Advertising of Medicinal Products in CEE & SEE

Life Sciences & Healthcare

Wolf Theiss

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This 2022 Wolf Theiss Guide is intended as a practical guide to the general principles and features of the basic legislation and procedures in countries included in the publication.

While every effort has been made to ensure that the content is accurate when finalised, it should be used only as a general reference guide and should not be relied upon as definitive for planning or making definitive legal decisions. In these rapidly changing legal markets, the laws and regulations are frequently revised, either by amended legislation or by administrative interpretation.

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Introduction

We are pleased to present Wolf Theiss' first regional guide dedicated to Life Sciences and Healthcare Law in Central, Eastern and Southeastern Europe (CEE/SEE).

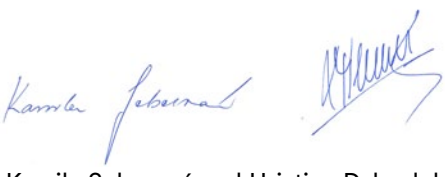
Our legal experts cover 13 countries across the CEE/SEE region. In this guide, we pool together our wide-ranging legal and practical expertise to provide a **360-degree overview of medical advertising regulation in the CEE/SEE region**.

During the Covid-19 pandemic, the region faced a sweeping need to improve access to medicinal products. The pharmaceutical industry, regulatory bodies and stakeholders had to re-think the process of public access to medicines and devise novel channels for the supply and treatment of patients. Consequently, issues concerning the legitimacy of online promotions, direct channels to HCPs/patients, new methods of promotion (e.g. HCP portals, patient-targeted websites, etc.), online educational materials, congresses and events, among other things, have become highly relevant and have reminded us of the challenges these topics can pose.

This guide presents practical, straight-to-the-point and handy insight into the legal framework for the advertising and promotion of medicinal products. The input of our CEE/SEE legal experts navigates between European principles and national and regional specifics, and further delves into the interplay between statutory rules on medical advertising on the one hand and a second layer of self-regulation rules introduced by industry codes of conduct on the other (e.g. the EFPIA Code of Practice and national codes of conduct). The guide also covers a handful of non-EU jurisdictions, which each have their own specific legal requirements.

Wolf Theiss' Healthcare and Life Sciences team numbers more than 30 lawyers across the CEE/SEE, making us one of the most integrated and comprehensive life sciences practices in the region. Our lawyers' expertise in different legal areas of the industry gives us a strong understanding of the economic, regulatory and market environments across the region.

We hope readers find this guide practical and insightful. We would also like to thank all members of the Healthcare and Life Sciences team at Wolf Theiss who have contributed their expertise to this guide.



Kamila Seberová and Hristina Dzhevlekova

Contents


Poland
Ukraine
Czech Republic
Slovak Republic
Austria
Hungary
Romania
Slovenia
Croatia
Serbia
Bosnia & Herzegovina
Bulgaria
Albania

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Albania

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1. What laws and self-regulatory codes govern the advertising of medicinal products?

The advertising of medicinal products is regulated by:

- the Medicinal Products and Pharmaceutical Service Act (Act No. 105/2014);
- the Advertising of Medicinal Products Regulation (Ministry of Health Directive No. 25 of 17 January 2019); and
- the Deontological and Ethical Code of HCPs.

These instruments regulate the advertising of medicinal products and the situations in which HCPs may obtain funds/payment from pharmaceutical companies in Albania.

2. What are the main requirements for the advertising of medicinal products to the general public?

As a general rule, only OTC medicinal products may be advertised. It is prohibited to advertise medicinal products that are dispensable only under prescription by an HCP, as well as narcotics and psychotropic medicines. It is also prohibited to give out samples of medicinal products directly or indirectly to individuals.

All advertising of OTC products in the media should contain the trade name and INN name of the product; should advise individuals to consult the product leaflet; and should mention the side effects, among other things. Advertising must not mention the name of a pharmacy where the product is sold.

All advertising should contain the following statement: Please consult your doctor or pharmacist before use.

3. What kind of approvals are required?

Any company that has a wholesale or retail licence to trade medicinal products in Albania may advertise medicinal products subject to the conditions mentioned above. However, they must first obtain the approval of the Agency on Drugs Control to advertise medicinal products.

4. Are there any exceptions for non-promotional information?

The following activities are not considered advertising:

- Advertising of medicinal products which target qualified HCPs;
- Visits of HCPs to other qualified HCPs with the purpose of promoting medicinal products;
- Donations of samples;
- Sponsorship of promotional meetings/conferences organised for HCPs. Such sponsorship activities must be duly regulated by an agreement between the parties;
- Sponsorship of scientific congresses organised for HCPs. Such sponsorship activities must be duly regulated by an agreement between the parties;
- Sponsorship of participants at such scientific congresses organised for HCPs;
- Sales catalogues;
- Pricelists, notifications, warnings and information relating to packaging changes and adverse reactions, among other things; and
- Information on human health or diseases, unless they contain any reference, even indirectly, to a medicinal product.

5. Can information on unauthorised medicinal products (such as press releases), clinical studies, scientific data or off-label information be published?

Advertising must not reference data received through clinical trials of patients. Moreover, advertising should only reference the medicinal product leaflet and no other scientific data.

6. What rules apply to comparative advertising?

There are no specific rules on comparative advertising. However, it is prohibited to say that a particular medicine is the only medicine available for a given medical condition or to refer to companies trading the medicine.

7. Are there specific rules for the advertising of medicinal products on the internet or social media?

Yes. Websites advertising medicinal products must be divided by their advertising target groups: one for the general public and another for HCPs. Advertising to HCPs must be password-protected and must not be accessible to anyone other than HCPs.

Websites advertising medicinal products should be regularly updated. Individuals can ask questions by email to receive additional product information.

8. What are the rules for hospitality and sponsorship of events and the participation of healthcare professionals?

According to the Medicinal Products and Pharmaceutical Service Act (Act No. 105/2014, Art 55.4), the following activities involving HCPs are not considered to fall within the advertising of medicinal products and are permitted:

- Advertisement of medicinal products which target qualified HCPs;
- Visits of HCPs to other qualified HCPs with the purpose of promoting medicinal products;
- Donations of samples;
- Sponsorship of promotional meetings/conferences organised for HCPs. Such sponsorship activities must be duly regulated by an agreement between the parties;
- Sponsorship of scientific congresses organised for HCPs. Such sponsorship activities must be duly regulated by an agreement between the parties; and
- Sponsorship of participants at such scientific congresses organised for HCPs.

9. Can gifts or donations be given to healthcare professionals or healthcare organisations? If so what restrictions/limits apply?

According to Art 55 of the abovementioned act, entities (i.e pharmaceutical companies) that organise such events or that give such payments to HCPs under lawful agreements in the cases mentioned above should report these activities/payments to the Agency on Drugs Control and Medical Devices once a year. This has the aim of monitoring such payments to ensure maximum transparency.

According to Arts 59 and 60 of the Deontological and Ethical Code of HCPs, HCPs must not ask for or accept gifts which are non-justified, illegal or compromising, from any individual or entity that trades in medicinal products or medical devices. An exception to this rule is when an HCP receives legally justified funding to perform or participate in accredited activities that are organised with a view to the education and professional development of an HCP.

Moreover, HCPs are not permitted to:

- enter into a partnership with or hold a shareholding in a pharmaceutical company or a company that trades in medical devices for the purpose of obtaining illegal financing;
- perform visits (medical consultations) to places where medicines or medical devices are being sold;
- promote a certain medicine, except where that promotion is for educational or scientific reasons. In such cases, HCP must be very careful and make sure the promotion is objective and compliant with the ethical and deontological principals. HCPs must not promote medicines on behalf of a specific company or for its personal activities.

10. Is there any transparency initiative or disclosure project concerning cooperation with HCPs/HCOs?

The Sponsorship Act (Act No. 7892 of 21 December 1994) prohibits carrying out any sponsorship for the purpose that the sponsor will obtain financial benefits (i.e. a pharmaceutical company cannot sponsor an HCP in order to get back any kind of financial benefit).

11. What enforcement mechanism is in place for breach of advertising, hospitality or transparency rules and what are the penalties or other legal consequences for non-compliance?

All advertising of medicinal products that is in breach of the Advertising of Medicinal Products Regulation and the Medicinal Products and Pharmaceutical Service Act is punishable by a fine of ALL 500,000 (approximately EUR 4,270) and, if repeated, with revocation of licence. The same penalty applies to breaches of transparency rules.

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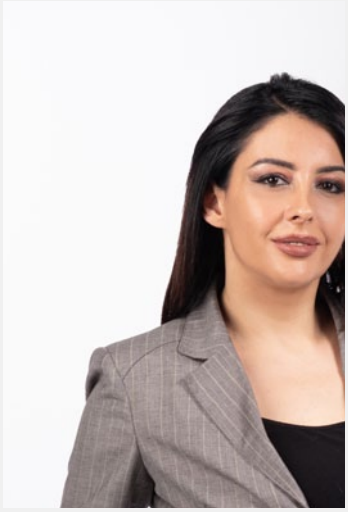

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Advertising of Medicinal Products in CEE & SEE

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Austria

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1. What laws and self-regulatory codes govern the advertising of medicinal products?

The advertising of medicinal products is regulated by Sections 50 *et seq* of the Austrian Medicinal Products Act (*Arzneimittelgesetz*, AMG).

At the self-regulatory level, the Code of Conduct (CoC) of the Association of the Austrian Pharmaceutical Industry (Pharmig) also contains rules regarding the advertising of medicinal products and the interaction between pharmaceutical companies on the one hand and health care professionals (HCPs) and health care organisations (HCOs) on the other. Roughly 120 pharmaceutical companies are currently members of Pharmig and are thus bound by this Code.

2. What are the main requirements for the advertising of medicinal products to the general public?

The following medicinal products cannot be advertised to the general public: (1) prescription-only medicines; (2) non-prescription-only medicines that nevertheless bear a name that contains the same coined word or phrase or the same scientifically common expression as the name of a prescription-only medicine, and (3) registered homeopathic medicinal products. Vaccines used in vaccination campaigns carried out or supported by regional authorities are exempt from restriction (1) above (this is particularly relevant to the Covid-19 pandemic).

As regards medicinal products that generally can be advertised to the general public, the AMG contains regulations that aim to ensure that this advertising nature is not concealed and that fact-based information is conveyed. The AMG also prohibits any content, language or images that may be abusive, alarming or misleading in nature from appearing in the advertisement.

3. What kind of approvals are required?

There is no requirement for any approvals in relation to advertising medicinal products to the general public.

4. Are there any exceptions for non-promotional information?

Yes. Section 50(2) AMG states that the provisions on advertising for medicinal products do not apply to:

- correspondence and documents which are non-promotional and necessary for responding to a specific inquiry regarding a determinate medicinal product;
- sales catalogues and price lists, provided they do not contain information on medicinal products; and
- information on human or animal health or diseases, provided the information does not include any (indirect) reference to any medicinal product.

Similarly, and more broadly, Article 4.1 of the Pharmig CoC provides that non-promotional information is admissible, such as:

- correspondence and documents which are non-promotional and necessary for responding to a specific inquiry regarding a determinate medicinal product;
- sales catalogues and price lists, provided they do not contain information on medicinal products;
- issue-related information regarding diseases or human health, provided the information does not include any (indirect) reference to any medicinal product;
- information forming part of pharmacovigilance efforts as coordinated with the proper authorities;
- company-related information such as for investors or present or future employees, including financial data, research and development programme reports and information regarding regulatory developments concerning the company and its products;
- information about non-authorised medicinal products in response to a documented inquiry made by an HCP;
- correspondence with authorities such as during the marketing authorisation process, as part of pharmacovigilance efforts, or regarding inspections;
- texts approved by authorities such as SPCs and patient leaflets;
- informational or educational materials, provided these materials are inexpensive, have direct bearing on the HCP's business practice, and directly enhance patient care;
- items of medical utility that are aimed directly at the education of HCPs and patient care, provided they are inexpensive and do not offset routine business practices.

5. Can information on unauthorised medicinal products (such as press releases), clinical studies, scientific data or off-label information be published?

Informational or educational materials and items of medical utility may include the name of the pharmaceutical company, but must not include the name of any prescription-only medicinal product unless that name is essential for the correct use of those items by the patient. Where names of companies or products may be specified in accordance with the above, they must always be specified in a manner that complies with the applicable promotion and advertising requirements as prescribed by Section V (Promotional and Advertising Requirements) AMG.

As regards off-label use, neither the AMG nor the Pharmig CoC regulate anything in relation to non-promotional, scientific information or publications. Section 50a(4) AMG states, regarding advertising, that lay advertising must not contain statements that go beyond the labelling, directions for use or summary of product characteristics (SmPC) and that advertising targeted at HCPs may contain statements supplementing the statements on the labelling, the directions for use or the summary of product characteristics (SmPC) as long as they do not contradict these statements but instead confirm or clarify these statements in a sense that is compatible with them without distorting them.

