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Pharmaceutical Advertising 2025

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Poland: Law & Practice
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Poland: Trends & Developments
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POLAND

Law and Practice

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Czyżewscy Law Firm has years of experience in providing legal services to entities operating in the life sciences area. The firm is widely recognised in Poland as top specialists in advertising and marketing of medicinal products and medical devices, as well as in reimbursement of medicinal products and pricing of healthcare services. The firm also has strong expertise in regulatory issues, related to registration, marketing or distribution of drugs, medical devices, cosmetics, and food supplements. It supports its clients in such matters on a daily basis, including assisting clients in reimbursement proceedings, their marketing or advertising activities, registration or post-registration proceedings, relations with competitors, and distribution of their products. The firm's scope of work also covers clinical trials, distribution issues, patents and trade marks and other related issues. Experts from Czyżewscy Law Firm regularly publish content and give comments in business media and professional press. Specialists from Czyżewscy are invited to participate in debates and public consultations related to reimbursement and medical law.

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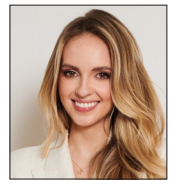

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1. Pharmaceutical Advertising: Regulatory Framework

1.1 Laws and Self-Regulatory Codes Concerning the Advertisement and Promotion of Medicines

Regulations concerning advertisement and promotion of medicines are specified in numerous acts of Polish law, as well as several self-regulatory codes adopted by industry organisations of Marketing Authorisation (MA) holders. The general rules are set out in the Act of 6 September 2001 – Pharmaceutical Law (hereinafter referred to as: the "Pharmaceutical Law"). They are further clarified and extended in the regulation of the Minister of Health of 21 November 2008 on advertising of medicinal products (hereinafter referred to as: the "regulation on advertising of medicinal products").

The promotion of medicines shall also comply with the provisions of the Act of 16 April 1993 on combating unfair competition and the Act of 29 December 1992 on radio and television broadcasting. Moreover, there are internal rules of good practice on advertising created in particular by the Polish Association on Self-Medication Industry (PASMI) and the Employers' Union of Innovative Pharmaceutical Companies (INFARMA).

1.2 Application and Influence of Self-Regulatory Codes on the Advertisement and Promotion of Medicines

The self-regulatory codes of good practices apply and should be used by the companies which are the signatories to them (members of organisations which adopted the regulations in question). They are not generally applicable provisions in the Polish law order. They apply and are binding only on the companies which have signed the organisation's internal act adopting the self-regulatory code and which are affiliated with the organisation in question. Rules set forth in such codes are treated as the good practices rules.

2. Scope of Advertising and General Principles

2.1 Definition of Advertising

The notion of advertising of medicinal products is defined in Article 52, Section 1 of the Pharmaceutical Law, which states that "advertising of a medicinal product is an activity comprising of informing or encouraging the use of a medicinal product with the aim of increasing: the number of prescriptions, supplies, sales or consumption".

According to Section 2 of the aforementioned Article, advertising covers, in particular:

- advertising of a medicinal product addressed to the public;
- advertising of a medicinal product addressed to persons authorised to issue prescriptions or persons trading in medicinal products;
- visiting persons authorised to issue prescriptions or persons trading in medicinal products via sales or medical representatives;
- proving samples of medicinal products;
- sponsoring of promotional meetings for persons authorised to issue prescriptions or persons trading in medicinal products; and
- sponsoring of conferences, conventions and scientific congresses for persons authorised to issue prescriptions or persons trading in medicinal products.

2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information

According to the regulations of the Pharmaceutical Law, patient-facing information on human or animal health or diseases is not considered as advertising, provided that it does not refer – even indirectly – to any medicinal products. Any such reference makes the content qualified as promotion and it must comply with the conditions provided for advertising. Nevertheless, information placed on the packaging and attached to the packaging of medicinal products, if it is consistent with the MA granted, is not considered as an advertising, as well as commercial catalogues or price lists, or answers to questions by responsible entities, unless, of course, they contain direct marketing messages.

2.3 Restrictions on Press Releases Regarding Medicines

Press releases regarding medicines are allowed under Polish law, but if they concern a specific drug, they may be considered as advertising (depending on the context and aim of such a press release). In that case, they must meet the conditions specified for the audience they are addressed to. In order for a public release, which refers to a specific medicinal product, not being considered as advertising, it must be clear, taking into account the press release's content, form and circumstances of its distribution, and that it is aimed at achieving a different purpose than a promotional one.

Requirements for Press Releases Addressed to the General Public

First of all, the press release, which amounts to advertising of a medicinal product, addressed to the general public (or if there is any possible way that it can face the public audience) must comply with the subsection 6 of Section 1 of the regulation on advertising of medicinal products, which specifies the elements that any form of visual, audio and audiovisual advertising of medicinal products must contain. They are:

- the name of the medicine;
- the commonly used names of active substances, and in the case of a medicinal product containing more than three active substances, the term "combination product";
- the dose of the active substance or the concentration of the active substance, excluding the combination product;
- the pharmaceutical form;
- the therapeutic indications for use; and
- the MA holder.

If the press release is meant for the general public, it must also contain a warning, allowed in three forms specified in the regulation on advertising of medicinal products, which are the following.

- "This is a medicine. For your safety, use it according to the patient information leaflet inserted to the package. Do not exceed the maximum dose. If in doubt, consult a doctor or pharmacist."
- "This is a medicine. For your safety, use it according to the patient information leaflet inserted to the package and only if it is necessary. If in doubt, consult a doctor or pharmacist."
- "This is a medicine. For your safety, use it according to the patient information leaflet inserted to the package. Pay attention to the contraindications. If in doubt, consult a doctor or pharmacist."

Moreover, if the information on the medicinal product is placed in the press available for the

public audience, it must follow restrictions listed below:

- a medicinal product must not be presented by public figures, scientists, persons with medical or pharmaceutical education background or suggesting that they have one;
- it must not refer to the recommendations of public figures, scientists, persons with medical or pharmaceutical education background or suggesting that they have one;
- it must not suggest that:
  (a) it is possible to avoid medical advice or surgery, especially by making a diagnosis or recommending treatment by correspondence;
  (b) even a healthy person taking such medicinal product will improve their health;
  (c) failure to take such medicinal product may make one's health condition worse – this restriction does not apply to protective vaccinations;
  (d) the medicinal product is a food, a cosmetic or other consumer product; and
  (e) the effectiveness or safety of the medicinal product is due to its natural origin;
- it must not suggest that taking such medicinal product guarantees the right result, that there are no side-effects or that the result is better or the same as in the case of other treatment methods or treatment with other medicinal products;
- it must not include content that may lead to misdiagnosis by citing detailed case descriptions and referring to symptoms of the disease;
- it must not refer, in an inappropriate, alarming or misleading form, to therapeutic indications; and
- it must not contain inappropriate, disturbing or misleading descriptions of graphically depicted lesions, injuries to the human body or results of the medicinal product on the human body or its parts.

