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Promoting Medical Products Globally

Handbook of Pharma and MedTech Compliance

POLAND

Poland

Introduction

Issues relating to the advertising of medicinal products under the Polish legal system are primarily regulated by the Pharmaceutical Law of 6 September 2001 (Journal of Laws of 2008, No 45, sec. 271, as amended) which implements certain provisions of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. Therefore, the rules for advertising medicinal products in Poland are in principle compliant with the requirements of Community Law. Pharmaceutical Law provides for, among other things:

- a distinction between advertising addressed to the general public and advertising addressed to healthcare professionals;
- a requirement that advertising cannot be misleading and that it shall objectively present the medicinal product and clearly set out its rational usage;
- a prohibition on the advertising of medicinal products available only by prescription to the general public; and
- a prohibition on the advertising of products which have not been authorised.

In accordance with Polish law, supervision of pharmaceutical advertising is mainly administrative in nature and is overseen by the Chief Pharmaceutical Inspector (the "CPI").

Should an advertisement fail to comply with Pharmaceutical Law regulations, the following sanctions may be applied:

- prohibition on the further broadcast or publishing of the advertisement in question;

- an order to publish the decision of the CPI and/or to issue a corrective statement in places (media) in which the banned advertisement has been published or broadcast; and

- an order to remove the ascertained breaches from public consumption (e.g., withdrawal of publications in which the prohibited advertisement appears).

Applicable Laws

The advertising of medicinal products is regulated by the following legal acts:

- Pharmaceutical Law of 6 September 2001 (Journal of Laws of 2008, No 45, item 271, as amended) ("Pharmaceutical Law"); and

- Regulation of the Minister of Health of 28 November 2008 on advertising of medicinal products (Journal of Laws, No 210, item 1327).

In addition to these laws, there are also various acts of a general nature which are applicable to pharmaceutical advertising. These include, for example, the Act of 16 April 1993 on Combating Unfair Competition (Journal of Laws of 2003, No 153, item 1503, as amended), the Civil Code and the Penal Code.

The advertising of medicinal products is also covered by codes of conduct adopted by industry or professional associations. They are not binding laws and cannot be enforced by the state, but provide for sanctions which can be applied by the associations on its members. The following codes are relevant:

- The Code of Good Marketing Practices of the Pharmaceutical Industry, Interactions with Healthcare Professionals and Patient Organisations adopted by the Employer's Union of

Innovative Pharmaceutical Companies ("INFARMA").[1] As INFARMA is a member of the European Federation of Pharmaceutical Industries and Associations ("EFPIA"), the Code of Ethics of INFARMA is based on the Code of Practice regarding the promotion of prescription-only medicines to, and interactions with, healthcare professionals adopted by EFPIA. This code is applicable only to prescription products.

- The Prescription Medicines Pharmaceutical Marketing Ethics Code, which was adopted on 28 February 2006 by the Economic Chamber, the Polish Pharmaceutical Industry and Medical Devices Chamber, and the Polish Pharmaceutical Industry Employers' Association. We do not refer further to this code as it is not binding for newly established companies operating in Poland which are members of EFPIA and INFARMA.
- The Physicians' Ethics Code.
- The Republic of Poland Pharmacists' Ethics Code.

Advertising vs. Information

Pharmaceutical Law defines the advertising of a medicinal product in a similar way to Directive 2001/83/EC. It is described as being any activity consisting of the provision of information about, or encouraging the administering of, medicinal products with the aim of increasing the number of prescriptions, supply, sale or consumption of medicinal products. It includes, in particular:

- advertising addressed to the general public;
- advertising addressed to persons authorised to prescribe, or persons engaged in the trade of, medicinal products;

[1] (English version available at: http://infarma.pl/code-of-ethics/about-the-code.html?L=2)

- visits to persons authorised to prescribe, or persons engaged in the trade of, medicinal products by medical and sales representatives;
- supplying samples of medicinal products;
- sponsoring promotional meetings for persons authorised to prescribe, or persons engaged in the trade of, medicinal products; and
- sponsoring of conferences, meetings, or scientific congresses for persons authorised to prescribe, or persons engaged in the trade of, medicinal products.