6. What rules apply to comparative advertising?

Section 53(1) No. 3 AMG prohibits elements in lay advertising that suggest that the effect of the medicinal product is equivalent or superior to that of another treatment or medicinal product.

No specific rules apply to the comparative advertising of medicinal products targeted at HCPs, which is instead subject to the general regulations of the Austrian Unfair Competition Act (*Bundesgesetz gegen den unlauteren Wettbewerb*, UWG). Section 2a UWG states that comparative advertising is admissible as long as it is not aggressive, misleading, disparaging, abusive or otherwise unfair.

7. Are there specific rules for the advertising of medicinal products on the internet or social media?

While the AMG and the Austrian Distance Selling Regulation (*Fernabsatz-Verordnung*) regulate the distance selling (which includes internet sales) of medicinal products in detail (and prohibit distance selling for prescription-only medicinal products), there are no rules regarding the advertising of medicinal products online or on social media. This topic is only

(indirectly) touched on in Section 53(1) No. 13 AMG, which prohibits lay advertising from including anything that may encourage prescription-only medicinal products from being obtained through distance selling.

The fact that advertising and information targeted at the general public are regulated differently from that targeted at HCPs suggests that pharmaceutical companies wishing to provide (promotional and/or scientific) information on their websites or on social media must have suitable technical mechanisms in place to prevent the general public from accessing any content that is only suitable for HCPs.

From our experience, it is advisable to obtain the competent authority's (the BASG) approval of any content to be published online before making it accessible.

8. What are the rules for hospitality and sponsorship of events and the participation of healthcare professionals?

Section 55a AMG prohibits the granting, offering or promising of any premium or financial or material benefit for the sale of medicinal products to persons authorised to prescribe or dispense them unless the benefit is of minor value and relevant to the medical or pharmaceutical practice. The demand, promise or acceptance of such benefits is also prohibited.

Representation expenses in connection with sales promotion events must always be strictly limited to their main purpose. Only those entitled to prescribe or dispense will be entitled to have their expenses reimbursed.

However, this prohibition does not apply to the direct or indirect payment of reasonable travel and accommodation expenses and participation fees at scientific events exclusively related to the profession. Representation expenses must always be strictly limited to the main scientific purpose of the event. Travel and accommodation expenses, participation fees and representation expenses must not be paid to persons other than those entitled to prescribe or dispense.

9. Can gifts or donations be given to healthcare professionals or healthcare organisations? If so what restrictions/limits apply?

The law also explicitly requires particular care to be taken to avoid any appearance of improperly influencing the therapeutic decisions or recommendations of persons authorised to prescribe and dispense medicinal products.

In essence, Article 7 (on events for HCPs) and Article 8 (on interactions with HCPs and HCOs) of the Pharmig CoC contain similar rules. Pharmig Guidance 1/2014 (on caps for meals and hospitality) also states that costs for meals during events within the meaning of Article 7 of the Pharmig CoC and/or as part of business meals for the purpose of exchanging information within the meaning of Article 8.2f of the Pharmig CoC are, in any case, to be regarded as appropriate if the amount does not exceed EUR 75.00 per person per meal (including taxes and/or duties and tips).

Article 8.5 of the Pharmig CoC states that pharmaceutical companies must not make donations or grants to individual HCPs. Donations and grants, be they in cash or in-kind, to HCOs are only admissible if they are made for the purpose of supporting healthcare, research or educational efforts or are provided as part of scientific or subject-matter specific activities. Donations and grants by pharmaceutical companies must never constitute an inducement to recommend, to prescribe or to dispense any particular medicinal product.

Pharmaceutical companies must keep back-up material showing each donation or grant including the nature, scope and purpose of that donation or grant, the recipient of the donation or grant and the recipient's consent to the disclosure of that donation or grant by the pharmaceutical company.

10. Is there any transparency initiative or disclosure project concerning cooperation with HCPs/HCOs?

Article 9 of the Pharmig CoC provides for transparency regarding all interactions between pharmaceutical companies on the one hand and HCOs and HCPs on the other hand (i.e. comprising all transfers of value in connection with research and development, donations and grants, events and fees for services and consultancy, including all expenses). Disclosures must be made on the company's website once per year and by no later than 6 months after the reporting period has ended, and the information disclosed must, in principle, remain in the public domain for at least 3 years from the date of initial disclosure.

11. What enforcement mechanism is in place for breach of advertising, hospitality or transparency rules and what are the penalties or other legal consequences for non-compliance?

The AMG establishes administrative fines of up to EUR 25,000 (up to EUR 50,000 in case of recurrence) for inadmissible advertising or inadmissible interaction between pharmaceutical companies and HCPs (Section 84(1) No. 19 and 20 AMG). The Act further

states that injunctive relief against inadmissible advertising may be sought in the competent commercial courts by the Austrian Federal Economic Chamber, the Federal Chamber of Labour, the Austrian Chamber of Agricultural Workers, the Presidential Conference of the Austrian Chambers of Agriculture, the Umbrella Organisation of Social Insurance Institutions, the Austrian Federation of Trade Unions, the Patients' Ombudsman Association, the Association for Consumer Information, the Austrian Senior Citizens' Council, Pharmig, the Austrian Medical Chamber and the Austrian Chamber of Pharmacists.

The Pharmig CoC provides for a judicial-like, two-instance procedure for dealing with infringements of the CoC, in the course of which fines from EUR 5,000 up to EUR 100,000 or, in case of recurrence, up to EUR 200,000, may be imposed, as well as publication of the offence, thus aiming at a deterrence effect due to the pillorying it brings about.

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Advertising of Medicinal Products in CEE & SEE

Life Sciences & Healthcare

Bosnia and Herzegovina

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1. What laws and self-regulatory codes govern the advertising of medicinal products?

On a general note, Bosnia and Herzegovina (BiH) is a country with a complex internal organisation and legal system. It consists of two separate entities, the Federation of Bosnia and Herzegovina (FBiH) and Republika Srpska (RS), in addition to an autonomous district under the direct sovereignty of the State, Brcko District of BiH (BDBiH). Essentially, separate legal regimes apply in each of these parts, although certain matters are regulated by State laws that are applicable in all parts of the country.

The advertising of medicinal products is regulated at State level.[1]

The following legislation applies to the advertising of medicinal products:

- Medicinal Products and Medicinal Devices Act (Official Gazette BIH, No. 58/2008);
- Advertising of Medicinal Products and Medical Devices Ordinance (Official Gazette BIH, No. 40/2010).

2. What are the main requirements for the advertising of medicinal products to the general public?

All advertising of medicinal products must provide true and scientifically proven information about medicinal products. This is with the aim of ensuring ethical compliance and their adequate and rational use. Advertising must not mislead users. All advertising of medicinal products must also comply with the approved guidelines and the summary of the main characteristics of the medicinal product.

Only non-prescription medicinal products carrying a distribution permit may be advertised to the general public.

The following are explicitly prohibited from being advertised to the general public:

1 Although medicinal products and regulatory authorities are stipulated by state-level regulations, due to the complex political situation in BiH, has adopted an independent Law on Medicinal Products and Medical Devices (Official Gazette RS, No. 118/2021) by which, inter alia, an independent RS Agency for Medicinal Products and Medicinal Devices is established. We will not refer to the respective law and regulatory agency in this opinion, bearing in mind that the law is in collision with the state regulation and that the grounds for the adoption is disputable.

- medicinal products issued on prescription;
- medicinal products on the list of medicinal products prescribed at the expense of compulsory health insurance within primary, secondary and tertiary healthcare; and
- all medicinal products containing psychotropic substances and narcotic drugs (UN Single Convention on Narcotic Drugs of 1961 and UN Convention on Psychotropic Substances of 1971).

This prohibition does not apply to public health protection drives or to the prevention of emergencies (epidemics, major natural disasters, war or other states of emergency). In these cases, advertising is permitted with the aim of informing the general public about the use of certain medicinal products through public media.

3. What kind of approvals are required?

Advertisers must provide the Medicinal Products and Medicinal Devices Agency ("Agency") with the content of each medicinal product advertisement prior to submitting the advertising material to public media. Once the advertiser has submitted a complete application to the Agency, and unless the Agency prohibits the advertising of a particular medicinal product for exceptional circumstances, the advertisement may be forwarded to the public media for advertising.

4. Are there any exceptions for non-promotional information?

Medicinal products must not be dispensed to the general public for promotional purposes.

5. Can information on unauthorised medicinal products (such as press releases), clinical studies, scientific data or off-label information be published?

A medicinal product must not be advertised to the general public if the medicinal product does not carry a distribution permit. No legal provisions cover the publication of clinical studies, scientific data or off-label information.

6. What rules apply to comparative advertising?

Comparative advertising is not specifically regulated.

7. Are there specific rules for the advertising of medicinal products on the internet or social media?

In the case of online advertising, the main page of the advertisement – a link is not sufficient – must carry the warning: "Carefully read the instructions for the medicinal product before use. For more information about the indications, warnings and adverse reactions of the medicinal product and medical device, consult your doctor or pharmacist".

8. What are the rules for hospitality and sponsorship of events and the participation of healthcare professionals?

Promotional meetings must always be limited to the basic purpose of the meeting itself and must host only the professional public. All professional and scientific meetings, and lectures organised or funded by manufacturers, distribution permit holders and importers or wholesalers of medicinal products must be based on science and must be educational.

The content of such meetings must not have an exclusively promotional purpose. All other contents of meetings must support the main purpose of the meeting. Meetings must be intended exclusively for professional public.

9. Can gifts or donations be given to healthcare professionals or healthcare organisations? If so what restrictions/limits apply?

Distribution permit holders, manufacturers of medicinal products, legal and natural persons trading in medicinal products and legal and natural persons acting on their behalf or their associations may not offer direct or indirect material benefits to persons prescribing or dispensing medicinal products.

Professionals who promote a medicinal product may give gifts not of a high value to healthcare professionals. Only gifts which have symbolic value and which are related to medical or pharmaceutical practice (e.g. pens, notepads, calendars and other similar things of lesser value) may be given.

A free sample of a medicinal product may be given provided that it does not differ from the usual packaging, that it is the smallest package with marketing authorisation in Bosnia and Herzegovina and that the sample is clearly labelled with the words "free sample – not for sale". Free samples must include the package leaflet pursuant to distribution permit.

When offering a free sample of a medicinal product to a healthcare worker, healthcare professionals are required to attach an approved summary of the main characteristics of that medicinal product. Any free sample of a medical device must be accompanied by approved instructions. Healthcare professionals may be given free samples of a medicinal product, upon their written request and signing for receipt, only once per year, up to a maximum of two of the smallest original packages.

10. Is there any transparency initiative or disclosure project concerning cooperation with HCPs/HCOs?

Holders of distribution permit must keep a record of all free samples given. These records must contain the name and surname of the health professional, the name of the institution or private practice, and the date when the free sample was delivered.

11. What enforcement mechanism is in place for breach of advertising, hospitality or transparency rules and what are the penalties or other legal consequences for non-compliance?

Providing material benefits to a healthcare professional is punishable by fines of between BAM 20,000 and BAM 50,000 (approximately EUR 10,000 to EUR 25,000) for legal entities and between BAM 3,000 and BAM 10,000 (approximately EUR 1,500 to EUR 5,000) for representatives of legal entities.

The following violations are punishable by fines of between BAM 5,000 and BAM 15,000 (approximately EUR 2,500 to EUR 7,500) for legal entities and BAM 3,000 and BAM 16,000 (approximately EUR 1,500 to EUR 3,000) for representatives of legal entities:

- advertising a prescription-only medicinal product to the general public by attributing characteristics which the medicinal product does not have;
- exaggerating the positive effects of a medicinal product or in any other way misleading the general public;
- directly targeting advertising at children;
- giving free samples to the general public;
- advertising a medicinal product that does not carry a distribution permit.

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Advertising of Medicinal Products in CEE & SEE

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Bulgaria

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1. What laws and self-regulatory codes govern the advertising of medicinal products?

The advertising of medicinal products is governed by the Bulgarian Medicinal Products in Human Medicine Act ("MPHA") and Ordinance No. 1 of 25 January 2012 on the requirements for advertisements of medicinal products ("Ordinance"). The Bulgarian Drug Agency ("BDA") is the competent supervisory authority overseeing the production, marketing (including advertising) and distribution of medicinal products.

The local industry organisation of pharmaceutical companies is the Association of Research-based Pharmaceutical Manufacturers in Bulgaria ("ARPharM"), which in 2020 adopted a Code of Conduct and Ethics based on the EFPIA code of conduct ("Code"). The Code serves as a self-regulatory source of rules and is binding only on ARPharM members.

