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A practical cross-border insight into pharmaceutical advertising

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General Chapters:

Country Question and Answer Chapters:

Japan

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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?

In Japan, the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics (Law No. 145 of August 10, 1960, as amended) (the "Pharmaceutical Affairs Act") governs the advertising of medicinal products. In connection with the regulations on medicinal product advertising under the Pharmaceutical Affairs Act, the Standards for Fair Advertising Practices concerning Medicinal Products (Notice No. 1339 of October 9, 1980, as amended) (the "Standards for Fair Advertising Practices") issued by the Director-General of the Pharmaceutical Affairs Bureau of the Ministry of Health, Labour and Welfare (the "MHLW") provides certain rules prohibiting false or excessive advertising.

With respect to promotional activities for medicinal products, there are several codes of practice relating to industry-level self-regulation, including the Code of Practice for Promotion of Ethical Drugs (Part II of the "JPMA Code of Practice" established in 2013 by the Japan Pharmaceutical Manufacturers Association (the "JPMA"), as amended) (the "Code of Practice").

In relation to premium offers through promotional activities by companies, the Act against Unjustifiable Premiums and Misleading Representations (Law No. 134 of May 15, 1962, as amended) prohibits the inducement of customers by means of unjustifiable premiums to ensure fair competition. In accordance with this Act, the Fair Trade Council of the Ethical Pharmaceutical Drugs Marketing Industry (the "FTC-EDMI") established the Fair Competition Code concerning Restriction on Premium Offers in the Ethical Pharmaceutical Drugs Marketing Industry (enforced on July 1, 1984, as amended) (the "Fair Competition Code"). The Fair Competition Code was established upon certification by the Japan Fair Trade Commission (the "JFTC") and the Consumer Affairs Agency (the "CAA").

1.2 How is "advertising" defined?

According to Notice No. 148 of September 29, 1998, issued by the Pharmaceutical Safety Bureau of the former MHLW, "advertising" subject to the Pharmaceutical Affairs Act is defined as that which fulfils all of the following conditions:

(a) it is clearly intended to induce consumers to purchase products;

(b) it specifies the names of particular medicinal products; and

(c) it is capable of being viewed by the public.

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

The Pharmaceutical Affairs Act does not have any specific provisions requiring pharmaceutical companies to implement any such arrangements. However, many pharmaceutical companies have established processes for reviewing and approving advertisements and other promotional materials in accordance with the Code of Practice to ensure that their advertisements comply with applicable laws and codes of practice. Article 4(9) of the Code of Practice provides that "member companies [of the JPMA] must appoint a management representative for promotional materials and advertising, etc. and establish an in-house auditing system so that only internally audited promotional materials and advertisements are used".

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?

There are no particular legal or code requirements for companies to have specific SOPs governing advertising activities. However, as described in the answer to question 1.3, it is common for companies to adopt internal review procedures and systems to ensure that the contents of their advertisements comply with legal requirements.

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 Pharmaceutical Affairs Act does not require prior approval by a regulatory or industry authority to advertise medicinal products. However, a pharmaceutical company may consult with a regulatory or industry authority regarding the contents or method of advertising in advance in order to confirm whether the advertising complies with applicable laws or codes of practice.

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?

Although the Pharmaceutical Affairs Act does not clearly stipulate that the regulatory authorities have the power to stop further publication of such advertisements, the authorities regulate advertisements via administrative guidance when they consider that an advertisement is in breach of the Pharmaceutical Affairs Act. However, the regulatory authorities cannot insist on the issuance of a corrective statement. In addition, if a regulatory authority finds that a marketing authorisation holder or manufacturer of medicinal products has committed a material violation of the Pharmaceutical Affairs Act, the Minister of the MHLW has the power to rescind the company's pharmaceutical business licence and to order it to suspend all or part of its business for a given period. Companies have the right to appeal these dispositions by the regulatory authorities under the Administrative Appeals Act (Law No. 160 of September 15, 1962, as amended).

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?

