Japan

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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 Act (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, issued by the Director-General of the Pharmaceutical Affairs Bureau of the former Ministry of Welfare, as amended) ("Standards for Fair Advertising Practices") define the applicable baseline standards for advertising practices with respect to medicinal products. In addition, there are a number of codes of practice relating to industry-level self-regulation of promotional activities for medicinal products, 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 ("FTC-EDMI"), as amended) (the "Fair Competition Code"). The Fair Competition Code was established upon certification by the Japan Fair Trade Commission ("JFTC") and the Consumer Affairs Agency ("CAA") in accordance with the Act against Unjustifiable Premiums and Misleading Representation (Law No. 134 of May 15, 1962, as amended).

1.2 How is "advertising" defined?

According to Notice No. 148 of September 29, 1998, issued by the Pharmaceutical Safety Bureau of the former Ministry of Welfare, "advertising" under the Pharmaceutical Affairs Act is defined as that which fulfils each 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 viewed by the public.

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

The Pharmaceutical Affairs Act does not have any provision requiring pharmaceutical companies to implement any such arrangements. However, many pharmaceutical companies have established a process for reviewing and approving advertisements and other promotional materials in accordance with the Code of Practices to ensure that their advertisements comply with legal requirements. Article 4(9) of the Code of Practices provides 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".

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

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

1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?

The Pharmaceutical Affairs Act does not require advance approval by a regulator or industry authority to advertise medicinal products. However, a pharmaceutical company may consult with a regulator regarding the products' advertising in order to ensure that the advertising complies with legal requirements before it is used.

1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?

Although the Pharmaceutical Affairs Act does not clearly specify that the authorities have powers to stop further publication of such advertisements, the authorities control and restrict advertisements that breach the Pharmaceutical Affairs Act and the Standards for Fair Advertising Practices via administrative guidance. However, the authorities cannot insist on the issuance of a corrective statement. With respect to a marketing authorisation holder or

manufacturer of medicinal products, if there is a serious offence, the Minister of the Ministry of Health, Labour and Welfare ("MHLW") may cancel the company's licence and may order it to suspend all or part of its business for a given period if the company violates the Pharmaceutical Affairs Act or other laws and ordinances related to pharmaceutical affairs. The company has a right of appeal according to the Administrative Appeal Act (Law No. 160 of September 15, 1962, as amended).

1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? To what extent may competitors take direct action through the courts?

Violation of the Pharmaceutical Affairs Act and/or the Standards for Fair Advertising Practices is subject to an administrative penalty issued by the MHLW. As for violation of the Fair Competition Code, the FTC-EDMI (and if necessary, the CAA and/or the JFTC) 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 established 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 in any given case. There are cases where pharmaceutical companies have received an administrative penalty for excessive advertising. In addition, cases of serious breaches of the Pharmaceutical Affairs Act are subject to criminal sanction (i.e. imprisonment with work for not more than two years or a fine not exceeding two million yen, or both, according to the Pharmaceutical Affairs Act Article 85). Such serious sanctions against a company, together with a public announcement, would have a significantly negative impact on that company's business reputation in Japan. There is limited scope for competitors to take direct action in respect of violations of these rules.

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 Act may be investigated by the competent authorities (i.e. the MHLW 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 FTC-EDMI, but may also be investigated separately by the CAA and/or the JFTC.

1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?

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

2 Providing Information Prior to Authorisation of Medicinal Product

2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?

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

In connection with the prohibition of advertising of unauthorised medicine, according to the commentary of the Code of Practices, in the following cases it is permissible to provide information on unauthorised medicine:

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

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

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

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

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

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

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 under the Pharmaceutical Affairs Act, as described in the answer to question 2.1.

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

Issuing press releases about unauthorised medicinal products for advertising purposes is prohibited under the Pharmaceutical Affairs Act. However, according to the commentary of the Code of Practices, the provision of information regarding products under development to the company's shareholders based on the relevant laws and regulations is permitted, unless the information is intended to be used for the promotion of such products.

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

Companies are prohibited from sending such information to healthcare professionals for advertisement purposes under the Pharmaceutical Affairs Act, as described in the answer to question 2.1.

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

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

2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?

