

The International Comparative Legal Guide to:

Pharmaceutical Advertising 2009

A practical insight to cross-border Pharmaceutical Advertising work



Published by Global Legal Group with contributions from:

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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, 1970, 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. As to 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 Japan Pharmaceutical Manufacturers Association (“JPMA”), as amended) (the “Code of Practices”) and the “Fair Competition Rules concerning Restriction on Provision of Unjustifiable Premium in Manufacture of Ethical Drugs” (enforced on July 1, 1984, by the Fair Trade Council of the Ethical Pharmaceutical Drugs Manufacturing Industry, as amended) (the “Fair Competition Rules”). The Fair Competition Rules were 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;
- (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 have an appointment two or three months before the consultation.

In addition, according to Article 4 (2) and relevant regulations of the Act against Unjustifiable Premiums and Misleading Representation, the Fair Trade Commission may, whenever necessary, designate a period of fifteen (15) days and require the entrepreneur concerned to submit data as reasonable grounds for the representation he has made. In such cases, if the entrepreneur fails to submit the data, the representation concerned shall 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 refer to the answer provided under the heading of the next question.

1.4 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, the Code of Practices stipulates that pharmaceutical companies should establish and maintain an appropriate management system in which advertisements should be screened before use by the responsible person. 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.

1.5 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 rights of appeal according to the Administrative Appeal Law.

1.6 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 to violation of the Fair Competition Rules, the Fair Trade Council of the Ethical Pharmaceutical Drugs Manufacturing Industry (and if necessary, 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, shall take adequate procedures. In general, we should indicate that 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 and the Fair Competition Rules are subject to criminal sanction (i.e., up to two years imprisonment and/or up to a 1 million yen fine). 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.

1.7 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 1.6 above. Also, matters regarding The Fair Competition Rules may be assessed by another self-regulatory body named the Fair Trade Council of the Ethical Pharmaceutical Drugs Manufacturing Industry, but may also be investigated by the Japan Fair Trade Commission independently.

1.8 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 Monopolisation 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, it is subject to criminal, administrative or civil sanctions in accordance with the type, nature and materiality of such breach. The Japan Fair Trade Commission may bring criminal or administrative proceedings.

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?

The Pharmaceutical Affairs Law stipulates that no person shall advertise the name, manufacturing process or indications and effects of medicinal products before the approval for manufacture of the same. 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 permissible provision of information prior to the authorisation of a medicinal product:

- (a) a full and proper exchange of scientific information concerning a medicinal product, including appropriate dissemination of investigational findings in scientific communications media and at scientific conferences;
- (b) exhibition or distribution of promotional material, subject to the prescribed guidelines, at international congresses or symposia; and
- (c) public disclosure to stockholders and others concerning any medicinal product as may be required or desirable under relevant law, rules or 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. We can find no difference as to whether or not such a meeting is sponsored by the company responsible for the product.

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?

It is prohibited for companies to issue 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?

It is prohibited for companies to send 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 make 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 advertising. No proper guidelines have been issued on market research for medicinal products, but 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 certain detailed information to 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, address from which to request further information to be available and the year and month of preparation for such advertisements.

3.2 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 restriction under the Pharmaceutical Affairs Law. However, the Code of Practices 4.(4) stipulates that a pharmaceutical company should make comparative claims by using objective data when it makes and uses promotional materials and advertisements and otherwise. Therefore, while it is not required to clearly specify the data in promotional materials or advertisements, it is required to make comparative claims 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 case of misleading representation, the Japan Fair Trade Commission may require the entrepreneur concerned to submit data presenting reasonable grounds supporting such representation.

3.3 What rules govern comparator 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 comparator advertisements, as follows:

- (a) comparison by indicating issues incapable of exemplification or that have not been exemplified;
- (b) comparison based on unfair grounds such as emphasis on issues inconsequential to selection of products by consumer as if they were important, or arbitrary selection of the compared products; and
- (c) advertisements disparaging another company and/or its products.

