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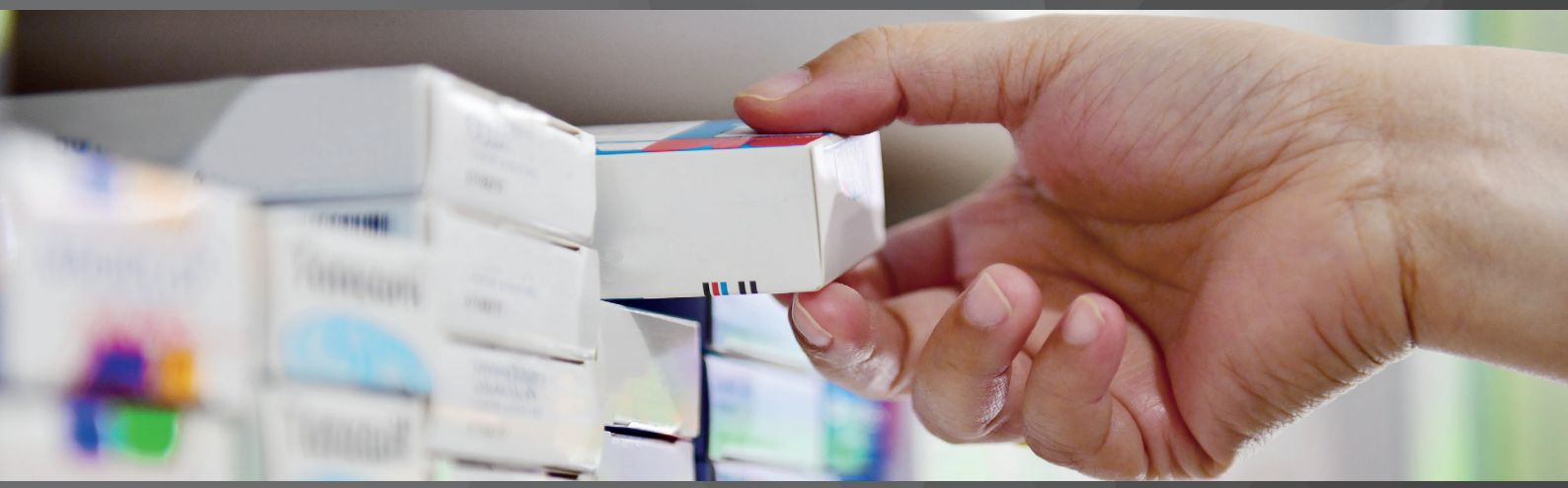

Pharmaceutical Advertising 2021

A practical cross-border insight into pharmaceutical advertising

18th Edition

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Poland

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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 primary sources for the advertising of medicinal products are: the Act of 6 September 2001 on the Pharmaceutical Law ("Pharmaceutical Law"); the Regulation of the Minister of Health of 21 November 2008 on Advertising of Pharmaceutical Products ("Regulation on Advertising of Pharmaceutical Products"); and the Act of 12 May 2011 on Reimbursement of Medicines, Foodstuffs Intended for Particular Nutritional Uses and Medical Devices ("Act on Reimbursement").

Some additional requirements, regarding comparative advertisements and fair market practices, are provided for in the Act of 16 April 1993 on Combating Unfair Competition and the Act of 23 August 2007 on the Prevention of Unfair Market Practices.

Additional rules and guidelines are provided by codes of conduct and ethics:

- INFARMA (Polish union of innovative pharmaceutical companies) Code of Good Practices (implementing in Poland the EFPIA Code of Practice). Since 1 January 2021, INFARMA's new Code of Good Practices has been in force, replacing the existing Code of Good Practice for the Pharmaceutical Industry and the Transparency Code;
- IFPMA Code of Practice; and
- Physicians' Code of Ethics.

1.2 How is "advertising" defined?

The advertising of a medicinal product is broadly defined in the Pharmaceutical Law as any activity consisting of providing information or encouraging the use of a product with the purpose of increasing the number of issued prescriptions or the supply, sale or consumption of medicinal products.

The general outline of what we should understand under this term gives us the examples indicated in the Pharmaceutical Law, such as: the advertising of medicinal products addressed to the general public or to persons qualified to prescribe them or to supply them; visits by medical and sales representatives to persons qualified to prescribe medicinal products or to supply them; the supply of samples of medicinal products; and sponsorship of promotional meetings, conferences, meetings and scientific congresses.

