PROMOTION OF PHARMACEUTICALS AND MEDICAL DEVICES

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GENERAL

1. What laws and codes of practice govern the promotion and advertising of pharmaceuticals and medical devices in your jurisdiction? Please also include any relevant industry and self-regulatory codes.

The Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (the 'PMD Act') is the primary statute regulating the promotion and advertisement of pharmaceuticals and medical devices in Japan. The Ministry of Health, Labour and Welfare (the 'MHLW'), which is the governmental authority with responsibility for regulating pharmaceuticals and medical devices under the PMD Act, has issued the Guideline concerning Promotional Information Provision Activities of Prescription Drugs (the 'PIPA Guideline'), which provides for rules on the promotion and advertisement of pharmaceuticals. There are also various industry rules concerning the promotion and advertisement of pharmaceuticals and medical devices that were established by the relevant industry organisations in Japan. For example, the Japan Pharmaceutical Manufacturers Association (JPMA), which is an industry organisation of pharmaceutical companies in Japan, has established its Code of Practice and Promotion Code for Prescription Drugs, which apply to the promotion and advertisement of pharmaceuticals by its member companies. The Japan Federation of Medical Devices Associations (JFMDA), which is an industry organisation of medical device companies in Japan, has established the Promotion Code of the Medical Device Industry, which applies to the promotion and advertisement of medical devices by its member companies. Japanese rules governing promotion and advertising activities generally can also apply, such as the prohibition of misleading representations under the Act against Unjustifiable Premiums and Misleading Representations.

2. How is 'advertising' defined? If relevant in your jurisdiction, what is the difference between promotion and advertisement of pharmaceuticals? Of medical devices?

The definition of 'advertising' is not specified in the PMD Act. However, according to a regulatory notice issued by the MHLW, the 'advertising' of pharmaceuticals and medical devices is generally considered to be constituted if the following three criteria are met: (1) there is clear intent to solicit customers; (2) the name of the specific pharmaceutical/medical device product is evident; and (3) it is perceivable by ordinary persons.

The promotion of pharmaceutical and medical devices is generally considered to be broader than advertising. Under the JPMA Code of Practice, 'promotion' means 'to engage with healthcare professionals in the provision, collection, and communication of drug information and promote the proper use and adoption of prescription drugs on the basis of those interactions'. Under the JFMDA Promotion Code of the Medical Device Industry, 'promotion' refers not only to so-called sales promotion but also to 'the provision, collection, and communication of information on medical devices to medical institutions, healthcare professionals, etc. to ensure proper and safe use of medical devices'.

3. Which are the regulatory and supervisory authorities that regulate and enforce the promotion and advertisement of pharmaceuticals and medical devices? What is the relationship, if any, between any self-regulatory process and the supervisory and enforcement function of the competent authorities?

The MHLW is the governmental authority that regulates and enforces the rules on the promotion and advertisement of pharmaceuticals and medical devices under the PMD Act. The industry organisations (ie, the JPMA for pharmaceuticals and the JFMDA for medical devices) regulate and enforce their industry organisation rules on the promotion and advertisement of pharmaceutical/medical devices, which are applicable to their member companies. The supervisory and enforcement function of the MHLW is based on the regulatory authority granted under the Japanese statute (ie, the PMD Act), and is subject to statutory provisions governing the process for administrative actions taken by the Japanese Government. The supervisory and enforcement functions of the JPMA and JFMDA are based on the pharmaceutical/medical device companies' membership to these industry organisations, and are subject to the respective industry organisation rules for the processes for exercising these supervisory and enforcement functions.

4. Are there other product types that fall under the same regulations on promotion (and advertisement) as pharmaceuticals, such as food supplements, special nutritional products? If so, are there any special considerations for the promotion (and advertisement) of such other product types?

Quasi-pharmaceutical products and cosmetics are subject to the same advertisement regulations under the PMD Act that apply to pharmaceuticals and medical devices. Quasi-pharmaceutical products can include certain vitamin and calcium tablets, insecticides and hair dye. The MHLW has issued guidance on

the interpretation of the advertisement rules under the PMD Act that take into account special considerations for quasi-pharmaceutical products and cosmetics. For example, quasi-pharmaceutical products and cosmetics have more flexibility in the use of a brand name that differs from the officially approved product name.