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

2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products 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. However, if such market research involving healthcare professionals is conducted for the purpose of promoting unauthorised medicinal products, it would be deemed as advertising of unauthorised medicinal products prohibited 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 which must appear in advertisements directed to healthcare professionals. However, the Guidelines for Preparation of Outline of Prescription Pharmaceutical Product Information and for Preparation of Advertisements of Prescription Drugs Inserted in Scientific Journals, which is a self-regulatory code issued by the JPMA, stipulate that certain detailed information must appear in advertisements directed at healthcare professionals. Such advertisements must include, among others, precise descriptions of the brand name, generic name, therapeutic category, regulatory classification, presence or absence of listing on the National Health Insurance price list, a contact address from which to request further information, and the date of preparation of such advertisements.

3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not 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 Act 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 to 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 the general public to product names.

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 understood 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 Act 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, and 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?

Article 66(2) of the Pharmaceutical Affairs Act 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 healthcare professionals have guaranteed the indications and effects or properties/performance of the medicinal

products. Therefore, it is possible that the inclusion of endorsements by healthcare professionals in promotional materials may lead to a violation of the Pharmaceutical Affairs Act, 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 or provide instructions on how to use them.

3.4 Is it a requirement that there be data from any or a particular number of "head to head" clinical trials before comparative claims are made?

There is no such requirement under the Pharmaceutical Affairs Act. However, Article 4(4) of the Code of Practices stipulates that comparative claims should be made based on scientific data when included in promotional materials, 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 be based on reasonable data which might be obtained through head-to-head trials. Also, please note that Article 4(2) of the Act against Unjustifiable Premiums and Misleading Representation stipulates that, in the case of misleading representations, the CAA may require the company concerned to submit data presenting reasonable grounds supporting such representations.

3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product which had not yet been authorised in Japan?

In connection with the Act against Unjustifiable Premiums and Misleading Representation, the JFTC 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 on 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 name and/or the brand name of its products 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 healthcare professionals?

Article 5(2) of the Fair Competition Code stipulates, as an example, that it is not restricted by 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, if, in accordance with the definition of "advertisement" described in the answer to question 1.2 above, 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, generic name and presence or absence of listing on the National Health Insurance price list), as well as an address from which one may request further information. In addition, such advertisements must not include information concerning the safety or effectiveness of the given product (i.e. indications and effects, methods of use and dosage of such products), and must indicate clearly that such information is provided 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 healthcare 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 products in their practice. The Fair Competition Code stipulates, in detail, the terms and conditions of the permitted provisions of such samples.

4.2 Is it possible to give gifts or donations of money to healthcare professionals? 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 "discounts" 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 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 healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply?

The above answer to question 4.2 is also true 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 a study is requested by such institutions. Please note, however, that pharmaceutical companies should comply with the detailed guidelines under the Fair Competition Code, such as the Standards of Premium Offers and the Standards of Donation issued by the JFTC and the CAA.

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

It is possible to provide such goods and services as long as they comply with the Pharmaceutical Affairs Act, the Standards for Fair Advertising Practices and the Fair Competition Code and relevant guidelines. In particular, the Standards for Fair Advertising Practices, which prohibit advertisements that are misleading by representing effects which are different from the primary effects of the drugs (Article 3(9) thereof) and those which urge overuse of the drugs (Article 4 thereof). Please also refer to the answers to questions 4.1 and 4.2 above.

4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?

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

4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed?

The Fair Competition Code 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 a 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 a refund scheme, based on whether or not the product works, is unlikely to be an issue in regard to prescription-only medicines.

The possibility that such a refund scheme may be considered a promotion, representing assurances of the effectiveness and safety of the product, could also apply 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 healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?

The Hospitality-related Guidelines under the Fair Competition Code govern the offering of hospitality to healthcare professionals. The guidelines clearly specify what is permissible when pharmaceutical companies entertain healthcare professionals and the maximum amount which can be spent for such entertainment, and prohibits providing particular forms of entertainment (golf, karaoke, etc.).

The Code of Practices also stipulates that the offering of hospitality to healthcare 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 healthcare professionals who belong to a public hospital such as a national hospital organisation, such pharmaceutical company and such healthcare professionals may 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 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?