On the other hand, the following materials are not considered advertising of medicinal products:

- information on (and attached to) packaging conforming with marketing authorisation ("MA");
- correspondence containing informative materials that are not of a promotional nature and are needed to address questions about a particular medicinal product (including materials referring to unauthorised products available on a named-patient basis);
- informative non-public announcements relating to packaging changes and adverse reaction warnings (which may not include references to product properties);
- trade catalogues or price lists containing no references to product properties or therapeutic indications; and
- information regarding human and animal health or diseases, provided that it includes no direct or indirect reference to medicinal products.

The above shows that the concept of "advertising" must be distinguished from simply informative material of a non-promotional nature. The main difference between information and advertising is a real aim of disseminating the information – when it is other than increasing the use of medicine, it should not be considered advertising. Nevertheless, this distinction may be sometimes difficult to determine.

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?

There are no explicit requirements on formal arrangements consisting of "sign off" or approval of promotional materials. However, Marketing Authorisation Holders ("MAHs") are obligated to keep draft advertisements for two years from the end of the calendar year in which an advertisement was disseminated.

Upon request of the Pharmaceutical Inspection authorities, a MAH must present:

- a copy of each advertisement addressed to the public, including details on the date and means of distribution of the advertisement; and
- information on each advertisement addressed to persons qualified to prescribe medicinal products or persons supplying medicinal products.

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 is no obligation to implement SOPs nor to employ personnel with a specific role related to advertising under Polish law.

However, companies may only employ as medical or commercial sales representatives persons having sufficient technical knowledge which allows them to present adequate and accurate information on the advertised medical products. The MAH shall also ensure that such persons collect and send to the MAH all information on medicinal products and especially inform the MAH about any adverse reactions reported by the persons visited. Additionally, the MAH shall provide a training system for its medical representatives.

In order to decrease risks related to illegal advertising, it is recommended for companies to implement internal organisational and procedural systems guaranteeing their full control over advertising and promotional activities.

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?

There is no requirement for pharmaceutical companies to notify the authority about the planned advertisement or its details. This applies also to addressees of such advertisements (e.g. persons participating in the events sponsored by a pharmaceutical company).

Polish law does not provide any legal mechanism to acquire in advance an approval of the authority for planned activity. Pharmaceutical companies may, however, request industry organisations for such advice. They usually provide such assistance to their members.

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?

The Main Pharmaceutical Inspector may order, by way of a decision: discontinuation of the advertisement incompliant with the regulations in force; publication of the issued decision at places where the advertisement was previously published; and publication of a corrective statement or removal of the identified infringement. The above decisions shall be immediately enforceable. In most cases, the Main Pharmaceutical Inspector applies the sanction prohibiting further publication or broadcast of the advertisement infringing the applicable provisions regulating the advertising of pharmaceutical products.

The decision may be appealed by way of a motion for re-examination (the case is then once again assessed by the Main Pharmaceutical Inspector), and may be later submitted for review by the administrative courts.

In addition to the abovementioned, the rules of unfair competition may apply. Namely, if the advertisement is considered to be an unfair commercial practice or act of unfair competition, the President of the Office of Competition and Consumer Protection may issue a decision ordering the advertiser to cease infringement. The entrepreneur whose interest is threatened or infringed by the advertisement may also seek protection in court proceedings (i.a. cessation of the prohibited practices and removal of the effects of the prohibited practices may be sought).

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?

Apart from the sanctions mentioned in question 1.6 above (e.g. cessation of the prohibited practices), in a case of non-compliance with the rules governing advertising, a company may be subject to a fine, which is imposed by the court in criminal proceedings.

Moreover, non-compliance with the prohibition of giving benefits of any kind (financial or personal) to healthcare professionals authorised to write prescriptions may result in fines of up to 5% of the turnover of the reimbursed products (or if there was no sale of any products for which a reimbursement decision was issued – a fine of 100 times the value of the benefit).

In case of violation (or threat of violation) of a competitor's own interests, certain measures may be taken, particularly on the basis of unfair competition rules. The competitor may demand to:

1. cease the prohibited activity;
2. eliminate its effects;
3. publish one or several corrective statements;
4. pay damages and accounts of profits; and
5. if the activity is deliberate – pay a specific amount to a social cause.

The claims listed in points 1–3 and 5 above may also be raised by a national or regional organisation protecting the interests of entrepreneurs.

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?

Self-regulatory bodies and competent authorities operate separately from one another. As a rule, the authorities may investigate matters constituting a breach of law and a relevant code independently from self-regulatory bodies. Accordingly, any decisions regarding advertisements already taken by a self-regulatory body are not binding for authorities.