Finally, it is not allowed to address any promotional press release to the public audience, if it concerns:

- prescription-only medicinal products;
- medicinal products that contain narcotics and psychotropic substances; and
- medicinal products that are included on the lists of reimbursed medicines, in accordance with specific regulations, and medicinal products that are allowed to be issued without prescription but their name is identical to those included on the lists mentioned above.

Requirements for Press Releases Addressed to Healthcare Professionals

If a promotional press release is addressed to healthcare professionals (persons entitled to issue prescriptions and persons trading with medicines), it must comply with subsection 12 of Section 1 of the regulation on advertising of medicinal products and contain the following elements:

- the name and the commonly used name of the medicinal product;
- qualitative and quantitative composition with regards to the active substances and those excipients (substances formulated alongside active ingredients) that are important for the proper use of the medicinal product;
- the pharmaceutical form;
- the therapeutic indications for use;
- the dosage and the method of administration;
- the contraindications;
- special warnings and precautions for use;
- the side-effects;
- the MA holder;

- the number of the MA and the name of the authority that issued it; and
- the information on the granted category of availability and for medicinal products included on the lists of the refunded medicines – also the information on the official retail price and maximum amount of the surcharge borne by patients.

According to Article 54 of the Pharmaceutical Law, such press release also needs to comply with information provided in the Summary of Product Characteristics (SmPC).

2.4 Comparative Advertising for Medicines

Comparative advertising is allowed under Polish law, however, there are no specific regulations for medicines. Nevertheless, it needs to comply with general provisions for advertising set forth in the Act of 16 April 1993 on combating unfair competition.

According to Article 16, Section 3 of the aforementioned Act, comparative advertising must be consistent with good morals and comply with the following rules:

- it must not be a misleading advertisement;
- it compares products meeting the same needs or intended for the same purpose, in a fair manner, which is verifiable on the basis of objective criteria;
- it objectively compares one or more relevant, characteristic, verifiable and typical features of these products, which may include a price;
- it does not cause confusion in the market to distinguish between the advertiser and its competitor, or between their products or services, trade marks, business signs or other distinctive signs;
- it does not discredit the goods, services, activities, trade marks, business signs or other distinctive signs, as well as the circumstances of the competitor;
- for goods with protected geographical indication or protected designation of origin, the advertising always refers to goods with the same indication;
- it does not take unfair advantage of the reputation of a competitor's trade mark, business designation or other distinctive sign, or of protected geographical indication or protected designation of origin of competing products; and
- it does not present the product as an imitation or copycat of a product bearing a protected trade mark, protected geographical indication or protected designation of origin or other distinctive indication.

3. Advertising of Unauthorised Medicines or Unauthorised Indications

3.1 Restrictions on the Provision of Information Concerning Unauthorised Medicines or Indications

The general rule, set forth in Article 56 of the Pharmaceutical Law, states that the advertising of medicines is not allowed, if:

- the medicine in question is not authorised for marketing in Poland; and
- it is placed to market without the need of obtaining a MA (eg, in a procedure of a targeted import).

Moreover, according to Article 129, Section 2, Point 1 of the aforementioned Act, unlawful advertising of an unauthorised medicinal prod-

uct constitutes a criminal offence and it is subject to a fine.

Nevertheless, there are few strictly defined exceptions. It is possible to provide information to HCPs in a form of medical information which does not constitute an advertisement for a drug, and it is also possible to inform the public that a given company is in the process of registering a drug for a specific disease (without providing its brand name).

3.2 Provision of Information During a Scientific Conference

There is no prohibition for providing information on unauthorised medicines or indications during scientific conferences addressed to healthcare professionals, as long as it is not of an advertising or promotional nature, but it is purely medical information. There is no difference if it is a local or international conference.

3.3 Provision of Information to Healthcare Professionals

As long as it is medical information, provided completely separately from advertising of the MAH's medicinal products, there are no restrictions on the reactive or proactive transfer of information. However, such non-promotional information should rather be delivered to healthcare professionals by medical teams of pharmaceutical companies, not by employees of sales or marketing teams, and not during promotional meetings.

3.4 Provision of Information to Healthcare Institutions

In cases of sending information concerning unauthorised medicines or unauthorised indications to healthcare institutions, the requirements and restrictions specified for providing it to healthcare professionals shall apply (see **3.3 Provision of Information to Healthcare Professionals**).

3.5 Information About Early Access or Compassionate Use Programmes

The legality of providing information about early access or compassionate use is not determined in the Polish regulations at this time. However, due to the ban on advertising medicines not authorised for marketing in Poland, informing about such programmes to the public should be excluded; information on such programmes could potentially be distributed in a purely informative, non-promotional manner to healthcare professionals.

4. Advertising Pharmaceuticals to the General Public

4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public

Restrictions Applied to All Medicines

The Pharmaceutical Law provides some general rules that apply both to the advertisement of prescription-only and over-the-counter (OTC) medicines.

Article 56 states the prohibition of advertising medicines which have not been authorised for marketing in Poland or have been placed to market without necessity of obtaining a MA (for example, following the specific procedure on targeted import). The advertising that contains information, which is contrary to the SmPC, is strictly prohibited as well.

Moreover, Article 53 of the Pharmaceutical Law sets forth that advertising of a medicinal product:

- must not be misleading, should present a medicinal product objectively and must provide information about its rational use;
- may not consist of offering or promising any benefits, directly or indirectly, in exchange for the acquisition of a product or for providing evidence that such acquisition has taken place; and
- must not be directed to children or contain any elements addressed to them.

Restrictions Applied to Prescription-Only Medicines

The Article 57, Section 1 of the Pharmaceutical Law states that a product is not permitted to be advertised to the general public if it concerns:

- prescription-only medicines;
- medicines that contain narcotics and psychotropic substances; and
- medicinal products that are included on the lists of refunded medicines, in accordance with specific regulations, and medicinal products that are allowed to be issued without prescription but their name is identical to those included on the aforementioned lists.

