Japan

Somuku Iimura

Nishimura & Asahi

Yoko Kasai

1 General - Medicinal Products

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

In Japan, the "Pharmaceutical Affairs Law" (Law No. 145 of August 10, 1960, as amended, *inter alia*, Articles 66-68) and the "Standards for Fair Advertising Practices concerning Medicinal Products" (Notice No. 1339 of October 9, 1980, by the Director-General of the Pharmaceutical Affairs Bureau of the former Ministry of Welfare) ("Standards for Fair Advertising Practices") define universally applicable baseline standards for marketing practices with respect to medicinal products. Regarding self-regulation in the pharmaceutical industry, there are a number of codes of practice, including but not limited to, the "Code of Practices for Promotion of Ethical Drugs" (established on March 24, 1993, by the Japan Pharmaceutical Manufacturers Association ("JPMA"), as amended) (the "Code of Practices") and the "Fair Competition Code concerning Restriction on Premium Offers in the Ethical Pharmaceutical Drugs Marketing Industry" (enforced on July 1, 1984, by the Fair Trade Council of the Ethical Pharmaceutical Drugs Marketing Industry, as amended) (the "Fair Competition Code"). The Fair Competition Code was established upon certification by the Japan Fair Trade Commission in accordance with the "Act against Unjustifiable Premiums and Misleading Representation".

1.2 How is "advertising" defined?

"Advertising" under the Pharmaceutical Affairs Law and the related ministerial guideline is defined as that which fulfils all of the following conditions:

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

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

(c) it is capable of being acknowledged by the general 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?

There is no regulation which directly requires companies to ensure compliance with the various laws and Codes of Practice on advertising.

However, regarding the Pharmaceutical Affairs Law, companies may consult with the competent prefectural government before advertising. Please note that this process does not lead to formal approval since a consultation is not equivalent to the no-action letter system, and the Tokyo Metropolitan Government, for example, has announced that companies need to make an appointment two or three months before such consultation.

In addition, according to Article 4(2) and relevant regulations of the Act against Unjustifiable Premiums and Misleading Representation, the Consumer Affairs Agency may, whenever necessary, designate a period of fifteen days and require the companies concerned to submit data as reasonable grounds for the representations they have made. In such cases, if the entrepreneur fails to submit the data, the representation concerned will be deemed a misleading representation. It follows that companies are required to collect and keep data and documents which support the truth and fairness of their representations before advertising. Please also refer to the answer provided under the heading of the next question.

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 is no regulation which directly requires companies to have specific SOPs governing advertising activities. However, according to the Code of Practices Article 4(9), it is stated that "Member Companies must appoint a Management Representative for promotional materials and advertising, etc. and establish an in-house auditing system so that only audited promotional materials and advertisements are used". Therefore, companies are required to establish such in-house auditing systems.

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?

It is not necessary that advertisements be approved in advance of use by a regulatory or industry body in every case, although advice may be given on ambiguous issues if such bodies are consulted. However, as stated in the previous answer to question 1.4 above, the Code of Practices stipulates that pharmaceutical companies should establish and maintain an appropriate management system in which advertisements should be screened by the responsible person before use. It also stipulates that such responsible person is expected to be one who has specialised skills and knowledge concerning medical information, i.e., doctors or pharmaceutical chemists.

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 court may have powers to stop further publication and/or require that a pharmaceutical company make corrections with respect to any advertisement which is issued in breach of the Pharmaceutical Affairs Law or other laws. On the other hand, no specific laws or regulations clearly give the authorities power to insist on the issuance of a corrective statement. If a pharmaceutical company receives administrative punishment for "a breach of law" but such administrative punishment is exercised illegally or unreasonably, the company has a right of appeal according to the Administrative Appeal Law.

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?