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?

The actions which may be taken on the basis of unfair competition are listed in question 1.7 above. Actions based on unfair competition law may be taken by the competitors of a given entity and to a limited extent also by a national or regional organisation protecting the interests of entrepreneurs (i.e. competitors of an entity being in breach). The actions based on unfair market practices may be taken by consumers and to a limited extent also by the Ombudsman, the Financial Ombudsman, a local commissioner of the consumers and a national or regional organisation protecting the interests of consumers might also instigate proceedings.

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)?

The advertising of medicinal products that are not authorised for the Polish market (both advertisements addressed to the general public and to professionals) is prohibited under the Pharmaceutical Law. Nevertheless, providing information on unauthorised medicines to healthcare professionals upon their request if it is not of a promotional nature should be allowed.

However, some objections may arise if a pharmaceutical company provides such information regardless of the request or consent of a healthcare professional. It may be considered advertising and, since it is not based on the SmPC, may constitute a violation of the law.

From a practical point of view, determining the admissibility of a given communication requires analysis of its form and the way it was presented. As a general rule, presenting any information at a meeting sponsored by the pharmaceutical company is more likely to be considered unlawful than presenting data at an independent event.

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

Information on unauthorised medicines or off-label indications may not be included in advertisements. However, the Main Pharmaceutical Inspector is of the view that such information may be published in a professional literature. Moreover, the authority stated that providing healthcare professionals with a copy of the reimbursement decision for certain off-label indications should be permissible, since it constitutes an action of a strictly informative character.

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.

In general, there are no specific requirements regarding press releases. Issuing press releases about unauthorised medicines or off-label information would most likely be considered advertising. However, there are differences depending on the target audience. Publishing information about unauthorised medicines and/or off-label information in professional media would be acceptable as long as the information is of purely scientific nature. Please also see question 2.2.

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

Polish law does not expressly allow such information to be provided even if requested by healthcare professionals. However, if such information is not of a promotional nature, in particular, if it is a response to a submitted question about the product, it should not be considered an advertisement and would therefore be allowed. Any proactive activity in this respect may be considered promotional.

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?

In 2011, the Pharmaceutical Law was amended. By virtue of this amendment, trade catalogues and price lists containing exclusively basic information on a product (including non-approved products imported on a named-patient basis), such as name, dosage, form and price, are not considered advertising, provided that their contents do not include any claims as to the product's properties or its therapeutic indications.

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?

Polish law does not provide for such an exception. In practice, such provision of information is likely to be considered promotion of unauthorised medicines, which is prohibited under Polish law.

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?

Healthcare professionals cannot be involved in any activity of a promotional character. Pharmaceutical companies may, however, engage physicians for clinical trials, observational studies or other research projects, which are not of a promotional nature. Thus, such research exercises should be conducted for a specific scientific purpose. In this respect, the INFARMA Code of Good Practices may be helpful with its detailed rules on non-interventional studies. They set standards for such studies in order to prevent their misuse for promotion of pharmaceutical products.

3 Advertisements to Healthcare Professionals

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

As a general rule, advertisements addressed to healthcare professionals must contain information consistent with the SmPC and the dispensing category. The Regulation on Advertising of Pharmaceutical Products sets forth the extensive list of specific information that must be provided, which includes: the name of the medicinal product and the international non-proprietary name; qualitative and quantitative composition of active substances and additives that are essential for proper application

of the medicinal product; the pharmaceutical form, therapeutic indications or indications for use, dosage and method of administration, and contraindications; special warnings and precautions for use; adverse reactions; the MAH; the MA number; and the name of the authority that granted the authorisation.

With regard to products reimbursed from public funds, information concerning its official retail price and the maximum surcharge amount paid by the patient must also be provided.

Moreover, the information should be reliable, up to date, verifiable and sufficiently complete to enable the addressee to make his or her own opinion of the therapeutic value of the medicinal product concerned. It should be also indicated when the information was prepared or last updated. Any quotations, tables and visuals from scientific papers must be truly and faithfully copied and the source of information disclosed.

The pharmaceutical company should ensure such an advertisement cannot be accessed by the general public. For instance, when presented on the Internet, the website should require recipients to log in and verify their professional status. In case of non-compliance with this requirement, the pharmaceutical company may be liable for the unlawful advertising of medicinal products to the public.

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?