However, the concept of "advertising" must be distinguished from simply information concerning medicinal products. The latter must be neutral and should not contain elements which are persuasive or subjective.

According to Pharmaceutical Law, the following activities are not deemed to be advertising:

- information placed on packaging or attached to packaging of medicinal products, provided that it is in accordance with marketing authorisation;
- communications accompanied by informative material of a non-promotional character which are considered necessary in order to answer questions regarding a particular medicinal product, including products admitted to market without marketing authorisation;
- announcements of an informative character not addressed to the public regarding, in particular, changes to packaging and warnings about adverse reactions, provided that the contents do not refer to the properties of pharmaceutical products (this provision results in interpretational doubts as to the admissible scope of information provided to patients);

- commercial catalogues and price lists containing only the medicinal name, trade name, dose, pharmaceutical form and price of a medicinal product, including products admitted to market without marketing authorisation and, with regard to reimbursable products, the official retail price, provided that the contents do not refer to the properties of pharmaceutical products, including therapeutic indications; and

- information regarding human or animal health or diseases, provided that it does not relate, even indirectly, to medicinal products.

Please note that sometimes the distinction between advertising and information can be difficult to determine. This applies, in particular, to activities such as health promotion campaigns and health management programs. There are no official papers issued by authorities that provide explicit guidance on this issue and so each advertisement must be evaluated on a case-by-case basis.

General Advertising Rules

The advertising of medicinal products, whether addressed to healthcare professionals or to the general public, can only relate to products authorised for marketing in Poland and cannot include elements which do not conform with the Summary of Product Characteristics ("SmPC").

Moreover, the advertising of a medicinal product:

- cannot be misleading and must objectively present the medicinal product and clearly set out its rational usage;

- must not be based on the offering or promising, directly or indirectly, of any profits whatsoever in exchange for the purchase of medicinal products or the provision of any evidence of purchase; and

- may not be aimed or contain elements aimed at children.

In light of existing provisions, note that an advertisement may only contain the medicinal name, trade name and trademark of a product, all of which must not contain references to medical indications, pharmaceutical form, dosage, advertising slogans or other advertising content. The term "advertising content" is vague and results in interpretational doubts.

Advertisements Addressed to Healthcare Professionals

General

Pharmaceutical Law lists two professional groups who are considered "healthcare professionals":

- persons authorised to issue prescriptions for medicinal products (in principle, doctors); and
- persons engaged in the trade of medicinal products (in principle, wholesalers and pharmacists).

An advertisement for a medicinal product addressed to healthcare professionals should include the following:

- information consistent with the SmPC and information concerning the category of the product, and with regard to a reimbursable product, information about the official retail price and the maximum additional patient co-payment;
- the name of the medicinal product and its trade name;
- the qualitative and quantitative components of active substances, as well as any additives that are of material importance for the proper application of the medicinal product;
- the pharmaceutical form;
- therapeutic indications or indications for use (an advertisement may include only some therapeutic indications

as long as the other information included refers exclusively to these indications);

- dosage and form of administration;
- information on contraindications;
- special warnings and precautionary measures to be applied when using the product;
- information on side effects;
- the name of the marketing authorization holder ("MAH"); and
- the marketing authorisation number and the name of the body that granted the authorisation.

The abovementioned data shall be provided in compliance with SmPC, or if not in line with SmPC – provided the documentation contains such data – approved in the proceedings for granting marketing authorisation.

Advertising addressed to healthcare professionals shall be presented in such a way that it does not reach persons to whom it is not addressed.

The regulations require that all documentation addressed to persons authorised to prescribe, or persons engaged in the trade of, medicinal products contains information that is accurate, up-to-date, verifiable and sufficiently comprehensive to enable the recipient to form his or her opinion of the therapeutic value of the medicinal product concerned. It shall also contain information referring to the date on which the documentation was initially prepared and the last time it was updated. Quotations as well as tables and other illustrative matter taken from medical journals or other scientific works shall be faithfully reproduced and contain a precise citation of their source.