2. What are the main requirements for the advertising of medicinal products to the general public?

Requirements for advertising differ depending on whether it targets HCPs (healthcare professionals with a right to prescribe medicines) or the general public.

As a rule, only non-prescription medicinal products may be advertised to the general public (an exemption applies for the promotion of vaccination campaigns approved by the Ministry of Health). The advertising of medicinal products containing narcotic substances, as well as the display of advertising materials targeted at HCPs in places where they can be accessed by patients, are also explicitly prohibited.

3. What kind of approvals are required?

Advertising targeted at both target groups (HCPs and the general public) should meet certain requirements in terms of its content – e.g. it should be in accordance with the Summary of Product Characteristics, contain only accurate and not contain misleading information, etc.

Advertising is permitted only for medicinal products that carry market authorisation under the MPHA.

A designated advertising authorisation by the BDA is also required to advertise medicinal products to the general public in Bulgaria.

Advertising to HCPs is subject only to prior notification to the BDA.

4. Are there any exceptions for non-promotional information?

Sales catalogues, pricelists and any information, instructions and/or warnings relating to changes in packaging or adverse effects are not considered advertising (as long as they do not include advertising data). The same applies to correspondence about a specific issue concerning a medicinal product and to information about human health or diseases, provided they do not, directly or indirectly, refer to a particular medicinal product.

5. Can information on unauthorised medicinal products (such as press releases), clinical studies, scientific data or off-label information be published?

Given the broad definition of "advertising" under the MPHA (i.e. *any form of information, presentation, promotion or offer intended to encourage the prescription, sale or use of a medicinal product*) and given that the advertising of unauthorised medicinal products is strictly prohibited, any promotional activities involving unauthorised medicines are unlikely to be permissible in Bulgaria. A case-by-case assessment should be made to decide whether or not the publication of information about unauthorised medicines is for promotional purposes.

Any publication of information from unpublished clinical studies and off-label scientific data in advertising materials (including towards HCPs) is explicitly prohibited. It is, however, possible to include information from scientific publications in advertisements to HCPs, provided that this information is accurately reproduced and includes a reference to the source.

6. What rules apply to comparative advertising?

The ARPharM Code provides sector-specific guidelines on the comparative advertising of medicinal products. The Code allows comparative advertising only towards HCPs and sets limitations as to when such advertising is permissible (e.g. it is not permissible when the comparison is between medicinal products with differing therapeutic characteristics, when the advertisement creates confusion regarding the advertised medicinal products and/or its trademark, and when it contains disparaging statements about a competitor, etc.).

Outside of the ARPharM Code, there are no specific requirements on the comparative advertising of medicinal products. Therefore, the general rules under the Bulgarian Competition Protection Act and the Bulgarian Consumer Protection Act apply.

7. Are there specific rules for the advertising of medicinal products on the internet or social media?

The advertising of prescription medicinal products on the internet is prohibited. Only OTC products may be advertised on the internet and on social media in compliance with the general requirements under the MPHA and the Ordinance.

In terms of online advertising targeted specifically at HCPs, the Ordinance imposes an obligation on market authorisation holders to ensure that only HCPs have access to such advertising.

8. What are the rules for hospitality and sponsorship of events and the participation of healthcare professionals?

Bulgarian law does not explicitly prohibit event sponsorship by manufacturers of non-prescription medicinal products targeted at the general public. Nor is there any explicit requirement for events to be related to scientific and medicinal endeavours. Nonetheless, hospitality and event sponsorship may be considered advertising of medicinal products and should comply with all general local regulations.

Medicinal products may be specifically advertised to HCPs (including through sponsorship) at promotional meetings, scientific congresses and conferences and other scientific events attended only by HCPs. Subject to certain exceptions, the sponsors of such events may reimburse the HCPs for their travel, accommodation and registration expenses.

The ARPharM Code sets additional rules on hospitality and sponsorship. For example, events must be held in appropriate locations away from venues known for their entertainment facilities or that may be considered extravagant.

9. Can gifts or donations be given to healthcare professionals or healthcare organisations? If so what restrictions/limits apply?

Bulgarian law explicitly prohibits HCPs from directly or indirectly advertising medicinal products. In addition, HCPs must not accept any monetary or proprietary benefits from market authorisation holders, medicinal product manufacturers, their representatives or other traders of medicinal products, in consideration for or as an incentive for prescribing a specific medicinal product.

Donations of authorised medicinal products are permitted provided that they are notified in advance to the BDA. Furthermore, they may only be made to medical institutions in Bulgaria (not to individual HCPs). Donations cannot be made if they are an inducement to the medical institution to recommend, purchase, supply, sell and administer the medicinal product in question.

10. Is there any transparency initiative or disclosure project concerning cooperation with HCPs/HCOs?

The ARPharM Code introduces a self-regulatory transparency and disclosure mechanism based on the EFPIA Disclosure Code.

The Code sets out the minimum standards for the disclosure by pharmaceutical companies of transfers of value to HCPs and HCOs. The Code includes detailed guidelines on how pharmaceutical companies should comply with their disclosure obligations (e.g. individual and collective disclosure of the value transferred through donations and supporting events).

The Code further sets out specific requirements for interactions between pharmaceutical companies and HCPs and HCOs concerning medical education, provision of informational or educational materials, provision of medical samples, etc.

11. What enforcement mechanism is in place for breach of advertising, hospitality or transparency rules and what are the penalties or other legal consequences for non-compliance?

Breaches of advertising requirements are subject to administrative fines by the BDA of BGN 10,000–20,000 (approximately EUR 5,000–10,000). The Director of the BDA may also order the suspension of any breaching advertisement. In addition, HCPs engaging in the direct/indirect advertising of medicinal products may also be sanctioned by the BDA with a fine of BGN 1,000–5,000 (approx. EUR 500–2,500).

Violations of the transparency and disclosure requirements under the ARPharM Code are assessed by the ARPharM Ethics Commission, which is its supervisory body. The latter has the power to impose financial sanctions of BGN 2,000–7,000 (approximately EUR 1,000–3,500), as well as to report violations to the competent authorities.

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Advertising of Medicinal Products in CEE & SEE

Life Sciences & Healthcare

Croatia

Wolf Theiss

1. What laws and self-regulatory codes govern the advertising of medicinal products?

The principal rules governing the advertising of medicinal products are set out in the Medicinal Products Act (OG 76/13, 90/14, 100/18), the Manner of Advertising Medicinal Products Ordinance (OG 43/15, the "Ordinance"), the Media Act (OG 59/04, 84/11, 81/13), the Electronic Media Act (OG 111/2021) and the Unlawful Advertising Act (OG 43/09).

Pharmaceutical companies also adhere to the ethical codes introduced by professional associations, such as the Code of Conduct of Innovative Pharmaceutical Companies in Interactions with Healthcare Professionals, Healthcare Organisations and Patient Organisations ("Code of Conduct"), adopted by the Croatian Innovative Pharmaceutical Initiative ("IFI") in 2020.

2. What are the main requirements for the advertising of medicinal products to the general public?

Rules on advertising differ depending on whether it is targeted at the general public or at healthcare professionals who are authorised to prescribe or dispense medicinal products, which are most often doctors or pharmacists ("HCP").

Advertising targeted at the general public may only be undertaken for non-prescription medicinal products. Certain exceptions apply to public health actions (e.g. vaccination campaigns) subject to the prior approval of the Ministry of Health.

3. What kind of approvals are required?

Audio-visual media services and programmes may be sponsored by medicinal product manufacturers, who may promote their name or reputation but may not promote prescription-only medicinal products. Telesales of prescription-only medicinal products are prohibited.

The promotion of medicinal products that contain narcotic or psychotropic substances is prohibited.

Advertising targeted at both the general public and HCPs must include the information required by the Medicinal Products Act, the Ordinance and, where applicable, the IFI Code of Conduct.

Advertising must only focus on authorised medicinal products (except for at professional and scientific conferences and in professional literature). Otherwise, no specific external approvals or internal procedures are required for the advertising of medicinal products.

4. Are there any exceptions for non-promotional information?

Sales catalogues, pricelists, notifications, labelling, package leaflets, instructions for use, information and expert materials relating to, for example, packaging changes or warnings of adverse reactions, are not considered advertising. The same applies to (i) any impartial and objective information on human health or diseases, prevention and available methods of treatment, unless they contain any reference to a specific medicinal product; and (ii) correspondence between HPCs, pharmaceutical industry representatives and relevant marketing authorisation holders which is accompanied by non-promotional material and responds to specific questions regarding a particular medicinal product.

5. Can information on unauthorised medicinal products (such as press releases), clinical studies, scientific data or off-label information be published?

For any announcement or published information to qualify as advertising, that information must have an advertising purpose (i.e. to promote the prescription, dispensation, sale or consumption of a particular product in any form). Whether this requirement is met must be assessed on a case-by-case basis.

Information on unauthorised medicinal products and/or off-label use cannot be published unless it serves solely scientific or educational purposes – at professional and scientific conferences and in the professional literature. For this information to be published, the following conditions must also be met: (i) the procedure for granting a marketing authorisation must have been initiated; and (ii) the usual name of the product must be used, without specifying the name of the manufacturer. Certain exceptions apply in the case of international professional and scientific conferences held in Croatia.

The information presented in advertising must not contradict the Summary of Product Characteristics ("SmPC"). For the advertising of medicinal products to HCPs, information may be included from scientific publications, but this must be accurately reproduced and the source must be disclosed.

6. What rules apply to comparative advertising?

The basic rule is that comparative advertising is admissible only if it is targeted at HCPs.

Under the IFI Code of Conduct, comparative advertising may only compare different medicinal products based on their relevant and comparable product characteristics.

Otherwise, there are no specific rules on the comparative advertising of medicinal products, and the general provisions of the Unlawful Advertising Act apply. In particular, comparative advertising must only compare goods or services which satisfy the same need or which are intended for the same purpose, and must objectively compare one or several relevant, important, verifiable and typical characteristics of goods or services, which may also include a price comparison.

7. Are there specific rules for the advertising of medicinal products on the internet or social media?

In the case of prescription-only medicinal products, website content must be divided into two parts: (i) one section targeted exclusively at HCPs (protected by a username and password); and (ii) one section for the general public (which should not be linked to the website intended exclusively for HCPs).

Websites targeted at the general public may contain a list of prescription medicinal products, provided that the following are referenced: medicinal product name and/or common name, and a copy of the authorised package leaflet. Articles on disease information, prevention and available treatment methods must not contain links to the medicinal products referenced on those lists.

All mandatory information and other statutory advertising requirements must be met. This applies to banners as well as to other forms of online promotion.

8. What are the rules for hospitality and sponsorship of events and the participation of healthcare professionals?

The Ordinance permits the organisation and sponsorship of scientific and educational seminars and congresses attended by HCPs, as well as the payment of HCPs' expenses for travel, accommodation, meals/refreshments and participation. Hospitality provided to HCPs during promotional meetings and scientific congresses must be reasonable and

secondary to the purpose of the meeting. Hospitality must not be provided to persons other than the HCPs themselves, such as to family members.

Additional rules are set out in the IFI Code of Conduct. For example, the Code of Conduct prescribes that HCPs should not be offered sponsorship to attend seminars and congresses in compensation for the time spent in attending the event or in exchange for recommending, prescribing, purchasing, supplying, selling or administering medicinal products.

The payment of HCPs' expenses for travel, accommodation, refreshments/meals and participation is also permitted. The costs of travel and accommodation payable by companies should be equal to their actual value. The rules that companies should follow when arranging hospitality include the following: (i) travel expenses may be paid only for economy-class air travel, and for business class only in exceptional circumstances; and (ii) the choice of accommodation in the venue of the event should primarily be between hotels of 4 stars or less. Other rules under the IFI Code of Conduct, including rules regarding refreshments/meals, should also be followed.

9. Can gifts or donations be given to healthcare professionals or healthcare organisations? If so what restrictions/limits apply?

The Ordinance prohibits the offering of gifts, money, promises, rewards or other incentives when advertising to HPCs who are authorised to recommend, prescribe or dispense medicinal products, unless they are of negligible or symbolic value (up to HRK 70 net – approximately EUR 9.5) and related to the HCP's practice/profession.

Samples of medicinal products may only be provided to HCPs in a limited number per calendar year and in the smallest available packages at the written request of the HCP.

The IFI Code of Conduct allows HCPs to be provided with (i) informative and educational materials, provided that the individual gross purchase value of those materials does not exceed HRK 500 (approximately EUR 67) and that they are relevant for the HCP's/HCO's practice and beneficial for patients; and (ii) items of medicinal use intended for the education of HCPs and beneficial for patients, provided that the individual gross purchase value of those items does not exceed HRK 500 (approximately EUR 67) and that providing those items does not lead to a reduction of business operational costs for the recipient.