If a company fails to comply with the Pharmaceutical Affairs Act, it will be subject to an administrative penalty imposed by the MHLW. As for breach of the Fair Competition Code, the FTC-EDMI (and, if necessary, the CAA and/or the JFTC) will implement the necessary measures to rectify such breach. Also, upon violation of the terms of the Code of Practice, the Promotion Code Committee, which was established by the JPMA as a self-governing regulatory body, will take necessary measures. Although the actions taken by the regulatory or industry authorities depend on each case, generally speaking, these rules tend to be strictly enforced in Japan. There are a number of cases where pharmaceutical companies have received an administrative penalty for excessive advertising. In addition, material breaches of the Pharmaceutical Affairs Act are subject to criminal sanctions (i.e., imprisonment with work for not more than two years or a fine not exceeding two million yen, or both, pursuant to Article 85 of the Pharmaceutical Affairs Act). Serious sanctions against a company, together with a public announcement, would have a significant adverse impact on that company's business reputation in Japan. As for standing, the direct action that competitors can take through the courts is limited.

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?

Basically, the self-regulatory process and the supervisory and enforcement function of the competent authorities are separate. Matters regarding the Pharmaceutical Affairs Act may be investigated by the competent authorities (i.e., the MHLW and/or the competent prefectural government) and cannot be regulated by any self-regulatory body. On the other hand, matters regarding the Code of Practice can be assessed by the JPMA. In practice, the competent authorities can investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and that are already being assessed by a self-regulatory body like the JPMA. Also, there are situations where the authorities take up matters based on an adverse finding of a self-regulatory body. Similarly, in terms of enforcement under the Act against Unjustifiable Premiums and Misleading Representations, matters regarding the Fair Competition Code may be assessed by another self-regulatory body, but may also be investigated separately by the CAA and/or the JFTC.

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?

Under the Unfair Competition Prevention Act (Law No. 47 of May 19, 1993, as amended), a person whose business interests have been infringed or are likely to be infringed by 'unfair competition' may seek an injunction suspending or preventing the infringement against the person that infringed or is likely to infringe such business interests. In relation to advertising, for example, announcement or dissemination of a falsehood that may damage the business reputation of a competitor constitutes 'unfair competition' under the Unfair Competition Prevention Act. In addition, any act that falls under the definition of 'unfair trade practices' is prohibited under the Act on Prohibition of Private Monopolization and Maintenance of Fair Trade (Law No. 54 of April 14, 1947, as amended) and related guidelines issued by the JFTC; however, there is no specific regulation focusing on advertising.

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)?

Under the Pharmaceutical Affairs Act, advertising regarding the name, manufacturing process or indications and effects of an unauthorised medicinal product is strictly prohibited.

In connection with the prohibition of advertising of unauthorised medicines, according to the commentary on the Code of Practice, the following types of information provision on unauthorised medicines should be permissible:

(a) the adequate and appropriate exchange of scientific information about a drug (for example, the presentation of research findings in a meeting of any academic society or in a scientific journal);

(b) the display of scientific exhibition materials about an unapproved drug in accordance with separate guidelines in a meeting of any international academic society, provided that the subject drug has been approved by another country. (Please note that since such exhibition is an exception, associated scientific literature and related materials cannot also be distributed at the exhibition.);

(c) the supply of peer-reviewed scientific literature upon the request of a doctor; or

(d) the disclosure of information regarding products under development to the company's shareholders in accordance with laws and regulations.

However, according to the commentary on the Code of Practice, the provision of information on unauthorised drugs in a seminar sponsored by a pharmaceutical company is prohibited.

With regard to the provision of off-label information, it is also subject to the same restrictions on the advertising of unapproved drugs as above.

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

Under the Pharmaceutical Affairs Act, information on unauthorised medicines and/or off-label information may not be published for advertisement purposes, as noted in the answer to question 2.1.

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 and/or off-label information for advertising purposes is prohibited under the Pharmaceutical Affairs Act. However, according to the commentary on the Code of Practice, the provision by a company of information on products under development to its shareholders in accordance with the relevant laws and regulations is permitted, unless the information is intended to be used for the promotion of such products.

