COUNTRY COMPARATIVE GUIDES 2023

The Legal 500
Country Comparative Guides

Japan
PHARMACEUTICAL ADVERTISING

Contributor

Iwata Godo

Shinya Tago

Managing Partner | stago@iwatagodo.com

Landry Guesdon

Registered Foreign Attorney | lguesdon@iwatagodo.com

Minako Ikeda

Counsel | minako.ikeda@iwatagodo.com

This country-specific Q&A provides an overview of pharmaceutical advertising laws and regulations applicable in Japan.

For a full list of jurisdictional Q&As visit **legal500.com/guides**

JAPAN
PHARMACEUTICAL ADVERTISING

1. What laws are used to regulate advertising on medicines in your jurisdiction?

The Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics (Act No. 145 of 10 August 1960, as amended) ("PMD Act") and other relevant laws and ordinances, including the Order for Enforcement of the PMD Act ("PMD Act Enforcement Order"), regulate marketing activities in relation to drugs. Promotional activities are not expressly regulated by the PMD Act, except for drug information or the advertising of drugs. The PMD Act, supplemented by various administrative notices and guidelines issued by the Ministry of Health Labour and Welfare of Japan ("MHLW"), sets basic standards for the advertising of drugs.

Official guidelines published by the MHLW include the Standards for Fair Advertising Practices concerning Pharmaceuticals, etc. (PSEHB Notification No. 0929-4 of 29 September 2017) ("Fair Advertising Standards") and Commentary on, and Points of Note in, the Guidelines (PSEHBCND Notification No. 0929-5 of 29 September 2017). A person advertising drugs should make efforts to disseminate accurate information and drug advertisements should not include false, misleading or deceptive information or exaggerated statements. The Fair Advertising Standards include an interpretation of the PMD Act on the description of names, indications or dosage/administration, and so on, of drugs to prevent misuse or abuse.

The Guidelines regarding the Provision of Marketing Information on Prescription Drugs (PSEHB Notification No. 0925-1 of 25 September 2018) ("Guidelines on Marketing Information") are intended to facilitate proper advertising and similar actions with respect to pharmaceutical detailing and the supply of prescription drug marketing information to ensure the proper use of drugs. They apply to the provision of marketing information by marketing authorisation holders and their contractors, partners and drug wholesalers. The Guidelines cover the provision of information for the promotion of sales, for example by enhancing the recognition of the name or efficacy/safety of a specific prescription drug, regardless of whether it is performed actively or passively. Marketing materials include materials and information used for such activities regardless of the method and form, including verbal explanations, videos and data transmission in electromagnetic form. The Guidelines also apply to medical representatives, medical science liaison professionals, and all employees, regardless of their job title or department.

General laws are also relevant, in particular:

- The Act on the Prohibition of Private Monopolisation and the Maintenance of Fair Trade (Act No. 54 of 14 April 1947, as amended)
- The Unfair Competition Prevention Act (Act No. 47 of 19 May 1993, as amended) ("UCPA")
- The Act against Unjustifiable Premiums and Misleading Representations (Act No. 134 of 15 May 1962, as amended) ("AUPMR")
- The Criminal Code (Act No. 35 of 24 April 1907, as amended)
- The National Public Service Ethics Act (Act No. 129 of 13 August 1999, as amended)

The AUPMR regulates premiums and representations relating to transactions of goods and services to ensure fair competition and protect the interests of consumers. It prohibits unjustifiable premiums and misleading representations, including through advertisements (*Articles 4 and 5, AUPMR*). Industry organisations have established self-imposed industry standards in pursuance of Article 31 of the AUPMR (*see Question 2*).

2. Are there any self-regulatory or other codes of practice which apply to the

advertising of medicines? a) If there are any such codes, to whom do they apply (companies, or healthcare professionals, for example)? b) What is the legal status of the self-regulatory codes?

a) If there are any such codes, to whom do they apply (companies, or healthcare professionals, for example)?

