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Practical cross-border insights into pharmaceutical advertising

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1 General – Medicinal Products

1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

The advertising of medicinal products is governed by:

a. The Pharmaceutical Law Act of 6 September 2001.
b. The Regulation of the Minister of Health of 21 November 2008 on the advertising of medicinal products.

In addition, the advertising of medicinal products is also regulated by the codes of industry organisations, e.g.:

1. The Code of Good Practice of INFARMA (The Employers' Union of Innovative Pharmaceutical Companies).
2. The Code of Ethics 2020 of Medicines for Europe (which has been adopted by the Polish Association of Pharmaceutical Industry Employers).

1.2 How is "advertising" defined?

The Pharmaceutical Law Act defines advertising as any activity that involves providing information about or encouraging the use of a medicinal product with the aim of increasing the number of prescriptions or the supply, sale or consumption of medicinal products.

1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

The law does not impose any special obligations on companies as regards meeting the statutory requirements concerning the advertising of medicinal products. The industry codes of good practice require that a responsible person should approve advertising material.

1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?

There are no legal requirements for companies to have specific standard operating procedures (SOPs) or to employ personnel. Such requirements are stipulated in the industry codes of good practice – according to the Code of Good Practice of INFARMA, advertising material must be approved by personnel for compliance with code requirements, the legal provisions and the SmPC. Moreover, in accordance with the Code of Ethics 2020 of Medicines for Europe, all materials and information intended for use outside the company must be evaluated and approved by the relevant persons before they are disseminated or used.

1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?

No, there is no requirement for such promotional material to be pre-approved by a regulatory body in Poland. The industry codes of good practice require a relevant person to approve advertising material before it is disseminated.

1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?

Yes, the authorities have the power to stop the further publication of an advertisement if they believe it has been issued in breach of the law. The Chief Pharmaceutical Inspector supervises compliance with the law on advertising and may issue a decision:

1. to cease the showing or running of medicinal product advertisements that violate applicable regulations;
2. to publish the decision in places where the advertisement that violates applicable regulations was shown and a correction of the misleading advertisement; or
3. to remedy the deficiencies.

The decisions referred to in (1) and (3) are immediately enforceable.

The above decisions of the Chief Pharmaceutical Inspector may be appealed against to the Province Administrative Court in Warsaw.

1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases, please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?

In addition to the above-mentioned decisions of the Chief

Pharmaceutical Inspector, an entity that conducts unauthorised advertising of medicinal products or advertising in violation of the provisions of the Pharmaceutical Law Act is subject to an administrative fine. The Chief Pharmaceutical Inspector supervises compliance with the regulations of the law on advertising. These rules are strictly observed by the Chief Pharmaceutical Inspector, and the most common penalty imposed by the Inspector is enforced cessation of medicinal product advertisements, e.g. for cold syrups. Competitors may raise claims under the Act on Combating Unfair Competition.

1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?

The Chief Pharmaceutical Inspector is an independent authority that supervises the advertising of medicinal products. Industry organisations may also impose penalties provided for in their codes in the event of violations and notify the Chief Pharmaceutical Inspector of such decisions, who, however, is not bound by the resolution of the industry organisations.

1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?

Advertising of a medicinal product in breach of the provisions of the Pharmaceutical Law may constitute an act of unfair competition and give rise to claims by competitors under the Act on Combating Unfair Competition. The potential scope of the claims that may be filed is very broad. A party whose interest has been infringed or threatened, in the case of an act of unfair competition may demand: the discontinuation or removal of the effects of the prohibited actions; the making of a statement (once or many times) in the appropriate form and with the required content; redressal of the damage on general terms; the handing over of unjustifiably gained profits; and the award of an appropriate sum for a social purpose, if the act was culpable. The court may also order the destruction of advertising materials. Civil proceedings under this procedure may be initiated independently of the administrative proceedings before the Chief Pharmaceutical Inspector.

2 Providing Information Prior to Authorisation of Medicinal Product

2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?

Only medicinal products that have been authorised in Poland may be the subject of advertising. Advertising medicinal products within the scope of off-label information is prohibited. These prohibitions do not limit the right to full information regarding scientific and medical progress, provided that it is not of an advertising nature.

2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?