Violation of the Pharmaceutical Affairs Law and/or the Standards for Fair Advertising Practices is subject to administrative punishment by the Ministry of Health, Labour and Welfare. As for violation of the Fair Competition Code, the Fair Trade Council of the Ethical Pharmaceutical Drugs Marketing Industry (and if necessary, the Consumer Affairs Agency and/or the Japan Fair Trade Commission) will implement required measures to preclude such violations. Also upon violation of the terms of the Code of Practices, the Promotion Code Committee, which was organised by the JPMA as a self-governing regulatory body, will take necessary measures. In general, these rules are enforced strictly, although there may be certain differences depending on the specific requirements of a given case. There are cases where a pharmaceutical company has received an administrative punishment for excessive advertisements. In addition, cases of serious breach of the Pharmaceutical Affairs Law are subject to criminal sanction (i.e., imprisonment with labour for not more than two years or a fine not exceeding two million yen, or the cumulative imposition of imprisonment with labour and a fine, according to the Pharmaceutical Affairs Law Article 85, item 4). Such serious sanctions against a company, together with a public announcement, would place it at a considerable disadvantage with respect to its business reputation in Japan. In respect of procedures for pursuing violations of these rules, the scope for direct action taken by competitors 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?

Matters regarding the Pharmaceutical Affairs Law may be investigated by the competent authorities (i.e., the Ministry of Health, Labour and Welfare and/or the competent prefectural government) and may not be regulated by any self-regulatory body. On the other hand, matters regarding the Code of Practices can be first assessed by the JPMA, the self-regulatory body which is referred to in questions 1.1 and 1.7 above. Also, matters regarding the Fair Competition Code may be assessed by another self-regulatory body named the Fair Trade Council of the Ethical Pharmaceutical Drugs Marketing Industry, but may also be investigated by the Consumer Affairs Agency and/or the Japan Fair Trade Commission independently.

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?

Any act which falls under the definition of 'unfair competition' is prohibited by the Act on Prohibition of Private Monopolization and Maintenance of Fair Trade and related guidelines prescribed by the Japan Fair Trade Commission, as well as the Unfair Competition Prevention Law. If a pharmaceutical company is in breach of the above-mentioned laws and guidelines, the Japan Fair Trade Commission may bring criminal or administrative proceedings, and it may be subject to criminal, administrative or civil sanctions in accordance with the type, nature and materiality of such breach.

2 Providing Information Prior to Authorisation of Medicinal Product

2.1 To what extent is it possible to make information available to health 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's variants not authorised)?

The Pharmaceutical Affairs Law stipulates that no person may advertise the name, manufacturing process or indications and effects of medicinal products before the approval for manufacture of that product. In accordance with the Code of Practices, however, this restriction is not intended to abridge the right of the scientific community and the public to be fully informed concerning scientific and medical progress. The following are examples of the permissible provision of information prior to the authorisation of a medicinal product in accordance with the commentary regarding the Code of Practices Article 1(3):

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

(b) the display of scientific exhibition materials about an unapproved drug in accordance with a separate guideline in a meeting of any international academic society. Although described as unapproved drugs, they must have been approved by some country, and in the case that they have not been approved by any country, such exhibition cannot be permitted. Moreover, such exhibition may be permitted in exceptional cases, and associated scientific literature and related literature cannot be distributed;

(c) the supply of a reprint of a research paper or previously reviewed scientific literature upon the request of a doctor; or

(d) the disclosure of medical information to stock holders in accordance with laws and regulations.

It is understood that the above interpretation is basically in accordance with the IFPMA (International Federation of Pharmaceutical Manufacturers Associations) Code of Pharmaceutical Marketing Practices. Although the foregoing requirements are strictly reviewed, insofar as they are satisfied, it is possible to provide information prior to the authorisation of a medicinal product at scientific meetings, even if such meetings are sponsored by the company responsible for the product.

The position is the same with regard to the provision of off-label information. According to the Standards for Fair Advertising Practices, which is related to the Pharmaceutical Affairs Law, representations of effect and efficacy of medicines which are required to be approved should be within the scope of the approved effect and efficacy. Additionally, the exemptions above are also true with respect to off-label information.

2.2 May information on unauthorised medicines be published? If so, in what circumstances?

Information on unauthorised medicines may not be published for advertisement purposes. Insofar as the above-noted conditions are satisfied (i.e., in the answer to question 2.1), it is possible to publish information on unauthorised medicines, but only for purposes of scientific and medical progress.

2.3 Is it possible for companies to issue press releases about medicinal products which are not yet authorised? If so, what limitations apply?

Companies are prohibited from issuing press releases about unauthorised medicinal products for advertisement purposes. Insofar as the above-noted conditions are satisfied (i.e., in the answer to question 2.1), it is possible for companies to issue press releases about medicinal products which have not yet been authorised, but only for purposes of scientific and medical progress.