There are various regulatory categorisations stipulated in the Japanese law that apply to food supplements and special nutritional products. The regulatory treatment of food supplements and special nutritional products under Japanese law differ depending on the regulatory categorisation applicable to the product. In addition to the quasi-pharmaceutical products regulated under the PMD Act, there are also various regulatory categorisations for food supplements and special nutritional products that are regulated under Japanese food regulations, such as the Health Promotion Act and the Food Labeling Act. Japanese food regulations also stipulate various regulatory requirements concerning the promotion and advertising of food products, such as the information that is required to be indicated and restrictions on the health claims that can be made in respect of the product.

CONSUMER MARKETING

5. Is it possible to promote (or advertise) all forms of pharmaceuticals and medical devices (eg, prescription only or professional use products) directly to the public? Are there restrictions on public promotion (advertisement) in your country and if so, which ones?

In Japan, publicly promoting or advertising prescription drugs and other professional use products is generally prohibited. The MHLW has issued regulatory guidance that prohibits public promotion and advertisement for pharmaceutical drugs that are used by physicians or are provided for use under the prescription or instruction of physicians. The MHLW regulatory guidance also generally prohibits public promotion and advertisement for medical devices provided for physician use.

6. Is promotion (and advertising) of pharmaceuticals and medical devices through the internet and social media regulated in your jurisdiction? If so, what are the rules and related restrictions?

Regulatory rules on the promotion and advertising of pharmaceuticals and medical devices generally apply to promotional and advertisement activities regardless of the medium, whether it be oral, written, by electronic means, or through the internet or social media. Industry organisation rules also provide for certain rules on the promotion and advertisement of pharmaceuticals and medical devices through the internet and social media. For example, the JPMA Promotion Code for Prescription Drugs stipulates rules that are applicable when its member pharmaceutical companies use their website to provide healthcare professionals with product-related information. For example, such website information is considered permissible for purposes of the public promotion and advertisement of prescription drugs, if the website fulfils the following conditions: (1) 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 confirms that the information is targeted at healthcare professionals; (2) the information is appropriate for healthcare professionals; and (3) if the company website targeting healthcare professionals is linked with any external website, the content and the website are appropriate for healthcare professionals and the owner (author) of the linked website is apparently recognised.

7. Must promotions (and/or advertisements) receive prior approvals from regulators before use and if so, what is the procedure (please provide a high-level description)?

Under the PMD Act, the package inserts of pharmaceutical and medical device products are required to be filed in advance with the regulatory authority, but there is no requirement for regulatory filing or prior regulatory approval of promotional materials and advertisements of pharmaceuticals and medical devices. It is primarily the responsibility of the marketing authorisation holder to prepare and review the materials used for the promotion and advertisement of its pharmaceutical and medical device products. The PMD Act requires that the marketing authorisation holder establishes and implements proper internal compliance systems within the company, which is generally considered to include measures to ensure the proper review of promotional and advertisement materials.

8. May information on unauthorised pharmaceuticals and/or off-label information be promoted (advertised)? If so, in what circumstances and under which modalities?

The promotion and advertisement of unauthorised pharmaceuticals and off-label information are generally prohibited in Japan. MHLW has issued guidance on limited situations in which information on unauthorised pharmaceuticals and off-label information can be provided. However, there are stringent requirements that must be satisfied to allow for such a provision of information, and this information cannot be provided for promotional or advertisement purposes. Under the PIPA Guideline, unauthorised pharmaceuticals and off-label information can be provided only if and to the extent requested by the recipient (eg, healthcare professionals), and there are various requirements that must be met, including,

for example: the provision of information must be separated from ordinary promotional activities; the information must be limited to those requested and the recipient must be limited to the person that requested the information; information cannot be summarised, abbreviated or emphasised; negative information must be properly provided; it must be clearly indicated that authorisation has not been obtained for the information provided; and records of the information provision activity must be properly kept.