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

Under the Pharmaceutical Affairs Act, companies are prohibited from sending such information to healthcare professionals for advertisement purposes, as stated in the answer to question 2.1.

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

The principles of the ECJ judgment have not been incorporated into legislation or practical guidance in Japan.

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?

There is a possibility that such provision of information on unauthorised medicines or indications to healthcare institutions may be deemed prohibited advertising of unauthorised medicines under the Pharmaceutical Affairs Act. Therefore, the details of the information that will be sent to healthcare institutions to enable them to plan ahead in their budgets for such products should be carefully reviewed to determine whether it constitutes advertisement of unauthorised medicines.

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?

There are no specific guidelines that have been issued on market research exercises concerning possible launch materials for unauthorised medicinal products or indications. However, if such market research involving healthcare professionals is conducted for the purpose of promoting specific unauthorised medicinal products or indications, it would be deemed prohibited advertising of unauthorised medicinal products under the Pharmaceutical Affairs Act.

3 Advertisements to Healthcare Professionals

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

The Pharmaceutical Affairs Act does not specify the information that must appear in advertisements directed to healthcare professionals. However, the Guidelines for Preparation of Outline of Prescription Pharmaceutical Product Information and for Preparation of Advertisements of Prescription Drugs Inserted in Scientific Journals, which is a self-regulatory code issued by the JPMA, stipulate that certain detailed information must appear in advertisements directed at healthcare professionals. Such advertisements must include, among others, precise descriptions of the brand name, generic name, therapeutic category, regulatory classification, presence or absence of listing on the National Health Insurance price list, a contact address from which to request further information, and the date of preparation of such advertisements.

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?

The information that may appear in advertisements to healthcare professionals is subject to the restrictions under Article 66 (Prohibition of false or exaggerated advertisements) and Article 68 (Prohibition of advertisements of unauthorised medicinal products) of the Pharmaceutical Affairs Act and the Standards for Fair Advertising Practices.

In particular, it should be noted that product information summaries or advertisements regarding prescription drugs must not be supplied to the general public, other than to healthcare professionals, under the Standards for Fair Advertising Practices. Therefore, when distributing materials, such as calendars and posters, adequate caution must be exercised to prevent the exposure of the general public to product names.

There are no particular restrictions that prohibit the provision of advertisements that refer to studies not mentioned in the SmPC. In this connection, Article 4 of the Code of Practice stipulates that it should be fully understood that brochures, advertisements in medical journals, websites targeting healthcare professionals, audio-visual materials such as slides and videos, and other promotional materials

are important media tools for the dissemination of drug information, and those materials should be produced and used in compliance with the Pharmaceutical Affairs Act and relevant self-regulations, such as the Guidelines for Specifying Product Information Summaries for Prescription Drugs. The information contained therein must be accurate, fair and objective, and be based on scientific data. Further, Article 4(6) of the Code of Practice stipulates that extraordinary data must not be presented in such a way as to give the impression that the data represents a universal fact.

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

The Pharmaceutical Affairs Act prohibits advertisements that could be misunderstood as indicating that healthcare professionals have guaranteed the indications and effects or properties/performance of the subject medicinal products. In relation to this restriction, depending on the context, there may be cases where the inclusion of endorsements by healthcare professionals in promotional materials could be deemed as excessive advertising prohibited under the Pharmaceutical Affairs Act. The Standards for Fair Advertising Practices also provide that, as a general rule, pharmaceutical companies must not advertise using healthcare professionals to specify and recommend certain medicines or provide instructions on how to use them.

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 explicit requirement that data must be used in comparative claims under the Pharmaceutical Affairs Act. However, Article 4(4) of the Code of Practice stipulates that comparative claims should be made based on scientific data when included in promotional materials, advertisements and otherwise. In other words, comparative claims need to be made based on reasonable data, which might be obtained through "head-to-head" clinical trials. In addition, it should be noted that when a company makes comparative claims, such claims should be supported by reasonable data under the Act against Unjustifiable Premiums and Misleading Representations.