Yes, if the information is not of an advertising nature, and cites data from medical or scientific literature, published research, as well as scientific evidence presented at scientific congresses or symposiums (provided that such evidence has been included in materials available to the public, e.g. on the website of a given scientific congress or in abstracts published in indexed medical journals (e.g. supplements); in any case, it is necessary to cite the exact source, date of publication and last update).

2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. mainstream public media), please specify.

It is unlawful for companies to issue press releases to the public about unauthorised medicines and/or off-label information. However, it can be assumed that a conference/symposium targeted at professionals is allowed.

2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?

If the information is not of an advertising nature, it can be sent to healthcare professionals. Due to the possibility of including the use of a given medicine off-label in reimbursement, information sent to healthcare professionals should also include the official retail price and the maximum amount of the contributory payment to be incurred by the patient.

2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?

The ruling amended a provision of the law – the amended provision states that such activity does not constitute the advertising of medicinal products.

2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?

This kind of information cannot be sent to institutions to enable them to plan ahead in their budgets.

2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?

It is not possible for companies to involve healthcare professionals in such activity.

3 Advertisements to Healthcare Professionals

3.1 What information must appear in advertisements directed to healthcare professionals?

Advertising of a medicinal product directed at persons authorised to write prescriptions or persons that distribute medicinal products should contain certain pieces of information referred to in Reg. 54(1) and (2) of the Pharmaceutical Law Act.

Also, pursuant to § 12(1) of the Minister of Health Regulation of 21 November 2008 on the advertising of medicinal products, advertising of a medicinal product addressed to persons authorised to issue prescriptions or persons trading in medicinal products must contain the following data:

1. the name of the medicinal product and the name commonly used;
2. the qualitative and quantitative composition of the active substances and those excipients that are essential for the proper use of the medicinal product;
3. pharmaceutical form;
4. indication or therapeutic indications for use;
5. dosage and method of administration;
6. contraindications;
7. special warnings and precautions for use;
8. side effects;
9. identification of the marketing authorisation holder;
10. the number of the marketing authorisation and the name of the authority that granted it; and
11. the information referred to in Reg. 54(1) of the Pharmaceutical Law Act.

3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?

Documentation sent to healthcare professionals should contain information that is accurate, up to date, verifiable and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the medicinal product, and should state the date on which it was drawn up or last revised. Quotations, tables and other illustrative matter taken from scientific journals or other scientific works should be faithfully reproduced and the sources indicated. All claims made in advertising must be substantiated and supported by the current state of knowledge. The advertisement may contain information derived from scientific sources, which supplement the information contained in the SmPC, provided that it is not inconsistent with the SmPC.

3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?

There is a rule that prohibits the advertising of medicinal products by healthcare professionals and by persons who it is implied have medical training.

3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?

There are no special requirements under the law. Pursuant to the industry codes of good practice, the comparison should refer to the properties of the products being compared, as defined by test results, which should be objectively reliable and verifiable. It should be possible to check the information contained in the comparison by stating the source of the information presented with the date of publication or last update.

3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?

Article 55(2)(2) of the Pharmaceutical Law Act does not explicitly limit the scope of application of the prohibition of comparing effectiveness only to cases where it is possible to recognise the products or methods being compared.

No, it is not possible to refer to a competitor's product or indication that has not yet been authorised in our jurisdiction.

3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?

The distribution of scientific papers and/or proceedings of congresses to healthcare professionals is permitted. The advertisement may contain information derived from scientific sources, which supplement the information contained in the SmPC, provided that it is not inconsistent with the SmPC.

3.7 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?

"Teaser" advertisements are not permitted under the law.

3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?

There is a prohibition on advertising medicinal products that have not been approved for sale on the territory of Poland and on advertisements that contain information that is not compatible with the SmPC. So, in this case, such promotion of medicinal products is forbidden.

4 Gifts and Financial Incentives

4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?

The advertising of a medicinal product involving the free supply of samples may only be directed to persons authorised to write prescriptions on the following conditions:

1. a person authorised to write prescriptions has sent a written request to a medical or sales representative to supply samples of a medicinal product;
2. the person supplying samples keeps documentation of the samples supplied;
3. each sample supplied is not larger than the smallest package of a medicinal product approved for sale on the territory of the Republic of Poland;
4. each sample supplied is marked "free sample – not for sale";
5. the SmPC or the Veterinary SmPC for a veterinary medicinal product is attached to each sample; and
6. the number of samples of the same medicinal product supplied to the same person is not more than five packages over a year.