Article 58.1 of Pharmaceutical Law provides that advertising addressed to healthcare professionals which involves the awarding, offering or promising of material profits, gifts and other facilities, prizes or trips, as well as the organizing and funding of meetings promoting medicinal products, is forbidden when the hospitality offered "goes beyond" the main purpose of the meeting.

Although Pharmaceutical Law does not provide expressly for the possibility of covering expenses (such as registration fees and hotel accommodation) related to the participation of a healthcare professional in an academic event, based on provisions permitting the sponsorship of meetings (Article 52.2.5), payment for such expenses should be deemed permissible. This is also confirmed by the provisions of the Code of Ethics of INFARMA, which expressly allows such expenses to be covered within certain set limits.

The Code of Ethics of INFARMA contains detailed restrictions with regard to acceptable limits of hospitality, as follows:

- meetings organized or sponsored by or on behalf of a MAH should be organized at locations appropriate for the main purpose of these meetings; venues which are considered eccentric or known for providing entertainment should be avoided;
- meetings organized or sponsored by or on behalf of a MAH should not be held abroad unless this is justified by substantive or organizational aspects, especially if the majority of the invited guests come from outside of the event's home country;
- hospitality offered should not be excessive; it should be limited to covering the costs of travel, accommodation, boarding and registration fees associated with participation in the conference; the reimbursement of costs should apply to the participants in the meetings only, and not to persons

accompanying them, including family members; hospitality offered cannot include the sponsoring or organizing of entertainment, including sporting or leisure events; and

- the MAH, or entities/persons acting on his or her behalf, should use objective criteria based on substantive prerequisites when selecting persons to be invited to a meeting.

Samples of Products

Samples of medicinal products may be provided only to persons authorised to issue prescriptions (and therefore not to persons trading in medicinal products) in accordance with the following restrictions:

- a person authorised to issue prescriptions must request a sample in writing;
- the entity supplying the sample must monitor and keep records of the supplied samples;
- only products authorised for marketing in Poland may be issued as samples;
- the sample cannot be larger than the smallest packaging unit authorised for sale in Poland (in this respect, Pharmaceutical Law is inconsistent with the regulations of the Directive 2001/83/EC, which refers not to the smallest registered product, but to the smallest presentation of such product on the market);
- the SmPC must be attached to the sample;
- samples must be clearly marked: “Free sample – not for sale”;
- not more than five packages of a sample product can be delivered to a given person per calendar year; and

- it is not permissible to distribute samples containing psychotropic or intoxicating substances;

Please note that samples of medicinal products are not marketable. The distribution of samples must also be differentiated from donations of medicinal products, which is discussed further in the section on "Donations."

Gifts

In general, providing gifts to medical practitioners is regarded as a form of advertising of medicinal products. Pharmaceutical Law allows such gifts only if:

- they are offered to persons authorised to prescribe, or persons trading in, medicinal products;
- their total value amounts to no more than PLN100, or approximately EUR25 (public authorities represent the view that this amount should be understood as the gross value at retail level);
- they have been marked with the company logo or the name of the medicinal product; and
- they are of a medical or pharmaceutical nature.

The rules on gifts apply to any material benefits offered by pharmaceutical companies to healthcare professionals, such as in relation to scientific journals or professional training (whereas such professional training must be differentiated from sponsorship of participation in scientific events).

Gifts offered to healthcare professionals must be distinguished from donations. Donations of money or other material benefits to persons authorised to prescribe, or persons trading in, medicinal products are not permitted.

Donations

In principle, donations of money or equipment, or the financing of services, should only be made to public institutions (such as public hospitals). They may not be given to individual persons in an institution, but only to the institution as a whole. They cannot be given to private entities, such as partnerships of physicians or businesses operated by physicians (or other healthcare professionals), because in such a case the donation could be considered a disguised illegal gift to a physician. In some exceptional cases, donations to private hospitals which perform, to a large extent, public functions (i.e., patient services which are financed from public funds) may be admissible.