The above restrictions do not apply to protective vaccinations specified in the Chief Sanitary Inspector's communication, issued pursuant to Article 17, Section 11 of the Act of 5 December 2008 on the prevention and control of infections and infectious diseases in humans.

Restrictions Applied to Over-the-Counter Medicines

Rules applied to OTC medicines' advertising addressed to the general public are set forth in Article 55 of the Pharmaceutical Law. It provides that:

- a medicinal product must not be presented by public figures, scientists, persons with medical or pharmaceutical education background or suggesting that they have one;
- it must not refer to the recommendations of public figures, scientists, persons with medical or pharmaceutical education background or suggesting that they have one;
- it must not suggest that:
  - (a) it is possible to avoid medical advice or surgery, especially by making a diagnosis or recommending treatment by correspondence;
  - (b) even a healthy person taking such medicinal product will improve their health;
  - (c) failure in taking such medicinal product may make one's health condition worse – this restriction does not apply to protective vaccinations;
  - (d) such medicinal product is a food, a cosmetic or other consumer product; and
  - (e) the effectiveness or safety of such medicinal product is due to its natural origin;
- it must not suggest that taking a medicinal product guarantees the right result, that there are no side-effects or that the result is better or the same as in the case of other treatment methods or treatment with other medicinal products;
- it must not consist of content that may lead to misdiagnosis by citing detailed case descriptions and referring to symptoms of the disease;
- it must not refer to inappropriate, alarming or misleading forms to therapeutic indications; and
- it must not contain inappropriate, disturbing or misleading descriptions of graphically depicted lesions, injuries to the human body or results of the medicinal product on the human body or its parts.

4.2 Information Contained in Pharmaceutical Advertising to the General Public

Any visual, audio and audiovisual advertising of medicinal products addressed to the general public must contain some essential elements listed in subsection 6 of Section 1 of the regulation on advertising of medicinal products, which are the following:

- the name of the medicine;
- the commonly used names of active substances, and in the case of a medicinal product containing more than three active substances, the term "combination product";
- the dose of the active substance or the concentration of the active substance, excluding combination products;
- the pharmaceutical form;
- the therapeutic indications for use; and
- the MA holder.

Such advertising must also contain a warning specified in the aforementioned regulation. The warning is allowed to be in one of the following forms.

- "This is a medicine. For your safety, use it according to the patient information leaflet inserted to the package. Do not exceed the maximum dose. If in doubt, consult a doctor or pharmacist."
- "This is a medicine. For your safety, use it according to the patient information leaflet inserted to the package and only if it is necessary. If in doubt, consult a doctor or pharmacist."
- "This is a medicine. For your safety, use it according to the patient information leaflet inserted to the package. Pay attention to the contraindications. If in doubt, consult a doctor or pharmacist."

The provisions also specify the placement of those warnings in the advertisement, the size of their visual forms and the length of their audio forms.

The regulations do not indicate any specific information that is prohibited, but, for example, they require that the data contained in the advertisement be consistent with the characteristics of the medicinal product. This means that information that is not in line with this characteristic cannot be provided. The regulations do not require indicating the price of the drug, and, what is more, these prices are set by pharmacies and other sales points, not by the manufacturers.

4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

Under Polish law there are no specific regulations on interactions between patients or patient organisations and industry. Nevertheless, good practices for collaboration between innovative pharmaceutical companies and patient organisations have been specified in the self-regulatory Code of Good Practices, adopted by the Employers' Union of Innovative Pharmaceutical Companies (INFARMA).

Provisions of the aforementioned Code of Good Practices state that co-operation should be based on mutual respect and should guarantee the independence of patient organisations in their actions, and the views expressed and decisions made by each partner will have equal value. Companies that have adopted this regulation are obliged to disclose a list of patient organisations, to which they give monetary, substantial in-kind or non-material assistance. This list should include a brief description of the assistance provided, as well as its value.

When it comes to significant non-material assistance, the value of which is difficult to estimate, descriptions should include the characteristics of the benefits received by the patient organisation. This information is published on the pharmaceutical company's local website, or, if there is no local website, on the company's global website or on INFARMA's website and it should be updated at least once a year.

5. Advertising to Healthcare Professionals

5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

Elements which must be contained in advertising addressed to healthcare professionals are specified in subsection 12 of Section 1 of the regulation on advertising of medicinal products and they are:

- the name and the commonly used name of the medicinal product;
- qualitative and quantitative composition with regard to the active substances and the excipients that are important for the proper use of the medicinal product;
- the pharmaceutical form;
- the therapeutic indications for use;
- the dosage and the method of administration;
- the contraindications;
- special warnings and precautions for use;
- the side-effects;
- the MA holder;
- the number of the MA and the name of the authority that issued it; and
- the information on the granted category of availability and for medicinal products included on the lists of refunded medicines – also, the information on the official retail price and maximum amount of the surcharge borne by patients.

The general restrictions on advertising of medicines, set forth in Article 53 of the Pharmaceutical Law, are applicable. In this regard, the advertising:

- must not be misleading, should present the medicinal product objectively and provide information about its rational use;
- may not offer or promise any benefits, directly or indirectly, in exchange for the acquisition of a product or for providing evidence that such acquisition has taken place;
- must not be directed to children or contain any elements addressed to them; and
- advertising of a medicinal product, which is a reminder of the full advertisement, in addition to its own name and common name, may contain only a trade mark that does not contain references to medicinal indications, a pharmaceutical form, dosage, advertising slogans or other advertising content.

5.2 Reference to Data Not Included in the Summary of Product Characteristics

The general rule, set forth in Article 54 of the Pharmaceutical Law, states that advertising of medicinal products addressed to professionals shall comply with information provided in the Summary of Product Characteristics. Relying on data on file or other clinical trials may be inconsistent with the above.

5.3 Advertising of Combination Products

There is no direct prohibition of advertising on combination products under Polish law. Nevertheless, the recipient of the advertisement should be able to distinguish that companion or complementary diagnostics are not part of a medicinal product. All contents referring to the

medicine in question need to comply with the SmPC. The rules noted in **5.2 Reference to Data Not Included in the Summary of Product Characteristics** apply as well. Such advertisement shall also comply with the regulations for advertising medical devices if it is a medical device.

5.4 Advertising of Companion Diagnostics

As mentioned, the main rule on advertising of companion diagnostics is that it shall be understandable and clear for the recipient of advertising that it is not a part of the medicinal product, and advertising shall not be misleading. In particular, it must not mislead the recipient with regard to the intended purpose, safety and performance of the companion diagnostics. Such advertisement shall also comply with the regulations for advertising medical devices if it is a medical device.

