a rule, companies adopt their own internal documents (e.g. policies, standards operating procedures) regulating their processes of developing and approval of advertising and promotional materials.

Please note, the Draft Law of Ukraine “On Medicinal Products” (registration number 5547 dated 21.05.2021), which was adopted by the Ukrainian Parliament in the first reading, implies establishment of procedure for the approval of advertising and promotion of medicines within companies. However, as far as this Draft Law is pending the second reading, the legislative requirements may be changed.

According to the APRaD Code of Ethics (Section 20) each member company must establish a scientific service responsible for providing information on its medicinal products. The scientific service should include a physician or, where appropriate, a pharmacist who will be responsible for approving any promotional material prior to release. Such person must certify that he/she has checked the final form of the promotional material and that he/she believes that it meets the requirements of the APRaD Code of Ethics and applicable legislation,
complies with the summary of product characteristics and provides fair and truthful information about the medicinal product. Besides, each member company must appoint at least one senior employee who shall be responsible for supervising the company to ensure that the standards of the APRaD Code of Ethics are met.

6. Do companies have to have material approved by regulatory bodies prior to release?

Current Ukrainian legislation does not impose an obligation on companies to have advertising / promotional material approved by regulatory bodies prior to its release.

Besides, companies have a right to voluntarily apply to the Ukrainian antitrust & competition authority – Antimonopoly Committee of Ukraine (AMCU) in order to obtain an opinion of the AMCU (in the form of recommendatory explanations) on the compliance of the company’s draft advertising / promotional material with the requirements of the Law of Ukraine “On Protection against Unfair Competition”, which inter alia prohibits dissemination of misleading information.

Please note, until the year 2016 a special procedure was applied by the Ministry of Health of Ukraine for approval of information contained in the advertising of medicines for children and adolescents, and issuance of permits for advertising of medicines for children and adolescents, which was envisaged by the Order of the Ministry of Health of Ukraine dd. June 10, 1997 No. 177. This procedure is not applicable anymore. However, in the year 2018 there was a new legislative initiative to empower the Ministry of Health of Ukraine to approve advertising materials for medicines, but such a legal act was not adopted. Thus, we cannot exclude those similar legislative initiatives may appear in the future.

7. Is comparative advertising for medicines allowed and if so, what restrictions apply?

According to the Ukrainian legislation (Article 11 of the Law of Ukraine “On Advertising”) comparative advertising for medicines is allowed, if it meets a number of criteria, inter alia:

- does not contain signs of unfair business practice (e.g. is not misleading and aggressive);
- compares homogeneous (similar) products;
- objectively compares the characteristics / price of products;
- does not discredit;
- does not create confusion;
- compares products with the similar indication of origin;
- a competitor’s product protected by trademark is not imitated, etc.

Comparative advertising may contain pictures, references to products, trademarks under which the product is manufactured (i.e. the product that is compared with), name of the competitor.

Taking into account that the abovementioned requirements for comparative advertising are quite new (i.e. were adopted in December 2019), the Antimonopoly Committee of Ukraine has not developed a clear position on the comparative advertising yet. In particular, the Antimonopoly Committee:

- does not have unified approaches to comparative advertising due to small quantity of practical cases under the new legislative requirements mentioned above (as of the beginning of the year 2021);
- questions which medicines can be considered to be similar (homogeneous);
- is sure that comparative advertising is a potential source of unfair competition.

8. Is it possible to provide information on unauthorised medicines or unauthorised indications? Is it possible to provide information on unauthorised medicines or unauthorised indications during a scientific conference directed at healthcare professionals, or to send information to healthcare professionals?

According to the Law of Ukraine “On Medicinal Products” (Article 26) information on medicinal products (including medicinal products that are not registered or are at the stage development or implementation into production) includes the name, characteristics, medicinal properties, possible side effects, – such information may be published in publications intended for medical and pharmaceutical professionals, as well as in materials, distributed at specialized seminars, conferences, symposiums on medical topics.

Moreover, Article 21 of the Law of Ukraine “On Advertising” which contains special requirements and restrictions of medicinal products (e.g. prohibits advertising of unregistered medicines, prescription-only medicines and some other categories of medicines), does not apply to advertising of medicines, which is
placed in specialized publications for medical institutions and doctors, as well as distributed at seminars, conferences, symposiums on medical topics.

Thus, under the current Ukrainian legislation, a company may provide information on unauthorised medicines or unauthorised indications in specialized publications for medical institutions and healthcare professionals or at seminars, conferences, symposiums on medical topics.

However, according to the APRaD Code of Ethics a prescription-only medicinal product must not be promoted prior to the grant of the marketing authorization allowing its sale or supply or outside of its approval indications.

9. Please provide an overview of the rules that apply to advertising to the general public for prescription only medicines and over the counter medicines, an indication of the information that must or must not be included.