In general, all the information contained in the advertisement must be consistent with the SmPC (e.g. it is not possible to refer to studies showing possible off-label use of the product). However, the advertisement may refer to scientific evidence not explicitly included in the SmPC, as far as they remain compliant with the SmPC.

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

Yes, such restrictions apply with respect to the advertising to the general public. The advertising of medicinal products addressed to the general public shall not include presentation or recommendation of the medicinal product by persons publicly known, scientists as well as healthcare professionals or by persons who only suggest that they hold a medical or pharmaceutical degree.

Moreover, participation of physicians in the promotion of medicinal products is not positively perceived by Polish physicians' self-governing bodies as it is considered not compliant with the Physicians' Code of Ethics.

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?

Polish law does not cover such specific requirement. However, it seems that general rules on comparative advertisements should apply.

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?

A comparative advertisement is generally permitted under Polish law, but it shall meet the requirements set out in the Act of 16 April 1993 on Combating Unfair Competition. Such advertising must: not be misleading; compare only the products and services fulfilling the same needs or intended for the same purpose in an objective and verifiable manner; compare few material, characteristic, verifiable and typical features; not create confusion in the market between the advertiser and its competitor or between compared products, trademarks, and logos; not discredit a competitor's products, distinguishing marks, trademarks, names or business; in respect of products protected by a geographical name of origin, relate to products bearing the same distinguishing marks; not use the reputation of distinguishing marks of the competitor in an unfair manner; and not present a product as another product which bears a protected trademark or distinguishing marking.

Furthermore, with regard to the advertising of a medicinal product directed to patients, stating that taking the medicinal product guarantees a better effect or equivalent effect in comparison to another medicinal product is not allowed.

The advertising of products which have not yet been authorised on the Polish market is forbidden; therefore, comparative advertising by referring to non-authorised products or indications could violate this rule.

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

In general, scientific papers as well as proceedings of congresses, which refer either directly or indirectly to a medicinal product, may be regarded as advertising. If they do not constitute endorsement to use/purchase/prescribe a given product, but only present scientific issues, such papers may be provided to healthcare professionals.

Nonetheless, such distribution may fall within the scope of rules on gifts to healthcare professionals, since they apply to any material benefits addressed to the healthcare professionals by pharmaceutical companies (as indicated in question 4.2 below).

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?

Such activity is not expressly prohibited; therefore, in practice, it requires case-by-case analysis to state whether it was undertaken for advertising purposes. Such "teaser" advertisements would not fall within the definition of pharmaceutical advertising as far as such information is not aimed at increasing the number of prescriptions, deliveries, sales or consumption of a medicinal product.

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?

Under Polish law, all data contained in advertising aimed at the

general public must comply with the information set out in the product's SmPC. Accordingly, advertising for a particular indication will be possible only if it is included in the SmPC. The holder of the MA for Product A will be able to indicate in the SmPC that Product A may be used with Product B in that indication, provided that the SmPC will be approved by the competent authorities. If the SmPC has been accepted, such combination use may be promoted by the holder of the MA for Product A.

The holder of the MA for Product B cannot promote such combination use until it is expressly allowed under Product B's SmPC. Therefore, the holder of the MA for Product B must first vary the SmPC for Product B before promoting such combination use.

4 Gifts and Financial Incentives

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

Samples of medicinal products may be provided only to professionals entitled to prescribe medicinal products. In this respect, the following requirements shall be met:

- a given healthcare professional has to request a respective company to provide him/her with samples in writing (such person may receive a maximum of five samples of each medicine per year);
- the entity supplying the sample must maintain appropriate records of the supplied samples;
- each sample cannot be larger than the smallest packaging unit authorised for marketing sale in Poland;
- samples should bear the claim "free sample – not for sale" (in Polish: "*próbka bezpłatna – nie do sprzedaży*") and be accompanied with the SmPC; and
- samples of intoxicants and psychotropic products cannot be provided.

Some additional requirements are set out in the INFARMA Code of Good Practices, which states that it is prohibited to provide more than four samples of the same medicinal product to one person within a calendar year and to provide samples of a given medicinal product after two years from the first time this person made a written request to obtain samples of the given medicinal product. Moreover, samples may be provided only with respect to new medicinal products, where a medicinal product shall be considered new:

- for five years from the first placement of the product on the market in Poland; or
- if it is covered by a MA, which is extended to include a new indication, for five years from the date on which the decision extending the MA to include the new indication becomes effective.

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.

