International
Comparative
Legal Guides

Pharmaceutical Advertising 2020

A practical cross-border insight into pharmaceutical advertising

17th Edition

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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 10 August 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. 0929-04 of 29 September 2017) (the "Standards for Fair Advertising Practices") issued by the Director-General of the Pharmaceutical Safety and Environmental Health Bureau of the Ministry of Health, Labour and Welfare (the "MHLW") provide certain rules prohibiting false or excessive advertising. In addition, the Guidelines on Information Provision in connection with Promotional Activities for Ethical Drugs issued recently by the MHLW (Notice No. 0925-01 of 25 September 2018) (the "Guidelines on Information Provision") provide certain rules for the provision of information for ethical drug promotional activities to be complied with by pharmaceutical companies.

There are also industry-level self-regulating codes of practice on promotional activities for medicinal products, including the Code of Practice for the Promotion of Ethical Drugs (the "Code of Practice") established in 2013 by the Japan Pharmaceutical Manufacturers Association (the "JPMA").

With respect to benefits and premium offers for the promotion of ethical drugs, 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 (the "Fair Competition Code"), along with several guidelines for benefits and premium offers and contributions to medical institutions. The Fair Competition Code is a specific adaptation for the pharmaceutical industry of general rules under the Act against Unjustifiable Premiums and Misleading Representations (Law No. 134 of 15 May 1962, as amended), which prohibits the inducement of customers by unjustifiable premiums to ensure fair competition. 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 29 September 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) clearly intended to induce consumers to purchase products;
(b) specifies the names of particular medicinal products; and
(c) 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 provide any specific requirements for pharmaceutical companies to implement particular arrangements to ensure compliance with the various laws and codes of practice on advertising. However, in practice, pharmaceutical companies usually have in place their own verification procedures for advertising medicinal products, to comply with applicable laws and codes of practice. In this regard, the Code of Practice provides that member companies of the JPMA must appoint a manager in charge of validating promotional materials and establish certain in-house verification procedures for advertising. In addition, the Guidelines on Information Provision require pharmaceutical companies to establish an internal audit office to monitor their promotional activities and review promotional materials, which must be independent from departments in charge of detailing for prescription drugs.

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

In connection with the provision of information for ethical drug promotional activities, the Guidelines on Information Provision require pharmaceutical companies to have SOPs to be followed by their employees in the course of information provision in their promotional activities for ethical drugs.

Despite the Guidelines on Information Provision, as described in question 1.3, pharmaceutical companies usually adopt in-house verification procedures 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 still has the option to consult with a regulatory or industry authority regarding the advertising before use, 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?

The Pharmaceutical Affairs Act does not explicitly provide that the regulatory authorities have the power to stop further publication of such advertisements nor to insist on the issue of a corrective statement; however, when the advertisement is in breach of the Pharmaceutical Affairs Act, and the authority finds that it is necessary to prevent the occurrence or spread of hazards to public health, the MHLW may order the pharmaceutical company to take necessary measures to improve operations, which include taking corrective and preventive action on the validation process of its advertising. The regulatory authority also has the power to rescind the company's pharmaceutical business licence or order the suspension of all or part of the business operations for a given period if it finds that the company's advertising violates the Pharmaceutical Affairs Act. Companies have the right to appeal these dispositions by the regulatory authorities under the Administrative Appeals Act (Law No. 160 of 15 September 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? If there have not been such cases, please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?

Failure to comply with the rules governing the advertising of medicines under the Pharmaceutical Affairs Act is subject to criminal sanctions, which will be imprisonment with work for not more than two years or a fine not exceeding two million yen, or both (Article 85 of the Pharmaceutical Affairs Act). As described in question 1.6, the MHLW strictly enforces the rules on the advertising of medicines under the Pharmaceutical Affairs Act through administrative action, which includes issuing an order to take necessary measures to improve the company's operations. There are a number of cases where the competent authorities ordered the pharmaceutical company to take necessary measures to improve their advertising-related operations. Such administrative action, along with a public announcement, would have a significant adverse impact on that company's business reputation.