It is possible, but in a limited sense, provided that such payment is kept to a modest level and does not influence a doctor in the prescription of medicinal products. In accordance with the Fair Competition Code, 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 healthcare professionals who belong to a public hospital, such as a national hospital organisation, such payment may 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 healthcare professionals to attend?

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

5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?

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

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

Article 5(4) of the Fair Competition Code provides that it is not against the Fair Competition Code if pharmaceutical companies pay healthcare professionals reasonable compensation and costs for post-marketing surveillance studies, trials and otherwise.

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

It is possible to pay healthcare professionals reasonable compensation and costs to take part in market research, on the condition that the relevant guidelines regarding payment for research under the Fair Competition Code are complied with.

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

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

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 as advertisements of the specific prescription-only medicine. We recommend consulting with the relevant regulatory authority in advance if there is doubt as to whether or not the campaign is permissible.

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

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, and to base them on scientific evidence.

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

Although there is no specific requirement in law, the JPMA has established a self-regulatory code for member companies to make information publicly available about donations, grants, benefits in kind or any other support provided by them to healthcare professionals and patient groups (the "Transparency Guidelines"). The Transparency Guidelines recommend that member companies make information publicly available about their financial contributions to patient support groups for the previous fiscal year through their website. The disclosed information includes contributions to groups' meeting costs, grants for supporting patient groups, payments for writing articles and payments for information which member companies have provided to patient support groups.

7 Transparency and Disclosure

7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, what information should be disclosed, and when and how?

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

7.2 Has your national code been amended in order to implement the 2013 EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations and, if so, does the change go beyond the requirements of the EFPIA Disclosure Code or simply implement them without variation?

No specific national code has been amended in order to implement the 2013 EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations.

7.3 If the EFPIA Disclosure Code has not been implemented in Japan, is there a requirement in law and/or 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 information should be disclosed, from what date and how?

Although there is no specific legal requirement, the Transparency Guidelines recommend that member companies make information publicly available about their financial contributions to healthcare professionals for the previous fiscal year through their website. The disclosed information includes contributions to research and development costs, grants for academic research, payments for writing articles and payments for information that member companies have provided to healthcare professionals. The Transparency Guidelines also recommend that member companies make information publicly available about financial contributions to patient groups in the same manner.

8 The Internet

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

Internet advertisements of medicinal products are also subject to advertising regulations under the Pharmaceutical Affairs Act, if the advertisements meet all of the above conditions which are referred to in the answer to question 1.2.

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

8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?

The commentary 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 healthcare professionals, according to the commentary of the Code of Practices, such a website is permissible as one of the methods of information services and not as promotion to the general public, if the following requirements are fulfilled:

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

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

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

8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?

There are no specific rules regarding reverse linking of website advertising. However, under the Pharmaceutical Affairs Act, website links will be deemed to be advertisements if the purpose of inclusion of those links is judged to be intended inducement to consumers, as they are easily capable of being viewed by the public. Therefore, the company may be held responsible for the content of the independent site in both cases.

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

A pharmaceutical company may include on its website any information that it includes in advertisements and other promotional materials in other formats, provided that the website complies with the applicable legal requirements.

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

There are no specific rules, laws or guidance controlling the use of social media by companies regarding pharmaceutical advertising. If the advertising using social media meets all of the above conditions that are referred to in the answer to question 1.2, such advertising is subject to the advertising regulations under the Pharmaceutical Affairs Act.

9 Developments in Pharmaceutical Advertising

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

There have not been specific significant developments in relation to the rules relating to pharmaceutical advertising in the last year.

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

There are no specific significant developments in the field of pharmaceutical advertising expected in the next year.

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

There has been a trend over the last year or so whereby pharmaceutical companies have developed their transparency guidelines and disclosed the amount of research and development expenditure, research grant, etc., which is paid to healthcare institutions in order to ensure transparency in the relationship with healthcare institutions.

9.4 Has your national code been amended in order to implement the 2013 version of the EFPIA Code on the promotion of prescription-only medicines to, and interactions with, healthcare professionals (the EFPIA HCP Code) and, if so, does the change go beyond the new requirements of the EFPIA HCP Code or simply implement it without variation?

There is no specific national code which has been amended in order to implement the 2013 version of the EFPIA Code.

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