The Pharmaceutical Law expressly allows gifts of a value not exceeding PLN 100 to be provided to healthcare professionals, provided that they have been marked with the company logo or the name of the medicinal product and they are of a medical or pharmaceutical nature. Please note that, in case of doctors, Polish courts have previously considered even gifts of a value of PLN 50 to constitute bribery.

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.

As a general rule, donations to institutions such as hospitals, e.g. donations of money or equipment, are allowed. Such donations cannot be given to an individual person employed in such an institution or to private entities, e.g. businesses operated by physicians, as it may be considered an unlawful donation to a physician. However, even a donation to a hospital may be questionable if its aim was clearly to influence the decision-making process of the institution or professionals in favour of the donor. Donations or gifts given to healthcare organisations are only allowed if:

- they are explicitly intended to support healthcare or research;
- they are documented and the documentation is kept by the donor; or
- they are not incentives to recommend, prescribe, purchase, supply, sell or use specific medicinal products.

There are no specific monetary limits provided.

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?

The Pharmaceutical Law does not allow free donations to healthcare professionals (see question 4.2 above). It should prevent healthcare professionals from being influenced by the pharmaceutical companies and the prospect of economic gain. Physicians should prescribe medicinal products solely on the basis of objective assessment. Such assessment may be supported by educational materials furnished by a pharmaceutical company, but must primarily result from the doctor's freedom of conscience and current medical knowledge.

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?

Under the Pharmaceutical Law, advertising of a medicinal product shall not involve offering or promising any benefits directly or indirectly for purchasing the medicinal product or for delivery of evidence that the medicinal product has been purchased. The offer of a volume-related discount to institutions purchasing medicinal products may be considered an unlawful material benefit. Moreover, with regard to reimbursed medicines, a manufacturer of reimbursed medicinal products cannot differentiate prices of such products in agreement with wholesalers as this will mean the prices are fixed. For reimbursed products, all other forms of incentives are also prohibited, e.g. conditional sale, discount, donation and participation in loyalty programmes.

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?

In general, provision of additional services or equipment shall be remunerated in order not to be considered an unlawful material benefit connected with the purchase of products. With regard to the reimbursed products, any volume-related additional services could also be regarded as a prohibited incentive or benefit under the Act on Reimbursement. Under the Act on Reimbursement, no incentives or benefits of any kind (financial or personal) may be offered to healthcare professionals authorised to write prescriptions.

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?

Refund schemes addressed to the general public are likely to be considered advertising; therefore, they are not allowed for prescription-only medicines. Similarly, such schemes cannot be offered in respect of reimbursed products as it would constitute forbidden incentives.

Based on the above, a refund scheme could, in principle, be acceptable for non-prescription medicines. However, it is likely that offering a refund scheme could violate rules on combating unfair competition.

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?

In general, any discount may be considered a benefit and therefore may not be permissible. However, such solutions may be implemented within the negotiation of the reimbursement price for a medicinal product. The Act on Reimbursement introduces an open scope of solutions which may be applied as a risk-sharing instrument, including, among others, risk-sharing agreements ("RSA"). The Act on Reimbursement, however, does not provide for any specimens of a document which would cover the content of RSA. Thus, specific solutions are developed under negotiations, which are conducted in a non-standardised way.

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?

Polish law does not explicitly cover this matter. Similar to cooperation between pharmaceutical companies and healthcare organisations, such cooperation should be allowed if it applies to activities supporting healthcare or scientific progress, which are not incentives to recommend, prescribe, purchase, supply, sell or use specific medicinal products. Such cooperation must also be in compliance with anti-corruption laws.

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

Generally, Polish law does not prohibit pharmaceutical companies from sponsoring the continuation of medical education, provided that sponsorship is not aimed at the promotion of a given company or a given product, in which case it will be regarded as advertising.

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?

The Polish Criminal Code sets forth general anti-bribery rules, which are also applicable to interactions between pharmaceutical companies and healthcare organisations and individuals serving public functions. Both taking and giving bribes is prohibited under the Polish Criminal Code. The crime of corruption of persons holding public functions carries a penalty of imprisonment for six months to eight years or, if more severe, 12 years.

Moreover, apart from the above, there is also a possibility of corporate criminal liability, which is regulated under the Act on the Liability of Collective Entities. This Act states that if an individual has been found guilty of a particular criminal offence in a criminal proceeding, then a collective entity (such as a pharmaceutical company) may also be held liable under certain circumstances.