In addition, the MHLW became able to order administrative surcharges on false and excessive advertising under the Amendment to the Pharmaceutical Affairs Act that was enacted on 27 November 2019 and will be effective on 1 August 2021. In principle, the surcharges will be calculated as 4.5 per cent of the total revenue from the subject product(s) sold during the period in which the violating advertising was conducted.

If a company fails to comply with the rules on promotional activities of medicines under the Fair Competition Code, it will be subject to a penalty imposed by the FTC-EDMI. If the FTC-EDMI finds that the pharmaceutical company violates the Fair Competition Code, the FTC-EDMI may issue a warning letter to the company claiming that the company should take necessary action to correct the violations identified. Further, if the FTC-EDMI finds that the company still violates the Fair Competition Code after receiving such warning letter, the FTC-EDMI may: impose a monetary penalty of not more than one million yen; exclude such company from the FTC-EDMI; or ask the CAA to take necessary administrative action against the company.

Direct action through the courts in relation to the advertising infringement in the Pharmaceutical Affairs Act that competitors can take through the courts is limited. As described in question 1.9 below, if the advertising includes false allegations that could harm the business reputation of a competitor, the competitor may seek an injunction suspending such advertising under the Unfair Competition Prevention Act (Law No. 47 of 19 May 1993, as amended).

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 MHLW and/or the competent prefectural government is responsible for the supervision and enforcement of the pharmaceutical advertising rules under the Pharmaceutical Affairs Act. In practice, such competent authorities may investigate matters regarding the Pharmaceutical Affairs Act, even though the self-regulatory body of the JPMA, already having assessed such matters, has rendered a decision in accordance with the Code of Practice.

Similarly, the FTC-EDMI is responsible for the supervision of the Fair Competition Code, and it may investigate its member company to assess whether its promotional activities comply with the Fair Competition Code and render a decision to such member company. The CAA and/or the JFTC, which are the competent authorities responsible for the enforcement of the Act against Unjustifiable Premiums and Misleading Representations, may also investigate matters based on the assessment by the FTC-EDMI and render a decision to the subject company.

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, 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 Monopolisation and Maintenance of Fair Trade (Law No. 54 of 14 April 1947, as amended) and related guidelines issued by the JFTC; however, there is no specific regulation focusing on pharmaceutical advertising under this Act.

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.

Although the Pharmaceutical Affairs Act does not explicitly exclude certain forms of exchange of scientific information on such medicines at scientific meetings, in the commentary on the Code of Practice, the JPMA commented that this prohibition on the advertising of unauthorised medicinal products should not be intended to prevent the right of the scientific community and the public to be fully informed concerning scientific and medical progress and that this prohibition should not be intended to restrict the following types of information provision:

(a) the full and proper 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 at an international scientific conference, on condition that the subject drug has been approved by another country;
(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 a company's shareholders, as may be required under 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.

In addition, under the Guidelines on Information Provision, upon the request of healthcare professionals, the provision of information on unapproved drugs, off-label drugs, or dosage and administration that are not approved in Japan is permissible only if all of the following conditions are met:

(a) such information should be provided separately from the other information provision activities for the promotion of ethical drugs;
(b) the information to be provided should be limited to that requested by the healthcare professionals and should be provided only to the healthcare professionals who made the request;
(c) pharmaceutical companies must not purport to have received a request from healthcare professionals despite no such request having been made;
(d) the information to be provided must not contain false or exaggerated statements, should be accurate and supported by scientific and objective evidence, and must not be summarised, incomplete or exaggerated;
(e) when providing test results or papers regarding research in which pharmaceutical companies are involved, such research should be properly managed in accordance with the "Ministerial Ordinance Concerning Standards for Implementation of Clinical Trials for Medical Drugs" (Ministry of Health and Welfare Ordinance No. 28 of 1997), the "Clinical Research Act" (Act No. 16 of 2017) or regulations equivalent thereto;
(f) negative information, such as the increased risk of adverse reactions and the fact that no significant difference has been proven by clinical trials, should also be provided in a proper manner;
(g) the fact that the efficacy and effect (indication), dosage and administration of the ethical drug with respect to which information is to be provided have not been approved should be clearly explained; and
(h) the details of the information provision, such as the background, recipients, and content of the information to be provided, should be recorded and such records should be retained.

