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A practical cross-border insight 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 regulated in the Act of 6 September 2001, the Pharmaceutical Law ("Pharmaceutical Law"). The matter is also governed by the Regulation of the Minister of Health of 21 November 2008 on advertising of pharmaceutical products and the Act on Reimbursement of Medicines, Foodstuffs Intended for Particular Nutritional Uses and Medical Devices of 12 May 2011 ("Act on Reimbursement").

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

- INFARMA Code of Good Practices in Pharmaceutical Industry (implementing in Poland the EFPIA Code on the Promotion of Prescription-Only Medicines to, and interactions with, Healthcare Professionals);
- INFARMA Disclosure Code (implementing in Poland the EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations);
- IFPMA Code of Practice;
- POLFARMED Code of the Pharmaceutical Marketing Ethics of Prescription-Only Medicines;
- Physicians' Code of Ethics; and
- Pharmacists' Code of Ethics.

1.2 How is "advertising" defined?

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

The following materials are not considered as advertising of medicinal products:

- information on (and attached to) packaging conforming with marketing authorisation;
- correspondence containing informative materials that are not of 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 relating to human and animal health or diseases, provided that it includes no direct or indirect reference to 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?

No formal arrangements consisting of "sign off" or approval of promotional materials are imposed on companies. Marketing authorisation holders are, however, obligated to ensure that draft advertisements are stored for two years from the end of the calendar year in which the advertising was broadcast.

1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities? If so, what aspects should those SOPs cover?

Companies are not required by law to implement SOPs. However, under the Code of the Pharmaceutical Marketing Ethics of Prescription-Only Medicines, companies are required to implement internal organisational and procedural systems guaranteeing their full control over advertising and promotional activities and compliance with the Code.

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?

The law does not provide for any official approvals of pharmaceutical advertising. There is also no possibility to request a prior approval by the regulatory authorities.

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 is authorised to issue a decision prohibiting further publishing of the advertisement infringing the applicable provisions regulating the advertising of pharmaceutical products and removing its effects. The Main Pharmaceutical Inspector may order the company to publish such decision in places where the advertisement was previously published or to publish a corrective statement. 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.

Advertising contrary to law may also, in certain circumstances, infringe collective interests of consumers in the meaning of the Act of 16 February 2007 on Competition and Consumer Protection. In such case, the Chairman of the Office of Competition and Consumer Protection may issue a decision ordering the advertiser to cease infringement and also impose a fine reaching up to 10% of last year's revenue of the perpetrator. An addressee of such decision is entitled to appeal to the Court of Competition and Consumer Protection.

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? To what extent may competitors take direct action through the courts?

The Pharmaceutical Law specifies that 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. A decision imposing the obligation to cease advertising may be issued by the Main Pharmaceutical Inspector or the Chairman of the Office of Competition and Consumer Protection; the latter may also impose fines (as described above).

Furthermore, competitors and consumers are also entitled to take direct actions. Pursuant to the Act of 16 April 1993 on Combating Unfair Competition, an entrepreneur whose interest is threatened or infringed by the act of unfair competition (in this case, advertising contrary to law or good business practices) may demand that the competitor:

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

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

Under the Act of 23 August 2007 on Counteracting Unfair Market Practices, a consumer whose interest is threatened or infringed by the release of an illegal advertisement is entitled to demand the advertiser take action as listed above. These claims might also be raised, *inter alia*, by a local consumer advocate and a national or regional organisation protecting the interests of the consumers.

The claims connected with the acts of unfair competition or unfair market practices are pursued in civil proceedings before general courts. Prior to filing a lawsuit, a claimant may file a motion for preliminary injunction to stop the infringing practice during the court proceedings.

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 two mentioned processes are mostly independent. The authorities may investigate matters constituting a breach of law and a relevant code independently from self-regulatory bodies. It is worth noting that according to the Code of the Pharmaceutical Marketing Ethics of Prescription-Only Medicines mentioned in question 1.4 above, when a self-regulatory body issues a decision which is not observed by an entity in breach, the case may be referred to the Main Pharmaceutical Inspector.