Donations to HCOs can be made if: (i) they are made for the purpose of supporting health care, research or education; (ii) they are documented and kept on record by the donor/grantor; (iii) they do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal product; and (iv) all approvals of competent authorities/bodies are obtained (e.g. the HCO must obtain clearance from the Croatian

Ministry of Health if receiving a donation of medicinal products, medical devices and services/monetary support exceeding a given monetary value).

10. Is there any transparency initiative or disclosure project concerning cooperation with HCPs/HCOs?

The IFI Code of Conduct sets forth an annual disclosure obligation for the transfer of value/remuneration and expenditures for engaging HCPs or HCOs.

11. What enforcement mechanism is in place for breach of advertising, hospitality or transparency rules and what are the penalties or other legal consequences for non-compliance?

The Ministry of Health is the supervisory body for the advertising of medicinal products. Breaches of advertising rules may result in fines of up to HRK 150,000 (approximately EUR 20,000) for companies and up to HRK 15,000 (approximately EUR 2,000) for managing directors.

In addition, the IFI's Ethics Committee may, depending on the gravity of the violation of the IFI Code of Conduct (and of the transparency rules introduced by the IFI), (i) issue a reprimand and/or a fine of up to HRK 350,000 (approximately EUR 46,700); (ii) publish the decision on the violation; and/or (iii) exclude the company from the IFI.

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Advertising of Medicinal Products in CEE & SEE

Life Sciences & Healthcare

Czech Republic

Wolf Theiss

1. What laws and self-regulatory codes govern the advertising of medicinal products?

The principal rules applicable to the advertising of medicines are set out in the Advertising Act (Act No 40/1995 Coll.), and the Civil Code (Act No 89/2012 Coll.).

The State Institute for Drug Control (SUKL) has laid out its interpretative practice in Guidelines UST-27 (Regulation of the advertising of medicinal products for human use and human tissues and cells) and UST-16 (Sponsorship and provision of gifts and other benefits to professionals).

Pharmaceutical companies also adhere to the ethical codes introduced by the professional associations such as the AIFP (a member organisation of EFPIA) and CAFF (a member organisation of Medicines for Europe) Codes.

2. What are the main requirements for the advertising of medicinal products to the general public?

Rules on advertising differ depending on whether it is targeted at the general public or at HCPs (persons authorised to prescribe or dispense medicinal products, which is most often a doctor or pharmacist).

Only non-prescription medicinal products may be advertised to the general public. However, an exemption applies to human pharmaceuticals used during vaccination campaigns approved by the Ministry of Health.

Advertising targeted at both the general public and HCPs must include all information required under the Advertising Act. This act expressly prohibits the promotion of medicines containing narcotic or psychotropic substances.

3. What kind of approvals are required?

Advertising must only promote authorised medicinal products. Other than that, no specific external approvals or internal procedures are required to advertise medicinal products.

4. Are there any exceptions for non-promotional information?

Sales catalogues, pricelists, notifications, warnings and information relating to packaging changes and adverse reactions, among other things, are not considered advertising. The same applies to information about human health or diseases, unless they contain a reference, even indirectly, to a medicinal product.

5. Can information on unauthorised medicinal products (such as press releases), clinical studies, scientific data or off-label information be published?

For any announcement or published information to qualify as advertising, that information must have been provided with a clear advertising purpose (i.e. to promote the sale or consumption of a particular product – either now or in the future). This must be assessed on a case-by-case basis. For example, in the case of substances undergoing clinical trials, there is no certainty that these will actually be placed on the market. Therefore, information about the early phases of clinical trials and their results cannot automatically be classed as being for advertising purposes. However, this interpretation may change if it becomes likely that the product will ultimately be placed on the market (i.e. if it enters the later phases of a clinical trial or if the product is already undergoing a marketing authorisation procedure in any country).

Information on off-label use or other data cannot be published unless it serves solely scientific or educational purposes.

The information presented in advertising must not contradict the Summary of Product Characteristics (SmPC). When advertising medicines to HCPs, information may be included from scientific publications, but this must be accurately reproduced and the source must be disclosed.

6. What rules apply to comparative advertising?

As a general rule, comparative advertising can only be targeted at HCPs.

Otherwise, there are no specific rules for the comparative advertising of medicines, and the general provisions applicable under the Civil Code apply. In particular, comparative advertising must compare goods or services which satisfy the same need or which are intended for the same purpose, and must objectively compare one or several relevant, important, verifiable and typical characteristics of goods or services, which may also include a price comparison.

7. Are there specific rules for the advertising of medicinal products on the internet or social media?

There are no specific rules or guidelines on online advertising or promotional communication.

In the case of advertising targeted at HCPs, the current interpretative practice of the SUKL provides that it is sufficient for any person visiting the website to confirm that he or she is an HCP as defined by the Advertising Act.

As regards the information mandatory in advertising, the SUKL accepts that online advertising may contain a link to the SmPC for this purpose as long as all other advertising requirements are met. This should apply to banners as well as other forms of online promotion.

8. What are the rules for hospitality and sponsorship of events and the participation of healthcare professionals?

The Advertising Act permits the sponsorship of seminars and congresses attended by HCPs and the payment of HCPs' expenses for travel, accommodation, refreshments and participation. Hospitality provided to HCPs during promotional meetings and scientific congresses must be reasonable and secondary to the purpose of the meeting. Hospitality must not be provided to persons other than the HCPs themselves, such as to family members.

The only sponsorship fees admissible for virtual scientific congresses are participants' participation fees and contributions to the event organiser.

Additional rules are set out in the ethical codes introduced by individual associations. (AIFP, CAFF). For example, events must be held at appropriate locations away from any venues known for their entertainment facilities or that may be considered extravagant.

9. Can gifts or donations be given to healthcare professionals or healthcare organisations? If so what restrictions/limits apply?

No gifts, promises, offers or other incentives may be offered to HCPs in relation to advertising unless they are of negligible value (up to approximately EUR 60 per year) and relate to their profession. Samples of medicinal products may only be provided to HCPs in a limited number per calendar year and in the smallest available packages and must only be provided at the written request of the HCP.

10. Is there any transparency initiative or disclosure project concerning cooperation with HCPs/HCOs?

The AIFP, a Czech association of innovative firms, has launched a transparency initiative at the heart of which is its Disclosure Code, which implements an initiative similar to that introduced by the EFPIA. Most large generic firms have signed up to this initiative.

11. What enforcement mechanism is in place for breach of advertising, hospitality or transparency rules and what are the penalties or other legal consequences for non-compliance?

The Advertising Act establishes that the State Institute for Drug Control (SUKL) is the supervisory body for the advertising of medicines (with the exception of TV and radio advertising). Financial sanctions can reach up to CZK 2,000,000 (approximately EUR 80,000).

As regards the transparency initiative introduced by the AIFP, compliance with the Disclosure Code and possible violations are assessed in accordance with the AIFP Code of Conduct by the AIFP Ethics Committee, which is the AIFP's supervisory body.

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Advertising Medicinal Products in CEE & SEE

Life Science & Healthcare

Hungary

Wolf Theiss

1. What laws and self-regulatory codes govern the advertising of medicinal products?

In Hungary, the advertising of medicinal products is regulated by Act XLVIII of 2008 on the basic conditions and certain restrictions on commercial advertising ("Commercial Advertising Act"), which provides the framework for all advertising relating to commercial activities.

A more specific regulation is provided in Act XCVIII of 2006 on the general provisions relating to the reliable and economically feasible supply of medicinal products and medical aids and on the distribution of medicinal products ("Medical Distribution Act"), which establishes industry-specific provisions on the advertising of medicinal products.

Further detailed rules concerning commercial practice towards customers are contained in Health Minister Regulation No 3/2009.

Moreover, in line with general EU customs and soft law, the Hungarian Advertisement Code maintained by the Self-Regulatory Advertisement Board lays down further detailed rules, which are supported and followed by market players.

Additionally, pharmaceutical companies also strictly adhere to and follow the ethical codes introduced by well-known professional associations in the industry, such as the EFPIA code and the Ethical Code of Pharmaceutical Communication ("Communication Code"), as well as its local Hungarian counterpart the Association of Innovative Pharmaceutical Manufacturers, which was founded in 1992 and has a membership of 26 Hungarian (or Hungarian-operating) pharmaceutical companies.

2. What are the main requirements for the advertising of medicinal products to the general public?

Rules differ depending on whether advertising is targeted at the general public or at HCPs (persons authorised to prescribe or dispense medicinal products).

The advertising of medicinal products is only permitted for over-the-counter medicines, subject to the restrictions described below. The advertising of prescription-only medicinal products eligible for Hungarian social insurance reimbursement remains prohibited.

Promotional activities targeted at HCPs are generally permitted, subject to meeting the stringent requirements laid down in the Medical Distribution Act.

The contents of all advertisements aimed at both target groups (HCPs and the general public) must always meet certain strict regulatory requirements. For instance, they must be consistent with the summary of characteristics, and they must only contain accurate, non-misleading information.

3. What kind of approvals are required?

Only authorised OTC medicinal products may be advertised (i.e. no study-phase medicinal products or unapproved medicinal products may be advertised or marketed in Hungary). Otherwise, no specific approvals are required from any external authority for the advertising of medicinal products.

4. Are there any exceptions for non-promotional information?

Exceptions apply to the following, which are considered non-promotional information:

- communications (publications, studies, press releases) or information relating to human health, medicine or diseases, provided they do not reference any specific or identifiable medicinal product;
- commercial pricelists, provided that they do not contain information on the effects of a medicinal product;
- labels and information leaflets;
- information provided on adverse effects and reactions.

5. Can information on unauthorised medicinal products (such as press releases), clinical studies, scientific data or off-label information be published?

It is prohibited to disguise commercial activities as non-commercial or scientific communications (in particular, to disguise advertising or disclosures) that appear to convey non-commercial information. Clinical evaluations, post-marketing surveillance programmes, and post-authorisation studies (including retrospective studies) are generally not considered disguised commercial activities. However, the primary purpose of such evaluations, programmes and studies must be of a scientific or educational nature. If the publisher is compensated for editorial content, the sponsorship should be transparent, and it must present its findings as independent.

6. What rules apply to comparative advertising?

Comparative advertising may only be used and published if it complies with the strict minimum requirements set out by the Hungarian Competition Authority. Furthermore it must follow all applicable sector-specific guidelines.

These guidelines provide that comparative advertising must:

- be objective, transparent, scientifically justified and clearly understandable, and must not contain misleading information;
- not discredit or unfairly prejudice the competitor;
- not misuse the product or trademark of a competitor (e.g. by gaining unfair advantage);
- not use or publish any information or advertising of another company as if it were its own (even in the form of a sublicensed copy);
- provide specific data and refer to sources when making any price comparison.

7. Are there specific rules for the advertising of medicinal products on the internet or social media?

No specific additional provisions apply. The same requirements apply regardless of which communication medium or channel is used to convey or publish such advertising.

8. What are the rules for hospitality and sponsorship of events and the participation of healthcare professionals?

Events aimed at or organised for HCPs can only be organised for professional, scientific or educational purposes. The financial support provided to attending HCPs cannot exceed 5% of the prevailing monthly minimum wage.

All direct or indirect support (i.e. sponsorship) provided for an event must always be reasonable, must remain secondary to the main scientific objective of the event and must not be extravagant. Only HCPs and registered individuals engaged in the supply and distribution of medicinal products and/or medical devices may be invited to such trade and promotional events. Any support provided (directly or indirectly) for events and

programmes for purely professional and scientific purposes must always be reasonable in scope and must remain secondary to the main scientific objective of the meeting. Further details of such events are also set out in the Communication Code.

9. Can gifts or donations be given to healthcare professionals or healthcare organisations? If so what restrictions/limits apply?

Health Care Professionals ("HCPs"): Support may be provided for participating in trade events and training courses. This type of in-kind support may be provided to cover only the expenses (such as travel expenses, accommodations, entry fees) arising directly out of or in connection with attending the professional events. Acceptance of gifts by HCPs that exceed 5% of the prevailing monthly minimum wage is prohibited. Gifts must be relevant for conducting professional activities.

Health Care Organisations ("HCOs"): Orders can only be placed by individuals authorised by law, up to a maximum of two packaging units per year per person. Samples of a medicinal product cannot exceed the quantity required for a period of one month. The packaging and information documentation included must clearly indicate that these are sample products and are not intended for commercial use". Their delivery must be recorded.

10. Is there any transparency initiative or disclosure project concerning cooperation with HCPs/HCOs?

Promoters must notify the National Institute of Pharmacy and Nutrition ("OGYÉI") 15 days prior to any event or training course organised or financially supported by the relevant company.