The provision of off-label information is also subject to the same restrictions on the advertising of unapproved drugs under the Pharmaceutical Affairs Act.

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 must not be published for promotional purposes, as described in 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? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. mainstream public media), please specify.

Issuing press releases about unauthorised medicines and/or off-label information for promotional purposes is prohibited under the Pharmaceutical Affairs Act. However, as described in question 2.1, if such press releases are not intended to promote a specific medicinal product and are required in order to inform shareholders of product development as a part of a company's financial information, it could be argued that such press releases should not be considered as advertising of unauthorised medicines. Whether or not the information provided via press releases could be deemed information intended to promote specific medicinal products to the public depends on the case, and the specific contents of the information should be carefully reviewed prior to issuing the press releases.

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

As described in question 2.1, such information must not be sent to healthcare professionals under the Pharmaceutical Affairs Act.

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?

Such provision of information on unauthorised medicines or indications to healthcare institutions may be considered as promotion of unauthorised medicines or indications prohibited under the Pharmaceutical Affairs Act.

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. The JPMA provides the list of information to be included in advertisements directed to healthcare professionals in the Guidelines for Preparation of Outline of Prescription Pharmaceutical Product Information: name of the product (both brand name and generic name); therapeutic category; regulatory classification; indications and usage; dosage and administration; warnings and precautions; presence or absence of listing on the National Health Insurance price list; name of the marketing authorisation holder with a contact address; information concerning the limit on the prescription period (if any); conditions on marketing authorisation (if any); and the preparation date of the advertisement.

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?

As described in question 2.1, advertisements of unauthorised medicinal products are prohibited (Article 68 of the Pharmaceutical Affairs Act). Also, the advertising of medicinal products must not be false or exaggerated in relation to the name, method of manufacturing, or indications or effects (Article 66 of the Pharmaceutical Affairs Act). Furthermore, the Standards for Fair Advertising Practices prohibit the advertising of prescription-only medicinal products to the general public. As described in question 3.1, advertisements to healthcare professionals must comply with the rules provided in the Guidelines for Preparation of Outline of Prescription Pharmaceutical Product Information.

There are no particular restrictions that prohibit the provision of advertisements that refer to studies not mentioned in the SmPC. However, if studies are referred to in advertisements, the description of such studies should not contradict the studies mentioned in the SmPC. The data of the studies included in the advertisements must be accurate, credible, and supported by scientific evidence.

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 (Article 66, paragraph 2 of the Pharmaceutical Affairs Act). Specifically, the Standards for Fair Advertising Practices prohibit the advertising of medicinal products, which includes endorsements, recommendations, or testimonials by healthcare professionals.

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 there should be data in any "head to head" clinical trials before comparative claims may be made in the advertisement of medicinal products.

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?

Advertisements that may disparage different medicinal products or competitors are prohibited under the Code of Practice. The Code of Practice also provides that any comparison made between different medicinal products should be capable of substantiation, and the brand names of comparative drugs must not be included in comparative advertisements. The JPMA provides certain rules on comparative advertisements of medicinal products in the Guidelines for Preparation of Outline of Prescription Pharmaceutical Product Information. For example, commentary regarding the efficacy and safety of comparative drugs should not be included when results of a clinical comparative study are placed in advertisements. Furthermore, referring to a competitor's product or indication that has not yet been authorised in comparative advertisements is not allowed. In this connection, the Guidelines on Information Provision also prohibit pharmaceutical companies from disparaging other companies' products to assert the superiority of their own products.

In addition, general rules on comparative advertisements under the Act against Unjustifiable Premiums and Misleading Representations also apply to comparative advertisements of medicinal products. The JFTC provides guidelines on comparative advertisements, and advertisements which include the following comparisons are deemed impermissible:

(a) comparison by indicating information that is not substantiated and which is incapable of being substantiated;
(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; or
(c) advertisements disparaging another company and/or its products.