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?

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

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)?

According to the general principles, trading in unauthorised medicinal products is prohibited. The Pharmaceutical Law expressly prohibits the advertising of medicinal products not authorised to the Polish market (both addressed to the general public and to professionals). It is, however, arguable that the possibility of providing professionals with such information is desirable. Such data should be of a scientific and not of an advertising nature in order not to violate the provisions of the Pharmaceutical Law.

Advertising of medicinal products, irrespective of whether they are addressed to the general public or to healthcare professionals, cannot include information contrary to the SmPC. This means that commercial communications cannot use any claims or refer to any indications which are not based directly on the SmPC.

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 in a meeting sponsored by the company is more likely to be considered as 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?

According to the position of the Main Pharmaceutical Inspector, the information on off-label use may only be published in professional literature, not in any promotional materials. In the past, off-label information published on a pharmaceutical company's website was considered as unlawful even if the company claimed that it was merely information, not promotional materials, and despite the fact that the off-label use was indirectly 'authorised' by the decision of the Minister of Health granting reimbursement for certain off-label indications.

It is also worth noting that the authority has stated that sending copies of the reimbursement decision for off-label indication would be, in its view, an action of a strictly informative character (which implies that such communication would be accepted by the Main Pharmaceutical Inspector).

2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply?

Issuing press releases about unauthorised medicines or off-label information is not permitted, as such materials would be most likely considered as advertising. Please see question 2.2 above for possible exceptions.

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

There is no explicit regulation in Polish law that would allow information to be sent even when requested by healthcare professionals. However, if such information is not of a promotional nature, in particular, when it does not refer to the name of the product but is generic and is a response to a submitted question about the product, it should not be considered as an advertisement and would therefore be allowed. Therefore, any information should be sent to healthcare professionals only if requested and should not be of a promotional nature.

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.

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?

Physicians may not be engaged in actions aimed at the promotion of any medicinal product or its indications. They may only participate in a given research exercise provided that its nature is strictly scientific and not promotional.

3 Advertisements to Healthcare Professionals

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

Advertisements directed to healthcare professionals must include information consistent with the SmPC, as well as information on the approved dispensing category and, in the case of a product reimbursed from public funds, information concerning its official retail price and the maximum surcharge amount paid by the patient. The specific list of information which must be provided is extensive and is set forth in the Regulation of the Minister of Health of 21 November 2008.

The information should be reliable, up-to-date, verifiable and sufficiently complete so that the addressee can make his own judgment of the product's therapeutic value. The materials should also indicate the date they were prepared or last updated. Any quotations, tables and visuals from scientific papers must be truly and faithfully copied and the source of information disclosed.

Advertising directed to healthcare professionals must be distributed in a manner ensuring that it is not 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. The pharmaceutical company is responsible for securing the materials intended for healthcare professionals and may be liable for 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?

An advertisement may refer only to some of the therapeutic indications, but in such case all the remaining information in the advertisement must be related only to those chosen indications. The advertisement cannot include information inconsistent with the SmPC.

Advertising should not refer to studies which are contradictory to the contents of the SmPC or present information that does not appear in the SmPC. For instance, it is not possible to refer to studies showing possible off-label use of the product.

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

Such restrictions apply only with regard to advertising to the general public. Nevertheless, Polish physicians' self-governing bodies consider participation of physicians in the promotion of medicinal products as contrary to the professional code of conduct.

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 is no such specific requirement in Polish law.

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?

Under Polish law a comparative advertisement is governed by the rules of unfair competition and trademark protection and is generally permitted under Polish law only if it is not contrary to good practice.

Furthermore, with regard to the advertising of a medicinal product addressed to the general public, the Pharmaceutical Law forbids assuring that the effect of one medicinal product is superior or the same as of another medicinal product. It must also be remembered that advertising of products which have not yet been authorised on the Polish market is forbidden – 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?