The intention of promotional activities as well as the persons carrying out (medical representatives) these promotional activities must be notified to the OGYÉI.

HCPs are not subject to any notification obligation.

11. What enforcement mechanism is in place for breach of advertising, hospitality or transparency rules and what are the penalties or other legal consequences for non-compliance?

Compliance with the above requirements and relevant legislation is monitored by the OGYÉI, which acts as the competent authority. The sanctions imposed depend on the details and extent of the infringement. These can vary anywhere from a simple warning to a large fine (up to HUF 500 million – approximately EUR 1.4 million), and even to suspension of the company's operations or of the distribution of the infringing product.

As regards to the transparency initiative described above, a "health sanction" is imposed, which may result in a simple warning for less severe cases or even in a fine ranging anywhere between HUF 30,000 to HUF 5 million (approximetely from EUR 80 to EUR 14,000) in the event of breaching the notification obligation. The sanction applied depends on the seriousness of the infringement.

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Advertising of Medicinal Products in CEE & SEE

Life Sciences & Healthcare

Poland

Wolf Theiss

1. What laws and self-regulatory codes govern the advertising of medicinal products?

The advertising of medicinal products is primarily regulated by two legal acts: (i) the Pharmaceutical Act of 6 September 2001 ("Pharmaceutical Act") implementing Directive 2001/83/EC of the European Parliament ("EU Directive"); and (ii) the Minister of Health Regulation 2008 on the advertising of medicinal products ("Regulation").

Additional advertising regulations apply to: (i) reimbursed drugs, under the Reimbursement of Medicines, Foodstuffs Intended for Particular Nutritional Uses and Medical Devices Act of 12 May 2011; (ii) comparative advertising and fair market practices, under the Unfair Competition Act of 16 April 1993 ("Unfair Competition Act") and the Unfair Market Practices Act of 23 August 2007 ("Unfair Market Practices Act"); (iii) the advertising of goods on radio and television, under the Radio Broadcasting and Television Act of 29 December 1992.

In addition to these laws, the advertising of medicinal products is regulated by codes of conduct adopted by industry and business organisations ("Industry Codes"). Although these are not binding laws, pharmaceutical companies that are members of those organisations must comply with the Industry Codes under pain of sanctions which the organisations can impose on their members. The most relevant Industry Codes are: (i) the Code of Good Practice adopted by the Employers' Union of Innovative Pharmaceutical Companies INFARMA (implementing in Poland the Code of Practice of the EFPIA – European Federation of Pharmaceutical Industries and Associations) ("Code of Good Practice"); (ii) the Physicians' Ethics Code; and (iii) the Republic of Poland Pharmacists' Ethics Code.

2. What are the main requirements for the advertising of medicinal products to the general public?

Although rules differ depending on whether advertising is targeted at the general public or at healthcare professionals ("HCPs"), some overarching advertising rules do apply. These include a prohibition on advertising (i) products not authorised for marketing in Poland; and (ii) elements which do not conform to the Summary of Product Characteristics ("SmPC").

Only non-prescription medicinal products may be advertised to the general public. The law expressly prohibits the public advertising of prescription drugs, medicines containing narcotic or psychotropic substances, and reimbursed drugs. Moreover, any advertisement of a medicinal product to the general public must comply with a number of requirements under the Pharmaceutical Act and the Regulation.

In particular, advertising of medicinal products must not:

- be misleading – instead, it should present the medicinal product objectively and should provide information on the rational use of the medicinal product;
- offer or promise any benefits directly or indirectly in exchange for purchasing the medicinal product;
- be directed at children or contain any element directed at them; and
- involve well-known persons, scientists, persons with medical or pharmaceutical education – nor must it involve persons suggested as having such education or refer to the recommendations of such persons.

Furthermore, advertising must contain mandatory elements and a warning – the precise wording of which is provided in the Regulation. However, work is underway to change the wording of the warning on the safety of medicinal products under the Regulation. Specifically, the amendment bill going through the Polish Parliament suggests three different versions of the warning (currently, there is only one version of the warning), the main message of which will be: "This is a medicine. For your safety, use it in accordance with the package leaflet."

3. What kind of approvals are required?

Apart from the rules applicable to the advertising of medicinal products, no external approvals or procedures are required.

4. Are there any exceptions for non-promotional information?

Under certain conditions, informative non-public announcements (referring to packaging changes, adverse-reaction warning, among other things), trade catalogues, pricelists, and information on and attached to the packaging of medicinal products, are not considered advertising. The same applies to information on human health and diseases, unless they contain any reference, even indirectly, to a medicinal product. In this context, advertising must be distinguished from information concerning the medicinal products. Any activity consisting of providing information about or encouraging the use of a medicinal product with the aim of increasing the number of written prescriptions, the supply, the sale or the consumption of a medicinal product is regarded as advertising. Whether information constitutes advertising or non-advertising should be assessed on a case-by-case basis.

5. Can information on unauthorised medicinal products (such as press releases), clinical studies, scientific data or off-label information be published?

Information on unauthorised medicinal products and off-label indications cannot be published unless it serves solely scientific or educational purposes – for instance, it is published in professional literature.

Scientific data, analysis and research results taken from specialist literature or scientific journals may be presented in advertisements for a medicinal product as long as they are presented in their original form, together with the source and date of publication or last revision.

6. What rules apply to comparative advertising?

Rules on comparative advertising are provided for in the Unfair Competition Act.

For an advertisement to be permissible under the act, it must:

- not be misleading;
- only compare goods or services that satisfy the same needs or are intended for the same purpose, in a reliable and objective manner;
- objectively compare one or more important, characteristic, verifiable and typical features of those goods or services (e.g. price);
- not give rise to mistakes in distinguishing between the advertiser and the competitor or between their goods, trademarks etc.;
- not discredit goods, trademarks etc.;
  (when advertising goods that have a protected geographical indication) always refer to goods with the same indication;
- not make dishonest use of the repute of a trademark or present the goods or service as an imitation or copy of goods or service bearing a protected trademark or a protected geographical indication.

Importantly, in the case of comparative advertising targeted at the general public, it is forbidden to claim that the effects of taking one medicinal product are better than or equivalent to those of another treatment method or treatment with another medicinal product.

7. Are there specific rules for the advertising of medicinal products on the internet or social media?

There are no specific rules. Differences between the rules on advertising to the general public and at HCPs apply accordingly to the advertising on the internet and social media.

However, the decisions of the Chief Pharmaceutical Inspector (the "CPI") may cast some light on how the general rules are interpreted in the context of advertising online and on social media. For example, according to the CPI, websites containing advertising of medicinal products directed at HCPs must be protected against access by unauthorised persons, and it is not enough simply for a website to require users to declare that they are an HCP. Moreover, for prescription medicinal products, an image of the product packaging and the full contents of a leaflet or the SmPC may be published on any website (although the advertising of prescription medicinal products to the general public is forbidden).

Moreover, INFARMA's Code of Good Practice contains some guidance and rules specific to online advertising. For example, in some circumstances, signatories of the Code are also responsible for information spread by their staff on their private social media account if, for instance, such an individual may be reasonably perceived as representing a signatory of the Code.

8. What are the rules for hospitality and sponsorship of events and the participation of healthcare professionals?

Hospitality offered to HCPs during meetings to promote medicinal products is permitted as long as it does not exceed the main purpose of the meeting. Although not specified in Polish provisions, the EU Directive explicitly forbids extending hospitality to persons other than health professionals (e.g. their companions). It is established market practice to pay the expenses of HCPs participating at such meetings, such as travel, meals, registration fees and accommodation. INFARMA's Code of Good Practice further elaborates on hospitality rules for its members. For instance, it indicates the maximum permissible values for meals (PLN 200 for meals offered in Poland and the equivalent of EUR 100 for meals offered outside Poland). Moreover, INFARMA members are not permitted to organise or sponsor any event outside Poland unless it is justified by organisational or substantive reasons (e.g. if most of the invitees coming from outside Poland).

9. Can gifts or donations be given to healthcare professionals or healthcare organisations? If so what restrictions/limits apply?

No gifts, promises, offers or other incentives may be offered to HCPs in relation to advertising unless: (i) they are of negligible value (up to PLN 100 – approximately EUR 23); (ii) they relate to their professional medicinal or pharmaceutical practice; or (iii) they bear a mark advertising a given firm or medicinal product. Samples of a medicinal product may only be provided to HCPs in a limited number (five per calendar year of the same medicinal product), in the smallest available packages and at the written request of the HCP. They must bear the caption "free sample – not for sale".

10. Is there any transparency initiative or disclosure project concerning cooperation with HCPs/HCOs?

Under sectoral regulations, apart from a register of the samples provided, which should be kept by the pharmaceutical company providing the samples, there is no legal obligation to disclose any transfer of value between HCPs/HCOs and pharmaceutical companies. However, each signatory of INFARMA's Code of Good Practice must publish, within 6 months of each year end, information on transfers of value that are directly or indirectly connected to medicinal products (whether in cash, in kind or otherwise, but excluding rebates, discounts and other commercial facilitations that are part of the ordinary course of the purchasing and sale of medicinal products). Reports should be prepared based on INFARMA's template, published online (either on INFARMA's or a given member's website), and should indicate the value of each transfer (or, if this is not possible due to a lack of the HCP's consent, on aggregate).

11. What enforcement mechanism is in place for breach of advertising, hospitality or transparency rules and what are the penalties or other legal consequences for non-compliance?

The CPI supervises compliance with advertising legislation. The CPI may then issue a decision ordering: (i) the discontinuation of any medicinal product advertisement that violates the law; (ii) the publication of that decision in all places where the unlawful advertisement was displayed and a correction of the misleading advertisement; and (iii) the making good of any violations. Moreover, a company may be fined under criminal proceedings in the courts.

If an advertisement is regarded as unfair under the unfair competition rules, the competitor may demand, among other things, that the advertisement be discontinued and that the effects of the advertisement be eliminated, and that any loss suffered as a result of the unfair competition practice be repaid.

Finally, the general anti-bribery rules also apply to interactions between pharmaceutical companies, HCPs/HCOs and individuals serving public functions. The giving and taking of bribes is punishable with imprisonment of up to 12 years if the bribe is of considerable value.

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Advertising of Medicinal Products in CEE & SEE

Life Sciences & Healthcare

Romania

Wolf Theiss

1. What laws and self-regulatory codes govern the advertising of medicinal products?

The advertising of medicinal products is governed by Law No 95/2006 on healthcare reform ("Healthcare Law") and Order of the Ministry of Health No 194/2015 approving the Norms for evaluating and approving the advertising of medicines for human use ("Medicines Advertising Norms"). The National Agency for Medicines and Medical Devices of Romania ("NAMMDR") is the supervisory authority competent to oversee the production, marketing (including advertising) and distribution of medicinal products.

The most relevant associations are:

- the Romanian Association of International Medicines Manufacturers ("ARPIM"), which is a member of the European Federation of Pharmaceutical Industries and Associations ("EPFIA");
- the Romanian Association of Manufacturers of Non-Prescription Medicines, Food Supplements and Medical Devices ("RASCI"), which is a member of the European Association of Consumer Pharmaceutical Specialties (Association Européenne des Spécialités Pharmaceutiques Grand Public – "AESGP");
- the Association of Generic Medicines Manufacturers from Romania ("APMGR"), which is a member of Medicines for Europe;
- and the Romanian Advertising Council ("RAC"), a self-regulation association for advertising messages in various industries (including medicines).

2. What are the main requirements for the advertising of medicinal products to the general public?

Advertising requirements differ depending on whether the advert targets HCPs (healthcare professionals with the right to prescribe medicines) or the general public.

As a rule, only non-prescription medicinal products can be advertised to the general public (an exemption applies for the promotion of vaccination campaigns organised by the pharmaceutical industry and approved by the Ministry of Health).

The advertising of medicinal products containing narcotic substances to the general public is prohibited. Displaying advertising materials targeted at HCPs in places where they can be accessed by patients is also not permitted.

3. What kind of approvals are required?

Advertising materials can be disseminated to the public only after they have been approved by the NAMMDR. The approval number and date must be included on all advertisement materials, except for materials that are small in size, such as shelf labels and wobblers.

Advertisements to both target groups (HCPs and the general public) should meet certain requirements in terms of their content. For instance, they must correspond to the short product characteristic, they must contain only accurate and not misleading information, and they must invite the public to read the product leaflet or packaging information carefully.

Advertising is permitted only for medicinal products holding market authorisation under the Healthcare Law.

4. Are there any exceptions for non-promotional information?

As a general rule, any method of informing through direct contact (door-to-door) and any form of promotion designed to bring about the prescription, distribution, sale or use of medicines is considered to fall within the advertising of medicines.