Advertising of a medicinal product that consists of the free provision of samples of it may not concern medicinal products containing narcotic drugs or psychotropic substances.

4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.

It is prohibited to direct at persons authorised to write prescriptions and persons that distribute medicinal products advertising involving the gift, offer or promise of material benefits, presents and other inducements, prizes, trips and the organisation and financing of meetings to promote medicinal products during which hospitality exceeds the main purpose of those meetings.

Accepting the benefits mentioned above is prohibited.

These rules do not apply to the giving or accepting of items valued at under PLN 100 and relevant to the practice of medicine or pharmacy that bear a mark advertising a given firm or medicinal product.

4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply? If monetary limits apply, please specify.

There are no rules prohibiting donations to a hospital. Pursuant to the industry codes of good practice, donations or grants are presumed to be permitted when they are made for the clearly stated purpose of supporting health research or education and are documented and the documentation is kept by the donor.

4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?

No, it is not possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns. The advertising of a medicinal product addressed to healthcare professionals is permitted and may also emphasise the advantages of an advertised product and the benefits that the patient may gain from its use, but it should not interfere with the ability of the healthcare professionals to make their own decisions.

4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?

Directing advertising involving any benefits, including discounts, at persons authorised to write prescriptions and persons that distribute medicinal products is prohibited.

The issue of transfer of benefits to healthcare professionals is also regulated in Article 49(3) of the Reimbursement Act, which prohibits any company that manufactures or trades in reimbursed products from providing any incentives (e.g. conditional sales, discounts, rebates, discounts, packages and loyalty programmes, donations, prizes, trips, games of chance, *pari-mutuel* betting, all forms of lending, tied transactions, vouchers and coupons of any kind, as well as the granting of other unnamed pecuniary or personal benefits to beneficiaries and persons entitled).

4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable? If so, what rules apply?

Linking the purchase of a medicinal product with additional medical or technical services or equipment is prohibited.

4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?

The general rule is if a medicinal product does not meet the quality requirements specified for it, the Chief Pharmaceutical Inspector will make a decision on whether the medicinal product is to be withdrawn from the market. There are no regulations that would allow a refund scheme to be offered.

4.8 Are more complex patient access schemes or managed access agreements, whereby pharmaceutical companies offer special financial terms for supply of medicinal products (e.g. rebates, dose or cost caps, risk share arrangements, outcomes-based schemes), permitted in your country? If so, what rules apply?

More complex patient access schemes or managed access agreements, whereby pharmaceutical companies offer special financial terms for the supply of medicinal products, are not permitted.

4.9 Is it acceptable for one or more pharmaceutical companies to work together with the National Health System in your country, pooling skills, experience and/or resources for the joint development and implementation of specific projects? If so, what rules apply?

Cooperation between medical entities or other institutions of the healthcare system is permissible, if such cooperation does not have an advertising or sponsorship nature, which may be considered corruptive activity.

4.10 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?

There is no explicit prohibition to sponsor continuing medical education. In accordance with the industry codes of good practice, companies may not finance the participation of professionals in courses certified by accredited further training institutions (e.g. for example, a Master's degree), because these are not educational meetings or conferences, but forms of education that provide significant personal benefits to the individuals concerned.

4.11 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?

As a rule, contact between a pharmaceutical company and a healthcare professional must be based on clear and transparent rules. Companies striving to disclose their activities and expenses incurred for the benefit of physicians, medical entities or patient organisations introduce industry regulations on the basis of which they disclose the transfer of benefits. Benefits transferred to medical professionals, such as costs incurred in connection with the sponsorship of promotional meetings and scientific events and remuneration for the provision of services, are subject to disclosure. The activities of companies may be subject to investigation by the anti-bribery/anti-corruption supervisory authority. It must be noted that compliance with the rules on advertising is dealt with by a pharmaceutical inspection that is independent of the anti-corruption bodies.

5 Hospitality and Related Payments

5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?