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

Companies are prohibited from sending such information to health professionals for advertisement purposes. Insofar as the above-noted conditions are satisfied (i.e., in the answer to question 2.1), it is possible to send such information to health professionals, but only for purposes of scientific and medical progress.

2.5 May information be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?

It is considered possible to send such information in advance, unless in so doing the relevant pharmaceutical company contravenes any of the purposes of the Pharmaceutical Affairs Law, under which strict restrictions are imposed on providing information prior to the authorisation of a medicinal product. In other words, it is possible if such provision of information to institutions is actually intended to enable them to plan ahead in their budgets for products to be authorised in the future, and not intended to be advertisements.

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

The above answer to question 2.1 is also true with respect to this question. It may be permitted to the extent that the materials are not deemed advertisements. No specific guidelines have been issued on market research for medicinal products, however, the Code of Practices should be referred to on a case-by-case basis.

3 Advertisements to Health Professionals

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

The Standards for Fair Advertising Practices and other relevant rules stipulate that certain detailed information must appear in advertisements directed at health professionals. Such advertisements must include, for example, precise descriptions of the approved name, all indications and effects, methods of use, dosage of the medicinal product, a contact address from which to request further information, and the year and month 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 in the SmPC?

With respect to the restrictions on the information that may appear in the advertisements to healthcare professionals, Article 66 (Prohibition of false or exaggerated advertisements) and Article 68 (Prohibition of advertisements of unauthorised medicinal products) of the Pharmaceutical Affairs Law and the Standards for Fair Advertising Practices are also applied. In particular, please note that product information summaries or advertisements about prescription drugs must not be supplied to the general public, other than healthcare professionals, under the Standards for Fair Advertising Practices. Therefore, when distributing materials, for example, calendars and posters, adequate caution must be exercised to prevent the exposure of product names to the general public.

There are no specific restrictions that prohibit the provision of advertisements to healthcare professionals which refer to studies not in the SmPC.

However, Article 4 of the Code of Practices stipulates that it should be fully realised that brochures, advertisements in medical journals, websites targeting healthcare professionals, audiovisual 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 Law and relevant self-regulations, such as the Guidelines for Specifying Product Information Summaries for Prescription Drugs. The information contained therein must be correct, fair, and objective based on scientific data. Further, Article 4(6) of the Code of Practices 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 Law Article 66(2) stipulates that such material will be construed as corresponding to Article 66(1), which prohibits exaggerated advertisements to advertise, describe or circulate articles that might lead to a misunderstanding that physicians or other health professionals have guaranteed the indications and effects or properties/performance of the drug, quasi-drug, cosmetic or medical device. Therefore, it is possible that the inclusion of endorsements by healthcare professionals in promotional materials may lead to violation of the Pharmaceutical Affairs Law, if such advertisement is deemed an exaggerated advertisement. Additionally, The Standards for Fair Advertising Practices states that, in principle, pharmaceutical companies must not advertise using healthcare professionals to specify and recommend certain medicines and 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 are made?

There is no such requirement under the Pharmaceutical Affairs Law. However, the Code of Practices Article 4(4) stipulates that a pharmaceutical company should make comparative claims based on scientific data when it makes and uses promotional materials and advertisements and otherwise. Therefore, while there is no requirement to clearly specify the source of the data in promotional material or advertisements, it is a requirement that comparative claims are based on reasonable data which might be obtained through head-to-head trials. Also, please note that the Act against Unjustifiable Premiums and Misleading Representation, Article 4(2) stipulates that in the case of misleading representation, the Consumer Affairs Agency may require the entrepreneur concerned to submit data presenting reasonable grounds supporting such representation.

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 which had not yet been authorised in Japan?

The Japan Fair Trade Committee gives general examples of inappropriate comparative advertisements, as follows:

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

(b) comparison based on unfair grounds, such as an emphasis of the importance of issues which 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.

With respect to medicinal products, in addition to the above general rules, The Code of Practices stipulates that comparative advertisements must be conducted properly based on scientific data. In accordance with the commentary regarding the Code of Practices Article 4(4), it is important for healthcare professionals, in deciding which drug to use, to make a comparison between a new drug and an existing drug and to ascertain where and how they differ, and the drug which the new drug is being compared against must, in principle, be referred to using its generic name. Therefore, another company's brand name must not be used as part of that comparison without the consent of such company. The same restriction should be applied to a competitor's product which has not been authorised in Japan.

