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Japan - Pharmaceutical Law: Advertising, Gifts and Hospitality - A Shrinking Territory

Advertising and promotion, gifts and hospitality: in Japan, companies are facing a thicket of rules designed to ensure the ethical promotion of medicinal products and medical devices and equipment. This is fortunately mitigated by a high level of international convergence. The evolution of self-regulatory codes of conduct, in addition to the legal provisions, clearly illustrates current trends: more rigor, accountability and transparency in order to prevent abuses.

Legal framework - An overdose of codes and laws

In Japan, the advertising of medicinal products and other health products is regulated by a number of laws and regulations, including the Pharmaceutical Affairs Act (*yakuji hou* Act No. 145 of August 10, 1960; the "**Act**") and the Regulations on Fair Practices for the Advertising of Medicinal Products (Notice No. 1339 of October 9, 1980 from the Director General of the Bureau of Pharmaceutical Affairs; the "**Regulations**"). In addition, reference should be made to the Medical Care Act (*iryo hou*) and its guidelines concerning the advertising of medical treatments.

Key issues

As a result of industry self-regulation initiatives, there are also rules established by professional associations including the Japanese Pharmaceutical Manufacturers' Association ("**JPMA**"), an umbrella organisation which brings together and represents the pharmaceutical companies present in Japan on a voluntary basis. One of its objectives is to ensure compliance with ethical professional practices. As such, it requires its members to comply with a code of practices for the promotion of ethical drugs (the "**Promotion Code**"). The latest revision of the Promotion Code took effect on 1 September 2012. The JPMA has announced plans to further update the Promotion Code in 2012 with entry into effect in 2013: its scope will go beyond just promotional activities so as to reflect the most recent amendments to the code of the International Federation of Pharmaceutical Manufacturers & Associations ("**IFPMA**") on best practice for the promotion of medicines (which became the IFPMA Code of Practice on 1 September 2012). Although the rules of the JPMA are, in theory, applicable only to its members, they are also relevant to other companies to the extent that they often serve as reliable indicators of the views and position of the Ministry of Health, Labour and Welfare, the Japanese competition authority (the Fair Trade Commission of Japan ("**JFTC**")), the Japanese consumer protection authority (the Consumer Affairs Agency) or those of other agencies on certain topics that deserve some clarification or benchmarking. The Fair Trade Council of the Ethical Pharmaceutical Drugs Marketing Industry has adopted a code for fair competition which limits the benefits and premiums that can be offered for the promotion of ethical drugs (the "**Fair Competition Code**") approved by the JFTC, along with guidelines with respect to the Fair Competition Code and interpretive commentary for ease of understanding. The Fair Competition Code is, in some ways, a specific adaptation for the pharmaceutical industry of the wider body of rules contained in the Act against Unjustifiable Premiums and Misleading Representations (the "**UPMRA**"). General competition law provisions are equally applicable (in particular, the Antimonopoly Act, the Unfair Competition Prevention Act, etc.); the Penal Code and the National Public Service Ethics Act (Act No. 129 of August 13, 1999) also apply where bribery of civil servants is involved.

The advertising and promotion of medicinal products cover all forms of information provision, solicitation or inducement aimed at promoting the prescription, supply, sale or consumption of medicinal products. This covers advertisements in newspapers, brochures, medical or scientific journals, e-mails, CD-ROMs, posters, TV commercials, etc. For purposes of the Act, an 'advertisement', in order to be considered as such, must meet the following requirements: it must be designed to induce customers to buy a pharmaceutical product, it must indicate the name of the product, and it must be capable of recognition as such by the general public (which includes healthcare professionals).

Advertising without prescription: any need for regulatory approval or SOPs?

Whilst in certain jurisdictions, the advertising of medicinal products to both healthcare professionals and the general public is subject to prior approval by the authorities, neither regulatory controls on advertisements nor the establishment of in-house standard operating procedures are required in Japan. Companies still have the option to validate their advertisements by consulting with the regulator. Administrative and criminal sanctions apply for violations of the UPMRA and the Regulations. In worst case scenarios, the Ministry of Health can withdraw the authorisation to place products on the market (*iyakuhin tou no seizo hanbai no shonin*; the marketing authorisation or "**MA**"). The JPMA, which imposes internal control methods on its members (i.e., through a manager in charge of validating promotional materials and certain in-house verification procedures) to ensure that promotional activities are responsible and ethical, may also punish violations in order to put its members back on the right track. The Fair Trade Council intervenes in cases of violations of the Fair Competition Code, while the JFTC or the Consumer Affairs Agency may opt to play a more supporting role.