One of the forms of advertising medicines addressed to healthcare professionals provided for by law is the sponsorship of promotional meetings of medicinal products; Article 58(1) of the Pharmaceutical Law Act allows them, provided that the hospitality offered to the participants of the meetings does not go beyond the main promotional purpose of the meetings. This means that any non-substantive elements related to the participation of invited persons in the meeting, such as refreshments, should be incidental and should not obscure the main purpose of the meeting, in particular they should not be the reason for its organisation or the main attraction of the meeting (trip or award). It makes no difference if the hospitality takes place in another country.

5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?

In accordance with Article 52(2)(6) of the Pharmaceutical Law Act, sponsoring conferences, conventions and scientific congresses for persons authorised to issue prescriptions or persons marketing medicinal products is permitted. The hospitality offered at events organised solely for professional and scientific purposes should always be limited to the main scientific purpose of the event. It is permissible for the pharmaceutical company to cover the costs of the registration fee covering participation in the lectures, and additionally the costs of travel, accommodation and food of the participant on the days on which the event takes place. The company cannot cover the costs of persons accompanying doctors or pharmacists to scientific conferences, e.g. their family members. In addition, the industry codes of good practice specify quota limits related to, for example, food.

5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?

The pharmaceutical company will be held fully responsible by the regulatory authorities. For example, in one of its decisions, the Chief Pharmaceutical Inspector banned advertising of a drug that was contained in an invitation to the exhibition stand of a pharmaceutical company during a scientific congress. A competition was organised at this stand exclusively targeted at doctors, who received prizes, including a car navigation system, jewellery and vouchers for beauty salons.

5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?

In accordance with the Code of Medical Ethics, it is possible for doctors to provide expert services (training and research).

5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?

In accordance with the Code of Medical Ethics, doctors may accept payment from the manufacturer of medicines or medical devices

(equipment and medical equipment) for the work done (conducting training and research that increases medical or professional knowledge) if this payment is commensurate with their work.

5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?

Doctors should not participate in research that has the purpose of promoting products.

6 Advertising to the General Public

6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?

The advertising of a medicinal product to the general public cannot include:

1. a medicinal product being presented by well-known persons, scientists, persons with medical or pharmaceutical education or suggesting that they have such education; and
2. references to recommendations of well-known persons, scientists, persons with medical or pharmaceutical education or suggesting that they have such education.

Moreover, the advertising of a medicinal product to the general public may not contain material that:

1. suggests that:
   a. a medical consultation or surgical operation is unnecessary, in particular by offering a diagnosis or by suggesting treatment by mail;
   b. even a healthy person's health can be enhanced by taking the medicinal product;
   c. a person's health could be affected by not taking the medicine (this does not apply to the vaccines referred to in Article 57(2));
   d. a medicinal product is a foodstuff, cosmetic or other consumer product; or
   e. the safety or efficacy of the medicinal product is due to the fact that it is natural;
2. suggests that the effects of taking the medicinal product are guaranteed, are unaccompanied by adverse reactions or are better than or equivalent to those of another treatment method or treatment with a medicinal product;
3. could, by citing detailed descriptions of cases and symptoms of illness, lead to erroneous self-diagnosis;

3a. refers, in improper, alarming or misleading terms, to therapeutic indications; or

4. contains improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury or of the action of a medicinal product on the human body or parts thereof.

The advertising of a medicinal product to the public should contain the following necessary particulars:

1. the name of the medicinal product;
2. the name of the active substance in common use and, in the case of a medicinal product containing more than three active substances, the statement: "combination product";
3. the dose of the active substance or the concentration of the active substance, except in the case of a combination product;
4. pharmaceutical form;
5. the indication or therapeutic indications for use;
6. contraindications; and
7. an indication of the responsible person.

The data mentioned above must be submitted in wording that is consistent with the SmPC.

6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?

There is a prohibition on advertising prescription-only medicinal products to the general public.

6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?

It is assumed that such information campaigns are permitted. The wording of the provision sometimes may give rise to a precautionary interpretation, according to which advertising directed at the general public, the main protagonist of which is the vaccine itself as a prescription-only medicinal product, is prohibited, but information campaigns on vaccinations are permitted, even though they indirectly identify specific vaccines.

6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?