5.5 Restrictions on Reprints of Journal Articles for Healthcare Professionals

According to the provisions of Polish law, there is no prohibition for providing reprints of journal articles concerning medicinal products to healthcare professionals. However, if it is combined with marketing activities, it is considered as advertising medicinal products, so, in particular, the content shall comply with the SmPC. If the reprint is provided separately from drug advertising, only as medical information, it may contain information that goes beyond the SmPC.

5.6 Medical Science Liaisons

There is no direct prohibition under Polish Law for Medical Science Liaisons to interact with healthcare professionals, including discussion on scientific information concerning unauthorised medicines or indications. However, if such interactions are related to providing off-label information to HCPs, they must not contain any advertising or promotional content on medicinal products and it should be clearly separated from such actions, so it will not be considered as unlawful off-label advertising.

6. Vetting Requirements and Internal Verification Compliance

6.1 Requirements for Prior Notification/ Authorisation of Advertising Materials

The advertisements concerning medicinal products do not need any prior approval, authorisation or notification to regulatory authorities. Nevertheless, it is in a company's best interest to comply with the provisions of the law on advertising, so they will not be exposed to negative consequences from the Chief Pharmaceutical Inspector, who may prohibit advertising if it violates the regulations.

6.2 Compliance With Rules Concerning Medicinal Product Advertising

Under the binding law, there are no specific procedures related to achieving compliance of advertisements with the law before their release. The Chief Pharmaceutical Inspector performs a follow-up supervision over advertising of medicines. This authority is entitled to order to stop advertising if it does not comply with the legal regulations; and refusal to obey this order is a criminal offence subject to a fine. Companies make their best efforts to advertise their products in line with the law. Usually, they use qualified legal services and implement internal procedures regarding the principles on evaluating advertising materials.

7. Advertising of Medicinal Products on the Internet and Through Digital and Electronic Platforms Including Social Media

7.1 The Advertisement of Medicinal Products on the Internet

In the field of advertising activities on the internet, the general regulations applicable to drug advertising also apply.

The law regulates the conduct of advertising in: audiovisual, visual and audio forms. If an advertisement is transmitted on the internet or through digital and electronic platforms (including social media), the provisions generally applicable to the form of advertising in question and relevant to the audience apply.

7.2 Restrictions on Access to Websites Containing Material Intended for Healthcare Professionals

Restricted advertising (ie, directed to healthcare professionals) is subject to different requirements than advertising available to all internet and digital or electronic platforms users.

For example, it is permissible to publish content about Rx medicinal products on websites with restricted access, as long as it is only accessible to users who have been previously verified as authorised for prescribing drugs or selling them. Pharmaceutical companies must ensure that such content is not available to patients (ie, the general public).

7.3 Provision of Disease Awareness Information to the General Public Online

Companies are allowed to provide disease awareness information and materials to members of the general public online but as long as they do not even indirectly refer to medicinal products.

For example, a pharmaceutical company may, in principle, run an educational portal about the prevention of a particular disease, dedicated to patients. It is important, however, that the communications published in such a portal must not refer in any way to specific products (even if only indirectly).

Significantly, the authorities take a very restrictive approach to this requirement. Any reference in educational materials, even to the colour scheme/graphic design of a medicinal product (packaging) or an online product website, etc, is considered a violation of the above requirement.

7.4 Virtual Scientific Meetings

Pharmaceutical companies are allowed to sponsor scientific meetings, congresses and the participation of health professionals in these events, but the main purpose must be to provide medical information to visitors (rather than to maintain relationships and social ties).

If any medicinal products are advertised at such events, the general conditions stipulated for advertising of medicinal products shall be met.

The sponsor may provide educational materials from the conference to participants. However, the sponsor must first obtain, to the extent appropriate, a copyright or licence for the use of such materials, as well as (if applicable) permission for the use of the image (eg, the speaker's permission to provide a video of his or her speech).

In terms of virtual scientific meetings, the same regulations are applied in Poland as for live meetings (the provisions of Polish law do not

establish separate, specific requirements). There are no Polish law provisions, either, that would define when an event should be considered international.

However, professional organisations of pharmaceutical and medical companies have adopted their own regulations to address international events. These are, of course, not universally applicable regulations, but the members of the organisation undertake to comply with them.

An example of an organisation that has regulated (to some extent) the rules of international meetings is the Employers' Union of Innovative Pharmaceutical Companies (INFARMA), which has its own Code of Good Practice. Under this Code, with regards to international events in which the participation of a representative of the medical profession is sponsored by a signatory of the Code (under the terms of Article 20 of the Code), for the coverage of costs, the Code introduced by the EFPIA member organisation in the country where the person is practising his/her profession shall apply, subject to compliance with the Host Country Rule. In the event that more than one code, introduced by an EFPIA member organisation, applies and there is a conflict between them, the main rule is that the most stringent regulation applies.

7.5 Use of Social Media

Medicinal products can be promoted on the internet, but, depending on whether the advertisements are accessible to the patient or exclusively to HCPs, other restrictions apply.

It is prohibited to advertise to the public (to patients) for medicinal products:

- issued by prescription only;
- containing narcotics and psychotropic substances; and
- included in the lists of reimbursed medicines, in accordance with separate regulations, and allowed to be dispensed without a prescription with a name identical to those included in these lists.

This provision shall also apply to the advertising of a medicinal product whose name is identical to the name of a prescription-only medicinal product.

Nevertheless, this shall not apply to immunisations specified in the communication of the Chief Sanitary Inspector, issued pursuant to Article 17 (11) of the Law of 5 December 2008 on prevention and control of infections and infectious diseases in humans.

Importantly, advertising of a medicinal product to the public may not consist of:

- presentation of a medicinal product by persons known to the public, scientists, persons with medical or pharmaceutical education or suggesting the possession of such education; and
- referring to the recommendations of persons known to the public, scientists, persons with medical or pharmaceutical education or suggesting the possession of such education.

Therefore, running a social media profile promoting Rx drugs, for example, is not automatically excluded. Nevertheless, it involves the need to secure this profile against unauthorised access (so, for example, such a profile could be run in the form of a Facebook group with restricted access/obligatory registration of users). In practice, it can be significantly difficult to secure the process of verifying whether a given user has the

status of a person authorised to issue prescriptions or trade in medicinal products. In particular, neither the law, nor the jurisprudence of courts or regulatory bodies, prejudges what kind of security (access restriction) will be considered sufficient.