Scientific papers and/or proceedings of congresses may be provided to healthcare professionals if they do not constitute endorsement to use/purchase/prescribe a given product, but only present scientific issues. Otherwise, such materials will be classified as advertising.

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?

No express prohibition of publishing such information is contained in the applicable legal provisions. Such "teaser" advertisements would not fall within the definition of pharmaceutical advertising if they do not mention a specific product or contain encouragement to buy such product.

It should also be noted that pursuant to the Pharmaceutical Law, it is also possible to present short advertisements serving merely as a reminder of a full advertisement of a medicinal product. Such advertisement, in addition to its market name and international non-proprietary name, may only contain a trademark with no references to therapeutic indications, pharmaceutical form, dose, advertising slogan or other advertising content. Furthermore, according to regulatory authorities, such "reminder advertisement" may only be used after a full advertisement was broadcast.

4 Gifts and Financial Incentives

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

Yes, but the samples may only be provided to professionals entitled to write prescriptions. A given healthcare professional has to request a respective company to provide him/her with samples in writing. Moreover, the samples provided to professionals must be evidenced by the provider. A sample needs to constitute the smallest packaging of a product authorised on the market and should be marked with the sign 'free sample – not for sale' (pol. '*próbka bezpłatna - nie do sprzedaży*'). The sample must be accompanied with the SmPC. Moreover, one professional is entitled to obtain no more than five samples of one product per year. Samples of intoxicants and psychotropic products cannot be provided.

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

Medical practitioners may only receive gifts of a value not exceeding PLN 100 and which are related to their medical or pharmaceutical practice. Those gifts must be clearly marked with elements/trademarks of the advertising company or product. Donation of money is not allowed.

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?

Offering gifts and donations to healthcare institutions, etc., is not governed by any specific legal regime. It is usually argued that providing donations to institutions such as hospitals is allowed – it may be questioned if the donation was clearly meant to influence the decision-making process of the institution or professionals in favour of the donor. Donations to private institutions may be considered as disguised forbidden benefits.

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?

As a general rule, Pharmaceutical Law forbids free donations to healthcare professionals (see question 4.2 above) in order not to allow them to be influenced by the drug manufacturers. Medicinal products prescribed by a physician need to be selected by him/her 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 doctor's freedom of conscience and current medical knowledge.

A professional cannot be remunerated for prescribing a given product. 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. Non-compliance with this restriction may result in fines up to 5% of the turnover of the reimbursed products.

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?

Such discounts can be considered as a material benefit connected with the purchase of products that are not allowed under the Pharmaceutical Law. Furthermore, the Act on Reimbursement provides that a manufacturer of reimbursed medicinal products (or medical devices) cannot differentiate prices of such medicinal products in agreement with wholesalers, as 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?

Additional services should be provided upon remuneration in order not to be considered as an unlawful material benefit connected with the purchase of products. In case of reimbursed products, any volume-related additional services could also be regarded as a prohibited incentive or benefit under the Act on Reimbursement.

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 cannot be addressed to the general public, since it would constitute forbidden advertising suggesting that taking the medicinal product guarantees the appropriate effect. Similarly, such schemes cannot be offered in respect of reimbursed products as it would constitute forbidden incentives. With respect to other products, general regulations regarding combating unfair competition shall apply.

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

Generally yes, 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. It should be emphasised that no gifts or other benefits must be offered to participants or beneficiaries, since this would exceed the mere sponsoring of education and could be regarded as forbidden benefits. Furthermore, payment for a professional's expenses related to an educational meeting aimed at medical education will be classified as sponsoring. The extent of such payments may not exceed the level adequate to the main purpose of a given meeting.

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, such hospitality should not exceed a level adequate to the main purpose of a meeting or a trip, and it may be offered only 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.