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?

In terms of comparative advertisements, the JFTC provides guidelines on the comparative advertisements that are permissible under the Act against Unjustifiable Premiums and Misleading Representations. Under these guidelines, the following comparisons are deemed inappropriate comparative advertisements:

(a) comparison by indicating matters that have not been proven and are incapable of being proven;

(b) comparison based on unfair grounds, such as an emphasis on the importance of issues that are inconsequential to the selection of products by consumers, or an arbitrary selection of the products compared; and

(c) advertisements disparaging another company and/or its products.

In addition to the above general rules, the Code of Practice stipulates that comparative advertisements of medicinal products must be made properly, based on scientific data. Further, when a company intends to make a comparative advertisement, the comparative drug should be referred to using its generic name, unless another company agrees to the use of the brand name of the comparative drug. In other words, another company's name and/or the brand names of its products must not be used as part of that comparison without the consent of such company. The same restriction should apply to a competitor's product that has not been authorised in Japan.

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

Article 5(2) of the Fair Competition Code stipulates, as an example, that the provision of information or explanatory materials concerning medical/pharmaceutical data or a medicinal product manufactured by a pharmaceutical company is not restricted by the Fair Competition Code. Scientific papers and/or proceedings of congresses for doctors are included in such information and materials.

Notwithstanding the above, if the distribution of scientific papers and/or proceedings of congresses to healthcare professionals is designed to promote a specific medicinal product and falls within the scope of "advertising" described in the answer to question 1.2 above, the regulations on advertising under the Pharmaceutical Affairs Act will apply to such promotional activities.

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?

There are no particular regulations on "teaser" advertisements for medicinal products. In this connection, the Code of Practice stipulates that advertisements which are mainly composed of the names of medicinal products must be accompanied by certain medicinal information (i.e., therapeutic category, regulatory classification, generic name and presence or absence of listing on the National Health Insurance price list) as well as an address from which one may request further information. In addition, such advertisements must not include information concerning the safety or effectiveness of the given product (i.e., indications and effects, methods of use and dosage of such products) and must indicate clearly that such information is provided.

4 Gifts and Financial Incentives

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

A pharmaceutical company may provide healthcare professionals with samples of medicinal products, as long as the company supplies only the required minimum samples with medicinal information on the products. The Fair Competition Code provides the detailed requirements of the provision of samples of medicinal products.

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

Under the Fair Competition Code, offerings of inappropriate financial or material benefits to healthcare professionals that are accompanied by transactions of medicinal products are prohibited; however, a pharmaceutical company may offer financial or material benefits

that are recognised as "discounts" or "after-sales service" in light of normal business practices which ordinarily accompany medicinal products. The Code of Practice stipulates that, even if such offerings are permissible, a pharmaceutical company must not give gifts or donations of money which may influence the proper use of medicinal products or which may offend the decency of medicinal products. In particular, if a pharmaceutical company gives inappropriate gifts or donations of money to a healthcare professional who is a public official, the pharmaceutical company and the healthcare professional may be subject to a charge of bribery under the Penal Code (Law No. 45 of April 24, 1907, as amended) and/or under the National Public Official Moral Code (Law No. 129 of August 13, 1999, as amended).

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?

The above answer to question 4.2 is also true for healthcare organisations such as hospitals. In this regard, the Fair Competition Code provides that it is possible for a pharmaceutical company to pay remuneration, costs and expenses for post-marketing surveillance studies, clinical trials or other medical or pharmaceutical research or studies, if the company asks healthcare organisations to undertake such studies. When pharmaceutical companies donate equipment or fund the costs of medical or technical services, they should comply with the detailed guidelines under the Fair Competition Code, such as the Standards of Premium Offers and the Standards of Donations issued by the JFTC and the CAA.

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?