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

Article 5(2) of the Fair Competition Code stipulates, as an example, that it is not against the Fair Competition Code to provide information or explanatory materials concerning medical/pharmaceutical data or a medicinal product manufactured by such pharmaceutical company. The scientific papers and/or proceedings of congresses for doctors will be included in such information or materials.

Notwithstanding the above, in the case that, in accordance with the definition of "advertisement" in question 1.2, the scientific papers and/or proceedings of congresses distributed to doctors are interpreted as "advertising", the rules described above will be applied to such papers.

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

The Code of Practices stipulates that advertisements which are mainly composed of the name of medicinal products must be accompanied by certain medicinal information (i.e., therapeutic category, regulatory classification, general 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., catchphrases, indications and effects, methods of use and dosage of such products), and must indicate clearly that such information is provided on the drug package insert. In this sense, "teaser" advertisements are not permitted.

4 Gifts and Financial Incentives

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

It is possible, provided that the pharmaceutical company must supply only the required minimum samples, which must be accompanied by medicinal information on the products, since it is contemplated that such samples may be supplied to the prescribing professionals to familiarise them with the products, and to enable them to gain experience with the product in their practice. The Fair Competition Code stipulates in detail the terms and conditions of permitted provisions for such samples.

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

In accordance with the Fair Competition Code, inappropriate financial or material benefits, which are accompanied by transactions of medicinal products, should not be offered to medical practitioners in order to influence them in the prescription of medicinal products; provided, however, that a pharmaceutical company may offer financial or material benefits which are recognised as "discount" or "after-sales service" in light of normal

business practices, which ordinarily accompany medicinal products. The Code of Practices stipulates that, even if such offerings are permissible, a pharmaceutical company must not give gifts or donations of money which may threaten to influence the proper use of medicinal products or which may offend against the decency of medicinal products. On the other hand, if a pharmaceutical company gives inappropriate gifts or donations of money to a medical practitioner who is a public official, the pharmaceutical company and the medical practitioner may be subject to a charge of bribery under the Criminal 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 institutions 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 with respect to this question. In addition, the Fair Competition Code clearly states that it is possible to pay remuneration, costs and expenses for post-marketing surveillance studies, clinical trials or other medical or pharmaceutical research or study, if such study is requested by such institutions. On the other hand, if a pharmaceutical company gives inappropriate gifts or donations of money to a public hospital, such as a national hospital, the pharmaceutical company and the public hospital will be charged with bribery under the Criminal Code and/or under the National Public Official Moral Code.

4.4 Is it possible to provide medical or educational goods and services to doctors 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?

It is possible to provide such goods and services as long as they comply with the Pharmaceutical Affairs Law, the Standards for Fair Advertising Practices and the relevant rules which are elaborated in our answers to the above questions. In particular, we would like to draw your attention to the Standards for Fair Advertising Practices, which prohibit advertisements which would be misleading by representing effects which are different from the primary effects of the drugs (item 3(9) thereof) and those which would urge overuse of the drugs (item 4 thereof). Please 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?

There are not many cases in Japan where a pharmaceutical company supplies 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, a pharmaceutical company should specify the standard, timing and method of the discount in a prior agreement. Also, a pharmaceutical company must not offer excessive or discretionary discounts which create a potential risk that such pharmaceutical company may restrict wholesalers' business operations, including but not limited to, retail pricing, sales of competing goods and the scope of sales territory. In other words, 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 states that it is possible, provided that such offer must be confined to the extent that offers of goods or services are necessary in order to use the offerer's ethical pharmaceutical drugs in medical institutions, etc., or such as to enhance their efficacy or convenience (Article 5(1)). It is also possible to provide medical or pharmaceutical information or explanatory material 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 refund scheme. However, such a scheme may be considered a promotion representing assurances of the effectiveness and safety of the product, in which case it would be prohibited in Japan. In addition, in practice in Japan, pharmaceutical companies do not sell prescription-only medicine directly to hospitals, but instead sell to distributors. Therefore, such refund scheme, based on whether or not the product works, is unlikely to be an issue in regard to prescription-only medicine.