Criminal proceedings in Poland in corruption cases are conducted in the form of an investigation by public prosecutors or the Central Anti-Corruption Bureau. They are generally independent from the supervision of the pharmaceutical advertising performed by the Main Pharmaceutical Inspector. Therefore, public prosecutors may (and in practice they do) investigate matters even if they are already being assessed by other authorities or self-regulatory bodies. Tasks as part of the investigation may be entrusted to the police or other services appointed to combat crime.

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?

In principle, pharmaceutical companies may offer hospitality to healthcare professionals. However, the Pharmaceutical Law

provides that such hospitality is forbidden when it exceeds the level adequate to the main purpose of a meeting. Moreover, such an offer may be only addressed to healthcare professionals, not to their companions. The main purpose of a meeting needs to be related to medical or pharmaceutical practices and it is recommended that meetings are organised in locations that are adequate to their purpose.

Based on provisions permitting the participation of healthcare professionals in such meeting, payment for expenses related thereto should be deemed permissible. The expenses should be generally limited to covering the costs, such as travel, accommodation or engagement in the meeting. This is also confirmed under the INFARMA Code of Good Practices, which expressly allows such expenses to be covered within certain set limits.

This Code includes detailed principles on such hospitality, which cover, among others, the issue connected to the financing of meals. Thus, the permissible value is PLN 200 for meals offered in Poland. With regard to meals offered abroad, the amount is determined by the relevant local organisation; or if such an amount is not specified, EUR 100.

There are no general requirements for approving the arrangements if hospitality is offered 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?

Healthcare professionals might be entitled to remuneration for their contribution (as a speaker or moderator) to a scientific meeting, provided that such remuneration is adequate to the extent of their participation in the meeting. Paying for mere participation in a meeting (costs of travel, accommodation and enrolment fees) is also possible; however, it should be limited to what is "strictly necessary" for contribution in the event. For instance, the hospitality should not include the costs of entertainment (e.g. leisure activities) or accompanying persons.

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?

There are no specific rules regarding the extent of responsibility in such case. Generally, the initiator and any company engaged in the organisation of such meeting will be held responsible for the compliance of its content with the advertising rules. A pharmaceutical company may be held responsible for the events within its control. Therefore, it may be liable for the content of meetings organised or sponsored by the company. However, if the meeting is organised by an independent third party without the company's involvement, apart from providing sponsorship for a healthcare professional to attend, the company should not be responsible for its content.

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 general, pharmaceutical companies may engage and pay healthcare professionals for expert services provided by them. They may also cover other costs related to the provision of services, e.g. travelling expenses or other reasonable expenses which need to be incurred for the performance of the agreement.

Detailed restrictions in this respect are provided for in the INFARMA Code of Good Practices, which states that the above-mentioned cooperation shall satisfy all of the following conditions:

- a written or documented contract is signed before providing the services, stipulating the nature of the services to be provided, as well as the remuneration or the basis for calculating the remuneration for the services;
- there is a reasonable need for providing such services which has been clearly identified before ordering such services and before making arrangements with potential consultants;
- the consultant selection criteria are directly related to the identified need, while the persons responsible for the selection have the knowledge required for assessing whether given healthcare professionals meet these criteria;
- the number of service providers shall not exceed the reasonable number of persons required for the purpose of satisfying the identified need;
- the signatory of the INFARMA Code of Good Practices shall keep the appropriate documentation and shall appropriately use the services provided by the consultants;
- the involvement of healthcare professionals for providing a given service shall not be an inducement to recommend, prescribe, purchase, procure, sell or use the medicinal products; and
- the fee offered is appropriate to the market value of the services provided.

It is recommended that contracts with healthcare professionals include a clause obliging them to disclose that they act as consultants to the Code Signatory in any case in which they make written or oral public statements on a matter that is the subject of the contract or any other matter related to the Code Signatory.

Moreover, where pharmaceutical companies hire professionally active healthcare professionals as part-time employees, it is recommended that the contracts contain a clause obligating the hired person to provide information that he/she is employed by the given company in public appearances or written works regarding the subject matter of the employment. There should also be an obligation to inform other employers and other persons, to whom the employee represents the interests of his/her employer, of the contracted employment in question.

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

Healthcare professionals should not be engaged in any actions aimed at the promotion of a particular medicinal product. Any studies performed by physicians need to be of a strictly scientific nature. Pursuant to Physicians' Code of Ethics, a physician should disclose his or her relationship with the manufacturer of drugs or medical devices to patients who are to be subjected to studies sponsored by such a manufacturer.