The advertising of medicines to the general public shall comply with both: i) general rules, which are applicable to all types of advertising of any products, ii) special requirements and restrictions applicable to medicines.

Advertising is subject to a number of general requirements, inter alia:

1. The advertisement must not, inter alia:
   - contain misleading information (including incomplete, inaccurate or false information, in particular due to the chosen method of presentation, omission of certain facts or vagueness of wording that has affected or may affect the intentions of persons to purchase, order or sell products);
   - contain statements that are discriminatory on the grounds of human origin, social and property status, race and nationality, sex, education, political views, attitude to religion, language, gender and occupation, place of residence, as well as such that discredit the products of others;
   - provide information or call for actions that may cause violations of the law, cause or may cause harm to human health or life and / or the environment, as well as encourage the neglect of security measures;
   - use tools and technologies that have impact on the subconscious of consumers of advertising;
   - make allegations discriminatory against persons who do not use the advertised product;
   - use or imitate the image of national symbols of Ukraine;
   - advertise goods the production or sale of which requires a license, in the absence of the license;
   - contain an image of a natural person or use his/her name without the written consent of this person;
   - imitate or copy text, images, music or sound effects used in the advertising of other goods, unless otherwise provided by the laws of Ukraine in the field of intellectual property;
   - distribute advertising (including announcements of movies and TV movies), which contains elements of cruelty, violence, pornography, cynicism, humiliation of human honour and dignity, etc.

Advertisements for competitions, lotteries, prize draws, promotional events, etc. must contain information about the timing and venue of these events and indicate the source of information from which a person can learn about the conditions and venue of these events. Information on any changes in the conditions, place and terms of competitions, lotteries, prize draws, promotional events, etc. must be submitted in the same order in which it was distributed before.

2. Advertisements for the discount on prices for products or sale must contain information about the place, date of beginning and end for application of the discount or sale, as well as the ratio of the discount to the previous price of the products.

3. Advertising about the discount on prices for products or sale must contain information about the place, date of beginning and end for application of the discount or sale, as well as the ratio of the discount to the previous price of the products.

4. The volume of the sound of advertising broadcast on television and radio should not exceed the volume of the sound of the current program or transmission.

As for special requirements and restrictions applicable to the advertising of medicinal products:

1. It is allowed to advertise:
only such medicines, that are duly permitted for use in Ukraine;
- only over the counter medicines (i.e. those medicinal products that are available without a doctor’s prescription) and which are not included in the list of medicinal products prohibited for advertising under the Ukrainian legislation.

2. It is prohibited to advertise prescription-only medicinal products, as well as those medicines which are included into the list of medicinal products prohibited for advertising.

3. Advertising of doping substances and / or methods for their use in sports is prohibited.

4. **Advertising of medicines must contain:**
   - objective information about the medicinal product, and shall be carried out so that it is clear that the message is advertising, and the advertised product is a medicinal product;
   - the requirement to consult a doctor before using a medicinal product;
   - a recommendation for mandatory reading of the instructions for the medicinal product;
   - the warning text: “Self-medication can be harmful to your health”, which occupies at least 15 percent of the area (duration) of all advertising.

5. Advertising of medicinal products **shall not contain references to therapeutic effects in relation to diseases that are unamenable or difficult to treat.**

6. Advertising of medicines shall not contain:
   - information that may give the impression that consultation with a specialist is not required when using a medicinal product;
   - information that the therapeutic effect of the use of a medicinal product is guaranteed;
   - images of changes in the human body or its parts due to illness, injuries;
   - allegations that contribute to the emergence or development of fear of falling ill or deteriorating the health due to non-use of medicines advertised;
   - statements that facilitate the possibility of self-diagnosis for diseases, pathological human conditions and their self-treatment with the use of advertised medical products;
   - references to medicines as the most effective, safest, exceptional in the absence of side effects;
   - references to specific cases of successful use of medicines;
   - recommendations or references to the recommendations of medical professionals, scientists, medical institutions and organizations regarding the advertised product;
   - special expressions of gratitude, appreciation, letters, excerpts from them with recommendations, stories about the use and results of the advertised product from individuals;
   - images and names of popular people, heroes of films, TV and animated films, authoritative organizations;
   - information that may mislead a consumer about the composition, origin, effectiveness, patent protection of the advertised product.

7. **The participation of doctors** and other professional medical workers, as well as persons whose appearance imitates the appearance of doctors, **is prohibited in the advertising of medicinal products.**

8. It is prohibited to place in the advertising of medicinal products information which suggests that the medicinal product is a food, cosmetic or other consumer product or that the safety or efficacy of the medicinal product is due to its natural origin.