Donations of pharmaceutical products are subject to special restrictions regarding both:

- the pharmaceutical companies – as donators, the company must hold a wholesale licence since donations are regarded as a form of trading in relation to pharmaceutical products; and
- the beneficiaries – they must be one of the designated entities listed in the Regulation of the Minister of Health of 12 December 2002, on entities authorised to purchase medicinal products from a wholesaler (Journal of Laws of 2002, No 216, item 1831). In practice, the recipients of donations of medicinal products will primarily be healthcare institutions.

Clinical Trials, Observational Studies and Other Research Projects

Pharmaceutical companies are permitted to engage doctors for clinical trials, observational studies and other research projects, and to pay such doctors remuneration for their time and efforts. Such relationships are civil law arrangements under which the service of a doctor is offered in exchange for a material benefit (e.g., money, training or equipment) from a pharmaceutical company.

Any such arrangements must be distinguished from the advertising of medicinal products. Advertising is always a “one-directional” activity

performed by a pharmaceutical company for the benefit of a healthcare professional, whereby the healthcare professional does not provide any reciprocal service in return.

A civil law arrangement between a pharmaceutical company and a doctor assumes that both parties provide reciprocal services to each other. In particular, the service of a doctor must be tangible and valuable to the company, and the remuneration for this service must be adequate, i.e., correspond to the average market value.

While Pharmaceutical Law contains detailed rules on clinical trials (further defined in the Regulation of the Minister of Health of 2 May 2012, on Good Clinical Practice, Journal of Laws of 2012, item 489), the regulation of non-interventional studies is limited. Article 37al of Pharmaceutical Law provides only the following:

- a medicinal product must be applied in conformity with its marketing authorisation;
- the qualification for treatment cannot occur on the basis of a protocol but on the basis of medical practice, and decisions about the application of a drug are fully independent from decisions regarding enrolment in the study; and
- patient data must be evaluated using epidemiologic methods and no additional diagnostic or monitoring procedures may be subsequently applied to patients after the study has ended.

The Code of Ethics adopted by INFARMA contains detailed rules on non-interventional studies in order to prevent the misuse of these studies for disguised promotion of pharmaceutical products. These rules provide, among other things, that:

- studies should be conducted for a specific scientific purpose;
- studies should be conducted on a predefined number of patients and within a specified observation time, as described in the study protocol; the extension of the same study, or a

new study, with the same scientific objective in mind, is prohibited unless this is a result of a decision issued by the relevant authorities or generally binding legal regulations; submitting the study protocol to the relevant ethic commission is recommended;

- the study cannot be used to compare medicinal products;
- investigators may receive remuneration for conducting the study in accordance with the study agreement which corresponds to the time involved and workload and should reflect the practices adopted on the Polish market;
- the start of a non-interventional study must be announced to the public via a statement on the website of INFARMA (or any other appropriate association); and
- results should be prepared in the form of a final report within 12 months of the end of the observation of the last patient, and published or presented at a medical symposium within 24 months of the end of the observation of the last patient.

Advertising Addressed to the General Public

Advertising addressed to the general public must state:

- the name of the product;
- the trade name of the active substance and, with regard to a product containing more than three active substances, the description “complex product”;
- the dose of the active substance or its concentration, excluding complex products;
- the product’s pharmaceutical form;
- the product’s therapeutic indications;

- any contraindications; and
- the MAH.

Advertisements for non-prescription medicines must fulfil a number of other requirements, including complying with guidelines regarding advertisement proportions (content vs. warnings) or the wording of warnings (such as: “Before use, please familiarise yourself with a leaflet attached to the package or contact a physician or a pharmacist. Each drug used inappropriately threatens your health or life.”).