9. What rules govern comparative advertisements? Is it possible to use another company's information (including brand name) as part of that comparison? If so, which information and under which conditions? Would it be possible to refer to a competitor's product or indication which has not yet been authorised in your jurisdiction?

The MHLW has issued regulatory guidance prohibiting advertisement that constitutes slandering and defaming competitor products. Both the JPMA and JFMDA have established rules that prohibit the promotion of pharmaceuticals and medical devices that constitutes slandering and defaming competitor products. Comparative advertisements are strictly regulated in Japan because they may constitute slandering and defaming competitor products. Under the JPMA and JFMDA rules on the promotion of pharmaceuticals and medical devices, comparisons with other products must be based on scientific data and, in principle, must be made using generic names. It is generally not permissible to refer to a competitor's product or indication that has not yet been authorised in Japan because the promotion and advertisement of unauthorised pharmaceuticals and off-label information are prohibited.

DEALING WITH HEALTHCARE PROFESSIONALS AND HEALTHCARE INSTITUTIONS

10. How are healthcare professionals defined in your jurisdiction? Is there any regulation that restricts promotional (advertisement) communications directed to healthcare professionals? If so, what are those restrictions?

There is no universal definition of the term 'healthcare professionals' in the context of Japan's promotion (advertising) regulations. The scope of healthcare professionals differs from regulation to regulation. Many promotional (advertising) regulations, such as those in the PMD Act, do not distinguish between communications to medical professionals and communications to other parties. On the other hand, the Fair Competition Codes in the ethical pharmaceutical drug industry and medical device industry contain regulations that specifically address promotional communications to medical professionals. The Fair Competition Codes prohibit the offer of goods, money, or other economic benefits to healthcare institutions or healthcare professionals as a means of improperly inducing them to trade in ethical pharmaceutical drugs or medical devices. The Fair Competition Codes are self-governing regulations established by the Fair Trade Council, an organisation composed of members from each of the relevant industries, based on the Act against Unjustifiable Premiums and Misleading Representations. The Fair Competition Codes have been accredited by the Fair Trade Commission and the Commissioner of the Consumer Affairs Agency of the Japanese Government.

11. Are there specific rules governing promotional (and advertising) activity conducted virtually, including online interactions with healthcare professionals, virtual meetings and participation in virtual congresses and symposia?

In Japan, there are no specific rules governing promotional (and advertising) activities conducted virtually. In principle, the same rules for promotional (and advertising) activities conducted in person apply to such activities conducted virtually.

12. Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional (advertising) materials? If so, which ones and how such endorsements may take place?

The MHLW has issued regulatory guidance prohibiting advertisements of pharmaceuticals and medical devices that include endorsements by or recommendations from healthcare professionals, healthcare institutions, pharmacies, or any other organisation that may affect the perception of the general public with respect to the efficacy or performance of the subject products.

13. Is it possible to provide healthcare professionals with samples of medicinal products? Of medical devices? If so, what restrictions apply? Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.

Pharmaceutical companies and medical device companies may provide healthcare professionals with samples of their pharmaceuticals and medical devices subject to the restrictions and regulations set forth in the applicable Fair Competition Code for the relevant industry. The Fair Competition Codes generally provide that samples can be provided only for the purposes of: (1) pre-confirmation of the external characteristics of the products; and/or (2) trial use in clinical settings to assess the efficacy/performance

and safety of the products in advance. The Fair Competition Codes also provide specific limits on the amount/volume of products that can be provided as samples depending on the category of the subject product.

Gifts and donations of money to healthcare professionals are also regulated by the Fair Competition Code. The Fair Competition Code stipulates that donations of money are permitted only to the extent that they are appropriate in light of normal business practices, and provided they are in support of medical or pharmaceutical research, lectures and so on. However, donations that are, in effect, made to help shoulder expenses that should be paid by the healthcare institution itself are prohibited because they are viewed as a means of unfairly inducing business transactions. Gifts, in certain exceptional cases, such as when they are made as a generally recognised social ritual for expressing congratulations or condolences, are permitted, as long as they are not extravagant or excessive. In addition, when a healthcare professional is a public official or deemed public official, the acceptance of gifts, even gifts offered as a social ritual, is generally prohibited by the code of ethics established by the healthcare institution to which the healthcare professional belongs. In principle, there are no specific monetary limits on the amount of donations or gifts set forth in the Fair Competition Code or other regulations.