9. It is prohibited to advertise new medicinal products that are under consideration, but not yet approved for use yet.

10. **Persons engaged in the production and / or sale of medicines may sponsor TV, radio programs by providing information of an advertising nature about the name or trademark, except for any reference to prescription-only medicinal products.**

11. TV sale of medicines is prohibited.

10. **Are there any restrictions on interactions between patients or patient organisations and industry (e.g., consultation, sponsorship)? If so, please**
describe those briefly.

According to the APRaD Code of Ethics:

1. Donations and grants\(^1\) (in cash or in kind or otherwise) to patient organizations (POs) are only allowed, if: they are made for the purpose of supporting healthcare, research or education; they are documented and kept on record by the donor/grantor; and they do not constitute an incentive to recommend, purchase specific medicinal products. Donations and grants to individuals are not permitted.

2. No payment must be offered to compensate merely for the time spent by the PO’s representative in attending events organised or sponsored by or on behalf of a member company. The public use of an PO's logo and/or proprietary material by a member company requires written permission from that organisation. In seeking such permission, the specific purpose and the way the logo and/or proprietary material will be used must be clearly stated. Member companies must ensure that their sponsorship of POs is always clearly acknowledged and apparent from the outset.

3. No member company may require that it be the sole funder or sponsor of a PO or any of its programs.

4. All forms of hospitality offered to POs' representatives must be “reasonable” in level and strictly limited to the main purpose of the event. As a general rule, the hospitality provided must not exceed what those individuals would normally be prepared to pay for themselves.

5. Member companies shall disclose the amounts provided to POs in the framework of the collaboration.

6. It is prohibited for member companies to:
   a. Provide or offer any meal (food and beverages) to POs' representatives, unless, in each case, the value of such a meal does not exceed the following monetary threshold:
      - In Ukraine, the cost of one meal cannot exceed 1200 UAH (appr. EUR 35 including VAT) and the overall hospitality expenses per day should not exceed 2000 UAH (appr. EUR 59 including VAT) for non-personalized meals during conferences, seminars, etc;
   b. Provide gifts for the personal benefits (such as sporting or entertainment tickets to events, social courtesy gifts) for POs’ representatives (either directly or indirectly).
   c. Provide or offer cash, cash equivalents or personal services (i.e. those services which confer a personal benefit to the recipient);
   d. Provide or offer promotional aids\(^2\) to POs’ representatives in relation to the promotion of prescription medicines.

References

\(^{1}\) Donations and grants - providing funds, assets or services freely given for the purpose of supporting healthcare, scientific research or education, with no consequent obligation on the recipient to provide goods or services to the benefit of the donor in return.

\(^{2}\) A promotional aid is a non-monetary item given for promotional purposes, which does not include promotional materials.

11. Which information must advertising directed at healthcare professionals contain, and which information is prohibited? For example can information about clinical trials, or copies of journal be sent?

Misleading information is prohibited in any case.

The APRaD Code of Ethics contains some special requirements applicable to the information available during the advertising of prescription-only medicinal products to healthcare professionals:

1. A medicinal product must not be promoted prior to the grant of the marketing authorization allowing its sale or supply or outside of its approval indications.
2. Promotion must be consistent with the particulars listed in the summary of product characteristics of the relevant medicinal product.
3. All promotional material must include the following information clearly and legibly:
   - Essential information consistent
with the summary of product characteristics, specifying the date on which such essential information was generated or last revised;
- When appropriate, the selling price or indicative price of the various presentations and the conditions for reimbursement by social security bodies.

4. Where a promotion is intended as a reminder only, the requirements above are not required to be complied with, provided that the promotion includes no more than the name of the medicinal product or its international non-proprietary name, where this exists, or the trademark.

The APRaD Code of Ethics does not prohibit sending information about clinical trials or copies of journal to healthcare professionals.

12. May pharmaceutical companies offer gifts to healthcare professionals and are there any monetary limits?


1. All HCPs (notwithstanding they work for public and/or private healthcare organizations) shall not use their official powers, position and associated opportunities in order to gain illegal benefit for themselves or for other persons.

2. The notion “gift” is rather broad and comprises “money or other property, advantages, privileges, services or intangible assets which are provided or received for free or below minimum market price.”

3. HCPs working in public legal entities shall not receive gifts for making decisions in favour of the person/company which grants the gift.

4. HCPs working in public legal entities may accept gifts, if they meet the following criteria:
   - the gifts shall comply with generally accepted idea of hospitality, accept for cases such gift is related to the public functions of the HCP (for instance, the gift shall not be presented to induce certain medicines prescription by the HCP), and
   - cost of such gift provided within one time shall not exceed 1 minimum living wages for established for able-bodied person on the day of the gift acceptance (for example, UAH 2379, i.e. approx. EUR 77 - in October or November 2021), and
   - the total cost of all the gifts received from the same person or group of persons (including company or group of companies) during 1 year shall not exceed 2 minimum living wages established for able-bodied person as of the 1-st of January of the year when the gift is accepted (for example, UAH 4540, i.e. approx. EUR 148 – in 2021).