Moreover, Pharmaceutical Law provides for the following restrictions on advertising to the public:

- it cannot relate to prescription-only medicines or OTC medicines which have names identical to prescription medicines, medicines containing intoxicating or psychotropic substances, medicines included in reimbursement lists or medicines which have names identical to those included in reimbursement lists;
- it may not be presented by scientists, persons publicly known (this reference causes interpretational doubts) or persons who either have a medical or pharmaceutical education or imply that they have such an education;
- it may not refer to recommendations of scientists, persons publicly known or persons who either have medical or pharmaceutical training/qualifications or imply that they have such training/qualifications;
- it may not suggest that:
    - it is possible to avoid a doctor’s advice or surgery;
    - even a healthy person will improve his/her health if he/she uses the drug and that non-application of the drug may worsen a medical condition;

  - a medicinal product is a foodstuff, cosmetic or other consumer product; and
  - the effectiveness or safety of a product is a result of the natural character of that product;

- it may not assure the effectiveness of the drug, that there are no side effects, or that the effect of the drug is better or the same as another treatment;
- it may not lead to improper self-diagnosis;
- it may not refer to a product's therapeutic indications in a form which is inappropriate, unclear or misleading; and
- it may not give an incorrect, alarming or misleading picture of a disease or effect of the drug.

Advertising in Healthcare Institutions and Pharmacies

According to Article 13 point 2 of the Law of 15 April 2011, on healthcare activity (Journal of Laws, No 112, item 654, as amended), in the place of provision of healthcare services, economic activities other than healthcare activities (for example, advertising) can be conducted, provided that such activities are not disruptive to patients or to their treatment.

Despite some controversies concerning the ban on advertising by pharmacies, which entered into force on 1 January 2012, the advertising of medicinal products in pharmacies is allowed but only if it does not simultaneously constitute the advertising of a particular pharmacy.

Detailed rules on advertising medicinal products in healthcare institutions and pharmacies are provided by the Regulation on Advertising of Medicinal Products. The regulation provides that the advertising of medicinal products in healthcare institutions and pharmacies may not:

- disrupt normal activities conducted within a healthcare institution or pharmacy; and
- use sound and/or audio-visual forms.

Additionally, the advertising of medicinal products addressed to the general public in healthcare institutions must be placed only in waiting rooms, while advertising in pharmacies must be placed in a clearly delineated section and cannot limit the space designated for patients.

Pre-Approval

There is no requirement or possibility to acquire in advance an approval of a regulatory authority or industry/professional body for planned advertisements.

Pharmaceutical companies are not required to notify a regulatory body about the planned advertisement and its details. The same applies to addressees of advertisements, e.g., healthcare professionals participating in a congress sponsored by a pharmaceutical company or persons participating in such events do not have to report the sponsorship details. Internal staff regulations of an individual doctor may, however, require otherwise.

If consultation on the planned advertisement is needed, industry organizations usually provide assistance to their members, but this assistance does not guarantee the elimination of risk that an advertisement will be evaluated negatively by the relevant public authorities.

The CPI informally declares their intention to discuss the proposed advertising in order to ensure its compliance with the law. There is, however, no legal mechanism in place to request such advice and ensure it is received within a certain time, or to which reference can be made to it in order to receive justification for an action taken.

Sanctions

Administrative Sanctions

Most commonly, administrative sanctions will be applied to a MAH by the CPI. This is due to the general rule that the entity responsible for the advertising of a pharmaceutical product is the MAH for the product in question. Should the advertisement fail to comply with Pharmaceutical Law regulations, the following sanctions may be applied:

- prohibition on further broadcast or publishing of the advertisement in question;
- an order to publish the decision of the CPI and/or to issue a corrective statement in places (media) in which the banned advertisement has been published or broadcast; or
- an order to remove the ascertained breaches from public consumption (e.g., withdrawal of publications in which the prohibited advertisement appears).

The first and last orders mentioned above have an immediate effect. In most cases, the CPI will apply the sanction prohibiting further publishing or broadcast of an advertisement.

Frequently, companies will notify the CPI about observed breaches by their competitors of advertising rules. The CPI has full discretion as to whether to address such notifications, but generally they are often the first source of information regarding breaches for the CPI, and may therefore enable the CPI to take faster action if it is determined that a breach has indeed taken place.