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

The distribution of scientific papers at the request of healthcare professionals is allowed under the Code of Practice. Also, the information provision of general scientific information to healthcare professionals is not restricted by the regulations on the premium offer under the Fair Competition Code, unless it improperly influences transactions with healthcare professionals. However, if the distribution of scientific papers and/or proceedings of congress is designed to promote a specific medicinal product of the company, such activities could be considered as advertising or an improper offer of a gift or economic benefit, and thus subject to regulations under the Pharmaceutical Affairs Act and the Fair Competition Code.

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 provides that advertisements which are mainly composed of the names of medicinal products must be accompanied by certain product 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 the contact address for further information. In addition, such advertisements must not include information concerning the safety or effectiveness of the given product (e.g., indications and usage, dosage and administration, and warnings and precautions) and must clearly indicate that such information should be referred to in the package insert of the product.

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

Under the marketing authorisation and SmPC regulations under the Pharmaceutical Affairs Act, there are no applicable cases where Product A would be authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A. If combination use of Product A and Product B for a particular indication is approved by the regulatory authority, either the SmPC of Product A or Product B must include that indication, so an off-label information provision would not happen for both Product A and Product B in that case.

4 Gifts and Financial Incentives

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

Samples of medicinal products may be provided to healthcare professionals with their product information, only after a pharmaceutical company obtains marketing authorisation for such medicinal product. A pharmaceutical company must comply with the detailed requirements for the provision of samples of medicinal products, which are provided under the Fair Competition Code. The Code of Practice also notes that the quantity of samples to be supplied to healthcare professionals should be limited to the minimum for evaluation.

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

Under the Fair Competition Code, offerings of gifts or economic benefits to healthcare professionals in a manner likely to improperly induce the transactions of medicinal products are prohibited; however, a pharmaceutical company is permitted to offer gifts or economic benefits that are considered "discounts" or "after-sales service" for the subject medicinal products in light of normal business practices.

The Code of Practice provides that a pharmaceutical company must not give gifts or other items which may improperly influence the use of medicinal products or which may detrimentally affect the reputation of medicinal products.

In connection with this, the commentary of the Code of Practice provides, among others, that (i) gifts for the personal benefit (such as sporting or entertainment tickets, electronics items, social courtesy gifts, etc.) of healthcare professionals (either directly or through clinics and institutions) are prohibited, and (ii) providing or offering a promotional aid (a non-monetary item given for promotional purposes) to healthcare professionals in relation to the promotion of prescription-only medicines is prohibited (this will not apply to pens and notepads provided to healthcare professionals in the context of company-organised events for the purpose of taking notes during a meeting), as provided in IFPMA's Code of Practices (2019 edition).

Furthermore, inappropriate gifts or donations of money to a healthcare professional who works in the public sector (e.g., a national university hospital) may be considered bribes punishable under the Penal Code (Law No. 45 of 24 April 1907, as amended) and/or under the National Public Service Ethics Act (Law No. 129 of 13 August 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? If monetary limits apply, please specify.

The regulations on the offering of gifts or donations of money listed in question 4.2 also apply to healthcare organisations such as hospitals. The Fair Competition Code provides guidelines on the donations to medical institutions. For example, under certain conditions, a pharmaceutical company can donate money to university hospitals for education and research purposes. However, donation equipment or money for the purpose of taking over the debts or expenses that should be paid by the medical institutions during the course of its normal practice (such as the cost of a nurse) is restricted under the Fair Competition Code.

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

The Fair Competition Code prohibits the offering of goods and services by a pharmaceutical company to healthcare professionals that might influence the prescription or therapeutic decisions by healthcare professionals. However, under certain conditions provided in the Fair Competition Code, it is permissible to provide goods or services that are necessary for the use of the company's medicinal product, or goods or services that could enhance the utility or benefit of the subject product. As a matter of course, such goods or services should not influence prescribing patterns by healthcare professionals.

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 that are deemed to be discounts in light of normal business practices are not restricted as premium offers. In practice, medical institutions are usually provided medicinal products from wholesalers and not directly from pharmaceutical companies. In that case, pharmaceutical companies must not offer excessive or discretionary discounts that could lead to a restriction on wholesalers' business operations, including retail pricing, sales of competing goods, and the scope of the sales territory.