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

Generally, no. The prohibition of taking part in activities aimed at the promotion of a medicinal product is interpreted broadly.

Additionally, the Physicians' Code of Ethics forbids physicians from participating in any scientific research with 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?

Advertising of non-prescription medicines to the general public is permitted provided that it does meet the specific requirements set out in the Pharmaceutical Law. In particular, such advertising cannot suggest that:

- consultation with a doctor may be avoided;
- a product might improve the condition of a healthy person;
- the condition of a person might deteriorate in the case he/she does not use an advertised product (with the exception of preventive vaccinations);
- a medicinal product constitutes foodstuff, a cosmetic product, etc.; and
- the effectiveness or safety of a product is a result of the natural character of that product.

The specific requirements in this regard are included in the Regulation on Advertising of Pharmaceutical Products (see question 3.1).

Please note that a warning concerning the need to verify the content of the leaflet or to consult a doctor or a pharmacist must also be included (e.g.: "Before use, please familiarise yourself with a leaflet attached to the package or consult a physician or a pharmacist. Each drug used inappropriately threatens your health or life"). Inclusion of such warnings may minimise the number of cases in which a patient avoids medical consultations.

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

The Pharmaceutical Law expressly states that advertising of prescription-only medicines to the general public is prohibited.

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?

Yes, such campaigns shall be permitted under Polish law provided that they include simply information of a neutral character and do not encourage the purchase of particular medicinal products. Moreover, the Pharmaceutical Law also indicates that the information concerning human or animal health or diseases shall not be regarded as advertising of medicines, provided that it does not refer, even indirectly, to medicines.

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?

If such press release contains an element of endorsement, it will be regarded as advertising. Since non-scientific journals are accessed by non-professionals, press releases concerning prescription-only medicinal products are generally prohibited. Similarly, press releases on unauthorised medicines or unauthorised indications are generally prohibited under Polish law.

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

Although the advertising of unauthorised medicines or unauthorised indications is prohibited, companies may inform people about research initiatives and the products that they are currently working on. Therefore, they may be described in corporate brochures/Annual Reports. However, they shall be of a purely informative character, not aimed at increasing the use of a medicine.

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

Meetings with and the funding of patient organisations are allowed, provided that they comply with the general rules applicable to advertising to the public (please see the answer to the question 6.1 above). Thus, for instance, such measures cannot be used to promote prescription-only products.

Additional requirements regarding transparency are introduced by the INFARMA Code of Good Practices.

Donations and grants (whether in cash or in kind) to patient organisations are only permitted if:

- they are given for a clearly defined purpose of supporting healthcare, research or education;
- they are documented and records are kept by the donor; and
- they do not constitute an inducement to recommend, prescribe, purchase, supply, sell or use specific medicinal products.

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?

Under Polish law, the advertisement cannot involve offering or promising any benefits for patients in exchange for purchasing a medicine. In this respect, providing patients with items even of small value that are not strictly related to the given medicinal product may be considered unlawful.

Furthermore, with regard to the reimbursed products, there is special regulation which prohibits offering any material or personal benefits to patients in connection with reimbursed medicines.

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

The rules on funding of patient organisations (as described in question 6.6 above) shall apply accordingly to funding of patient support programmes.

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?

Under the Pharmaceutical Law, the President of the Office

for Registration of Medicinal Products, Medical Devices and Biocidal Products shall enter the clinical trial into the Central Register of Clinical Trials, which also includes the information on refusal to grant the authorisation for clinical trial. However, this data is not available to the public. No additional legal requirements to publicly disclose information on ongoing or completed clinical trials have been implemented.

Please note that the above conclusions may change when a new law on clinical trials comes into force in Poland. The draft of the new act on clinical trials is currently subject to legislative work.

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?

In general, there is no legal obligation to disclose transfers of value offered to the abovementioned entities imposed on the pharmaceutical companies. However, such information is in some cases made public by the beneficiaries due to the public functions they perform.

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?

Some rules regarding cooperation between pharmaceutical companies and healthcare professionals are provided in the INFARMA Code of Good Practices. However, it is binding only for its signatories.

Each signatory of the INFARMA Code of Good Practices shall disclose information about cooperation and related transfers of value to healthcare professionals and healthcare organisations within six months of the end of the relevant reporting period. A reporting period shall each time cover a full previous calendar year.

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?

Polish law does not require or allow a company to take any action if a healthcare professional refuses to agree to the disclosure. However, publishing information without consent may violate the provision of personal data protection. Thus, only cooperation with healthcare professionals who agree to disclosure is recommended.