14. What rules govern the offering of hospitality to healthcare professionals?

In principle, the Fair Competition Code prohibits the provision of hospitality to healthcare professionals, such as the provision of food, beverages and entertainment, and invitations to participate in expense-paid travel. However, the provision of food and beverages for the purpose of compensating those who play roles in the presentation of seminars, serve as a lecturer in in-house training sessions or participate in conferences and so on, is permitted, as long as those provided are not extravagant or excessive. The payment of travel expenses for a person's participation in meetings and so on is also permitted, within a certain range. However, for a healthcare personnel who is a public official or deemed public official, the code of ethics of the healthcare institution to which the healthcare professional belongs usually prohibits the receipt of hospitality, except in cases where the healthcare professional receives modest food and beverages at meetings that the healthcare professional attends as part of his/her duties.

15. Are donations made by permit/authorisation holders to healthcare institutions or organisations considered a promotional (advertising) tool? Is there a special regulation on donations?

The holders of marketing authorisation for pharmaceuticals or medical devices may not use donations to healthcare institutions or organisations as a promotional (advertising) tool. The general rule for donations is as described in the response to Question 13. The Fair Competition Code allows marketing authorisation holders to make donations and/or grants for educational purposes or research activities conducted by the healthcare institutions or organisations, except for cases where such activities are conducted independently by a healthcare professional in the pursuit of his/her personal interests. For permitted donations and/or grants, the Fair Competition Code stipulates certain requirements about the eligible recipients, as well as applicable procedures, such as limiting the usage of the funds to educational and research purposes only, and obtaining the result of the subject education/research for which the funds were used.

16. Can pharmaceutical laboratories or medical device manufacturers or their licensees support scientific or educational meetings? If so, is there any difference between these two sectors from the perspective of rules on the promotion of products?

Both pharmaceutical companies and medical device companies can support scientific or educational meetings by co-hosting such a meeting with academic societies, institutions or others, subject to compliance with the applicable regulations of the Fair Competition Code for the relevant industry. There is no substantial difference between the applicable regulations of the Fair Competition Code for the ethical drug pharmaceutical industry and those for the medical device industry on this point. Payments intended to help shoulder the expenses of the co-sponsored meetings or excessive payments beyond the amount properly owed are prohibited. The Fair Competition Code also provides some other requirements and rules for co-hosting scientific or educational meetings.

17. Please provide an overview of the rules around the industry and patient organisations' relationships, including funding.

While there is no legislation or other governmental regulation specifically applicable to the relationships between the pharmaceutical and medical device industry and patient organisations, the JPMA has established guidelines for interactions between pharmaceutical companies and patient organisations. The guidelines provide, among other things, that the member company: (1) shall enter into a written agreement with the patient organisation stipulating the contemplated activities and funding before starting an interaction; (2) shall not engage in advertising or promotional activities regarding ethical pharmaceutical drugs directed to the patient organisation; (3) shall not influence the statements or publications of the patient organisation; (4) shall recommend the patient organisation to obtain funding from multiple sources;

and (5) shall protect the privacy of patients and supporters of the patient organisation. The JPMA also established guidelines for the disclosure of information regarding funding provided by a member company to patient organisations.

18. Is it possible to delegate promotional (advertising) activities to a third party through a service agreement? If so, under which conditions? Is co-promotion regulated in your jurisdiction and if so, how?

Pharmaceutical companies and medical device companies in Japan can delegate promotional (advertising) activities to third parties. In the service agreement to be entered into for the delegation of promotional activities, it is essential to provide that the third-party service provider ensures its full compliance with the regulations applicable to the promotional (advertising) activities because any violation of those regulations by such a third-party service provider may be deemed a violation by the delegating pharmaceutical or medical device company. Co-promotion between multiple pharmaceutical companies or multiple medical device companies is also permitted in Japan. When conducting co-promotion, compliance with Japan's antitrust regulations is also important.