The possibility that such refund scheme may be considered a promotion, representing assurances of the effectiveness and safety of the product, could be the same as that applied to sales of over-the-counter 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 can sponsor continuing medical education in the same way as other businesses. However, even if the purpose of the investment is education, the above answer to question 4.2 is also applicable with respect to this question and the value of such investment must not be excessive.

5 Hospitality and Related Payments

5.1 What rules govern the offering of hospitality to health professionals? Does it make a difference if the hospitality offered to those health professionals will take place in another country?

The Code of Practices stipulates that the offering of hospitality to health professionals, such as a convivial party accompanied with lectures and symposia, should be kept to a modest level and should not offend against the decency of medicinal products. In the event that a pharmaceutical company offers inappropriate hospitality to health professionals who belong to a public hospital such as a

national hospital organisation, such pharmaceutical company and such health professionals will be charged with bribery under the Criminal Code and/or under the National Public Official Moral Code. In addition, the above applies even if the hospitality offered to those professionals takes place in another country.

5.2 Is it possible to pay for a doctor 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?

It is possible, provided that such payment should be kept to a modest level and should not influence a doctor in the prescription of medicinal products. In accordance with the Fair Competition Code, it is possible for pharmaceutical companies to 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 health professionals who belong to a public hospital, such as a national hospital organisation, such payment will be subject to a charge of bribery under the Criminal 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 doctors to attend?

It depends on the situation and what responsibility a pharmaceutical company should assume. Generally speaking, however, in the case in which a doctor or another third party is involved in illegal activities at the meeting, and if the pharmaceutical company that is sponsoring or organising such meeting does not know and should not have a reason to know of such illegal activities, the pharmaceutical company will not be responsible. However, if the pharmaceutical company were to be directly involved in illegal activities with doctors or another third party, for example, illegal advertisement activities, the pharmaceutical company may then be responsible for the activities.

5.4 Is it possible to pay doctors to provide expert services (e.g. participating in focus groups)? If so, what restrictions apply?

The above answer to question 5.2 is also true in response to this question, i.e., it is possible; provided that such payment should be kept to a modest level and should not influence a doctor in the prescription of medicinal products. In the case of health professionals who belong to a public hospital such as a national hospital organisation, such payment will be subject to a charge of bribery under the Criminal Code and/or under the National Public Official Moral Code. We are not aware of any specific rules or guidelines applicable to participation in focus groups.

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

Article 5(4) of the Fair Competition Code provides that it is not against the Fair Competition Code if pharmaceutical companies pay health professionals reasonable compensation and costs of post-marketing surveillance studies, trials and otherwise. Notwithstanding the above, in the case of health professionals who belong to a public hospital, such as a national hospital organisation, such payment will be subject to a charge of bribery under the Criminal Code and/or under the National Public Official Moral Code.

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

It is possible to pay health professionals reasonable compensation and costs of post-marketing surveillance studies, as stated in question 5.5. However, Article 3 of the Fair Competition Code stipulates that pharmaceutical companies should not provide premiums to medical institutions as a means of unfairly inducing such institutions to buy their products; therefore, such compensation and costs should only be paid to a reasonable extent. In the case of health professionals who belong to a public hospital such as a national hospital organisation, such unreasonable payment will be subject to a charge of bribery under the Criminal Code and/or under the National Public Official Moral 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?

It is possible. As to the applicable restrictions, the Pharmaceutical Affairs Law and the Standards for Fair Advertising Practices stipulate that, in relation to advertisements of non-prescription medicines to the general public, a pharmaceutical company must not make a false or exaggerated advertisement in relation to their name, method of manufacturing or indications or effects. However, please note that, in accordance with the amendment of the Pharmaceutical Affairs Law, which was not directly related to advertisement, and came into force on June 1, 2009, the amendment of the ministerial ordinance of the Law was made public on February 6, 2009, and also came into force on June 1, 2009. According to this amendment (of the ministerial ordinance), non-prescription medicines, excluding ones which have a low risk of adverse effects, are prohibited from being sold on the Internet or by other forms of mail order. Under the amended regulation, as noted above, it is not possible to advertise to market such medicines on the Internet or by other forms of mail order.