Regardless of the potential audience of the advertisement (general public or healthcare professionals), it is prohibited to advertise medicinal products:

- not authorised for marketing in the territory of the Republic of Poland;
- authorised for marketing without the need for authorisation; and
- containing information inconsistent with the Summary of Product Characteristics of Medicinal Products or the Summary of Product Characteristics of Veterinary Medicinal Products.

So it will certainly be out of the question to promote (even if only in the framework of closed advertising) a drug that has not yet been approved for marketing in Poland (and, for example, is only at the stage of clinical trials or has received registration in other countries, but not in Poland).

It should be noted that a pharmaceutical company is fully responsible for the actions of its employees in social media.

8. Pharmaceutical Advertising: Inducement/Anti-Bribery

8.1 Anti-Bribery Legislation Applicable to Interactions Between Pharmaceutical Companies and Healthcare Professionals

In Poland there are many regulations on anti-bribery. The following legal acts apply: the Criminal Code Act, the Polish Collective Entity Liability Act, the Act on Combating Unfair Competition, the Competition and Consumer Protection Act, the Pharmaceutical Law and Reimbursement Law, as well as personal data protection regulations. It is important to note that offering any benefit to a physician in return of prescribing a medicinal product is considered a bribe – a criminal offence, subject to serious penalties including imprisonment. This is due to the fact that a physician is considered a person performing public functions, if he or she prescribes medicinal products reimbursed from the public funds.

These areas are also regulated in industry codes. For example, the INFARMA Code of Good Practices establishes that the purpose of any contact with HCPs should be to increase their knowledge of therapeutic areas, disease entities, diagnostics and drugs available on the market, within the limits allowed by law or to improve the quality of patient care. Any direct or indirect financial transfers, on the other hand, may only serve this purpose and take place in accordance with the law, and in particular may not condition therapeutic decisions taken by the HCP.

The INFARMA Code of Good Practices also contains provision on transparency in relations of the pharmaceutical industry and healthcare professionals, healthcare organisations and patients' organisations. Any transfers of values to those entities should be revealed at least in an

aggregated form by pharmaceutical companies, which make such transfer of value.

It should be noted that pharmaceutical companies may grant donations, but in no case directly to HCPs (regardless of whether he or she works in a private or state facility). In principle, donations to healthcare institutions as well as patients' organisations are permitted.

8.2 Controls on the Provision by Pharmaceutical Companies of Benefits and/or Inducements to Healthcare Professionals

The INFARMA Code of Good Practice establishes that the purpose of any contact with HCPs should be to increase their knowledge of therapeutic areas, disease entities, diagnostics and drugs available on the market, within the limits allowed by law or to improve the quality of patient care. Any direct or indirect financial transfers, on the other hand, may only serve this purpose and take place in accordance with the law, and in particular may not condition therapeutic decisions taken by the HCP.

In practice, pharmaceutical companies most often establish a donation approval process within their business so that it is clearly independent of sales targets.

Some companies also use self-regulation, according to which they keep a record of the benefits transferred. This register is subsequently made public.

9. Gifts, Hospitality, Congresses and Related Payments

9.1 Gifts to Healthcare Professionals

The provision of gifts to healthcare professionals constitutes a form of advertising medicinal products and is regulated under the Polish Pharmaceutical Law. According to its provisions, gifts may be provided during promotional meetings, such as presentations or workshops, as well as during scientific congresses and industry conferences. Additionally, gifts can also be sent directly to healthcare professionals via mail, without the need for in-person contact.

It is important to emphasise that such gifts must comply with specific criteria. First and foremost, their material value cannot exceed PLN100 (as part of advertising activities). Furthermore, the nature of these gifts must be directly related to the practice of medicine or pharmacy. This means that the items should have practical use in the daily professional activities of healthcare professionals. All gifts must also be appropriately branded, meaning they should bear promotional information about a specific medicinal product or the pharmaceutical company itself.

Here is a new paragraph summarising the rules on providing gifts based on Articles 18 and 25 of the INFARMA Code of Good Practices:

Under the INFARMA Code of Good Practices, providing gifts to healthcare professionals and representatives of healthcare organisations is strictly regulated to ensure transparency and prevent undue influence. Article 18 prohibits offering any gifts with personal or recreational value, such as tickets to entertainment events or financial equivalents. Exceptions are made for low-value items such as pens, notepads, or bags clearly branded with the company's logo, which

are strictly intended for use during professional meetings. Additionally, Article 25 allows the provision of informational and educational materials or items intended for medical practice, provided their value does not exceed PLN100 gross, they are directly related to medical or pharmaceutical practice, and they offer tangible benefits to patient care. These materials cannot reduce the routine operational costs of the recipients and must be branded with the company's or product's name, except where otherwise inappropriate for practical use. These rules aim to uphold ethical standards and maintain the integrity of interactions between the pharmaceutical industry and healthcare professionals.

9.2 The Provision of Samples of Medicinal Products to Healthcare Professionals

It is permissible to transfer samples of medicinal products directly to the HCP, provided that:

- the HCP has requested in writing such samples from the pharmaceutical company's sales or medical representative;
- each sample supplied is no larger than the smallest package of a medicinal product authorised for marketing on the territory of the Republic of Poland;
- each sample supplied is labelled "free sample – not for sale";
- the number of samples of the same medicinal product supplied to the same person shall not exceed five packs per year; and
- the summary of product characteristics of the medicinal product will be provided with the sample.

The advertising of a medicinal product by providing free samples may not refer to medicines containing narcotic or psychotropic substances, or precursors of category 1, and if the recipient of such advertising is a pharmacist, it may not refer to medicinal products with an availability category other than that issued without a doctor's prescription (OTC).

The pharmaceutical company must maintain records of samples supplied to the HCP.

Based on Article 27 of the INFARMA Code of Good Practices, the following rules apply to the provision of medicinal product samples.

- The provision of samples is strictly regulated to ensure that they are used appropriately and ethically. Samples may only be provided to healthcare professionals authorised to prescribe medicinal products and must be supplied based on a written request. The request must be signed and stamped by the requesting healthcare professional and clearly indicate the details of the sample being requested.
- Samples cannot be provided as an incentive to recommend, prescribe, purchase, or use specific medicinal products. They are intended solely to allow healthcare professionals to become familiar with the product and gain practical experience with its use. Additionally, samples may not be used for patient treatment purposes.
- The number of samples provided is limited to no more than four samples of the same medicinal product per healthcare professional per calendar year. This restriction is further governed by the "4x2 rule", which allows the provision of samples only within two years following the product's initial launch on the Polish market or its first request for samples.
- Furthermore, samples must adhere to strict packaging and labelling requirements. Each sample must not exceed the smallest approved package size of the product

and must be marked clearly with the text: "free sample – not for sale". Samples cannot include controlled substances or psychotropic drugs.