5. Current Ukrainian anticorruption law does not stipulate limits for hospitality gifts presented to the HCPs working in private companies. But in any case, gifts shall not be presented to induce prescription of certain medicines or otherwise influence the HCP’s official decisions.

Under the APRaD Code of Ethics:

1. It is prohibited for member companies to:
   - Provide gifts for the personal benefits (such as sporting or entertainment tickets to events, social courtesy gifts) for HCPs and HCOs’ members (either directly or indirectly);
   - Provide or offer cash, cash equivalents or personal services (i.e. those services which confer a personal benefit to the recipient);
   - Provide or offer promotional aids(1) to HCPs, HCOs’ members in relation to the promotion of prescription medicines.
   - Provide or offer any meal (food and beverages) to HCPs, HCOs’ members, unless, in each case, the value of such a meal does not exceed a certain monetary threshold. In particular, in Ukraine, the cost of one meal cannot exceed 1200 UAH (approx. EUR 35 including VAT) and the overall hospitality expenses per day should not exceed 2000 UAH (approx. EUR 59 including VAT) for non-personalized meals during conferences, seminars, etc, and up
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1. To 1600 UAH per meal (appr. EUR 47 including VAT) for an individual interaction when a contract between a company and HCP is concluded or in line with current Ukrainian legislation.

2. Member companies may only offer hospitality when such hospitality is “appropriate” and otherwise complies with the provisions of the Code. Hospitality extended in connection with events must be limited to travel, meals, accommodation and genuine registration fees. Hospitality may only be extended to persons who qualify as participants in their own right. In exceptional cases of established health needs (e.g. disability or injury) where a participant requires assistance, the travel, meals, accommodation and genuine registration fee costs of an accompanying person can be reimbursed within the same parameters.

3. All forms of hospitality offered to HCPs, HCOs’ members must be “reasonable” in level and strictly limited to the main purpose of the event. As a general rule, the hospitality provided must not exceed what those individuals would normally be prepared to pay for themselves.

12. Reference

(1) A promotional aid is a non-monetary item given for promotional purposes, which does not include promotional materials.

13. Are pharmaceutical companies allowed to provide samples to healthcare professionals?

According to the current Ukrainian legislation medical samples are not permitted in Ukraine.

In particular, under the Law of Ukraine “Fundamentals of Ukrainian legislation on healthcare” (Article 78-1) medical and pharmaceutical professionals as well as rehabilitation specialists during their professional activity do not have the right to receive samples of medicines, medical devices, technical and other means of rehabilitation from business entities engaged in the production and / or sale of medicines, medical devices, technical and other means of rehabilitation, their representatives for use in professional activities (except in cases related to the conduct of clinical trials of medicines, medical devices, technical and other means of rehabilitation in accordance with a contract).

Besides, a new Draft Law of Ukraine “On Medicinal Products” (registration number 5547 dated 21.05.2021), which was adopted by the Ukrainian Parliament in the first reading on September 09, 2021 and is pending the second reading, proposes to allow free samples of medicinal products in exceptional cases, subject to a number of requirements, – but there is still a chance that these changes will not pass through the second reading.

14. Is sponsorship of scientific meetings or congresses and/or attendance by healthcare professionals to these events? If so, which restrictions apply? Do additional restrictions apply to events taking place abroad?

Pharmaceutical companies may finance scientific meetings / congresses as well as attendance by healthcare professionals to these events, in case of compliance with a number of requirements and restrictions.

Current Ukrainian legislation does not provide for any direct regulations, which would stipulate how pharmaceutical companies may organize financing of scientific events and the HCPs’ participation in such events. Therefore, we cannot exclude the risk of the law-enforcement bodies’ perception of such financing as: i) “illegal benefits” (for example, illegal benefits provided for prescribing medicines and/or obtaining a certain decision to be made by the HCP in the sphere of public procurement etc.) - in case there are no sufficient evidences proving lawful grounds for such financial support, or ii) “gifts” the value of which exceeds maximum amounts stipulated by current legislation of Ukraine (for more details please see Section 12 of this Guide). Thus, it is of vital importance for pharmaceutical companies to develop and implement a number of tools to mitigate such risks (inter alia in their internal policies, SOPs as well as contracts which regulate the model and requirements for financing scientific events as well as attendance by HCPs to such events).

According to the APRaD Code of Ethics:

1. All events(1) with the attendance of healthcare professionals must be held in “appropriate” locations and venues that are conducive to the main purpose of the event, avoiding those that are “renowned” for their entertainment facilities or are “extravagant.”

2. No member company may organize or finance an event that takes place outside its home country unless:
   - most of the invitees are from
outside of its home country and, given the countries of origin of most of the invitees, it makes greater logistical sense to hold the event in another country; or
  o given the location of the relevant resource or expertise that is the object or subject matter of the event, it makes greater logistical sense to hold the event in another country.