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

It is not possible, since 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 disease awareness campaigns are recognised as advertisements of prescription-only medicines in view of the particular medical condition targeted by the campaign, the purpose of the campaign, and the extent of involvement of the pharmaceutical company and other circumstances, such disease awareness campaigns could be

prohibited. We recommend consulting with the relevant authority (prefectural governments having jurisdiction over the advertising provider) in advance, if there is doubt as to whether the campaign is permissible or not.

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

It is not possible, since 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?

In accordance with the definition of advertisement in question 1.2, if the description of products and research initiatives is seen as the promotion of the particular products and is interpreted as "advertising", the rules described above will also be applied. In addition, of course, pharmaceutical companies are required to make such materials correct, fair and objective based on scientific evidence.

6.6 What, if any, rules apply to meetings with and funding of patient support groups, including any transparency requirement as regards the recording of donations and other support in corporate reports?

We could not find any such rule that is specifically intended to cover meetings with and funding of patient support groups.

7 The Internet

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

It is often difficult, especially on the Internet, to distinguish between non-product related information provisions to consumers and advertisements of particular products. Internet advertisements are recognised as "advertisements of medicinal products", and are subject to certain restrictions under the Pharmaceutical Affairs Law, such as a limitation on advertisement of medicinal products before their approval for manufacture, if the advertisement fulfils all of the above conditions which are referred to in the answer to question 2.1.

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 should be restricted.

Moreover, with respect to advertisements of unauthorised medicinal products, inspection and guidance are strengthened by the issuance of Notice No. 0301-1 of April 1, 2010, by the Compliance and Narcotics Division of the Pharmaceutical and Food Safety Bureau of the Ministry of Health, Labour, and Welfare, which enables the division to request providers who display such advertisements on the Internet to take measures to prevent displaying the advertisement of unauthorised medicinal products.

7.2 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 health professionals?

Notwithstanding the answer to question 7.1 above, the commentary of the Code of Practices states that it is necessary to restrict access from members of the general public, such as through the use of a password, in connection with the Standards for Fair Advertising Practices. Even in cases where there remains a possibility of access by individuals other than health professionals, according to the commentary on Article 4 of the Code of Practices, such a website is permissible as one of the methods of information services and not as promotion to patients, 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 health professionals; and

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

7.3 What rules apply to the content of independent websites that may be accessed by 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 proper rules in place regarding website advertising. However, under the Pharmaceutical Affairs Law, website links will be deemed to be advertisements as a unit if the purpose is judged to be to intend to induce consumers, as they are easily capable of being acknowledged by the general public.

Therefore, the company will be held responsible for the content of the independent site in both cases.

In addition, the above answer to question 7.2 is also true in the context of this question with respect to the Code of Practices.

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

Generally speaking, the above answers to questions 6.1 to 6.6 and questions 7.2 to 7.3 are also true with respect to this question because websites are also a form of advertising as can be seen in the answer to question 1.2. Regarding non-proprietary drugs, Article 3(I)(5) of the "Voluntary Standards regarding Advertising of Non-proprietary Drugs" (established on April 1, 2007, by the Japan Self-Medication Industry), which Standards do not constitute formal rules, stipulate that companies may advertise on their websites the effectiveness of their products or their components, as well as information about dosage and formulation. In this case, such companies are also required to indicate the source of the data, to submit the advertisement to the Advertising Review Board within one week, and not to accentuate their assurances of effectiveness and safety.

8 General - Medical Devices

8.1 What laws and codes of practice govern the advertising of medical devices in Japan?

The Pharmaceutical Affairs Law and the Standards for Fair Advertising Practices stipulate certain restrictions on advertising of medical devices as well as medicinal products. As for self-regulation and discipline, the "Fair Competition Code concerning Restriction on Premium Offers in the Medical Devices Industry" is applicable.

8.2 Are there any restrictions on payments or hospitality offered to doctors in connection with the promotion of a medical device?

The Fair Competition Code referred to in the answer to question 8.1 prohibits payments or the offering of hospitality to healthcare professionals for the purpose of unfairly inducing an order of medical devices. In the case of doctors who belong to a public hospital such as a national hospital organisation, such payment or hospitality will be subject to a charge of bribery and/or the provisions under the National Public Official Moral Code.