9.3 Sponsorship of Scientific Meetings

Pharmaceutical companies are allowed to sponsor scientific meetings, congresses and the participation of health professionals in these events, but the main purpose must be to provide medical information to visitors (rather than to maintain relationships and social ties).

If any medical products are presented at such events, the general conditions stipulated for advertising medicinal products shall be met.

There are no additional provisions of the Polish law that would define when an event takes place abroad. However, professional organisations of pharmaceutical and medical companies have adopted their own regulations to address international events. These are, of course, not universally applicable regulations, but the members of the organisation undertake to comply with them.

An example of an organisation that has regulated (to some extent) the rules of international meetings is the Employers' Union of Innovative Pharmaceutical Companies (INFARMA), which has its own Code of Good Practice. Under this Code, with regards to international events in which the participation of a representative of the medical profession is sponsored by a signatory of the Code (under the terms of Article 20 of the Code), for the coverage of costs, the Code introduced by the EFPIA member organisation in the country where the person is practising his/her profession shall apply, subject to compliance with the Host Country Rule. In the event that more than one code, introduced by an EFPIA member organisation, applies and there is a conflict between them, the main rule is that the most stringent regulation applies.

9.4 Sponsorship of Cultural, Sports or Other Non-Scientific Events

Organisation and funding of cultural, sporting or other non-scientific events in relation to scientific conferences by pharmaceutical companies is permitted, as long as the so-called "emanations of hospitality" do not go beyond the main purpose of the meeting. This term shall be understood as including any entertainment elements or additional points of the meeting's agenda not related to its main topic and intended to make the meeting more attractive for its participants, if they can be objectively considered as excessive.

Determining whether emanations of hospitality go beyond the main purpose of the meeting is sometimes very difficult, as Polish law does not itself set a limit which the meeting organiser should not exceed.

However, professional organisations of pharmaceutical and medical companies have adopted their own regulations to address these issues. These are, of course, not universally applicable regulations, but the members of the organisation undertake to comply with them.

An example of an organisation that has regulated hospitality rules internally is INFARMA. Among other things, members of this organisation have committed themselves to certain financial limits when organising a promotional meeting or conference. The limits set the maximum amount a company can spend in sponsoring accommodation or a meal for a meeting participant. In addition, other restrictions have also been introduced, such as the prohibition to organise events in luxury hotels with a category of five

stars and in places associated with entertainment or in sea or ski resorts.

9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

Pharmaceutical companies may grant donations, but in no case directly to HCPs. In principle, donations to healthcare institutions as well as patient organisations are permitted.

In any case, the donation should be targeted, in the sense that the purpose of the donation should be clearly defined in advance. The implementation of the donation should be reliably documented.

As a general rule, donations cannot be granted in connection with the promotion/advertising of a medicine or directly to the HCP. Such an action would expose the company to accusations of corruption or inducing HCPs to prescribe specific medicinal products.

On the other hand, the law does not specify specific requirements for donations to healthcare organisations or patient organisations. The general principles of the anti-corruption legislation should therefore apply.

In practice, pharmaceutical companies most often establish a donation approval process within their business so that it is clearly independent of sales targets.

The law does not explicitly regulate the permitted subject matter of donations. INFARMA, on the other hand, allows not only in-material but also monetary donations to healthcare organisations and to patient organisations (subject to certain conditions). Similarly, the Medicines for Europe Code of Conduct allows this. However, transparency is key.

9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

One should bear in mind in particular the provisions of the Law on Combating Unfair Competition. Entrepreneurs should apply uniform conditions to their counterparts. They certainly cannot make the prices of their products dependent, for example, on the level of prescribing of their products at a particular facility or by a particular doctor.

The Polish legislator has also introduced explicit prohibitions with regard to reimbursed products.

Namely, in particular (but not exclusively), discounts, rebates, and bundled transactions of an entrepreneur who is engaged in the manufacture or marketing of medicines that are subject to reimbursement are prohibited.

9.7 Payment for Services Provided by Healthcare Professionals

Under the law of Poland, co-operation with healthcare professionals is permitted, insofar as the services provided to the pharmaceutical company relate to healthcare, education or research. Under no circumstances may services be contracted (and paid for) that involve the HCP advertising medicinal products or services of a pharmaceutical company.

Payments for any services performed by HCPs shall in no way (even indirectly) constitute an inducement to prescribe medicinal products to patients.

Therefore, payment of remuneration to a healthcare professional – a speaker at a medical conference, for example – is permitted.

However, attention must be taken to ensure that the remuneration is fair to the market value of the service provided by the HCP, and that providers are selected according to their medical qualifications/specialisation. This may help to avoid the risk of possible allegations that the service contract and payment has a hidden purpose (being a sham contract).

The law does not clarify this scope, so here, too, the industry has decided to self-regulate.

INFARMA obliges signatories to the organisation's adopted code to, among other things, ensure that contracts with HCPs are in writing and that service providers are selected according to predetermined and objective criteria (such as specialisation and medical experience).

Separately, the Medicines for Europe Code of Conduct, adopted by the non-governmental non-profit organisation Medicines for Europe, states that remuneration to healthcare professionals for the provision of services must be at a rate that represents fair market value for the service, taking into account the qualifications, experience, professional role, rank and location of the person performing the work.

9.8 Prior Authorisations or Notifications for Activities Between Pharmaceutical Companies, Healthcare Professionals and Healthcare Organisations

Polish law generally does not require specific prior authorisation or notification (eg, employer approval or regulatory approval) for any of the activities described in this section.

However, failure to comply with the requirements carries serious consequences in a possible follow-up inspection.

Moreover, signatories of the INFARMA Code of Good Practice are obliged to obtain prior certification of all scientific events that they organise or sponsor, in accordance with the rules applicable in the Event Certification Procedure.

10. Pharmaceutical Companies: Transparency

10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value

As a general rule, the relevant public authority (public administration or court), acting within the limits of the legal authorisation, may request a pharmaceutical company to disclose detailed information (eg, for the purpose of conducting proceedings in a specific case). The requesting entity shall then indicate the specific scope of information to be disclosed. In principle, these requirements apply to all participants in the Polish market.