It is possible to file a motion for reconsideration of the decision with the CPI. The motion should be filed within 14 days from the receipt of the decision. Should the first instance decision of the CPI be upheld, an appeal can then be filed with the Voivodship Administrative Court.

At the final stage, the appeal can be filed with the Supreme Administrative Court.

Pharmaceutical Law provides for instruments enabling the CPI to conduct administrative control over advertising. A MAH is obliged to keep a copy of an advertisement for two years from the end of the calendar year in which the advertisement was distributed or broadcast. Upon request of the CPI, a MAH is obliged to present:

- a copy of each advertisement aimed at the public, including information detailing the date and means of distribution of the advertisement; and
- information concerning each advertisement aimed at professionals.

Criminal Sanctions

Both Pharmaceutical Law and the Penal Code set out criminal offences relevant to the advertising of pharmaceutical products. In principle, Polish law does not establish the criminal liability of a legal person. Therefore, penal sanctions cannot be imposed on a pharmaceutical company as such, but on a natural person who is found liable for unlawful advertising. Such sanction may only be imposed by a public court after criminal proceedings have been carried out.

The Pharmaceutical Law provides for criminal liability related to the following advertising practices (Articles 128-130):

- advertising of medicinal products by an unauthorized entity;
- advertising of medicinal products not approved for marketing in Poland;
- advertising contrary to the approved SmPC;
- public advertising of prescription products or non-prescription products that have a name identical to prescription medicinal products;

- public advertising of medicinal products containing intoxicating and psychotropic substances;
- public advertising of reimbursable products or products that have a name identical to medicinal products included in reimbursement lists;
- incomplete records of supplied samples;
- delivery of samples to unauthorized persons;
- non-compliance with the requirement to store specimens of, and information regarding, advertisements;
- non-compliance with any decision ordering: the cessation of the publication of, or conduct relating to, the advertising of a medicinal product; the publication of the decision in the place in which the advertisement appeared; the publication of the corrective statement; or the removal of identified breaches;
- providing or promising to persons authorised to prescribe, or persons trading in, medicinal products any benefits with a value exceeding PLN100, in particular, gifts, prizes, or travel benefits, or the organizing or financing for such persons of promotional meetings where the hospitality exceeds the main purpose of the meeting; and
- ascribing the characteristics of a medicinal product to a non-medicinal product.

The offences listed above are punishable by a fine which may vary from PLN100 to PLN1,080,000 (approximately 250,000).

To our knowledge, penal fines have not yet been imposed against individuals acting in the name of pharmaceutical companies. However, we are aware of notifications of breaches of criminal provisions made by the CPI to the prosecution bodies.

In addition to the abovementioned criminal offences, which refer specifically to the advertising of medicinal products, there are also general criminal offences provided for in the Penal Code which may be applicable to the advertising of medicinal products and relationships between pharmaceutical companies and healthcare professionals and institutions. These criminal offences regard, in particular, passive and active corruption in the public sector (Articles 228-231) and in the private sector (Articles 296-296a).

Certain criminal offences involving corruption under the Penal Code may lead to liability for a company. This liability does not apply to criminal offences relating to the advertising of medicinal products provided for by Pharmaceutical Law, with the exception of the prohibition on ascribing the characteristics of a medicinal product to a non-medicinal product, details of which are set forth in the Law of 28 October 2002, on Liability of Collective Entities for Prohibited Acts Subject to a Penalty (Journal of Laws, No 197, item 1661, as amended). If a natural person is found guilty of a particular criminal offence in criminal proceedings, then a collective entity such as a pharmaceutical company may also be held liable, if:

- the individual was acting in the name or for the benefit of this entity within the context of representing the entity, deciding on its behalf or carrying out an inspection on its behalf (this also covers any additional responsibility that may have granted throughout the course of adopting such a role);
- the entity obtained profit resulting from the actions of the individual; and
- the entity was responsible for failure to exercise proper due diligence in the selection of the individual or had control over the actions of the individual.