9 Developments in Pharmaceutical Advertising

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

There have been no significant developments in the last year.

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

There are no significant developments expected in the next year.

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

There has been an increase in drugs and health foods for beauty and dieting in the Japanese market. According to the Tokyo Metropolitan Government, regarding cases of infractions, there seems to be a trend towards drugs which claim to have unauthorised effects being more readily detected and an increase in infractions of the Pharmaceutical Affairs Law, Article 68 (Prohibition of advertisements of unauthorised medicinal products) involving health foods for beauty and dieting which claim to have medical effects.

Somuku Iimura

Nishimura & Asahi
Ark Mori Building, 1-12-32 Akasaka
Minato-ku, Tokyo 107-6029
Japan

Tel: +81 3 5562 9009
Fax: +81 3 5561 9711
Email: s_iimura@jurists.co.jp
URL: www.jurists.co.jp/en/

Mr. Iimura was born in Sapporo, Hokkaido, Japan. After studying at the University of Tokyo (LL.B., 1981), and the Legal Training and Research Institute of the Supreme Court of Japan (1986), he was admitted to the bar in 1986.
Mr. Iimura is a member of the executive committee of the firm and a member of the firm's antitrust group. He specialises in general corporate, M&A and antitrust related matters. He has considerable experience in handling pharmaceutical-related matters, including applications for new products, negotiation with jurisdictional authorities to defend clients, review of the indication of products and advertisements, including antitrust regulations relating thereto, and handling related disputes. He co-authored the Japan chapter of The International Comparative Legal Guide to Pharmaceutical Advertising 2010.

Yoko Kasai

Nishimura & Asahi
Ark Mori Building, 1-12-32 Akasaka
Minato-ku, Tokyo 107-6029
Japan

Tel: +81 3 5562 8871
Fax: +81 3 5561 9711
Email: yo_kasai@jurists.co.jp
URL: www.jurists.co.jp/en/

Yoko Kasai is an associate at Nishimura & Asahi. Ms. Kasai received her B.S. in Pharmaceutical Sciences from the University of Tokyo in 2005, and qualified as a pharmacist in 2005. She received her J.D. from the University of Tokyo, School of Law in 2008, and was admitted to the bar in 2009.
Ms. Kasai specialises in intellectual property, including patents, copyrights trademarks and unfair competition. Her practice focuses on pharmaceuticals, biomedical sciences, chemicals, information technology, entertainment, and e-commerce. She also handles pharmaceutical-related issues such as assisting in the applications for new products, negotiation with jurisdictional authorities to defend clients, and the review of the indication of products and advertisements.

NISHIMURA
& ASAHI

Nishimura & Asahi is one of Japan's premier full-service law firms, covering all aspects of domestic and international business and corporate activity. The firm currently has more than 500 Japanese and foreign lawyers and employs over 550 support staff, including tax accountants, and one of the largest teams of paralegals in Japan.

Through the enhancement of professional and organisational synergies, resulting from the firm's expansion, an unprecedented level of client service is made possible in highly specialised and complex areas of commercial law. Nishimura & Asahi understands its clients' growing needs and its fully integrated team of lawyers and professional staff are proud to share the same fundamental philosophy: an uncompromising commitment to excellence.

In order to further enhance its overseas practice, the firm opened a representative office in Beijing, China in June 2010, and an office in HCMC, Vietnam in November 2010.

Key areas of practice:

Acquisition Finance, Administrative Disputes, Antitrust, Asset Finance, Asset Management, Assistance to Administrative Organisations, Banking, Capital Markets, Civil & Commercial Disputes, Compliance, Corporate Crisis Management, Education and Professional Activities, General Corporate, Insurance, International Trade, International Transactions, IP Disputes, IP Licenses, Labour Law, M&A, PFI/Project Finance, Real Estate/Environmental, Restructuring/Insolvency, Specialised Disputes, Start-up Businesses, Structured Finance/Securitisation, Tax, Tax Disputes, Telecommunications/Media, Transnational Dispute Settlement, Trusts & Estates, Venture Capital/IP Finance.

Managing Partner: Mr. Masaki Hosaka

Languages Spoken: Japanese, English, Chinese (Mandarin) and French

Total number of lawyers: 498

Email: info@jurists.co.jp