Notwithstanding, signatories to both the Code of Good Practice of INFARMA and the Medicine of Europe Code of Conduct have committed to disclosing benefit transfers.

In the case of benefits to healthcare organisations, the disclosures relate to: grants and donations, costs in connection with events sponsored or organised by the company (eg, registration fees paid by the company for the participation of representatives of the organisation concerned), remuneration for services and consultancy.

In the case of benefits to HCPs, the information disclosed relates to: costs in connection with participation in an event (eg, the cost of registration fees that the company covered for the participation of the HCPs concerned or the doc-

tor's travel costs to the conference venue) and remuneration for services and consultancy provided by HCPs to the pharmaceutical company.

These data are published for each calendar year, on a dedicated platform or website of the signatory (at national or European level).

10.2 Foreign Companies and Companies That Do Not Yet Have Products on the Market

If a company is a signatory to a self-regulatory code of ethics (such as the INFARMA code), it must comply with its regulations regardless of whether it has already introduced its first product into the Polish market. Likewise, if the company acts towards Polish patients, then Polish authorities can take action against it under general laws (regardless of whether it is a signatory to industry codes).

11. Pharmaceutical Advertising: Enforcement

11.1 Pharmaceutical Advertising: Enforcement Bodies

Enforcement of advertising regulations is primarily handled by the Chief Pharmaceutical Inspector. However, in certain cases, the President of the Office of Competition and Consumer Protection is also competent, as well as common courts (civil and, in extreme cases, even criminal courts).

11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements

Pharmaceutical companies initiate proceedings against competitors for advertising violations if there is an act of unfair competition.

In the event of an act of unfair competition, the entrepreneur whose interest has been threatened or infringed may demand:

- the cessation of the prohibited acts;
- removal of the effects of the prohibited actions;
- making a single or repeated statement of appropriate content and form;
- compensation for the damage caused, on general principles;
- to surrender the unjustly obtained benefits, on general principles; and
- to award an appropriate sum of money for a specific social purpose related to the promotion of Polish culture or protection of national heritage – if the act of unfair competition was culpable.

11.3 Sanctions for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe

The Chief Pharmaceutical Inspector may impose such sanctions as:

- the cessation of the appearance or conduct of advertisements for medicinal products that are contrary to the applicable regulations;
- the publication of the issued decision in the places where the illegal advertisement appeared, and the publication of a correction of the misleading advertisement; and
- the removal of identified violations.

The President of the Office of Competition and Consumer Protection may impose financial penalties on an entrepreneur, in an amount not exceeding 10% of the turnover achieved in the financial year preceding the year of imposing the penalty, if the entrepreneur has, even unintentionally, violated the prohibition specified in law.

In civil cases, one must expect to be obliged to compensate for damages, including, for example, the publication of a statement/correction in the media, among other things, and in certain cases the entrepreneur may be required to pay towards a specific social cause.

In extreme cases, criminal liability may be involved.

11.4 Relationship Between Regulatory Authorities and Courts

Proceedings conducted before self-regulatory bodies are independent of those conducted by courts or public administrations. There may be a situation in which a court of general jurisdiction will not find a violation, while the same action will be a violation under the code of ethics (and vice versa).

11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

Over the past two years, the authors have not observed any particular trends when it comes to enforcement of regulations on the strict advertising of medicinal products.

On the other hand, it is additionally worth mentioning that a hefty fine was imposed on a pharmaceutical company (more than PLN5 million), in connection with the advertising of its products other than medicines. The case concerned this company's co-operation with influencers on social media. The President of the Office of Competition and Consumer Protection found that the pharmaceutical company had engaged in surreptitious advertising, as the influencers did not label their content in a way that allowed internet users to realise that they were dealing with product advertising.

12. Veterinary Medicines

12.1 Advertising Veterinary Medicines

As a general rule, there is no separate system of rules applicable to the advertising of veterinary medicines in the sense that the law regulating the advertising of medicines for humans also includes regulations for the advertising of veterinary products. Thus, the vast majority of Polish regulations, including pharmaceutical law, are common to medicinal products and, therefore, also to products for animals.

For example, general principles such as the prohibition of misrepresentation or the obligation to comply with the SmPC are, of course, also key in product campaigns of veterinary products.

On the other hand, some differences do exist, including the scope of mandatory content (SIL) or the content of cautionary statements in animal medicines advertisements.

The industry has also decided to self-regulate. It is worth pointing to the Code of Marketing Ethics, developed by the POLPROWET Association.

Trends and Developments

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Czyżewscy Law Firm has years of experience in providing legal services to entities operating in the life sciences area. The firm is widely recognised in Poland as top specialists in advertising and marketing of medicinal products and medical devices, as well as in reimbursement of medicinal products and pricing of healthcare services. The firm also has strong expertise in regulatory issues, related to registration, marketing or distribution of drugs, medical devices, cosmetics, and food supplements. It supports its clients in such matters on a daily basis, including assisting clients in reimbursement proceedings, their marketing or advertising activities, registration or post-registration proceedings, relations with competitors, and distribution of their products. The firm's scope of work also covers clinical trials, distribution issues, patents and trade marks and other related issues. Experts from Czyżewscy Law Firm regularly publish content and give comments in business media and professional press. Specialists from Czyżewscy are invited to participate in debates and public consultations related to reimbursement and medical law.

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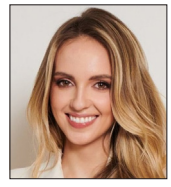

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Who Can Be a Recipient of Advertising of Prescription-Only Medicines?

Medicinal products advertising targeted at healthcare professionals

The question of which healthcare professionals may legally receive advertising for prescription-only medicines has become a pressing issue in Poland's regulatory and legal landscape. Recent changes in healthcare regulations, especially the expanding scope of prescribing rights granted to nurses, have created new opportunities but also raised significant legal and practical challenges. These developments force pharmaceutical companies to carefully navigate advertising campaigns to ensure compliance with stringent legal frameworks while maximising their effectiveness.

Traditionally, prescription-only medicines (POM) advertisements were primarily directed toward physicians, given their broad prescribing rights and central role in patient care; as well as pharmacists, as persons selling medicinal products to patients. However, the inclusion of nurses as prescribers, albeit with limitations, has blurred the boundaries of permissible advertising audiences. This shift underscores the growing complexity of the pharmaceutical advertising ecosystem in Poland.