Theoretically, any material that does not fall within the definition of medicines advertisement should not be regulated under dedicated medicines advertising legislation. However, this should be assessed on a case-by-case basis.

5. Can information on unauthorised medicinal products (such as press releases), clinical studies, scientific data or off-label information be published?

The Medicines Publicity Norms stipulate that the following are not considered advertising: (i) correspondence, possibly accompanied by non-advertising material, sent in response to individual questions from HCPs, but only if it relates exclusively to the subject of the letter or question and is not of a promotional nature; and (ii) general, non-promotional information about companies (such as information to current/potential investors or employees), including financial data, descriptions of research and development programmes, and discussions of regulations affecting the company and its products.

Information on off-label uses may only be provided in response to a duly documented request from an HCP. Otherwise, off-label advertising is prohibited.

Pharmacies may disseminate sales catalogues and pricelists to the general public on condition that such materials do not contain any promotional elements and that they are only disseminated to the public within the pharmacies themselves.

The Medicines Publicity Norms defines educational materials as materials that target the general public and/or HCPs with the aim of inform the target audience, in addition to leaflets about a pathology or a medicine used for scientific/educational purposes, and materials from awareness campaigns which do not encourage the prescription, distribution, sale, administration, recommendation or use of a medicine. Programmes aimed at increase the uptake of treatment are framed as educational material. All educational materials targeted at the general public must be approved by the NAMMDR.

6. What rules apply to comparative advertising?

Comparative advertising is permitted only if it is directed at HCPs and only if the following rules are observed:

- the comparison is not misleading;
- it does not use the trademark/brand name of a competitor, but it mentions international common names;
- the comparison does not refer to medicines with different therapeutic indications or different pharmaceutical forms;
- it objectively compares one or more essential, relevant, verifiable and representative characteristics of certain medicines, including the price;
- no confusion is created on the market between the advertiser and a competitor or between various trademarks, international common names or other distinctive signs of the advertiser and those belonging to a competitor;
- the trademark, international common name, other distinctive signs, activities or any other characteristics of a competitor are not discredited or denigrated;
- it does not take advantage of the reputation of a trademark, the international common name, the distinctive signs of a competitor or any other characteristics of a competitor without having evidence in support of those stated.

7. Are there specific rules for the advertising of medicinal products on the internet or social media?

Advertising of medicines on the internet is permitted. However, the rules stipulated in the legislation for advertising to the general public and HCPs must be strictly observed.

Advertising of medicines on the internet includes websites, email, forums, blogs and any other form of electronic support. It does not include social media, iOS and Android applications and any other mobile applications.

The advertising of medicines on social media or mobile apps is not permitted. Recently, the Romanian Competition Council issued a recommendation for the regulatory authorities to reconsider this interdiction and establish certain specific requirements for advertising to be carried out also on social media and mobile apps. However, as at the date of this guide, the regulatory authorities have not taken any steps to this effect.

The advertising of medicines by email to the general public is specifically prohibited.

The advertising of RX medicines to HCPs on the internet is permitted subject to specific conditions. For instance, the market authorisation holder must ensure that only HCPs have access to such advertising.

8. What are the rules for hospitality and sponsorship of events and the participation of healthcare professionals?

The sponsorship of promotional meetings at which HCPs participate, as well as the sponsorship of scientific congresses for HCPs and, in particular, travel expenses and accommodation for HCPs at those events, is permitted. Hospitality is allowed at scientific/professional meetings/congresses/events but must be limited to the main purpose of the meeting. Hospitality must not be extended to persons other than HCPs or to other persons for whom the scientific field covered is not of professional relevance.

It is prohibited for companies that sell medicines to directly or indirectly sponsor or fund the participation of head physicians or nurses, or the general managers and member of the directors' committee of emergency units, at conferences, congresses and other events. By way of exception, such sponsorship or funding can be awarded if the prior approval of the Ministry of Health is obtained.

9. Can gifts or donations be given to healthcare professionals or healthcare organisations? If so what restrictions/limits apply?

It is prohibited to provide, offer or promise any gifts or benefits in cash or in kind to HCPs for the purpose of prescribing, purchasing, supplying, selling or administering medicines.

By way of exception, (i) promotional branded items are permitted as long as they are of small value (i.e. maximum RON 150 (approx. EUR 30) including VAT, prior to branding) and are relevant for practising medicine or pharmacy; and (ii) samples of medicines may be offered to persons qualified to prescribe or distribute such products, subject to strict conditions relating to sample size, number of annual samples for RX, etc.

Sponsorships of goods and services to hospitals and other institutions from the healthcare field are permitted as long as (i) they are in the interest of the patients; (ii) they are not conditional on a medicine being prescribed, encouraged to be prescribed, or distributed; and (iii) they do not make reference to a medicine.

10. Is there any transparency initiative or disclosure project concerning cooperation with HCPs/HCOs?

Until 31 March each year, manufacturers, marketing authorisation holders (or their representatives in Romania), and wholesale and retail distributors of medicinal products should report to the Ministry of Health, through the NAMMDR, all sponsorship activities and expenditures made during the previous calendar year to HCPs, professional organisations, patients' organisations and any other types of organisations engaged in activities referring to human health or medical or pharmaceutical assistance. Failure to comply with this transparency obligation is sanctioned with a fine ranging from RON 10,000 (approximately EUR 2,000) to RON 30,000 (approximately EUR 6,000).

HCPs, professional organisations, patients' organisations and any other types of organisations engaged in activities referring to human health or medical or pharmaceutical assistance are also required to report to the Ministry of Health, through the NAMMDR, all sponsorships or other transfers of value, within the same deadline as mentioned above.

Members of professional associations (such as ARPIM and APMGR) will have to observe the ethical codes of those associations, which in certain cases contain more detailed provisions on sponsorship, which are nevertheless always in line with the Romanian legislation, and which provide supplementary transparency requirements, such as publishing transfers of value on the member's website in addition to the reporting required by law.

11. What enforcement mechanism is in place for breach of advertising, hospitality or transparency rules and what are the penalties or other legal consequences for non-compliance?

Any breach of the advertising requirements (including hospitality and transparency rules, which are regulated under the same legislation) is subject to administrative fines imposed by the NAMMDR, ranging from RON 10,000 (approximately EUR 2,000) to RON 30,000 (approximately EUR 6,000). This fine can be imposed on manufacturers, importers, wholesale distributors, marketing and authorisation holders. Depending on the nature of the breach, the National Consumer Protection Agency, the Ministry of Finance and the Romanian Audiovisual Council may also apply various fines together with complementary sanctions, such as prohibiting an advertisement from being broadcasted, suspending an advertisement until it is corrected, publishing the sanction decision or requiring the offender to issue an announcement.

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Advertising of Medicinal Products in CEE & SEE

Life Sciences & Healthcare

Serbia

Wolf Theiss

1. What laws and self-regulatory codes govern the advertising of medicinal products?

The principal legal source governing the advertising of medicinal products (in Serbian: *lekovi*) is the Medicinal Products and Medical Devices Act (Official Gazette of RS Nos. 30/2010, 107/2012, 113/2017 and 105/2017; the "Act"), with detailed rules then prescribed in secondary legislation – Manner of Advertising Medicinal Products or Medical Devices Regulation (Official Gazette of RS Nos. 79/2010 and 102/2018; the "Regulation").

In addition, the following items of legislation contain some provisions on the advertising of medicinal products: (i) Healthcare Act (Official Gazette of RS No. 25/2019); (ii) Controlled Substances Act (Official Gazette of RS Nos.99/2010 and 57/2018); (iii) Rulebook on the Contents and Method of Labelling the Outer and Immediate Packaging of a Medicinal Product, Additional Labelling and Contents of the Package Leaflet (Official Gazette of RS Nos. 41/2011 and 44/2018); and (iv) Statute of the Serbian Agency for Medicinal Products and Medical Devices ("ALIMS") (Official Gazette of RS Nos. 86/2011 and 67/2015).

As a professional association, the Serbian Pharmaceutical Chamber has adopted the following self-regulatory codes containing the following provisions, among others, relevant to the advertising of medicinal products: (i) Guidelines on Good Pharmacy Practice (Official Gazette of RS No. 27/2021, in force from 1 April 2023); and (ii) Code of Pharmaceutical Ethics (Official Gazette of RS No. 6/2007).

Also, pharmaceutical companies that are members of the Association of Innovative Medicine Manufacturers ("INOVIA") must adhere to the Code of Conduct for Advertising Prescription-only Medicines and Communications with Healthcare Professionals, which is modelled on the EFPIA codes.

Finally, general rules on advertising are laid down in the Advertising Act (Official Gazette of RS Nos.6/2016 and 52/2019; the "Advertising Act"), an umbrella law on advertising.

2. What are the main requirements for the advertising of medicinal products to the general public?

The Act and the secondary legislation define advertising as providing accurate information about a medicinal product to the general or professional public in any form with the aim of encouraging the prescription, supply, sale or consumption of the product. All information provided must be true and scientifically proven and must not mislead the public.

The general rules on advertising medicinal products to both the general and professional public prohibit the following: advertising a medicinal product which has no existing marketing authorisation (i.e. is not licenced); advertising a medicinal product in a misleading manner; advertising the success of a medicinal treatment in an exaggerated way; suggesting that a medicinal product can be classified as food, cosmetics or other items of general use; giving or promising financial, material or other benefits to encourage the prescription and dispensation of a medicinal product, etc.

The advertising of medicinal products to the general public is subject to even greater restrictions. In particular, it is strictly forbidden to advertise any of the following to the general public: prescription medicinal products; medicinal products issued at the expense of a health insurance fund; medicinal products containing opiates or psychotropic substances; and medicinal products for diseases such as tuberculosis, sexually transmitted or infectious diseases, chronic insomnia, diabetes and other metabolic diseases. The list is exhaustive, but the Ministry of Health may yet add other medicinal products to the list.

Moreover, medicinal products advertised to the general public must not be exclusively or mainly aimed at children, and medicinal products used for the treatment of children must not be targeted at children directly. Furthermore, advertisements of medicinal products to the general public must not carry the name of the pharmacy, private practice, specialist store or business name of the entity carrying out the wholesale trade of the medicinal product. Free samples of medicinal products to the general public are also prohibited.

3. What kind of approvals are required?

ALIMS must approve advertisements of medicinal products (promotional materials and other documents supporting the advertising). Such materials include leaflets, posters, any materials to be distributed at conferences, healthcare facilities or in public places, as well as commercials broadcast on television, social media and radio.

4. Are there any exceptions for non-promotional information?

Merely stating the name of the medicinal product, or its international non-proprietary name or a trademark if it serves only as a reminder, does not amount to advertising.

The following actions are also not considered to constitute advertising: 1) proper labelling of the medicinal product according to the applicable regulations; 2) providing information to the general and professional public in an objective way on the specifics of a medicinal

product in health magazines and health sections of other publications and other media outlets, in a non-misleading way, and with the purpose of answering specific questions regarding the medicinal product, provided that the information on the medicinal product are in line with the summary of product characteristics or the directions for use, and that only the international non-proprietary name and generic name of the medicinal product are used, given that this information itself does not contain advertising elements; 3) providing information on the medicinal product relating to a change of packaging, adverse reactions, or sales catalogues with pricelists, provided that the information does not contain elements of advertising; 4) providing information relating to the state of human health or diseases provided that the information does not contain any reference to the name of the medicinal product, even indirectly; 5) providing information in an objective way at international professional gatherings held in Serbia regarding a medicinal product that is not yet licenced in Serbia, but has been licenced in European Union or countries that have the same or similar conditions for the licensing of medicinal products, provided that the information does not contain elements of advertising.

5. Can information on unauthorised medicinal products (such as press releases), clinical studies, scientific data or off-label information be published?

As a general rule, legislation concerning the advertising of medicinal products only refers to medicinal products that have been licensed (authorised) for use in Serbia.

Any promotion of medicinal products to the professional public must be carried out in accordance with the summary of product characteristics, including the approved indications of the medicinal product.

When advertising medicinal products to the general or professional public, it is forbidden (i) to make claims or conclusions regarding the effectiveness of the medicinal products that are subject to clinical trial in Serbia or abroad, except in cases of post-marketing non-interventional studies of those medicinal products; and (ii) to promote a medicinal product that is undergoing changes to its summary of product characteristics or its directions for use.

Therefore, information on medicinal products that are subject to clinical trial or off-label use cannot be provided to the professional public, as a medicinal product may not be marketed until it has been approved (for a new indication) and the amendments to the marketing authorisation have been registered.

6. What rules apply to comparative advertising?

Comparative advertising is not generally prohibited by the Advertising Act, provided that certain conditions are met. However, the Regulation does not permit comparative advertising of medicinal products.