3. Monetary threshold shall be applied to hospitality (food and beverages) provided or offered to HCPs and HCOs’ members. For example, in Ukraine, the cost of one meal cannot exceed 1200 UAH (approx. EUR 35 including VAT) and the overall hospitality expenses per day should not exceed 2000 UAH (approx. EUR 59 including VAT) for non-personalized meals during conferences, seminars, etc.

As for events taking place abroad:

1. The monetary threshold set in the country where the event takes place must prevail (i.e. the host country principle applies);

2. Promotional information which appears on exhibition stands or is communicated to participants at international events may, unless prohibited or otherwise regulated by local laws and regulations, refer to medicinal products (or uses) which are not registered in the country where the event takes place, or which are registered under different conditions, as long as: any such promotional material is accompanied by a suitable statement indicating the countries in which the medicinal product is registered and makes clear that the medicinal product or indication is not registered locally, and any such promotional material which refers to the prescribing information (indications, warnings etc.) authorized in a country or countries where the medicinal product is registered must be accompanied by an explanatory statement indicating that registration conditions differ internationally.

Reference

[1] Events: all professional, educational, scientific or promotional events, meetings, congresses, conferences, symposiums, and other similar events (including advisory board meetings, visits to research or manufacturing facilities and planning conferences, training events or meetings with experts in connection to clinical trials and non-interventional studies) organised or financed by or on behalf of a member company.

15. What are the restrictions on the organisation of cultural, sports or other non-scientific events in relation to scientific conferences by pharmaceutical companies?

As we have mentioned in Section 14 of this Guide, current Ukrainian legislation does not provide for any direct regulations, which would govern organization of scientific events by pharmaceutical companies. Besides, there is a risk that the organisation / financing of cultural, sports or other non-scientific events in relation to scientific conferences by pharmaceutical companies may be considered by the law-enforcement authorities to be illegal benefits provided to HCPs participating in such events.

Please note, according to the APRaD Code of Ethics hospitality must not include financing or organizing entertainment events (e.g. sporting or leisure). The hospitality offered to HCPs in relation to the HCPs’ participation in the scientific event must be reasonable in level and strictly limited to the main purpose of the scientific event.

16. Is it possible to pay for services provided by healthcare professionals and if so, which restrictions apply?

Yes, it is possible to pay for services provided by healthcare professionals, in case a number of requirements and restrictions are complied with.

Under the Ukrainian legislation:

- HCPs are forbidden to receive illegal benefits from business entities engaged in the production and / or sale of medicines (the Law of Ukraine “Fundamentals of Ukrainian Legislation on Healthcare”, Article 78-1);
- “Illegal benefit” is defined as money or other property, advantages, facilities, services, intangible assets or any other benefits of non-material or non-monetary character, which are offered, promised, provided or received without lawful grounds (the Law of Ukraine “On Corruption Prevention”, Article 1).

As far as current legislation of Ukraine does not stipulate which grounds for providing benefits may be considered
lawful, the Ukrainian law-enforcement authorities may decide whether certain grounds are lawful or not in each particular case at their own discretion.

In practice, the direct rule of any legislative act or the enforceable agreement shall be treated as sufficient lawful grounds, until otherwise is proved by the law-enforcement authorities.

Certain categories of HCPs being public officials may receive payments and reimbursement of expenses related to their services provided to a company within the framework not prohibited by applicable law (for example – for scientific services, and for certain categories of HCPs – for reading lectures, speaking at conferences etc.) on a basis of the legal ground – the contract. In such cases, the payments for services as well as reimbursement of costs (i.e. benefits) are obtained by officials on a reimbursable basis (i.e. not for free), as they provide services/perform work for the company for such benefits.

17. Are pharmaceutical companies permitted to provide grants or donations to healthcare professionals or healthcare institutions? Does it matter if the grant or donation is monetary or in kind?

According to the APRaD Code of Ethics:

1. Donations and grants (in cash or in kind or otherwise) to healthcare institutions are only allowed, if:
   - they are made for the purpose of supporting healthcare, research or education;
   - they are documented and kept on record by the donor/grantor;
   - they do not constitute an incentive to recommend and/or prescribe, purchase, supply, sell or administer specific medicinal products.

2. Donations and grants to individuals (inter alia, to individual HCPs) are not permitted.

Besides, the Ukrainian legislation (inter alia, the Law of Ukraine “On Charity and Charitable Organizations”) contains a number of requirements for charitable donations and charitable grants.

18. Are pharmaceutical companies required to disclose details of transfers of value to healthcare professionals or healthcare institutions? If so, please indicate whether this is a legal requirement or not, and describe briefly what the companies must report and how. Do these transparency requirements apply to foreign companies and/or companies that do not yet have products on the market?