If the court finds a collective entity liable, this will result in:

- a fine of between PLN1,000 (approximately EUR250) and PLN5 million (approximately EUR1.1 million), which must be no more than 3 percent of the gross income of the entity in the year in which the criminal offence was committed; and
- confiscation of the obtained benefit or profit.

In addition, the court may apply, for a period of one to five years, the following sanctions:

- prohibition on the promotion or advertising of an activity, product or service;
- prohibition on the use of public funds;
- prohibition on accepting the support of international organizations of which Poland is a member;
- prohibition on applying for public tenders; or
- an order to make a public announcement of the verdict.

Sanctions on the Basis of the Code of Ethics of INFARMA

Under the Code of Ethics adopted by INFARMA, a disciplinary court has been created and given certain supervisory powers. Should an advertisement fail to comply with the code, the disciplinary court may impose the following sanctions:

- prohibition on practices which do not comply with the code, particularly the immediate withdrawal from all media of the infringing advertisement;
- admonition or reprimand;
- notification regarding the disciplinary court's verdict to the CPI;

- notification regarding the disciplinary court's verdict to the EFPIA or the International Federation of Pharmaceutical Manufacturers & Associations;
- notification regarding the disciplinary court's verdict to the entity or entities affiliated in terms of capital with the party which violated the code; or
- order to publish single or repeated statements of the disciplinary court's verdict or specified excerpts in the indicated media.

The abovementioned sanctions can be imposed simultaneously.

No right of appeal against a verdict of the disciplinary court is provided for.

Instruments Available to Competitors

In the case of breach of advertising rules, competitors are not allowed to take direct actions via regulatory bodies against an entity which has breached these rules. They may only, as mentioned above, notify the CPI about observed breaches, which may (but does not have to) result in official action being taken by the CPI.

However, if a competitor's own interests are violated, there are certain instruments in place to enable it to claim compensation under civil law, particularly on the basis of unfair competition rules.

The rules of unfair competition are governed by the Act on Combating Unfair Competition. The following types of advertisement which endanger or violate the interests of other entrepreneurs are deemed to be acts of unfair competition:

- an advertisement which does not comply with the law or so-called "good customs" guidelines (therefore any advertisement which does not comply with Pharmaceutical

Law may be considered an act of unfair competition if it violates entrepreneurs'/consumers' interests);

- an advertisement that, due to its misleading nature, may affect a customer's decision regarding the purchase of goods or services;
- an advertisement which exploits the personal feelings of customers by inciting fear or taking advantage of prejudices or the credulousness of children;
- hidden advertising which appears to provide objective information but instead encourages the purchase of goods or services; and
- an advertisement which substantially interferes with a person's privacy.

The Act on Combating Unfair Competition also provides for detailed rules on comparative advertisements. A comparative advertisement is considered an act of unfair competition if it does not comply with "good customs" guidelines. According to Article 16.3, an advertisement is deemed to comply with "good customs" guidelines if it fulfils the following requirements:

- it is not misleading;
- it compares products and services meeting the same needs or designed for the same purpose in an honest and verifiable way and using objective criteria;
- it compares one or a few important, characteristic, verifiable and typical features of goods or services, such as price;
- it does not lead to confusion on the market between the advertiser and its competitor, their goods or services, trademarks or brands;

- it does not discredit its competitor, its goods or services, activity, trademarks or brands;
- it does not use the reputation of a trademark, designation of an entity or any other distinguishing mark of the competitor in an unfair manner; and
- it does not present the goods as an imitation of any other goods bearing a protected trademark or other distinguishing mark.