Pharmaceutical companies may provide medical or educational goods and services to healthcare professionals as long as they comply with the Pharmaceutical Affairs Act, the Standards for Fair Advertising Practices and the Fair Competition Code and relevant guidelines. In particular, the Standards for Fair Advertising Practices prohibit advertisements that could lead to overuse of drugs (Article 4 thereof). Please also refer to the answers to questions 4.1 and 4.2 above.

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 Fair Competition Code, economic benefits which are deemed to be discounts in light of normal business practices are not restricted as premium offers. In connection to normal business practices, it is not common in Japan for pharmaceutical companies to supply medicinal products directly to medical institutions. In terms of the rules applicable to the offering of a volume-related discount to wholesalers purchasing medicinal products directly from a pharmaceutical company, the pharmaceutical company should specify the standard, timing and method of the discount in a prior agreement. Also, pharmaceutical companies must not offer excessive or discretionary discounts which create a potential risk that such pharmaceutical companies may restrict wholesalers' business operations, including retail pricing, sales of competing goods and the scope of the sales territory. In other words, the offering of a volume-related discount must be limited to an economic benefit, recognised as a "discount" in light of normal business practices in Japan.

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?

The Fair Competition Code provides that it is permissible to offer to provide, or to pay for, additional medical or technical services or equipment, provided that such offer is limited to the extent that offers of goods or services are necessary in order to use the subject medicinal products in medical institutions (Article 5(1)). It is also possible to provide medical or pharmaceutical information or explanatory materials concerning a medicinal product manufactured by such a pharmaceutical company (Article 5(2)).

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?

There is no specific restriction concerning such a refund scheme. However, such a refund scheme may be considered a promotion representing assurances of the effectiveness and safety of a product, in which case it would be prohibited under the Pharmaceutical Affairs Act. In terms of prescription-only medicine, however, it is uncommon for pharmaceutical companies to sell prescription-only medicine directly to hospitals (i.e., a pharmaceutical company, which holds marketing authorisation of a medicine, sells the medicine to distributors, and then those distributors sell it to hospitals). Therefore, such a refund scheme, based on whether or not a product works, is unlikely to be an issue in regard to prescription-only medicine.

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

There is no special restriction concerning investment in continuing medical education. Pharmaceutical companies may sponsor continuing medical education in the same way as other businesses. However, even if the purpose of the investment is education, the value of such investment must not be excessive as described in the answer to question 4.2.

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?

The Hospitality-related Guidelines under the Fair Competition Code govern the offering of hospitality to healthcare professionals.

The guidelines provide the rules on the offering of hospitality to healthcare professionals, including the maximum amount of such offers and the offering method (golf, karaoke, etc.).

The Code of Practice also stipulates that the offering of hospitality to healthcare professionals, such as a social party accompanied with lectures and symposia, should be kept to a modest level and should not offend the decency of medicinal products. In the event that a pharmaceutical company offers inappropriate hospitality to healthcare professionals who belong to a public hospital such as a national hospital organisation, the pharmaceutical company and the healthcare professionals may be charged with bribery under the Penal Code and/or under the National Public Official Moral Code.

The above rules also apply even if the hospitality offered to those professionals takes place in another country. There are no particular requirements that the arrangements should be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality is provided.

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?

Pharmaceutical companies may pay for a healthcare professional in connection with attending a scientific meeting to the extent that such payment is kept to a modest level and does not influence a doctor in the prescription of medicinal products. In accordance with the Fair Competition Code, pharmaceutical companies may pay reasonable honoraria and reimbursement of out-of-pocket expenses, including travel and accommodation, for speakers and presenters. It is also possible to pay a doctor for his/her time, if such payment is kept to a modest level. In the case of healthcare professionals who belong to a public hospital, such as a national hospital organisation, such payment may be met with a charge of bribery under the Penal Code and/or under the National Public Official Moral Code.

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?