Prescription-only medicines advertising directed to nurses

Under Polish law, nurses and midwives are authorised to issue prescriptions if they meet specific requirements concerning their qualifications. This right, outlined in Article 15a Section 2 Point 1 of the Act of 15 July 2011 on the Professions of Nurse and Midwife, is granted to those who:

1. hold at least a first-degree university diploma in nursing or midwifery; or
2. possess a specialist degree in nursing.

In addition to these educational prerequisites, nurses and midwives must complete a specialised course in prescribing. This course equips them with the knowledge and skills necessary to prescribe certain medicines, medical devices, and foodstuffs for special nutritional purposes. However, their prescribing rights exclude highly potent substances, narcotics, psychotropic substances, and certain other regulated categories.

The scope of prescribing rights for nurses and midwives is further defined by the Regulation of the Minister of Health of 18 January 2018, which provides a comprehensive list of active substances, diagnostic tests, and medical

devices that fall within their prescribing authority. In 2024, this regulation was amended to expand the list of substances and products nurses and midwives can prescribe, reflecting the evolving responsibilities of these professions in the Polish healthcare system.

These developments have positioned nurses and midwives as key players in patient care, particularly in areas requiring continuity of treatment. For example, they can now prescribe certain medications needed to maintain ongoing treatment plans, provided these medications fall within their legal prescribing scope. This expanded authority aligns with global trends in healthcare, where non-physician professionals increasingly take on roles traditionally reserved for doctors.

Expanded prescription rights: vaccines

A significant addition to nurses' prescribing rights is their authority to issue prescriptions for vaccines, particularly for adult immunisations. This change marks a pivotal step in broadening the role of nurses in preventive healthcare and public health initiatives. By allowing nurses to independently prescribe adult vaccines, the regulatory framework aims to improve vaccination rates and enhance access to essential preventive care.

However, this expansion raises complex questions about advertising practices. Pharmaceutical companies are now exploring the extent to which they can advertise vaccines directly to nurses. Key legal ambiguities include:

- whether vaccine advertisements aimed at nurses must exclusively focus on adult indications or if they can include pediatric indications for the same vaccine;
- how to ensure compliance with advertising regulations while effectively conveying product information to nurses; and
- how to make sure that the advertising of prescription-only medicines is addressed exclusively to persons authorised to be recipients of such advertising.

These issues remain unresolved, as the Chief Pharmaceutical Inspector has yet to provide clear guidance on the matter. The lack of definitive regulatory interpretation has created uncertainty for pharmaceutical companies, who risk facing penalties if their advertising is deemed non-compliant.

Regulatory challenges in advertising to nurses

Advertising prescription-only medicines to nurses is governed by strict rules designed to prevent such advertisements from reaching unauthorised recipients. According to Paragraph 12 Section 5 of the Regulation of the Minister of Health of 21 November 2008 on Advertising of Medicinal Products, advertisements directed at healthcare professionals must be carefully tailored to ensure they do not inadvertently reach audiences without prescribing authority.

While digital advertising offers tools for verifying professional credentials (eg, requiring a professional licence number before granting access to materials), distinguishing between nurses with and without prescribing rights remains a significant challenge. For example, publications targeting nurses as a general audience may include both those with and without prescribing authority, creating a grey area that could render such advertisements non-compliant.

Some experts argue that all nurses and midwives should be treated as a single category

for advertising purposes, with the exception of advertisements for products explicitly outside their prescribing rights, such as narcotics or psychotropic substances. However, this approach has not yet been formally endorsed by the Chief Pharmaceutical Inspector, leaving pharmaceutical companies to navigate this legal grey area with caution.

Free samples of medicinal products for pharmacists and nurses

Providing free samples of medicinal products is another advertising method regulated under Polish law. Article 54 Section 3 of the Pharmaceutical Law of 6 September 2001 allows samples to be distributed to healthcare professionals authorised to issue prescriptions, subject to strict conditions.

- The recipient must submit a written request for the sample.
- A record of all samples provided must be maintained.
- Each sample must be no larger than the smallest package of the medicine authorised in Poland.
- Samples must be labelled as "Free Sample – Not for Sale".
- A Summary of Product Characteristics (SmPC) must accompany each sample.
- No more than five samples of the same medicinal product may be provided to the same individual per year.

While pharmacists and nurses can issue prescriptions in specific cases, their ability to receive free samples is limited to products within their prescribing authority. Additionally, unlike doctors, pharmacists and nurses are not allowed to distribute free samples to patients. This restriction significantly reduces the practical utility of samples as a marketing tool for these groups.

For pharmacists in particular, the inability to use or evaluate samples themselves further diminishes the value of this advertising method. Without the ability to integrate samples into patient care or their professional evaluation process, providing free samples to pharmacists often fails to achieve the intended marketing outcomes.

Practical implications and broader challenges

Although Polish law permits advertising prescription-only medicines to certain healthcare professionals, practical and regulatory challenges frequently undermine the effectiveness of these campaigns. Key issues include:

- the difficulty of distinguishing between nurses with and without prescribing rights, which complicates targeted advertising efforts;
- the limited impact of free samples as a marketing strategy for pharmacists and nurses, given their inability to distribute or evaluate these samples; and
- ambiguities surrounding vaccine advertisements, particularly in cases where the product is indicated for both adult and pediatric use.

These challenges highlight the ongoing tension between expanding prescribing rights for non-physician healthcare professionals and ensuring compliance with strict advertising regulations. For pharmaceutical companies, navigating this landscape requires a delicate balance between legal compliance and effective marketing strategies.

Conclusion

The advertising of prescription-only medicines to healthcare professionals in Poland is a complex and evolving issue. While recent regulatory changes have expanded the prescribing rights of nurses and pharmacists, these changes have

introduced significant challenges for pharmaceutical advertisers. The lack of clear guidance from regulatory authorities, particularly regarding advertising to nurses and midwives, further complicates the situation.

Pharmaceutical companies must tread carefully, ensuring that their advertising practices comply with the law while effectively targeting authorised healthcare professionals. This requires not only a thorough understanding of the regulatory framework but also proactive engagement with legal experts to mitigate risks.

As the role of nurses and pharmacists in the healthcare system continues to grow, it is likely that these issues will remain at the forefront of legal and regulatory discussions. By addressing these challenges head-on, policymakers and industry stakeholders can work together to create a more transparent and effective advertising environment that supports healthcare professionals in their vital roles.

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