In addition, detailed rules on comparative advertisements of medicinal products are included in the Code of Ethics of INFARMA, which provides that:

- an advertisement should indicate the name, form and dosage of the compared medicinal products;
- the description of, restrictions associated with and the data used in the comparison must all be presented in a manner which is not misleading for the intended audience of the advertisement;
- the comparison may only concern medicinal products with similar properties or identical indications;
- the comparison may only concern particular characteristics of compared medicinal products and must be supported by studies;
- the comparison should concern one or several crucial characteristics and testable properties, such as the price of the compared medicinal products;
- the comparison should be objective, honest and verifiable; an opportunity to check the information presented in the comparison should be provided by indicating the source of

that information, along with the date of publication or most recent update;

- the advertisement cannot discredit competitive medicinal products or the MAH;
- the comparison of selected properties of the medicinal products should not be misleading as regards the properties being compared and properties not being compared, and cannot lead to mistakes being made in distinction between medicinal products, trademarks, entrepreneur's identification or other distinctive marks; and
- the advertisement cannot present a medicinal product as the imitation of a product bearing a protected trademark.

According to Article 17a of the Act on Combating Unfair Competition, another category of advertisement which can be regarded as an act of unfair competition is the sale of goods or services to consumers connected with providing some or all purchasers with a free bonus, which is different from the sold goods or service, unless the value of this bonus is insignificant. Interpretational doubts appear as to the "sameness" or "similarity" of the goods or services in question and to the "insignificance" of the value of the bonus.

An affected entrepreneur may seek protection in civil proceedings in a public court. The following can be sought in court proceedings:

- cessation of the prohibited activity;
- removal of the effects of the prohibited activity;
- making of one or several statements with the appropriate wording and in the appropriate form;
- remedying inflicted damage;

- surrendering unjust benefits; and
- in the case of an act of unfair competition for which the entity in breach in responsible, payment of a certain amount to a public benefit cause related to the support of Polish culture.

With the exception of claims for damages or claims for the surrender of unjust benefits, the other claims may also be raised by a regional or national organisation whose purpose is to protect the interests of entrepreneurs.

Trade Practices

The rules regarding trade practices are ambiguous. On the one hand, according to Article 53.2 of Pharmaceutical Law, the advertising of medicinal products cannot consist of offering or promising directly or indirectly benefits in exchange for the purchase of a medicinal product, or provision of evidence that a medicinal product has been purchased. On the other hand, Article 94.4 of Directive 2001/83/EC expressly excludes "normal" trade practices such as price discounts from the scope of advertising restrictions, but this has not, however, been implemented into Polish law.

In practice, Article 53.2 of Pharmaceutical Law is applied to promotions aimed at patients. The main rationale behind this provision is to discourage the offering of an incentive in the sale of a medicinal product.

In other words, therapeutic decisions should not be influenced by the prospect of economic gain. On the contrary, trade practices between manufacturers, wholesalers and retailers, relating to sales volume and other economic factors, comprise normal business conduct and should be excluded from this restriction. In fact, such trade practices are widely applied by traders when dealing with medicinal products.

Medical Devices

There are no specific rules relating to the advertising of medical devices. Rules on labelling, which in some cases may be applied to

advertising, are contained in the Act on Medical Devices of 20 May 2010 (Journal of Laws, No 107, item 679, as amended) and in its implementing regulations. General rules regarding unfair competition must also be taken into account. In particular, the advertising of medical devices cannot be misleading and must not ascribe properties of medicinal products to such devices.

Recommendations

In order to ensure compliance with the laws governing marketing activities concerning medicinal products in Poland, it should be noted that:

- the concept of advertising of a medicinal product has been defined very widely and therefore encompasses many different kinds of promotional activities relating to medicinal products;
- in order to avoid legal risk, if any doubt arises as to whether a given action constitutes either information or advertising, the stricter legal regime should be applied;
- the Polish regulations on advertising follow the implementation of EU provisions of similar law and therefore the rules for conducting advertising of medicinal products in Poland are, in principle, compliant with those applied in other European countries;
- on its webpage, the CPI publishes guides on current market practice and summaries of individual assessments conducted by Polish regulatory bodies, alongside its own decisions and reasons therefor, and it may be worth referring to such webpage for guidance before developing any advertisements or commencing promotional activities; and

- particular caution should be exercised in the case of promotional activities relating to reimbursed products due to unclear regulations in this regard (introduced recently by the Act on Reimbursement of Medicinal Products, Foodstuffs for Special Nutritional Purposes and Medical Devices of 12 May 2011).

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

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