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

As described in question 4.4, under certain conditions provided under the Fair Competition Code, it is permissible to offer to provide, or to pay for, additional medical or technical services or equipment, provided that such offer must be limited to the extent that offers of goods or services are necessary in order to use the subject medicinal products in medical institutions. The Fair Competition Code does not provide specific restrictions on package deals; however, it should be carefully reviewed whether such package deals could constitute "discounts" or "after-sales services" for the subject medicinal products in light of normal business practices, which are exempt from the offering of gifts and financial incentives regulated by the Fair Competition Code (see question 4.2).

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 are no specific rules for a refund scheme where the medicinal product does not work. 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 for a medicine, sells the medicine to distributors, and then those distributors sell it to hospitals). Therefore, such a refund scheme for prescription-only medicine is unlikely to occur in practice.

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

There are no specific rules for more complex patient access schemes or managed access agreements which enable pharmaceutical companies to offer special financial terms for the supply of medicinal products.

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

In Japan, there are no particular legislative restrictions on pharmaceutical companies working together with the National Health System for purposes of pooling skills, experience, and/or resources for the joint development and implementation of specific projects.

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

As described in question 4.2, under certain conditions provided in the Fair Competition Code, pharmaceutical companies may sponsor continuing medical education for healthcare professionals. Such sponsorship should not improperly influence the prescription or therapeutic decisions by healthcare professionals.

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

As described in question 4.2, improper gifts or benefits provided to healthcare professionals who work in the public sector may be considered bribery punishable under the Penal Code or the National Public Service Ethics Act. The National Police Agency and the Public Prosecutors Office are responsible for the supervision and enforcement of the anti-bribery/anti-corruption regulations. In practice, the competent anti-bribery authorities may investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, regarding which the MHLW or the JPMA already assessed a breach of the pharmaceutical advertising rules, including the Pharmaceutical Affairs Act.

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 Fair Competition Code, along with the hospitality guidelines, provides the rules on the offering of hospitality to healthcare professionals. The Fair Competition Code prohibits the offering of hospitality to healthcare professionals in a manner likely to improperly influence the medicinal product deal with healthcare professionals. This restriction does not, however, preclude the offering of hospitality to healthcare professionals that is offered along with certain gatherings hosted by pharmaceutical companies as a customary practice, as long as such offering is not extravagant or excessive in common-sense terms. As part of the hospitality guidelines, the FTC-EDMI provides certain conditions and a threshold on the costs of meals provided to healthcare professionals. Under these guidelines, for example, a pharmaceutical company is allowed to provide meals to a guest healthcare professional for up to 20,000 yen at an after-party of the symposia, conferences, and other meetings concerning the company's product.

The Code of Practice also states that the offering of hospitality to healthcare professionals during the events sponsored by the company should be moderate and reasonable. Furthermore, improper hospitality provided to healthcare professionals who work in the public sector may be considered bribes punishable under the Penal Code or the National Public Service Ethics Act.

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?

The Fair Competition Code does not preclude the payment for travel and accommodation fees to a healthcare professional in connection with attending a meeting for the presentation of the company's medicinal product. The pharmaceutical company may also pay the lecture fee and expenses to a healthcare professional attending such a meeting as a chairperson, guest speaker, or presenter.

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?

If a pharmaceutical company directly sponsors or organises a scientific meeting, the company is responsible for ensuring that the content and hospitality arrangements comply with the applicable regulations on promotional activities, including the Pharmaceutical Affairs Act, the Code of Practice, and the Fair Competition Code. Further, even where a pharmaceutical company organises a scientific meeting with the help of an independent third party, the company remains responsible for compliance with those applicable laws and regulations on the content and hospitality arrangements for the meeting.

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 Fair Competition Code does not preclude payment to healthcare professionals for expert services in connection with post-marketing surveillance studies of the medicinal product, clinical studies, and other scientific studies. The Fair Competition Code provides detailed requirements for such payment, and non-compliance with such requirements may be considered improper inducement of purchasing or prescribing the company's product.