The Code of Practices stipulates as to medicinal products, in addition to the above general rules, that comparator advertisements must be conducted properly based on objective scientific data. In accordance with the commentary of the Code of Practices, it is impossible to use another company's brand name as part of that comparison without the consent of such other company. The same restriction should be applied to a competitor's product which has not been authorised in Japan.

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

Article 5 (2) of the Fair Competition Rules stipulates, as an example, that it is not against the Fair Competition Rules 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 for doctors are interpreted as the "advertising", the rules described above will be applied to such papers.

3.5 Are "teaser" advertisements permitted, which 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 It is possible to provide health professionals with samples of products? If so, what restrictions apply?

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

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 Rules, 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 shall 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 will be subject to a charge of bribery under the Criminal Code (Law No. 45 of April 24, 1908, 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 Rules clearly state 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. Especially, 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?

In Japan, there are not so many cases 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.

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 Rules state that it is possible; provided that such offer must be confined to the extent that such additional services or equipment are contemplated as necessary or beneficial for use of the medicinal product manufactured by such pharmaceutical company. It is also possible to provide information or explanatory material concerning a medicinal product manufactured by such a pharmaceutical company.

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 promotion, representing assurances of 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?

We have 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, there is no difference 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 Rules, 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 situations 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 which is sponsoring or organising such meeting does not know and should not have reason to know of such illegal activities, the pharmaceutical company will not be responsible. On the other hand, 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 cannot find 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 Rules provides that it is not against the Fair Competition Rules 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. Article 3 of the Fair Competition Rules stipulates, however, that pharmaceutical companies should not provide premiums to medical institutions and otherwise as a means of unjustifiable invitation of the transaction as to medical production; therefore, such compensation and costs should be paid to the 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 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 will come into force on June 1, 2009, the amendment of the ministerial ordinance of the Law was made public on February 6, 2009 and will also come 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 will not be possible to advertise to sell 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?

It is possible; provided that, if such disease awareness campaigns are recognised as advertisements of prescription-only medicines based on a particular medical condition, purpose of the campaign, extent of involvement of the pharmaceutical company and other circumstances, such disease awareness campaigns are 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 basis.

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 prescription-only medicines’ information should be restricted. According to our experience, we feel most of such advertisements have been controlled well.

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 Code of Practices stipulates that it is necessary to restrict access from members of the general public, such as through the use of a password, as required by the Standards for Fair Advertising Practices. Even in cases where there remains a possibility of access by individuals other than health professionals, such a website will be permissible as one of the methods of information service and not as promotion to patients, if the following requirements are fulfilled:

- the identity of the pharmaceutical company and of the health professionals is readily apparent;
- access to the website can be gained only upon confirmation that the user is a health professional;
- the content is appropriate for the health professionals; and
- links are both appropriate and apparent to the health professionals.

In this sense, it would be sufficient for a pharmaceutical company to restrict access to its website on normally required level.

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 advertisement as a unit if the purpose is judged to be intended 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 advertising as can be seen in the answer to question 1.2. Regarding non-proprietary drugs, 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 a formal rule, 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 advertising to 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 Rules concerning Restriction on Provision of Unjustifiable Premium in Manufacture of Medical Devices" are applicable.

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

Fair Competition Rules referred to in the answer to question 8.1 prohibit payments or the offering of hospitality to health professionals to unfairly invite 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 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. However, as stated in our answer to question 6.1, in accordance with the amendment of the Pharmaceutical Affairs Law which was not directly related to advertisement, and will come into force on June 1, 2009, the amendment of the ministerial ordinance of the Law was made public on February 6, 2009 and will also come into force on June 1, 2009. According to this amendment (of the ministerial ordinance), non-proprietary drugs, 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. This amendment has been, and is likely to continue to be, a hot issue in the Japanese pharmaceutical industry. Please note that, under the amended regulation, as noted above, the advertising of such drugs will not be permitted.

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 medicines) involving health foods for beauty and dieting which claim to have medical effects.

9.4 Has your national code been amended in order to implement the current version of the EFPIA Code of October 2007?

There have been no amendments to date.

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