The advertising of medical products covers, among others, sponsorship of conferences, conventions and scientific congresses that are only for persons authorised to write prescriptions or persons that distribute medicinal products.

6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?

There are no specific restrictions that apply to describing products and research initiatives as background information in corporate brochures/Annual Reports. Such activity should not be considered advertising of a medicine but information of a non-advertising nature.

6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?

There are no specific rules under the law governing this matter. However, in accordance with the industry codes of good practice, pharmaceutical companies must comply with certain requirements. For example, such cooperation may not concern the advertising of a medicinal product, and must be transparent and its purpose and scope clear.

6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?

Giving samples of medicines to pharmacists or directly to patients is prohibited. In accordance with the industry codes of good practice, any cooperation between the company and the

patient organisation that involves financial support, significant in-kind support (e.g. products or equipment) must be in writing, specifying, amongst other things, the amount of funding, purpose and a description of significant in-kind support.

6.8 What are the rules governing company funding of patient support programmes?

Pharmaceutical companies have the right to engage patient organisations to provide services exclusively to support healthcare or research. It is permissible to support organisations with non-monetary benefits (training). Patient support programmes are company-sponsored, non-promotional arrangements designed to help patients who have agreed to such programmes, either directly or through their doctor, to better understand and/or manage their disease. Any cooperation between the company and the patient organisation that involves financial support, significant in-kind support (e.g. products or equipment) must be in writing, specifying, amongst other things, the amount of funding, purpose and a description of significant in-kind support.

7 Transparency and Disclosure

7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?

In accordance with the provisions of the Pharmaceutical Law Act, control over the conduct of clinical trials is exercised by the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (URPL).

The Central Register of Clinical Trials is a data register kept in the form of an IT system by the URPL. Information regarding new clinical trials is entered into the register. The register includes:

1. the title of the clinical trial;
2. the clinical trial protocol number;
3. the clinical trial number in the European Clinical Trials Database (EudraCT);
4. the names and addresses of the research centres where the clinical trial is being conducted;
5. the definition of the clinical trial phase;
6. the name of the investigational medicinal product;
7. the name of the active substance;
8. the number of participants in the clinical trial;
9. the characteristics of the groups of clinical trial participants;
10. the name, surname and place of residence or the name and seat of the sponsor;
11. the name, surname, title and academic degree of the researcher;
12. the name, surname, title and academic degree of the clinical trial coordinator, if participating in such trial;
13. the date of submission of the clinical trial;
14. the end date of the clinical trial;
15. information on the decision regarding the clinical trial; and
16. the clinical trial number in the Central Register of Clinical Trials.

7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?

There are no specific rules governing this matter – it is the subject of self-regulation by the pharmaceutical industry. Members of industry organisations are required to report annually on transfers of benefit provided by them to healthcare professionals, healthcare organisations and patient organisations. In accordance with the industry codes of good practice, the disclosure of benefits provided to medical professionals includes costs incurred in connection with the sponsorship of promotional meetings and scientific events, and fees for the provision of services. The disclosure is to take place on the company's website. The obligation to disclose any benefits applies to code signatories that conduct activities in the territory of Poland. As a rule, the information is provided on an individual basis by assigning each possible identified beneficiary an amount corresponding to the value from reports presented to him/her in a given settlement period. If, on the other hand, it is not possible to assign a given benefit to an individual entity, the information is provided collectively as the total amount transferred to unidentified beneficiaries.

7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?

Yes, this matter is the subject of self-regulation by the pharmaceutical industry. Members of industry organisations are required to report annually on transfers of benefit provided by them to healthcare professionals, healthcare organisations and patient organisations. In accordance with the industry codes of good practice, the disclosure of benefits provided to medical professionals includes costs incurred in connection with the sponsorship of promotional meetings and scientific events, and fees for the provision of services. The disclosure is to take place on the company's website. The obligation to disclose any benefits applies to code signatories that conduct activities in the territory of Poland. As a rule, the information is provided on an individual basis by assigning each possible identified beneficiary an amount corresponding to the value from reports presented to him in a given settlement period. If, on the other hand, it is not possible to assign a given benefit to an individual entity, the information is provided collectively as the total amount transferred to unidentified beneficiaries.

7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?