Where a company has directly sponsored or organised a scientific meeting, the company is responsible for ensuring that the content and hospitality arrangements comply with the regulations under the Fair Competition Code and other applicable guidelines. Where a company sponsors individual doctors to attend meetings organised by an independent third party, the company will be responsible for ensuring that the level of sponsorship is consistent with the Fair Competition Code and other applicable guidelines. A pharmaceutical company is not, in principle, responsible for the content of a meeting organised by an independent third party if that pharmaceutical company has not had any involvement or influence over such 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?

The above answer to question 5.2 is also true for this question (i.e., such payment may be possible, provided that it can be shown that it is compensation at fair market value for a service and has not been made for the purpose of promoting specific medicinal products).

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

Article 5(4) of the Fair Competition Code permits pharmaceutical companies to pay healthcare professionals reasonable compensation and costs for post-marketing surveillance studies, trials and otherwise.

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

It is possible to pay healthcare professionals reasonable compensation and costs to take part in market research if pharmaceutical companies comply with the relevant guidelines regarding payment for research under the Fair Competition Code.

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?

Pharmaceutical companies may advertise non-prescription medicines to the general public. The restrictions on advertisements of medicinal products under the Pharmaceutical Affairs Act and the Standards for Fair Advertising Practices, which stipulate that a pharmaceutical company must not make a false or exaggerated advertisement in relation to their name, method of manufacturing or indications or effects, apply to advertisements of non-prescription medicines to the general public. In addition, with respect to advertisements of non-prescription medicines, the Japan Self-Medication Industry provides the Guidelines for Fair Advertising Practices of OTC drugs as its voluntary standards.

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

The Standards for Fair Advertising Practices clearly prohibit advertisements of 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?

If a disease awareness campaign is recognised as an advertisement of prescription-only medicine considering the particular medical condition targeted by the campaign, the purpose of the campaign, the extent of involvement of the pharmaceutical company and other circumstances, the disease awareness campaign could be prohibited as an advertisement of prescription-only medicine. It is advisable that companies consult with the relevant regulatory authority in advance if there is doubt as to whether or not a campaign is permissible.

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

The Standards for Fair Advertising Practices prohibit the distribution of product information concerning prescription-only medicines to the general public for advertisement purposes. However, it may be possible for a company to issue press releases in order to announce its business development.

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

If the description of products and research initiatives in corporate brochures/annual reports is designed to promote particular products and falls within the definition of "advertising" described in the answer to question 1.2 above, the advertising regulations on medicinal products under the Pharmaceutical Affairs Act will also apply. In addition, pharmaceutical companies are, of course, required to ensure that such materials are accurate, fair and objective, and are based on scientific evidence.

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

Although there is no specific legal requirement, the JPMA has established a self-regulatory code for member companies to make publicly available information on donations, grants, benefits in kind or any other support provided by them to patient organisations. These guidelines recommend that member companies make publicly available information on their financial contributions to patient support organisations for the previous fiscal year through their websites. The information to be disclosed includes contributions to patient organisations' meeting costs, grants for supporting patient organisations, payments for writing articles and payments for information that member companies have provided to patient organisations.

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?

Pharmaceutical companies may provide items to or for the benefit of patients if they comply with the restrictions on premium offers under the Act against Unjustifiable Premiums and Misleading Representations. However, in terms of prescription drugs, as patients may not purchase prescription drugs directly from pharmaceutical companies, companies do not, in practice, provide items to or for the benefit of patients as premiums. In addition, it should be noted that companies may not provide advertisements of prescription drugs to patients, while the provision of items itself does not constitute advertising under the Pharmaceutical Affairs Act. In other words, provisions of novelty items with a specific drug's name to patients are subject to advertising regulations under the Pharmaceutical Affairs Act.

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?

There is no mandatory obligation for companies to disclose details of ongoing and/or completed clinical trials to the public.

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 particular legislative requirement for companies to make publicly available information on transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations.

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?

(1) Transparency of Financial Relationships with Healthcare Professionals and Healthcare Organisations.