19. Is it mandatory in your country to report transfers of value made by permit/authorisation holders to healthcare professionals?

Both the JPMA and JFMDA have established rules that require its member companies (ie, the marketing authorisation holders of pharmaceuticals or medical devices) to disclose the transfers of certain categories of value to healthcare professionals. Such categories include the payment of R&D expenses, educational and research grants, outsourcing fees and other fees, such as hospitality expenses. While disclosure under this self-imposed rule is not mandatory, most member companies publish the amounts of those transferred values annually. In addition, under the Clinical Trial Act, marketing authorisation holders of pharmaceuticals or medical devices who engage healthcare professionals for assistance with certain types of clinical trials must disclose the amounts of transfers of certain categories of value to such healthcare professionals, as well as to the healthcare institutions to which the healthcare professionals belong.

ENFORCEMENT

20. What penalties and other sanctions are associated with violations related to product promotion (advertisement)? Do supervisory authorities actively impose penalties and other sanctions? Are these penalties and other sanctions announced publicly?

Persons who violate the advertising regulations under the PMD Act, such as those who make false or exaggerated claims in advertisements regarding pharmaceuticals or medical devices, or who advertise unauthorised pharmaceuticals or medical devices for sale in Japan, may be subject to criminal penalties in the form of imprisonment and/or fines. In addition, those who make false or exaggerated claims in advertisements regarding pharmaceuticals or medical devices may be subject to an administrative monetary fine, the amount of which is calculated by multiplying the total amount received from sales of the subject pharmaceutical or medical device product over a certain period by a predetermined fine rate. Further, those who violate the advertising regulations under the PMD Act may be subject to a business improvement order, a business suspension order or the penalty of the revocation of a business licence under the PMD Act. In practice, criminal penalties and administrative orders are rarely imposed in cases of violations of the advertising regulation under the PMD Act, and, in most cases, the revision/withdrawal of the advertisement in question and improvement of the violator's operations is directed through reporting orders, investigations, and administrative instructions from the MHLW and/or the relevant prefectural government. Information about the imposition of criminal penalties and administrative orders based on such violations is usually made public, but reporting orders, results from investigations and administrative instructions are not. In the case of violations of the voluntary regulations of the JPMA or JFMDA, possible consequences applicable to member companies include warnings, membership suspension or expulsion from the association, and such matters are often reported publicly. Additionally, violations of the Fair Competition Codes may result in warnings, expulsion from the Fair Trade Council and possibly penalties, and such matters are often reported publicly.

21. Who is responsible for enforcement, and how strictly are the rules enforced? To what extent may competitors take direct action through the courts in relation to promotion (advertising) infringements?

It is mainly the MHLW and the prefectural governments that are responsible for the enforcement of advertising regulations under the PMD Act. The relevant industry associations (eg, JPMA, JFMDA and Fair Trade Councils) are responsible for the enforcement of their respective self-governing regulations, such as the Promotion Code and Fair Competition Code. In recent years, the MHLW, prefectural governments, and self-regulating industry organisations have been proactively monitoring and enforcing advertising and promotional activities related to pharmaceuticals and medical devices. In Japan, while competitors can report cases of violations in relation to promotion (advertising) regulations to the relevant

regulator, direct action initiated by competitors to prosecute infringements of (advertising) regulations through the courts does not occur.

FUTURE DEVELOPMENTS

22. Are any significant developments in the field of pharmaceutical or medical device promotion (advertising) expected in the next year or so? Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

The MHLW has been implementing a monitoring programme for marketing information provision activities carried out by pharmaceutical companies in Japan, whereby the MHLW collects information from various external sources, such as healthcare professionals, with respect to alleged improper marketing and promotional activities of pharmaceutical companies. The monitoring programme covers a wide variety of alleged misconduct that occurs in the course of marketing and promotional activities of pharmaceutical products, such as off-label promotion, misleading statements and inappropriate comparison with competitor products. The MHLW utilises the information collected through this monitoring programme to enforce and supervise the promotional and advertising activities of pharmaceutical companies in Japan.