There is no direct legislative requirement to make publicly available information on any transfers of value (ToV) to HCPs and HCOs from pharmaceutical companies.

However, such requirements are established by the APRaD.

According to the APRaD Code of Ethics:

1. Each Member Company must document and disclose ToV it makes, directly or indirectly, to or for the benefit of a recipient (HCP or HCO).
2. Disclosures must be made on an annual basis and each reporting period must cover a full calendar year:
   - The reporting period for the disclosure of transfers of value to recipients is set from 20 to 30 June of each year at the latest.
   - Disclosures must be made by each member company within 6 months after the end of the relevant reporting period and the information disclosed must remain in the public domain for a minimum of 3 years after the first disclosure of such information unless (i) a shorter period is required under applicable national laws or regulations, or (ii) the relevant legal basis for data protection (e.g. legitimate interests, legal obligation or the recipient’s consent relating to a specific disclosure) is no longer applicable.
3. Disclosures can be made in either of the following ways, provided that they are unrestricted and publicly available:
   - on the relevant member company’s website;
   - on a central platform of the APRaD.
4. Disclosures must be made pursuant to the national code of the country where the recipient operates and has its professional address. If a member company, its subsidiary or affiliate is not located in the country where
the recipient’s physical address is located, the member company must disclose such transfer of value in a manner consistent with the relevant national code.

5. Information must be disclosed in the official state language. Member companies are asked to disclose information not only in the state language but also in English. Each member company must document all ToVs required to be disclosed and maintain the relevant records of the disclosures made for a minimum 5 years after the end of the relevant reporting period, unless a shorter period is required under applicable national laws or regulations.

6. According to a general rule, ToV must be disclosed on an individual basis. Each member company must disclose, on an individual basis for each clearly identifiable recipient, the amounts attributable to ToV made to such recipient in each reporting period which can be reasonably allocated to one of the categories set out below:
   a. For ToV to an HCO:
      † Donations and grants,
      † Contribution to cost related to events,
      † Fees for services and consultancy;
   b. For ToVs to a HCP:
      † Contribution to cost related to Events,
      † Fees for services and consultancy.

7. As for aggregate disclosure: if ToV cannot be disclosed on an individual basis for legal reasons, a member company must disclose the amounts attributable to such ToV in each reporting period on an aggregate basis. Such aggregate disclosure must identify, for each category, (i) the number of recipients covered by such disclosure, on an absolute basis and as a percentage of all recipients, and (ii) the aggregate amount attributable to ToV to such recipients.

19. When if at all with a competent authority have to get involved in authorising advertising? Is advertising on the internet (including social media) for medicinal products regulated, and if so, how? Should companies include access restrictions on websites containing advertising or other information intended for healthcare professionals?

Under current Ukrainian legislation companies are not obliged to obtain a prior approval of the state authorities (e.g. approval of the Antimonopoly Committee of Ukraine or the State Service of Ukraine on Food Safety and Consumer Protection).

There are no specific rules for advertising of medicinal products on the Internet, – one must comply with general provisions which govern advertising of medicinal products.

As we have mentioned before, both the Law “On Medicinal Products” and the Law “On Advertising” contain an exemption for specialized publications intended for healthcare and pharmaceutical professionals: i.e. such publications may contain information on unregistered medicinal products as well as prescription-only medicinal products and medicines the advertising of which is prohibited. Therefore, a number of pharmaceutical companies which decided to place such information on their web-sites, in practice included access restrictions on such websites containing information intended for healthcare professionals.

However, the recent Ukrainian law-enforcement practice in this regard is quite ambiguous:

1. The Antimonopoly Committee of Ukraine once established a violation in the fact that prescription-only medicinal products had been advertised in an online specialized publication which was generally available (i.e. did not contain access restrictions). However, the court did not support this decision based on the lack of regulation for specialized publication, which allowed their decision-makers of the on-line magazine to determine its means to provide information to HCPs.

2. However, recently the State Service of Ukraine on Food Safety and Consumer Protection expressed another position, according to which only print publications (not online publications, web-sites) may be considered specialized ones.

20. Are there any anti-bribery rules apply to communications between pharmaceutical companies and healthcare professionals or healthcare organizations?

Under current Ukrainian legislation (the Law of Ukraine “Fundamentals of Ukrainian Legislation on Healthcare”,
Article 78-1) the medical and pharmaceutical professionals, as well as rehabilitation specialists are forbidden during their professional activity:

1. to receive illegal benefits from pharmaceutical companies or their representatives;
2. to receive from pharmaceutical companies and their representatives’ samples of medicines, medical devices, technical and other means of rehabilitation for use in professional activities (except in cases related to the conduct of clinical trials in accordance with a contract);
3. to advertise medicines, medical devices, technical and other means of rehabilitation, inter alia, to prescribe medicines on forms containing information of an advertising nature, and indicate the manufacturers of medicines / trademarks;
4. at the request of the consumer during the sale (release) of the medicinal product, not to provide information or provide inaccurate information about the presence in this pharmacy of medicinal products with the same active substance (under the international non-proprietary name), form of release and dosage, including conceal information that such medicinal product is being sold at a lower price.