The expenses should be generally limited to covering the costs, such as travel, accommodation or engagement in the meeting, as mentioned below in question 5.2. Under the Code of Good Practices in the Pharmaceutical Industry, the threshold for the value of meals is PLN 200 for meals offered in Poland and EUR 100 for meals offered abroad. 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?

A professional might be entitled to remuneration for his/her contribution (as a speaker or moderator) to a scientific meeting, provided that such remuneration is adequate to the extent of his engagement in the meeting. Paying for mere participation in a meeting (costs of travel, accommodation and enrolment fees) is also possible, provided that the physician submits a report on the topics of the conference. However, an additional payment for such person's time might be classified as offering a material benefit.

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. A pharmaceutical company may be held responsible for the events within its control, therefore it will be liable for the content of meetings organised or sponsored by the company. Where a 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 will 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?

Yes – but physicians may accept such remuneration only if the payment in question will not affect their objectivity or patients' trust. What is more, the payment needs to be adequate to the amount of work performed by the physician. A physician needs to make sure that a service in question is not aimed at the promotion of a medicinal product offered by a sponsor, as well as to disclose his/her links with a pharmaceutical company responsible for the expert service provided by the physician.

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. Physicians should also disclose their ties to a particular pharmaceutical company, including disclosures to the audience during lectures and to editors of publications.

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

Generally no – the prohibition to take part in activities aimed at the promotion of a medicinal product is interpreted broadly. Additionally, the Physicians' Code of Conduct forbids participation in any scientific research with the purpose of promoting products (see also question 5.4).

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?

Yes. Advertising should include the following information: the name of a product and the common name of an active substance; the dosage of the active substance; the pharmaceutical form; therapeutic indications and contraindications; and the identity of the marketing authorisation holder. A warning concerning the need to verify the content of the leaflet or to consult a doctor or a pharmacist must also be included.

Additional information which must be provided is listed in the Regulation of the Minister of Health of 21 November 2008.

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

It is not possible to advertise prescription-only medicines 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?

Yes, the provision of general information is permitted provided that it does not comprise any elements aimed at endorsement to use/purchase particular medicinal products. The provision of information on vaccination campaigns is expressly allowed in the Pharmaceutical Law.

6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply?

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.

In practice, when a pharmaceutical company aims to target professionals through advertisements (as in the case of advertising prescription-only medicines) it should undertake necessary measures to effectively restrict such content. It is not sufficient to merely include a warning that the material is only intended for professionals.

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

Products and research initiatives can be described in such brochures and reports provided that they are not used as a form of hidden advertising of medicinal products or classified as an endorsement to purchase or use the product. The materials should be marked as intended for investors, shareholders, etc., and should not be made available more broadly than usual for similar corporate materials; in particular, purposefully made available to patients.

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

Meetings with or the funding of patient organisations are allowed, provided that they comply with the general rules applicable to advertising to the public. Such measures cannot be used to promote prescription-only products. A product cannot be advertised by publicly known persons, doctors or pharmacists and may not refer to any recommendations made by those persons.

During meetings, a company cannot present information indicating that: (i) one may avoid consulting a doctor; (ii) a product might improve the condition of a healthy person; (iii) the condition of a person might deteriorate in the case he/she does not use an advertised product; (iv) a medicinal product constitutes food stuff, cosmetic, etc.; (v) the effectiveness of a product results from its natural origin; and (vi) the positive effect of using a product is guaranteed. What is more, the provided information: may not specify improper effects of a product with regard to the human body; cannot lead to improper self-diagnosis; or cannot refer, in improper, alarming or misleading terms, to therapeutic indications.

Provided that the above general rules are observed, a company is entitled to organise meetings with a patient and to finance patient support groups. Additional requirements regarding transparency are introduced by the Code of Good Practices in Pharmaceutical Industry implementing the EFPIA HCP Code.

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?