The marketing of drugs is governed by a combination of legislation (see Question 1) and codes of practice. Various industry self-regulations apply to promotional activities. The Japan Pharmaceutical Manufacturers' Association ("JPMA") is a voluntary industry group that unites and represents large pharmaceutical companies that are present in Japan. It is active through its self-regulation initiatives supplementing laws and regulations. The JPMA requires its members to comply with its code of practices for the promotion of prescription drugs to healthcare professionals ("JPMA Promotion Code"). The JPMA Promotion Code is part of the JPMA Code of Practice established in 2013 following amendments to the International Federation of Pharmaceutical Manufacturers and Associations ("IFPMA") Code of Practice that provides guidance to pharmaceutical companies on how to interact with healthcare professionals ("HCPs"), institutions and patient organisations. The IFPMA is a global voluntary organisation that represents the research-based pharmaceutical industry and its code applies to JPMA members.

In addition, the Fair Trade Council of the Ethical Pharmaceutical Drugs Marketing Industry ("FTC-EDMI") has adopted a code for fair competition and fair trade that limits the benefits and premiums that can be offered for the promotion of ethical drugs ("Fair Competition Code"). The Fair Competition Code (along with corresponding guidelines and interpretive commentary) has been approved by the Japan Fair Trade Commission (the Japanese competition law authority) ("JFTC"). It is a voluntary code but has semi-legal binding aspects and the JFTC can step in to prevent or put an end to violations. The Fair Competition Code is, to some extent, a specific adaptation for the pharmaceutical industry of the wider body of rules contained in the AUPMR.

The JPMA Promotion Code and the Fair Competition Code are among the most significant codes of conduct. The JPMA Code of Practice includes a number of basic principles regarding members' materials (brochures, adverts in medical journals, websites targeting HCPs, audiovisual materials) and provides that statements contained in such materials must be correct, objective and based on scientific data. For example:

- Statements regarding indications, dosage and administration, and any other statements, must not deviate from the approved items.
- No false, exaggerated, or misleading labels, layout or expression can be used regarding efficiency and safety.
- Fair statements must be made by presenting both efficiency data and safety data, including adverse reactions.
- Comparisons with other drugs must be based on scientific data, in principle made using generic names.
- Competitors or competitors' drugs must not be slandered or defamed.
- Extraordinary data must not be presented to give the impression that the data has universal value.
- Where an advertisement is aimed mainly at promoting only the name of a drug, the items described in an advertisement must include the following information:
    - brand name;
    - therapeutic category (product title);
    - regulatory classification;
    - non-proprietary name;
    - National Health Insurance (NHI) price listing status; and
    - contact details to request more detail.

In addition, the Japan Generic Medicines Association has adopted its own code of practice for the promotion of generic drugs. For over-the-counter ("OTC") drugs, the Japan Federation of Self-Medication Industries ("JSMI") has issued Guidelines for Proper Advertising of OTC Medicines.

b) What is the legal status of the self-regulatory codes?

Conduct that violates these self-regulatory codes is not necessarily unlawful. It is only illegal if it independently violates Japanese laws and regulations. The codes apply to association members but they are also carefully scrutinised by other industry players, as the rules can serve as reliable indicators of the views of the MHLW, the JFTC or the Consumer Affairs Agency (the Japanese consumer protection authority) on topics that deserve clarification or benchmarking. Also, see (a) above on possible JFTC intervention.

3. Is there a statutory or generally

accepted definition of “advertising”? a) What does the definition cover? – does it include patient information leaflets, for example, catalogues, disease awareness campaigns or correspondence, for example? b) Does the definition apply equally to all target audiences?

a) What does the definition cover? – does it include patient information leaflets, for example, catalogues, disease awareness campaigns or correspondence, for example?

Advertising under the PMD Act is defined in a ministerial notice issued by the Pharmaceutical Safety Bureau of the former MHLW (No.148 of 29 September 1998) as information (i) clearly intended to induce consumers to buy products, (ii) specifying the name of a medicinal product, and (iii) capable of being seen and perceived by the general public. In principle, disease awareness campaigns do not qualify as advertising unless they satisfy all three parts of the definition but must be implemented very carefully not to fall foul of the law.