According to the Law of Ukraine “On Corruption prevention” HCPs of public and private healthcare organizations are subject to liability for corruption offenses, inter alia, if they meet such criteria as performing organizational-and-management or administrative-and-household functions (e.g. if a HCP is chief physician, the head of the department, the head of the medical service etc.). Moreover, the Law of Ukraine “On Corruption prevention” provides for a number of restrictions and limitations related to “gifts” and “illegal benefits” provided to HCPs (for more details please see Sections 12, 14 and 16 of this Guide).

21. What are the rules (whether statutory or self-regulatory) which govern the offering of benefits or inducements to healthcare professionals?

Statutory and self-regulatory rules, which govern the offering of benefits or inducements to healthcare professionals, have been outlines in Sections 12 and 20 of this Legal Guide above.

22. Which bodies are responsible for enforcing the rules on advertising and the rules on inducement? Please include regulatory authorities, self-regulatory authorities and courts.

Such bodies as the Antimonopoly Committee of Ukraine, the State Service of Ukraine on Food Safety and Consumer Protection, the National Council of Ukraine on Television and Radio Broadcasting (concerning TV and radio advertising of medicinal products) and courts are responsible for enforcing the rules on advertising of medicinal products.

Besides, investigations related to violation of the rules on inducement may be carried out by the National Police of Ukraine, the National Anti-Corruption Bureau of Ukraine and the State Bureau of Investigations. In such cases sanctions may be imposed by courts (i.e. local courts of general jurisdiction and the High Anti-Corruption Court).

23. On what basis and before which bodies or courts can companies initiate proceedings against competitors for advertising infringements?

Companies can initiate proceedings against competitors for advertising infringements:

- in accordance with the Law of Ukraine “On Protection against Unfair Competition” – before the Antimonopoly Committee of Ukraine,
- in accordance with the Law of Ukraine “On Advertising” – before the State Service of Ukraine on Food Safety and Consumer Protection,
- courts.

24. What are the penalties, sanctions or measures that regulators or courts can impose for violating medicines advertising rules and rules on inducements to prescribe in your jurisdiction?

Different regulatory bodies may impose different measures for violating medicine advertising rules, for example:

1. The Antimonopoly Committee of Ukraine (AMCU) may:
   - issue binding recommendations
addressed to the company to cease dissemination of advertising which contains signs of violations of the legislation on protection against unfair competition;
   - impose on the company a fine of up to 5% of income (revenue) from the sale of the company’s products for the last reporting year preceding the year in which the fine is imposed, as well as the obligation to stop such violation.\footnote{1}

2. The State Service of Ukraine on Food Safety and Consumer Protection impose a fine on the advertiser in the amount of five times the cost of advertising for violation of regulatory requirements of the legislation on advertising.\footnote{2}

Violation of the rules on prohibition of inducements to prescribe medicines may entail a number of negative consequences:

1. Administrative liability of the HCPs – for violation of the restrictions imposed on HCPs during their professional activities (under Article 44 of the Code of Ukraine on Administrative Offenses);
2. Criminal liability for persons found guilty in corruption (i.e. a HCP and a representative of a pharmaceutical company and/or a third party);
3. Criminal liability for a legal entity (i.e. pharmaceutical company);
4. Reputational risks:
   - The Ukrainian legislation provides for entering the information about the persons held liable (under criminal, administrative, civil or disciplinary law) for corruption or corruption-related offences into the Unified State Register of persons who have committed corruption or corruption-related offenses, which certainly could adversely affect the reputation of both individuals and companies.
   - Please note that the access to the mentioned Register is publicly available.

5. Commercial risks – invalidity of agreements: agreements concluded as a result of corruption offences may be declared null and void.

References

\footnote{1} Art. 21 of the Law of Ukraine “On Protection against Unfair Competition”

\footnote{2} Part 4 of Article 27 of the Law of Ukraine “On Advertising”

25. What is the relationship between procedures before or measures taken by the self-regulatory authority and the procedures before or measures taken by courts/government competent authorities?

As a rule, the self-regulatory authorities do not impose sanctions (though they are entitled to), - they prefer to transfer this authority to national competent authorities.

According to the APRaD Code of Ethics, the APRaD requires an immediate cessation of the offending activity from the offending member company and a signed undertaking by such company to prevent a recurrence. Besides, sanctions, applied to member companies, shall be proportionate to the nature of the infringement, have a deterrent effect and take account of repeated offences of a similar nature or patterns of different offences. A combination of offence disclosure together with a fine is generally considered to be the most effective sanction.