The Code of Practice provides that healthcare professionals may be engaged as consultants and advisors for services such as speaking at and/or chairing meetings and events, involvement in medical/scientific studies, clinical trials or training services, participation in advisory board meetings, and participation in market research where such participation involves remuneration. The arrangement which covers these genuine consultancies or other services must, to the extent relevant to the particular arrangement, fulfil all the following criteria:

(a) a written contract or agreement must be agreed in advance of the commencement of the services which specifies the nature of the services to be provided and the basis for payment of those services;

(b) a legitimate need for the services must be clearly identified and documented in advance;

(c) the criteria for selecting consultants must be directly related to the identified need and the consultants must have the expertise necessary to provide the services;

(d) the number of consultants retained must not be greater than the number reasonably necessary to achieve the identified need;
(e) the hiring of the consultants to provide the relevant services must not be an inducement to prescribe, recommend, purchase, supply, and/or administer any medicine; and
(f) the compensation for the services must be reasonable and reflect the fair market value. The compensation arrangement may include reimbursement of reasonable expenses, including travel, meals and accommodation.

In addition, as described in question 2.1, advertising of a pre-approval medicinal product is strictly prohibited, the engagement of the healthcare professionals in advisory boards should be carefully examined to determine whether it conflicts with such advertising restriction before entering into a service agreement with healthcare professionals.

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

As described in question 5.4, a pharmaceutical company can pay healthcare professionals reasonable fees and expenses for post-marketing surveillance studies. The Fair Competition Code provides detailed guidelines on the payment for post-marketing surveillance studies to healthcare professionals.

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

A pharmaceutical company can pay healthcare professionals reasonable fees and expenses for their participation in market research, if the company meets certain standards on the payment for market 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?

Non-prescription medicines may be advertised to the general public. Such advertisement relating to non-prescription medicines is also subject to the restrictions on pharmaceutical advertising under the Pharmaceutical Affairs Act and the Standards for Fair Advertising Practices. It must not be a false or exaggerated advertisement in relation to the name, method of manufacturing or indications or effects of the non-prescription medicines; and it should not include any statements that could mislead the general public into believing that a healthcare professional has certified the efficacy and effects of the non-prescription medicines.

As a self-regulatory code for advertisements of non-prescription medicines, the Japan Self-Medication Industry provides the Guidelines for Fair Advertising Practices of OTC drugs.

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?

Under the definition of "advertising" (see question 1.2), a disease awareness campaign (not mentioning the name of a specific product) would not be considered advertising subject to regulations under the Pharmaceutical Affairs Act. However, a disease awareness campaign might be argued to be advertising in cases where only a specific prescription-only medicine exists for the treatment of the subject disease. In that case, such disease awareness campaign for the general public could be prohibited as an advertisement of prescription-only medicine.

In this regard, disease awareness campaigns regarding the target diseases of specific prescription-only medicines are subject to the Guidelines on Information Provision, and it is prohibited to recommend only treatment with a specific product or cause the general public to misunderstand that there are no means of treatment other than that with the specific product in the course of a disease awareness campaign. It is advisable that pharmaceutical companies consult with the relevant regulatory authority before launching disease awareness campaigns.

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

The Standards for Fair Advertising Practices prohibit the distribution of product information concerning prescription-only medicines to the general public for advertisement purposes. As issuing a press release concerning prescription-only medicines to non-scientific journals could be deemed part of promotional activities, it is likely to be considered advertising of prescription-only medicines to the general public, which is prohibited.

As described in question 2.1, even though the advertising of unauthorised medicines or unauthorised indications is prohibited under the Pharmaceutical Affairs Act, the Code of Practice does not preclude the disclosure of information regarding the development of medicinal products to a company's shareholders. If a company issues press releases referring to the development of unauthorised medicines or unauthorised indications, such press releases should contain only objective information relating to the development of the products and should not have any advertising or promotional effect on the subject products.

As described in question 2.3, if the contents of a press release are deemed as being intended to promote specific prescription-only medicines, such press release would be subject to the regulations on the advertising of unauthorised medicines or unauthorised indications under the Pharmaceutical Affairs Act, so the contents of press releases referring to the development of unauthorised medicines or unauthorised indications should be carefully reviewed in advance.

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 question 1.2, the advertising regulations on medicinal products under the Pharmaceutical Affairs Act will also apply.