According to the recommendations included in the INFARMA Code of Good Practices, if it is not possible, due to applicable law, to provide information on transfer of value on an individual basis, the data concerning such cooperation shall be presented in a collective manner. In such a case, the number of beneficiaries and the total amount corresponding to the value of benefits provided to such beneficiaries shall be provided.

8 The Internet

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

There are no specific rules related to Internet advertising; therefore, the general rules on advertising apply. Since an Internet advertisement is considered to combine audio-visual, audio or visual advertising, it should be assessed according to the provisions regulating such types of advertisements – depending on the content and method of advertising on the Internet.

Moreover, some additional requirements regarding the content of websites owned or sponsored by pharmaceutical companies are provided for in the INFARMA Code of Good Practices.

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?

The law does not expressly cover this issue. Some rules in this area may be concluded from decisions issued by the Main Pharmaceutical Inspector. The access to websites only for healthcare professionals should be ensured by adequate security measures. In this respect, popular pop-up boxes asking whether the user is a professional or warnings included in the main site are not considered sufficient. Only if an advertisement addressed to healthcare professionals may be not easily accessed by the general public, it would not be classified as advertising to the general public. For example, websites may, for instance, include entering a log-in/name and password together with a verification of whether the user is in fact a healthcare professional.

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?

Taking into account that the authorities broadly interpret the "indirect reference to medicines" condition, independent websites should comply with relevant regulations if they may be accessed by links from a company's website. However, there are no specific rules regarding whether a company would be held responsible for reverse-linking. In any case, users should be informed that they are being directed to another website sponsored by the company and the relevant measures should be adopted in order to ensure the compliance of the content of the independent site with relevant regulations.

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

Information published on a website must be of a neutral character (e.g. an image of product packaging with a name, basic information and characteristics of a given product). For prescription-only medicines, an image of the product's package,

along with the full contents of a leaflet or the SmPC is allowed. However, every omission in the information which can be explained only by an advertising purpose (for instance, omitting the list of contraindications or possible adverse effects) is prohibited. Moreover, disease awareness information is not treated as advertising of medicines provided that it does not refer, even indirectly, to medicines.

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

There are no specific rules governing such activity. However, the new INFARMA Code of Good Practices includes some rules on social media activity for the signatories to this Code. In particular, the signatories to this Code are responsible for all materials distributed using any digital channels, including for advertising of the medicinal products, as long as these materials were prepared, branded or sponsored by the signatory (or by a third party acting on behalf of the signatory).

The signatory to the INFARMA Code of Good Practices, who has a social media profile or page is responsible for the content published on this profile/page. For example: any reference to medicinal products may be considered an advertisement for a medicinal product and as such may be prohibited.

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.?

As above, Polish law does not provide any rules governing such activity. In accordance with the INFARMA Code of Good Practices, signatories to this Code are also responsible for information disseminated by their staff members using private social media profiles/pages if it can be reasonably considered that the staff member: a) acts on behalf of the signatory to the Code of Good Practices; or b) publishes content on such private profile/page at the direction or with the consent or with the assistance of the signatory to the Code of Good Practices. As a general rule, the signatories to the Code of Good Practices should implement internal guidelines governing the use of social media by their staff members, including in relation to private profiles/pages.

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?

The signatories to the INFARMA Code of Good Practices may organise webinars on their own or use the services of a third party. In this respect, the signatory shall remain responsible for the webinar, its content and for identifying the target audience.

Webinars can be also used for communication with external stakeholders (e.g. healthcare professionals, healthcare organisations, patients or payers), with the reservation that the same principles as in the case of websites shall apply (see the answers to the previous questions of section 8 above).

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?

No significant amendments to statutory provisions related to pharmaceutical advertising were brought in the last year, with the exception of the replacement of the existing Code of Good Practice for the Pharmaceutical Industry and the Transparency Code by the new INFARMA Code of Good Practices.

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

At the moment, there is no draft law on pharmaceutical advertising subject to legislative work in Poland. We do not expect any definite changes in the field of pharmaceutical advertising in the next year.

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

As in the recent years, the practice of the Main Pharmaceutical Inspector shows that strong emphasis is also put on enforcing the ban on advertising of pharmacies.

There is also a growing trend of implementing legal solutions in the area of advertising. A new draft act on medical devices, which is currently subject to legislative work, introduces a set of rules on advertising of medical devices and in vitro diagnostic medical devices ("IVD").

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