Advertising to the public and healthcare professionals

To the public

The Japanese market for self-medication drugs that may be bought without a prescription (i.e., over-the-counter) is huge. Advertising concerning this market is, subject to certain exceptions, permitted. Advertisements should be neither exaggerated nor misleading as regards the name of the product, its indications, effects and properties, or the manufacturing process. Even if marketing online or mail-order sales are restricted according to the risks associated with a particular non-prescription product, in principle there is no such problem for marketing medicinal products that are unlikely to have serious side effects. However, advertising prescription-only medicines to the general public is prohibited.

To healthcare professionals

Provided that certain requirements are observed, it is possible to advertise pharmaceutical products to healthcare professionals. The UPMRA prohibits advertisements which are misleading, false or simply contain exaggerations or distortions. Information that must appear in any advertisements aimed at healthcare professionals includes the product name, indications, warnings, precautions and adverse reactions, dosage and methods of use, the date of the advertisement, and contact details for more information. The Promotion Code imposes its own additional safeguards on members of the JPMA: they must anticipate the risks related to the possible dissemination of advertisements – which is not always easy to control (especially when published online) - to the general public through the medical and scientific press or through the use of new media. The advertisement must play a constructive role in providing information to healthcare practitioners, and it must be objective, accurate, fair and based on scientific evidence. No unseemly or inappropriate photographs or illustrations are permitted.

Making information available before the product is authorised - Any life before the marketing authorisation?

Under the terms of the Act, no medication should be advertised before it has obtained its MA. This prohibition does not aim to impede the right of the scientific community and the public to be fully informed concerning scientific and medical progress or to restrict the exchange of scientific information concerning a drug, in particular the dissemination of research results

within the scientific community or at scientific conferences. The interpretative commentaries of the JPMA clarify the provisions of the Promotion Code by giving a number of practical examples of permissible supply of information which are broadly in line with the IFPMA Code of Practice: the adequate exchange of scientific information during a symposium or publication of information on unauthorised medicines in a medical journal for the purpose of scientific progress; the display of academic and scientific materials on stands at exhibitions (while distribution is not permitted) at international scientific conferences or symposia that refer to unlicensed medication in Japan subject to compliance with certain requirements: the meeting must be a scientific event with a certain proportion of foreign speakers and participants, the materials relating to the medicinal products not registered in Japan must mention that the product in question is not available locally and the countries for which marketing authorisation has already been granted and must refrain from indicating the name under which the product will be marketed in Japan, etc.; the public disclosure of information intended for shareholders relating to a drug, to the extent that it complies with the law; and the sending of reprints of scientific or medical literature at a doctor's request. Circumstances vary and as the borderline between what is legal and what is questionable or prohibited is sometimes very thin, a company should conduct analysis on a case-by-case basis to assess the risks associated with a particular communication or promotion. The rules applicable to medicinal products without a valid MA of course apply equally to pharmaceutical products imported on a "named patient" basis in the context of urgent treatment of a named patient for a specified condition by the doctor who imports the product.

Comparative advertising

The Promotion Code and its interpretive commentaries outline the main provisions. The emphasis is on the importance of the comparison between existing and new products for a practitioner who must choose the most effective product for his or her patients. The comparison cannot focus exclusively on the more favourable elements; it should be objective and therefore focus on the essential characteristics which are significant, relevant and scientifically verifiable. In the absence of consent by a competitor (highly unlikely), its product cannot be referred to by its brand name but only by using its generic name. The JFTC provides some examples of inappropriate practices in this connection: pharmacological properties without any confirmed clinical consequences put forward for the purposes of a comparison; selecting meaningless comparison criteria which have no impact on the choice of medication; and using an advertisement to disparage a competitor and its products (including by means of false information on prices). The UPMRA authorises the Consumer Affairs Agency to require a pharmaceutical company to justify its claims in the case of any advertisements which may appear to be misleading. Where a comparative advertisement does not meet the required criteria, the Agency may propose its ban or withdrawal.

Hospitality, gifts, rewards and incentives

Certain jurisdictions prohibit medical professionals from receiving benefits in-kind or in cash from businesses that produce or market products covered by health insurance. This prohibition does not apply, under certain conditions, to benefits provided under agreements concluded between businesses and professionals since these agreements are intended for research or scientific evaluation, or for hospitality at exclusively professional and scientific promotional or sales events whereby the benefits remain ancillary to the main purpose of the meeting and are not extended to persons other than the healthcare professionals directly concerned.