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

There is no specific legislation which governs the meetings between pharmaceutical companies and patient organisations, nor funding to patient organisations. However, as described in question 7.3 below, 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?

As advertising of prescription-only medicines to the general public is prohibited, as described in question 6.2, a pharmaceutical company shall not offer gifts or benefits to patients in exchange for use of prescription-only medicines. As for non-prescription medicines, a pharmaceutical company is allowed to provide gifts or benefits to patients in exchange for purchasing the product or as a part of the promotion of the product, as long as such offering of gifts or benefits complies with the general restrictions on premium offers under the Act against Unjustifiable Premiums and Misleading Representations. The offering of gifts or benefits to the patients should not be: excessive leading to overconsumption; or abuse of non-prescription medicines by the patients.

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?

With respect to clinical trials that are required for applications for marketing authorisations of medicinal products under the Pharmaceutical Affairs Act, there is no statutory obligation for companies to disclose details of ongoing or completed clinical trials to the public.

However, the JPMA provides self-regulatory guidelines concerning the disclosure of clinical trial information via clinical trial registries and clinical trial results databases as outlined below:

(a) *Clinical Trial Registries* – A clinical trial registry serves as a repository for information on ongoing clinical trials. All confirmatory clinical trials and all exploratory efficacy trials (other than phase 1 trials) should be submitted for listing no later than 21 days after the initiation of patient enrolment. Such registration of clinical trials on any one of a number of free, publicly accessible, Internet-based registries should achieve the intended objectives. The registry should include the following information: brief title; trial description in lay terminology; trial phase; trial type (e.g., interventional); trial status; trial purpose (e.g., treatment, diagnosis, prevention); intervention type (e.g., medicinal product, vaccine); condition or disease; key eligible criteria, including gender and age; the location of the trial; contact information; and ingredient name or code of the investigational product.

(b) *Clinical Trial Results Databases* – A clinical trial results database serves as a repository for the summary results of completed clinical trials. The results of all confirmatory clinical trials and all exploratory efficacy trials conducted on a medicinal product that has been approved for marketing and is commercially available in at least one country should be publicly disclosed, regardless of the outcome. The results should be posted no later than one year after trial completion. Publication of clinical trial results in any free, publicly accessible Internet-based clinical trials databases (for example, the Japan Pharmaceutical Information Center database) should achieve the intended objectives.

On the other hand, with respect to clinical research (excluding clinical trials regulated under the Pharmaceutical Affairs Act), the Clinical Research Act (Law No. 16 of 2017), which came into effect on 1 April 2018, imposes a certain disclosure requirement on the manufacturers of medicinal products. The clinical research subject to such disclosure requirement is: (i) clinical research sponsored by manufacturers of medicinal products and clinical research related to the medicinal products of those companies; and (ii) clinical research studying medicinal products that have not been approved under the Pharmaceutical Affairs Act or off-label uses of medicinal products. The disclosure information includes the ID number of the Japan Registry of Clinical Trials (jRCT), the name of the entity sponsored by the company, the name of the medical research institution, the name of the governing body of the clinical research, and the total amount of the funds provided to the medical research institution. The information must be disclosed on the Internet in each fiscal year.

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

As described in question 7.1, under the Clinical Research Act, the manufacturers of medicinal products are subject to a certain disclosure requirement. The information required to be disclosed regarding transfers of value includes certain research funding, donations, and compensation for writing manuscripts, making presentations or other entrusted work that are provided by the manufacture of medicinal products to the healthcare professional that is responsible for the clinical research or to a medical institution, university or other healthcare organisation to which the healthcare professional belongs. The information must be disclosed on the Internet in each fiscal year.

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

The JPMA has established the following self-regulatory codes for member companies, and these codes have been amended by the JPMA to ensure consistency of the disclosure requirements under the Clinical Research Act:

(a) 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.

(b) 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?

Prior to the implementation of the Clinical Research Act, if an individual healthcare professional refused to agree to the disclosure of transfers of value from a company, the company would not be able to force the healthcare professional to disclose the information. However, under the Clinical Research Act, the manufacturers of medicinal products are obliged to disclose certain information about transfers of values as described in question 7.2. In practice, pharmaceutical companies provide transfers of value to individual healthcare professionals only after obtaining their written consent to such disclosure.