Namely, it is explicitly forbidden to give any impression that a particular medicinal product is better than others, or to indicate that the recommended medicinal product may be replaced by another when advertising a medicinal product to the general public.

Similarly, when advertising medicinal products to the professional public, it is forbidden to: encourage the belief that one medicinal product can be replaced by another from the same treatment group without a clear medical reasoning; devalue the therapeutic value of an authorised medicinal product; or otherwise raise suspicions regarding the value of another medicinal product.

7. Are there specific rules for the advertising of medicinal products on the internet or social media?

Advertising to the general public may be conducted through all public media, the internet, in public spaces and through all other forms of public advertising such as regular mail and leaflets. There are no specific rules applicable to online advertising

8. What are the rules for hospitality and sponsorship of events and the participation of healthcare professionals?

The sponsoring of scientific and promotional events for the professional public (by disbursing travel, refreshments and accommodation expenses and attendance fees for occupation-related scientific and promotional events) is considered a form of advertising. However, it is forbidden to sponsor scientific and promotional events for an amount higher than the expenses necessary and to provide financial, material or other benefits other than those described above.

When promoting a medicinal product to the professional public, it is forbidden to provide inducements to healthcare professionals – in the form of offering, giving or promising money or any other benefits – in exchange for them prescribing, issuing, supplying or recommending the use or sale of a particular medicinal product or medical device.

Advertisers may sponsor scientific or promotional gatherings (lectures, congresses, seminars and the like) for the professional public, but attendance must not be conditional on providing any material or non-material benefit as consideration for the sponsorship of those professional events. Professional events must be educational in nature and in line with scientific findings.

More detailed rules on the sponsorship of events and advertising are laid down in the Regulation.

9. Can gifts or donations be given to healthcare professionals or healthcare organisations? If so what restrictions/limits apply?

The Healthcare Act regulates gifts made to the professional public. It prohibits healthcare professionals from asking for or accepting money, gifts or any other benefit except for small non-monetary gifts or promotion samples with an individual value below 5% of the average net monthly salary in Serbia or with an aggregate value not exceeding one average net monthly salary. It remains unclear whether the aggregate value of permitted gifts is calculated in relation to each gift provider and each gift occasion, or in relation to all gifts received in a particular period (the reference period has not been specified).

The INOVIA Code (which is not mandatory, other than for INOVIA members, but is regarded as best practice) sets the monetary limit on the value of informational or educational material provided to healthcare professionals at EUR 30. It also sets a ceiling on the food and beverages provided to healthcare professionals at EUR 50. It prescribes that all forms of hospitality offered to healthcare professionals must be reasonable. The INOVIA Code also imposes industry rules on non-sponsorship donations and grants to individual healthcare professionals for attending professional events, as well as on donations and grants to associations of healthcare professionals or entities that provide healthcare or conduct research.

10. Is there any transparency initiative or disclosure project concerning cooperation with HCPs/HCOs?

The Regulation requires pharmaceutical companies marketing medicinal products to publish information on their websites about all professional events they have sponsored in the current and previous year, including the funds expended for those purposes. The INOVIA Code also requires its member companies to make information on donations and grants available to the public, including under its own Disclosure Code.

11. What enforcement mechanism is in place for breach of advertising, hospitality or transparency rules and what are the penalties or other legal consequences for non-compliance?

The Ministry of Health conducts inspections through its health inspectorate. The Act prescribes penalties for breaching its provisions on the advertising of medicinal products. Breaches are considered a commercial offence.

Monetary fines ranging from RSD 800,000 to RSD 2,000,000 (approximately from EUR 6,500 to EUR 17,000) may be imposed on a breaching entity, whereas fines of between RSD 80,000 and RSD 150,000 (approximately from EUR 680 to EUR 1,270) may be imposed on the responsible person within that entity.

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Advertising of Medicinal Products in CEE & SEE

Life Sciences & Healthcare

Slovak Republic

Wolf Theiss

1. What laws and self-regulatory codes govern the advertising of medicinal products?

The principal rules applicable to the advertising of medicinal products are set out in the Advertising Act (Act No. 147/2001 Coll.), which implements the relevant provisions of Directive 2006/114/EC on misleading and comparative advertising and Directive 2001/83/EC establishing the Community code relating to medicinal products for human use, and the Medicinal Products and Devices Act (Act No. 362/2011 Coll.).

The Broadcasting and Retransmission Act (Act No. 308/2000 Coll.) regulates advertisements of medicinal products broadcast on radio or television.

Pharmaceutical companies also adhere to the ethical codes introduced by professional associations. These include the Ethical Code of the Association of Innovative Pharmaceutical Industry (an EFPIA member) and the Ethical Code of GENAS – Association for Generic and Biosimilar Drugs (a member of Medicines for Europe).

2. What are the main requirements for the advertising of medicinal products to the general public?

Rules on advertising differ depending on whether it is targeted at the general public or at HCPs (persons authorised to prescribe or dispense medicinal products).

Only non-reimbursable, non-prescription medicinal products registered in the Slovak Republic may be advertised to the general public. The advertising of medicinal products containing narcotic or psychotropic substances to the general public is expressly prohibited. Exemptions from these restrictions apply to vaccination campaigns approved by the Slovak Ministry of Health.

Advertising targeted at HCPs is generally permitted, subject to the requirements laid down in the Advertising Act.

Regardless of the target group, all advertisements of medicinal products must:

- comply in all parts with the particulars listed in the SmPC;
- encourage the rational use of the medicinal product, by presenting it objectively and without exaggerating its properties; and
- not be misleading.

3. What kind of approvals are required?

No approvals are required for advertising. However, advertisements must be notified in advance to the State Institute for Drug Control (ŠUKL).

4. Are there any exceptions for non-promotional information?

The distribution of non-promotional information that does not meet the definition of advertising is generally unregulated. The Advertising Act does not consider the following activities to be advertising:

- labelling and package leaflets;
- correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product;
- reference material and information relating, for example, to changes in the packaging of a medicinal product, adverse-reaction warnings as part of general drug precautions, trade catalogues and price lists, provided they do not include any information on medicinal products;
- information relating to human health or diseases, provided it does not contain any direct or indirect reference to the medicinal product;
- information on online dispensation, the assortment of medicines and medical devices offered, their price and the costs associated with online dispensation;
- information on the use of medicinal products, the prices of medicinal products, generic substitutes, contraindications and interactions, digital applications containing information on medicinal products, the prices of medicinal products, generic substitutes and contraindications; and
- information containing only the name and price of a medicinal product or medicinal products.

5. Can information on unauthorised medicinal products (such as press releases), clinical studies, scientific data or off-label information be published?

The advertising of medicinal products that are not registered in the Slovak Republic, of products containing narcotic, psychotropic drugs or supplements, of prescription-only products and of reimbursable products is prohibited, except as part of vaccination campaigns authorised by the Slovak Ministry of Health and advertising targeted at HCPs.

Unauthorised products may be advertised to HCPs subject to meeting the general requirements laid down by the Advertising Act.

6. What rules apply to comparative advertising?

Under the Advertising Act, comparative advertising is permitted, if it:

- compares goods, services or real estate that meet the same needs or are intended for the same purpose;
- objectively compares one or more specific, typical, relevant and verifiable characteristics of the goods, services or real estate, including their price; in the case of goods with a designation of origin, if it only compares goods with the same designation;
- does not discredit or imply the trademarks, trade names, other distinguishing marks, goods, services, activities or circumstances of a competitor;
- does not unfairly take advantage of the reputation of a trademark, trade name or other distinguishing marks of a competitor or of the designation of origin of competing products;
- does not represent goods or services as imitations or copies of goods or services bearing a protected trademark or trade name;
- does not create confusion between traders, between the advertiser and a competitor, or between the trademarks, trade names, other distinguishing marks, goods or services of the advertiser and a competitor; and
- is not misleading.

7. Are there specific rules for the advertising of medicinal products on the internet or social media?

There are no specific rules or guidelines on online advertising or promotional communication. The general rules and restrictions applicable to the advertising of medicinal products also apply here.

8. What are the rules for hospitality and sponsorship of events and the participation of healthcare professionals?

The Advertising Act permits the sponsorship of seminars and congresses attended by HCPs and the payment of HCPs' expenses for travel, accommodation, refreshments and participation. Hospitality provided to HCPs during promotional meetings and scientific congresses must be reasonable and secondary to the purpose of the meeting. Hospitality must not be provided to persons other than the HCPs themselves, such as to family members.

The Medicinal Products and Medical Devices Act prohibits MAHs from sponsoring or otherwise supporting, directly or indirectly, any event other than a professional event or the participation of HCPs at any event other than a professional event. A professional event is any event held exclusively for a professional, scientific or educational purpose for healthcare professionals and may include, to a reasonable extent, accompanying activities. However the duration of such accompanying activities cannot exceed 20% of the duration of the event. The time required for travel and overnight stays is not included in the total duration of the event.

Although donations are generally not subject to income tax in the Slovak Republic, in-kind contributions given by MAHs to HCPs are an exception to this rule and are subject to taxation. This rule generally discourages HCPs from receiving in-kind benefits from the pharma industry. Only the following in-kind contributions are tax-exempt: (i) the value of meals at professional events held exclusively for educational purpose; (ii) the participation of HCPs at continuous education events, with the exception of accommodation and transport costs.

The rules on hospitality, event sponsorship and the participation of HCPs laid down in the Ethical Code of AIFP and the Ethical Code of GENAS also apply to the members of those local associations.

9. Can gifts or donations be given to healthcare professionals or healthcare organisations? If so what restrictions/limits apply?

The Advertising Act prohibits, when advertising medicinal products, the provision of gifts, pecuniary and material benefits and benefits to persons authorised to prescribe or dispense medicinal products, unless they are of negligible value.

However, MAHs may, upon written request, provide samples of medicinal products to a person authorised to prescribe medicinal products. The number of samples is limited to the two smallest available package sizes of the authorised medicinal product per year. This sample must be marked "FREE MEDICAL SAMPLE – NOT FOR SALE" and must be accompanied by an SmPC. Products that contain narcotics and psychotropic substances cannot be donated as samples.

10. Is there any transparency initiative or disclosure project concerning cooperation with HCPs/HCOs?

No later than 31 January and 31 July each year, MAHs must submit to the National Centre of Healthcare Information a report on their expenditure on promotion, marketing and monetary and in-kind contributions for the previous calendar half-year.

There are also specific reporting obligations with the tax authority and HCPs in relation to the monetary payments and in-kind contributions given by MAHs to HCPs.

11. What enforcement mechanism is in place for breach of advertising, hospitality or transparency rules and what are the penalties or other legal consequences for non-compliance?

For any breach of the rules laid down in the Advertising Act, the ŠUKL imposes penalties of up to EUR 166,000 and can also impose a prohibition on distributing advertisements and an obligation to publish the penalty decision.

For any breach of the rules laid down in the Medicinal Products and Medical Devices Act, the Ministry of Health can impose a penalty in the range of EUR 500 – 25,000.

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Advertising of Medicinal Products in CEE & SEE

Life Sciences & Healthcare

Slovenia

Wolf Theiss

1. What laws and self-regulatory codes govern the advertising of medicinal products?

The advertising of medicinal products in Slovenia is primarily governed by the Medicinal Products Act (*(ZZdr-2), Official Gazette RS No 17/14*, as amended, "MPA-2"), which implements Directive 2001/83 EC. The advertising of medicinal products to public entities and HCPs who are public officers is also subject to the limitations imposed by anti-corruption laws.

The self-regulatory regime is formed by the Codes of Conduct published by EFPIA and the Forum of International Research and Development Pharmaceutical Companies (an association representing the innovative pharmaceutical industry in Slovenia) ("Pharma Forum"). These Codes of Conduct are binding on the members of these associations.

2. What are the main requirements for the advertising of medicinal products to the general public?

Only non-prescription medicinal products with marketing authorisation may be advertised to the general public. In addition, medicinal products which contain narcotic or psychotropic substances cannot be advertised.

3. What kind of approvals are required?

The main requirements are that advertising must, among other things:

- be consistent with the summary of product characteristics, must encourage rational use of medicinal products and must not be misleading;
- be in the Slovene language (in areas where the Italian and Hungarian national communities live, the language of that national community must also be used);
- not be targeted mainly at children;
- not give the impression that a visit to the doctor is unnecessary;
- not use inappropriate or misleading terms about the possibilities of recovery;
- not give the impression that the health of the person will improve simply by taking this product or that it will worsen if this product is not taken.

4. Are there any exceptions for non-promotional information?

Sharing certain information is not considered advertising as long as it is not intended to promote the prescription, dispensation or use of medicinal products. For instance, this exemption applies to:

- basic medicinal product information (e.g. summary of product characteristics, packaging, leaflet approved by the marketing organisation);
- materials approved by the Slovene Agency for Medicinal Products and Medical Devices;
- information on changes to packaging, warnings of adverse effects and other general precautions; and
- sales catalogues and price lists which do not indicate the properties of the medicinal product.