The JPMA has established a self-regulatory code for member companies to make publicly available information on financial relationships with healthcare professionals and healthcare organisations. These guidelines recommend that member companies make publicly available information on their financial relationships with healthcare professionals and healthcare organisations for the previous fiscal year through their websites. The information to be disclosed includes research and development expenses for clinical trials, academic research support expenses, lecture fees, manuscript/writing fees, consulting fees, expenses for provision of information, and entertainment expenses.

(2) Transparency of Financial Relationships with Patient Organisations.

The JPMA has also established a self-regulatory code for member companies to make publicly available information on donations, grants, benefits in kind or any other support provided by them to patient organisations. These guidelines recommend that member companies make publicly available information on their financial contributions to patient organisations for the previous fiscal year through their websites. The information to be disclosed includes grants for supporting patient organisations, contributions to patient organisations' meeting costs, payments for writing articles and consulting fees.

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?

If an individual healthcare professional refuses to agree to the disclosure of transfers of value from a company, the company will not be able to disclose information about those transfers of value to the public, since the company cannot force the professional to agree to the disclosure of that information. However, in practice, it seems it is common for companies to provide transfers of value to individual healthcare professionals subject to their consent to such disclosure.

8 The Internet

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

Internet advertisements of medicinal products are also subject to advertising regulations under the Pharmaceutical Affairs Act if the advertisements fall within the scope of "advertising" referred to in the answer to question 1.2.

In addition, as explained above, since the advertisement of prescription-only medicines to the general public is prohibited by the Standards for Fair Advertising Practices, access by members of the general public to Internet websites which provide information about prescription-only medicines is restricted as well.

With respect to advertisements of unauthorised medicinal products, Notice No. 0301-1 of April 1, 2010, issued by the Compliance and Narcotics Division of the Pharmaceutical and Food Safety Bureau of the MHLW, makes it clear that the MHLW has the power to request providers who display such advertisements on the Internet to take measures to prevent advertisements of unauthorised medicinal products from being displayed.

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 commentary on the Code of Practice provides that it is necessary to restrict access to sites intended for healthcare professionals by members of the general public, such as through the use of passwords. According to the Code of Practice, even in cases where there remains a possibility of access by individuals other than healthcare professionals, such a website is permissible as one of the methods of information provision and not as promotion to the general public if the following requirements are fulfilled:

(a) the name of the pharmaceutical company is provided and it is noted that the information is targeted at healthcare professionals, and access is allowed only if the person who intends to access the website understands that the information is targeted at healthcare professionals;

(b) the content is appropriate for healthcare professionals; and

(c) the content of the linked website is appropriate for healthcare professionals and the owner (or author) of the linked website can be easily identified if the company's website targeting healthcare professionals is linked with any external websites.

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?

There are no specific rules regarding reverse linking of website advertising. However, if the purpose of inclusion of such linking to independent websites is the promotion of a specific medicinal product, there may be cases where such linking is considered advertising under the Pharmaceutical Affairs Act. If that is the case, the company may be held responsible for the contents of the independent websites concerning the medicinal product.

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

As explained above, a pharmaceutical company may not place advertisements for its prescription medicine on its website if it can be accessed by members of the public. As for advertising of non-prescription medicine, a pharmaceutical company may include on its website any information that it includes in advertisements and other promotional materials in other formats. If the information falls within the advertising described in the answer to question 1.2, it will be subject to the regulations under the Pharmaceutical Affairs Act.

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

There are no rules, laws or guidance specifically controlling the use of social media by companies for pharmaceutical advertising. However, if the advertising using social media falls within the scope of "advertising" referred to in the answer to question 1.2, such advertising via social media will be subject to the advertising regulations under the Pharmaceutical Affairs Act.

9 Developments in Pharmaceutical Advertising

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

There have been no significant developments specifically related to the rules relating to pharmaceutical advertising in the last year.

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

There are no specific significant developments in the field of pharmaceutical advertising expected 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?

There has been a trend over the last year or so whereby pharmaceutical companies have developed transparency guidelines and disclosed the amount of research and development expenditures, research grants, etc., that are paid to healthcare institutions, in order to ensure transparency in the relationships between pharmaceutical companies and healthcare institutions.

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