8 The Internet

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

Advertising of medicinal products on the Internet is subject to the same rules as pharmaceutical advertising regulations in any other media. Therefore, the Pharmaceutical Affairs Act and the Standards for Fair Advertising Practices also apply to such advertising.

Under the Pharmaceutical Affairs Act, the Minister of the MHLW or the prefectural governor may order the person who advertised the unauthorised medicinal products to stop such advertising. In addition, when the advertising of the unauthorised medicinal products is sent via the Internet, the Minister of the MHLW or the prefectural governor may request Internet providers to take measures to block such transmission of advertising on the Internet. For supervision and enforcement of these rules at the prefectural level, the MHLW provides guidelines for monitoring and guidance concerning Internet advertising that violates the Pharmaceutical Affairs Act (Notice No. 1217-1 of 17 December 2014, issued by the Compliance and Narcotics Division of the Pharmaceutical and Food Safety Bureau of the MHLW).

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?

As described in question 6.2, advertising prescription-only medicine to the general public is prohibited under the Standards for Fair Advertising Practices. Therefore, a pharmaceutical company is required to restrict access to the website that includes product information of prescription medicine.

The JPMA provides guidelines regarding such access restriction by the general public in the commentary on the Code of Practice, and it states that it is not necessary to block access to sites by using a password, if the sites meet the following requirements:

(a) the identity of the pharmaceutical company and of the intended audience (i.e., healthcare professionals only) should be readily apparent, and the site should be accessible only when the user confirms her status as a healthcare professional before entering the site;

(b) the content should be appropriate for healthcare professionals; and

(c) the content of the linked website should be appropriate for healthcare professionals and the owner (or author) of the linked website can be readily identified, when linking to 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 external linking from or to a pharmaceutical company-sponsored website. Whether the company will be responsible for the content of the independent website would need to be considered on a case-by-case basis. However, in general, if the integration of the content of independent websites and a company's website by such linking has a promotional effect on a specific medicinal product of the company, the content of independent websites could be considered part of pharmaceutical advertising that is subject to the Pharmaceutical Affairs Act. In that case, the company may be held responsible for the contents of the independent websites.

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

Information displayed on the website of the pharmaceutical company that may be accessible by the general public must comply with the laws and rules on pharmaceutical advertising as described in question 1.1. A pharmaceutical company may place advertising for non-prescription medicine on its website; however, advertising prescription-only medicine to the general public on the website is prohibited as described in questions 6.2 and 8.1.

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

The rules on pharmaceutical advertising on the Internet as described in question 8.1 also apply to the use of social media by companies; however, there are no specific rules, laws or guidance focusing on the use of social media for pharmaceutical advertising.

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?

On 27 November 2019, the Amendment to the Pharmaceutical Affairs Act, which includes amendments to the pharmaceutical advertising regulations, was enacted. Under this amendment, the MHLW will become able to order administrative surcharges on false and excessive advertising from 1 August 2021. The surcharges will be calculated as 4.5 per cent of the total revenue from the subject product(s) sold during the period in which the violating advertising was conducted (with the maximum period for calculation of these surcharges being three years). This new surcharge system includes, among others, the following rules:

(i) If the subject company receives an administrative order for improvement of business operations, the MHLW may suspend ordering the surcharges subject to certain requirements.

(ii) If the company voluntarily reports to the MHLW its false or excessive advertising violating the Pharmaceutical Affairs Act, the amount of the surcharge will be reduced by half (50 per cent).

(iii) If the company receives an order for surcharges on false or excessive advertising under the Act against Unjustifiable Premiums and Misleading Representations by the CAA as well, 3 per cent of the total revenue from the subject product(s) sold during the period in which the violating advertising was conducted will be deducted from the total surcharge amount ordered by the MHLW under the Pharmaceutical Affairs Act.

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

The detailed rules to enforce the new surcharge system on pharmaceutical advertising under the Pharmaceutical Affairs Act are expected to be developed 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?

With regard to pharmaceutical advertising, no specific general practice or enforcement trends have become apparent in Japan over the last year or so.

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