5. Can information on unauthorised medicinal products (such as press releases), clinical studies, scientific data or off-label information be published?

Only medicinal products with marketing authorisation may be advertised. Therefore, information on unauthorised medicinal products cannot be published.

Information on clinical studies and information on the results of clinical trials must be published in the clinical trial database (EudraCT database) in order to protect and promote public health.

Off-label information should not be published, as the MPA-2 requires all elements of advertising to be consistent with the summary of the main characteristics of the medicinal product.

Advertisements of medicinal products to the general public must not contain information that refers to the recommendations of scientists, health professionals or well-known persons who, due to their media influence, could encourage the consumption of the medicinal product.

6. What rules apply to comparative advertising?

The MPA-2 prohibits advertisements of medicinal products from indicating that one medicinal product is better than or equivalent to another medicinal product.

Further, the comparative advertising of medicinal products must be carried out in line with:

- other rules on the advertising of medicinal products under the MPA-2; and
- the rules on comparative advertising under the Consumer Protection Act.

Article 3.05 of the Codes of Conduct of Pharma Forum and EFPIA also briefly address comparative advertising, stating that any comparison between different medicinal products must be based on relevant and comparable aspects of those medicinal products. Comparative advertising should not mislead or belittle.

7. Are there specific rules for the advertising of medicinal products on the internet or social media?

There are no specific rules governing online or social-media advertising of medicinal products.

8. What are the rules for hospitality and sponsorship of events and the participation of healthcare professionals?

The MPA-2 requires meetings and the hospitality offered at meetings to be limited to the professional purpose of the meeting, namely to acquire additional knowledge about new medicinal products. Hospitality at meetings should be of secondary importance and should not be extended to persons who are not authorised to prescribe and dispense medicines. The limits to reasonable hospitality are also addressed in the Codes of Conduct of Pharma Forum and EFPIA.

9. Can gifts or donations be given to healthcare professionals or healthcare organisations? If so what restrictions/limits apply?

Gifts, monetary benefits and benefits in kind are prohibited unless they are of small or symbolic value and can be used to perform healthcare, veterinary or pharmacy activities.

Donations of medicinal products are subject to specific requirements, which includes notifying the Slovene Agency for Medicinal Products and Medical Devices.

The Codes of Conduct of Pharma Forum and EFPIA prohibit gifts from being extended to HCPs. Nevertheless, the Codes of Conduct do allow grants and donations to HCOs (in cash, in kind or in other forms) intended for the education of HCPs under certain conditions.

10. Is there any transparency initiative or disclosure project concerning cooperation with HCPs/HCOs?

The Codes of Conduct of the Pharma Forum and EFPIA contain a Disclosure Code, which introduces a regime requiring the public disclosure of transfers of value to HCPs and HCOs by pharmaceutical companies.

11. What enforcement mechanism is in place for breach of advertising, hospitality or transparency rules and what are the penalties or other legal consequences for non-compliance?

Failure to comply with the advertising and hospitality rules under the MPA-2 can be sanctioned with:

- corrective measures, such as an order to remedy the breach; and
- monetary fines.

Monetary fines range between EUR 8,000 and EUR 120,000 for an undertaking and between EUR 500 and EUR 5,000 for the responsible person of an undertaking.

As regards the Codes of Conduct, the supervisory committee supervises the correct implementation of the provisions of the Code of Conduct. In case of a breach, the supervisory committee may require the breach to be ceased immediately and a statement to be signed declaring that the breach will not be repeated.

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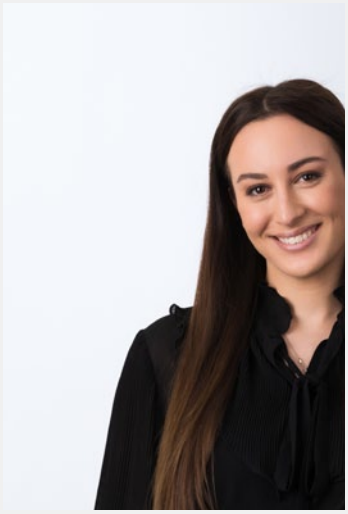

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Advertising of Medicinal Products in CEE & SEE

Life Sciences & Healthcare

Ukraine

Wolf Theiss

1. What laws and self-regulatory codes govern the advertising of medicinal products?

The advertising of medicinal products in Ukraine is mainly governed by the following regulations:

- Medicines Law of Ukraine No. 123/96-BP dated 4 April 1996 (as amended); and
- Advertising Law of Ukraine No. 270/96-BP dated 3 July 1996 (as amended).

Some pharmaceutical companies are also members of certain self-regulatory organisations and should follow their policies and codes. The most notable example in Ukraine is the Association of Pharmaceutical Research and Development (APRaD), which comprises pharmaceutical companies engaged in research and development of pharmaceutical supplies and equipment. Member companies should abide by the APRaD Code of Ethics, which covers such issues as the promotion of prescription medicines to healthcare professionals ("HCPs"), and member company interaction with HCPs and healthcare organizations ("HCOs").

2. What are the main requirements for the advertising of medicinal products to the general public?

Medicines and medical devices may be advertised to the general public only if they are permitted (approved) for use in Ukraine by the Ukrainian Ministry of Health (the "MoH") (in the case of medicines) and if they have passed the Ukrainian national conformity assessment procedure (in the case of medical devices). It is prohibited to advertise prescription-only medicines and medicines that are not permitted for use in Ukraine or for which advertising is prohibited (by order of the MoH). It is also prohibited to advertise doping and methods of its use in sports, etc.

All advertisements for medicines must contain: (i) objective information on the medicine, provided in a manner that makes clear that the information is an advertisement and that the advertised product is a medicine; (ii) a requirement to consult a doctor before using the medicine or medical device; (iii) a recommendation to read the instructions for the medicine. In addition, all advertisements should contain the warning "self-treatment may be harmful for health", which must take up no less than 15 percent of the space (length) of the advertisement.

It is prohibited to insert the following information in advertisements of medicines: (i) data regarding any guaranteed effect; (ii) information stipulating that their usage does not require consultation with a specialist; (iii) images of the effect of illness or injury to the human body or its parts; (iv) any other information prohibited by Article 21 of the Advertising Law. All advertisements of medicines and medical devices must be ordered by persons who have the relevant license/approval (in the case of medicines) or conformity certificate (in the case of medical devices).

The decision on whether a medicine may or may not be advertised (in general) is taken by the MoH (following a positive opinion from the MoH's State Expert Centre) when registering a medicine in Ukraine

3. What kind of approvals are required?

The law does not require the approval of specific advertising materials and/or promotional activities. However, the law does require the approval of outdoor (external) advertisements for medicinal products (if this advertising is allowed in principle); this approval is provided by the relevant municipal authorities.

4. Are there any exceptions for non-promotional information?

The Advertising Law makes a precise distinction between promoting medicinal products to the general public and promoting them to HCPs.

5. Can information on unauthorised medicinal products (such as press releases), clinical studies, scientific data or off-label information be published?

Only non-prescription medicines which are not included in the special list of medicines prohibited from advertising may be advertised to the general public in Ukraine. In other words, in Ukraine it is prohibited to advertise unauthorised medicinal products, prescription medicines and medicines expressly prohibited from advertising (e.g. medicines containing narcotic and psychotropic substances and precursors, medicines aimed exclusively at pregnant or breastfeeding women or children under the age of 12, and medicines aimed to treat tuberculosis, cancer, insomnia or diabetes).

However, this rule does not apply to the promotion of unauthorised or prescription-only medicines in specialised publications intended for medical institutions and doctors and

distributed at medical seminars, conferences or symposiums. The information that should be published in these cases includes the name, description, medicinal properties and possible side effects of the medicine.

6. What rules apply to comparative advertising?

There are no specific requirements or rules applicable to the comparative advertising of medicines and medical devices. Therefore, the general rules under the Advertising Law and the Unfair Competition Law apply, including the following:

- Advertisements should not contain characteristics of unfair practices as provided for by consumer legislation;
- Advertisements should compare similar goods which meet the same needs or which are intended for the same purpose, or should compare the activity covered by the same area or type;
- Advertisements should objectively compare one or more essential, comparable and representative characteristics of similar products or activities, including the price and information about the product that may influence the consumer's choice;
- Advertisements should not discredit or contain untrue information about the quality of similar goods of other manufacturers or sellers, and should not discredit the activity or condition of other persons, trademarks, trade names, other specifics of competitors or any indication of origin of goods;
- For products with an indication of origin, advertisements should only compare with goods of comparable indications of origin;
- Advertisements should not lead to confusion between the advertiser and its competitor or between the advertiser's goods, trademarks, trade names or other characteristics of the advertiser and those of its competitors;
- Advertisements should not include any imitation of a competitor's goods that are protected by a trademark or trade name.

7. Are there specific rules for the advertising of medicinal products on the internet or social media?

Ukraine does not have any separate (special) legislation on the advertising or promotion of medicinal products on the internet. Therefore, all general advertising regulations also apply to advertising on the internet and social media. For example, if information about a prescription-only medicine is published on the website of a specialised electronic publication that is meant for medical institutions and doctors, this should not generally be considered a violation of Ukrainian law. At the same time, it is recommended to make such publications inaccessible to the general public and to provide access to relevant HCPs only (e.g. username and password protection).

8. What are the rules for hospitality and sponsorship of events and the participation of healthcare professionals?

The Advertising Law permits the sponsorship of television and radio shows and programmes by producers and sellers of non-prescription medicines.

Hospitality is not defined in Ukrainian law. Nevertheless, hospitality seems to be covered by the broad definition of "gift" provided by the Anti-Corruption Law of Ukraine No. 1700-VII dated 14 October 2014 (as amended), which applies to HCPs who are public or private officials.

The term "public officials" includes any public officers at state or municipal level and other individuals who perform functions similar to public officials (for instance, the ministers of health and chief physicians of State and municipal hospitals). Public officials are prohibited from receiving gifts: (i) in connection with the performance of their duties; and (ii) from subordinates. They are only allowed to receive business gifts: (i) that comply with generally recognised hospitality norms; (ii) that are within the allowable value – approximately EUR 78 as at 1 January 2022 (this amount is subject to periodic change); and (iii) that are made without the intention of influencing the performance of their duties. Therefore, any HCP who is considered a public official must observe the requirements listed above.

There are no limitations on the value of gifts that may be given to HCPs who are private officials (the employees, executives ot contractors of private companies). However, according to the Healthcare Basics Law, all HCPs – regardless of their status (public/private officials and other HCPs who do not fall into these categories) – are also prohibited from receiving unjustified benefits while performing their professional duties. Because Ukrainian law defines "unjustified benefits" in very broad terms, there is always a risk that providing the individuals mentioned above with business meals, hotel/room stays or the

equivalent value may be potentially treated as providing unlawful benefits. To mitigate this risk: (i) hospitality should be reasonable and modest; and (ii) adequate documentation must be kept that shows the absence of any intention to bribe.

Given the above, all interaction with HCPs should be carefully considered, taking into account the notions of gifts and unjustified benefits.

9. Can gifts or donations be given to healthcare professionals or healthcare organisations? If so what restrictions/limits apply?

Donations (charity) can be provided to HCOs for a specific purpose and in accordance with the requirements of the Charity and Charitable Organisations Law of Ukraine No 5073-VI dated 5 July 2012 (as amended).

10. Is there any transparency initiative or disclosure project concerning cooperation with HCPs/HCOs?

The APRaD requires its members to report on their cooperation with HCPs/HCOs.

11. What enforcement mechanism is in place for breach of advertising, hospitality or transparency rules and what are the penalties or other legal consequences for non-compliance?

The Advertising Law contains enforcement mechanisms that:

- require advertisers and advertisement producers/distributors to eliminate any violation of advertising regulations;
- suspend the distribution of any advertisement that violates requirements on advertising ;
- impose fines on advertisers and advertisement producers/distributors.

Compliance with advertising regulations is monitored by the Ukrainian State Service on Food Safety and Consumer Protection (the "Consumer Protection Service") in the area of consumers' rights protection, and by the Ukrainian Antimonopoly Committee (the "AMCU") in the area of protection from unfair competitive practices.

Failure to comply with requirements for the advertising of medicines and medical devices may trigger penalties. The penalty imposed will depend on the type of violation.

For consumers' rights violations, the Consumer Protection Service may fine advertisers and advertisement producers/distributors up to five times the value of the distribution of the advertising materials.

For unfair competition violations, the AMCU may fine undertakings up to five percent of their income (revenue) from the sale of products (goods, works, services) during the previous reporting year.

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