In Japan, the Fair Competition Code provides that no inappropriate financial benefit or benefit in-kind can be provided or offered to healthcare professionals in exchange for prescribing or administering medicinal products. It is forbidden to offer or to provide anything to a healthcare professional for such purpose and under conditions that are likely to have an inappropriate influence on the healthcare professional's prescribing habits. This restriction does not, however, preclude the granting of discounts or the provision of after-sales services in accordance with standard commercial practices. Even if gifts are offered, they must be in compliance with good ethical practices and remain within the limits of decency imposed by the pharmaceutical industry and its core objectives. Furthermore, inappropriate gifts and donations made to a healthcare professional who works in the public sector may be deemed to be corruption punishable under the Penal Code or the National Public Service Ethics Act. Healthcare professionals can still be hired as consultants and advisors to provide certain remunerated services, notably including participation in medical or scientific studies, clinical trials or market research. Agreements covering such services must comply with the Fair Competition Code and the Promotion Code. With regard to sponsorship, companies may subsidise the continuing education of healthcare professionals or their participation in

professional events provided that their sponsorship remains within the limits of reasonableness. Finally, free samples of pharmaceutical products may be delivered to healthcare professionals for information purposes. The Fair Competition Code and the Promotion Code (and their guiding principles) stipulate the conditions governing the distribution of samples.

Strict compliance: hosts under pressure

The Fair Trade Council has updated its interpretive commentary on hospitality in line with the Fair Competition Code, with its most recent revisions taking effect in April 2012. The approach is tough with limited exceptions based on custom and common sense: no stand-alone entertainment, no leisure activities and no social activities shall be provided or paid for by member companies. In other words, no more karaoke, bibulous "*nijikai*", golf, baseball, or kabuki, etc. The commentary indicates the thresholds to be met (among others) in respect of "*settai*": one can still entertain one's guests for up to 20,000 yen during a convention; medical representatives may offer a "*bento*" lunch and a cup of tea up to a value of 3,000 yen during a briefing meeting with a practitioner; and a speaker at a conference will be entitled to food and drinks up to a maximum of 20,000 yen. The Fair Competition Code authorises the payment of reasonable fees and the reimbursement of nominal expenses, including travel expenses and accommodation, to healthcare professionals who are providing genuine services as speakers or presenters. In accordance with the Fair Competition Code and the Promotion Code, hospitality offered to healthcare professionals in the context of symposiums, conferences or other meetings organised or sponsored by a company to inform healthcare professionals about products or to supply them with scientific information should be offered at a modest and reasonable level. The Fair Competition Code and the Promotion Code apply even if the hospitality is offered in the context of overseas travel. Finally, the penalties described above in respect of the bribery of officials are equally likely to apply in this context (although there is a very small allowance, it is best to refrain from such practices).

Gifts and hospitality: more disclosure

The National Public Service Ethics Act already imposes on officials of a certain rank a requirement to account, on a quarterly basis, for any wining and dining or event in which they participate if the amount of the benefit exceeds 5,000 yen. The JPMA has adopted, for use by its members, a directive on transparency (**Transparency Guideline for the Relation Between Corporate Activities and Medical Institutions**) which should encourage them to disclose online and for the first time in 2013 in respect of the 2012 financial year the amounts paid in respect of the R&D and university research, the remuneration and various fees paid in return for lectures, writing articles or consultations, the fees paid in respect of seminars or events for providing scientific information on products, and hospitality expenses. This will clearly increase transparency of members' activities with medical institutions and other healthcare professionals (unless the toxic practices are "delegated" to the wholesalers), gain the public understanding of the industry's contribution to the advancement of life sciences and ensure that the public understands that corporate activities are conducted with high ethical standards and not only for profits. In the industry, a number of people may miss the lost opportunities for wining and dining while finance directors will be pleased to see the need for certain expenses that used to curb profits becoming (increasingly) part of a bygone era.

Where Japanese legal concepts have been expressed in the English language, the concepts concerned may not be identical to the concepts described by the equivalent English terminology as they may be interpreted under the laws of other jurisdictions.

Contacts

If you would like to know more about the subjects covered in this publication or our services, please contact:

Landry Guesdon
Counsel

T: +(81 3) 5561 6622
E: landry.guesdon
@cliffordchance.com

Miho Mizuguchi
Partner

T: +(81 3) 5561 6408
E: miho.mizuguchi
@cliffordchance.com