As a rule, the information is provided on an individual basis by assigning each possible identified beneficiary an amount corresponding to the value from reports presented to him in a given settlement period. If the healthcare professional refuses to agree, the information is provided collectively as the total amount transferred to unidentified beneficiaries.

8 Digital Advertising and Social Media

8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?

The Pharmaceutical Law Act does not specify in what forms advertising addressed to the public may be conducted. The Regulation on the advertising of medicinal products distinguishes between advertising in visual, audio and audio-visual form, but does not stipulate that a certain form must be used. Advertising of medicinal products can, therefore, be carried out in traditional forms or via the Internet (e.g., apps, social media). There are no indicated distribution channels for such promotion and the law does not prohibit the use of websites, apps or social media to promote medical products. As with advertising in the press, advertising aimed at professionals is not permitted on websites accessible to the public. The Chief Pharmaceutical Inspector also supervises Internet advertising within the scope of the available tools.

8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?

There are no processes/or verification steps required by law to ensure that advertising intended for healthcare professionals on websites, apps and social media is only accessible by professionals. A log-in requirement is widely recognised as providing an adequate level of security, in addition to tools to verify the user's entitlement; for example, by requiring a professional licence number and contact details to confirm the user's identity. Using a tick box is also common and considered sufficient. However, it is the company's responsibility to present the advertisement in such a way that it does not reach people for whom it is not intended.

8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?

Advertising of medicines may be carried out only by the marketing authorisation holder or the entity authorised to import in parallel or on behalf of these entities. Advertising medicines by an unauthorised person is punishable by a fine (Article 129(1) of the Pharmaceutical Law Act). In one of the decisions of the Chief Pharmaceutical Inspector, the advertising of a medicinal product was considered to be actions taken by entities outside the pharmaceutical industry, primarily by newspaper publishers who, on their own initiative, published selected information about a specific drug, regarding its benefits or use.

8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?

Those who advertise medicinal products by audio-visual, visual or audio means are required to display a special disclaimer, the content and method of which are laid down by law. In addition, such advertising should comply with other requirements for advertising to the public.

8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?

There are no specific rules or laws controlling the use of social media by companies – general rules on advertising of medicinal products apply. According to the industry codes of good practice, certain rules require, *inter alia*, that social media messages must comply with certain standards. Companies must ensure that the content and information are only available to the right audience and that the content and information are acceptable when read as a stand-alone message.

8.6 Are there any restrictions on social media activity by company employees using their personal accounts, including interactions with third parties through "likes", "applauds", etc.?

Pursuant to the industry codes of good practice, companies should have an appropriate social media policy for employees to ensure that individual employees monitor the company's social media and take appropriate action, including editing comments and ensuring likes do not cause the content to reach the wrong recipients.

8.7 Are there specific rules governing advertising and promotional activity conducted virtually, including online interactions with healthcare professionals, virtual meetings and participation in virtual congresses and symposia?

There are no specific rules governing this matter.

9 Developments in Pharmaceutical Advertising

9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?

There have been no significant developments in relation to the rules relating to pharmaceutical advertising in the last year under Polish law. However, there is a noticeable trend towards pharmaceutical companies making data on the benefits provided to healthcare professionals public. Mainly, this trend is reflected in generally applicable regulations (e.g. in the USA and France), but in other countries, it is the subject of self-regulation by the pharmaceutical industry (e.g. Poland). Steps to differentiate and separate the advertising of dietary supplements and OTC medicinal products in the legislation have been taken in order to not mislead patients as to the nature of the advertised product.

9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?

It will be important for Polish law to clarify the rules for advertising off-label products. As the law also allows for the use of a given medicine off-label to be reimbursed (Article 40 of the Reimbursement Act), it will be necessary to determine the principles of advertising such medicines.

9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

The Chief Pharmaceutical Inspector has limited possibilities to enforce compliance by companies. Where proceedings are pending in connection with unlawful advertising of medicinal products, the companies themselves will refrain from further publication of such advertising, which makes it necessary to discontinue the proceedings, and thus the practice of jurisprudence is limited.

Natalia Falęcka-Tyszka advises medical companies, manufacturers and distributors of medicinal products and medical devices, and other entities operating in the healthcare sector that must reflect the specific requirements of this sector in their operations.
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