26. Are there any recent enforcement trends in relation to pharmaceutical advertising in your jurisdiction? Please report any significant (publicly known) enforcement actions in the past two years.

On the 6th of January, 2021, the Antimonopoly Committee of Ukraine (“the AMCU”) published its Report on the results of its study to identify and halt unfair practices in the field of advertising of medicinal products, dietary supplements, treatment procedures, antiseptics and disinfectants for the years 2019-2020 (hereinafter – the “Report”).

After discussing this Report with the business sector, the AMCU issued its Recommendations for the application of the provisions of Article 15\textsuperscript{1} of the Law of Ukraine “On Protection against Unfair Competition” regarding the advertising of medicinal products (hereinafter – the “Recommendations”).

In the Report and the Recommendations, the AMCU defined a number of red flags in pharmaceutical advertising claims, inter alia:
• **Duration of action.** The AMCU does not recommend using such claims as “quick relief”, “immediate symptom removal”, “at the first application”, “in a few minutes”, unless this claim can be corroborated by the instruction for use of the medicinal product.

• **Leading position.** The AMCU does not recommend using such claims as “number one worldwide”, “leader”, “the newest” except as basing on actual and correct information. For example, one should not claim that a medicinal product is the leader worldwide if it is the leader in 50 countries, and only up-to-date ranking data may be used.

• **Price.** The AMCU does not recommend using such claims as “affordable price”, “moderate price”, “reasonable price”, as such price definition is highly subjective.

• **Quality.** The AMCU does not recommend using such claims as “high quality”, “the highest quality” without a proper confirmation.

• **COVID-19.** The AMCU does not recommend referring to a medicinal product’s property to treat or prevent COVID-19 unless there is a proper confirmation, such as official recommendations of the Ministry of Health of Ukraine, etc.

It may be concluded that in the field of pharmaceutical advertising, the AMCU definitely pays attention to:

• Incomplete / inaccurate / untrue / ambiguous / obscure information;
• Exaggeration of properties (including “the best”, “the biggest”), evaluative statements about properties;
• Inconsistency of advertising with the instruction for use of a medicinal product, statements about curative properties of medicinal products (without mentioning the need of combined use);
• Blurring of areas of application, etc.

Both of the most significant enforcement actions in the field of pharmaceutical advertising in the past two years relate to advertising of “anti-COVID-19” medicinal products.

The first case is related to the medicinal product “Decasan” produced by a Ukrainian company “Yuria-Pharm”. On TV, “Decasan” was advertised as “having an effect on all complex viruses, including coronaviruses”. The AMCU, however, found that:

1. The instruction for the use of this medicinal product did not contain information on such properties;
2. There were no results of clinical studies to confirm its therapeutic or prophylactic effect on COVID-19;
3. This information on COVID-19 treatment or prophylactics did not correspond to the official information of the WHO and the Ministry of Health of Ukraine.

In view of this, by its decision dated 2 July, 2020, the AMCU established dissemination of misleading information in the form of communicating untrue information and imposed a fine of UAH 528 004 (approx. EUR 17 300) on the pharmaceutical company.

The second case is related to the medicinal product of “Proteflazid” produced by another Ukrainian company - Ecopharm. The AMCU established the following circumstances:

1. A medicinal product “able to stop Chinese coronavirus” was mentioned in a piece of TV news. This piece of news also covered the comment of the person, who was a deputy director general of Ecopharm, that “the active ingredient completely blocks the virus”;
2. A letter addressed to the Minister for Health of Ukraine was published on the website of Ecopharm. The letter suggested providing “Proteflazid” as “humanitarian aid for preventing and treating COVID-19”;  
3. The website of Ecopharm also posted a report on the results of a study on the effects of “Proteflazid” on coronaviruses (in fact, non-human ones, which did not include COVID-19). This information was not corroborated by the instruction for use of “Proteflazid”.

In view of this, by its decision of 10 July, 2020, the AMCU established dissemination of misleading information in the form of communicating untrue information and imposed a fine of UAH 3 210 464 (approx. over EUR 105 000).

However, this decision was appealed, and in the end the Supreme Court came to a conclusion that the abovementioned decision of the AMCU must be rendered invalid and reversed. The arguments taken into account by the Supreme Court were the following:

1. The name of the medicinal product was not mentioned in a piece of news, and the person, who was a deputy director general of Ecopharm, provided his comments as a scientist in his own name (but not as a representative of the pharmaceutical company);
2. The letter addressed to the Minister and published on the website was not intended for the public and did not contain any advertising or claims on the effectiveness of “Proteflazid”;
3. The report on the website was meant not to promote “Proteflazid”, but to inform the public of the scientific results;
4. Since “Proteflazid” is a prescription-only medicinal product, the increase in demand of the general public for it is impossible to happen.

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