The Pharmaceutical Law does not allow for providing any material

benefits connected with the purchase of medicinal products. In this respect regulatory authorities have challenged the activities of providing patients with items of small value (e.g. socks, cosmetics, and cases for pills with no name of the product on it) while purchasing the medicinal products. Providing items that are not strictly related to the given medicinal product may be considered as unlawful.

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?

Polish pharmaceutical regulatory bodies keep a Central Register of Clinical Trials. 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. There is a self-regulatory initiative to publish the information on ongoing clinical trials conducted in Poland in the database kept by INFARMA (Polish union of innovative pharmaceutical companies).

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, what information should be disclosed, from what date and how?

There is no general obligation in the legislation to disclose transfers of value offered to the above 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. For instance, national and regional healthcare consultants who are advisors to governmental and local bodies in matters of health policy, medical education, etc., have, from 2014, been obligated to disclose any ties with pharmaceutical companies and any benefits exceeding PLN 380.

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, what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?

In December 2013, INFARMA adopted a Disclosure Code, which is binding for its signatories (33 pharmaceutical companies in Poland). Under the Code, the companies are obligated to document and disclose all the transfers of value offered to healthcare professionals or healthcare organisations in Europe. The data is made available on the website of each company within six months of the end of the 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?

There are no regulations in Polish law that would require or allow a company to take any action if a healthcare professional refuses to agree to the disclosure. As publishing information without consent may violate the provision of processing personal data, only cooperation with healthcare professionals who agree to disclosure is recommended.

According to INFARMA's practice, if the healthcare professional refuses to disclose the information on transfer, the data concerning cooperation with this healthcare professional should be presented together with other aggregated data.

8 The Internet

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

No separate set of regulations apply to Internet advertising. According to Polish legal writings, an Internet advertisement should be assessed according to the provisions regulating radio, TV or press advertisements – depending on the content and method of advertising on the Internet. Apart from that, the general rules on advertising apply. Additionally, content of websites owned or sponsored by pharmaceutical companies is specifically regulated under the Code of Good Practices in Pharmaceutical Industry.

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?

According to the Main Pharmaceutical Inspector, websites should include adequate security measures to prevent content directed to professionals from being accessed by the general public. Such measures may, for instance, include entering a log-in/name and password together with a verification whether the user is, in fact, professional. Warnings included in the main site or a pop-up asking whether the user is a professional are not considered as sufficient. If an advertisement addressed to professionals may be easily accessed by the general public, it will be classified as advertising to the general public and will have to comply with applicable limitations.

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?

Mere publication of a link cannot be regarded as a breach of the law unless the pharmaceutical company is aware that the website presents unlawful advertising. A pharmaceutical company is responsible for its own websites, but not for independent websites linking to the official company's website.

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.

Publication of advertisements addressed to the general public is also permitted, as long as such advertisements comply with the rules and restrictions applicable to the advertising of medicinal products.

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

There are no specific rules related to the use of social media for advertising in Poland. General rules for public advertising will apply.

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 2015.

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

No definite changes in the field of pharmaceutical advertising are expected in the next year. The need for further regulations or even the possible ban of medicinal products were discussed by the Polish legislator due to increasing over-the-counter drug consumption, but no specific proposal has been formulated yet. It was also argued that the total ban on advertising may not be in line with EU law. Nevertheless, it is possible that certain further restrictions on pharmaceutical advertisements will be proposed in 2016.

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

Over the last year, the Main Pharmaceutical Inspector took more interest in advertising conducted on social media and generally on the Internet. It may be expected that online advertising will be the subject of even more attention from the regulatory authorities.

The Inspector also delivered an interesting decision explaining that free samples for healthcare professionals may not be provided in anything other than the smallest packaging admitted on the market, even if the smallest packaging is not available on the market due to reasons independent from the marketing authorisation holder. In particular, the Inspector confirmed that suspension of marketing of smallest packaging due to the patent infringement action brought by a third party cannot justify providing samples in bigger packaging.

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