Articles 66 to 68 of the PMD Act regulate the advertising of medicines. Specifically, Article 66 prohibits the advertising, describing or dissemination of false or exaggerated statements on the name, manufacturing method, indications or performance of a drug. Statements that may be misunderstood as an endorsement of a drug by healthcare professionals are prohibited. Article 67 restricts advertising drugs for specially designated diseases (treating cancer, sarcoma and leukemia) to the general public. Article 68 prohibits advertising the name, manufacturing method and/or indications of a drug before the grant of a marketing authorisation.

The Fair Advertising Standards (see Question 1) prohibit the advertising of prescription drugs aimed at the general public. They include specific restrictions on advertisements under the PMD Act and also limit the use of premiums, prizes and rewards in this context. The Fair Advertising Standards apply to advertisements on all media, including newspapers, magazines, TV, radio, websites, and social media.

b) Does the definition apply equally to all target audiences?

Yes.

4. Are press releases regarding medicines allowed in your jurisdictions, and if so what are the restrictions on these (bearing in mind the target audience)?

Press releases about unapproved pharmaceutical products and off-label indications for promotional purposes are prohibited under the PMD Act. However, press releases may be permitted when they are not intended to advertise a product or disseminate off-label information as explained in Question 8 (e.g., shareholder information). Yet the JPMA Code of Practice emphasises that “information disseminated through press releases as well as disease education activities targeting ordinary citizens and patients and the provision of information to investors” must be scrutinized “so that there will be no suspicion that such communication of information constitute the advertisement of prescription drugs or recommendations of unapproved drugs or off-label uses.”

5. Are there any processes prescribed (whether by law or Codes of Practice) relating to the approval of advertising of medicines within companies?

The PMD Act is silent on this point. The Guidelines on Marketing Information require pharmaceutical companies to have standard operating procedures to deal with the supply of information against the background of their promotional activities for prescription drugs. They also require companies to set up a promotion oversight department responsible for monitoring promotional activities and review materials, which must be separate from the company’s sales and marketing divisions. The JPMA Code of Practice requires its members to establish internal verification procedures and to appoint a manager to sign off marketing materials. In practice, all pharmaceutical companies have their own in-house verification procedures.

6. Do companies have to have material approved by regulatory bodies prior to release?

The PMD Act does not require the prior approval of any regulatory or industry body to advertise pharmaceutical products. Pharmaceutical companies still have the option to consult with regulatory or industry bodies to confirm that their promotional materials comply with applicable laws and codes of practice.

7. Is comparative advertising for medicines allowed and if so, what restrictions apply?

The AUPMR does not prohibit comparative advertising. However, in accordance with the Guidelines for Comparative Advertising under the AUPMR issued by the Consumer Affairs Agency, the following comparative advertising is considered as misleading and likely to affect the appropriate selection of products by consumers:

- Comparison by indicating matters that have not been demonstrated and are incapable of being demonstrated.
- Comparison based on unfair grounds, for example, by putting the emphasis on the importance of certain aspects that are inconsequential to product selection by consumers, or on an arbitrary selection of the products being compared.
- Advertising that disparages competitors or their products.

The Fair Advertising Standards, etc. prohibit a pharmaceutical company from disparaging other companies' products in relation to quality, potency/effect, safety, or other drug-related aspects.

The JPMA Code of Practice provides that comparisons with other drugs must be conducted properly and based on scientific data, in principle using generic names. Competitors' drugs must not be slandered or defamed. The Code commentary stresses that comparing new drugs with drugs that have been previously used and finding out where and in what way they differ is extremely important in deciding which drug to use. Therefore, drugs should be introduced based on accurate data with scientific backing, in compliance with the JPMA's Guidelines for the Preparation of Product Information Brochure for Prescription Drugs, while avoiding ambiguous expressions that may lead to misunderstandings. When making a comparison with another drug, the drug that is being compared against must be referred to using its generic name (the use of rival manufacturers' logos or brands is prohibited without their consent, which is unlikely to be given).

8. Is it possible to provide information on unauthorised medicines or unauthorised indications? Is it possible to provide information on unauthorised medicines or unauthorised indications during a scientific conference directed at healthcare professionals, or to send information to healthcare professionals?

Article 68 of the PMD Act provides that no person can advertise the name, manufacturing process, indications or performance of a drug before the grant of a marketing authorisation.

The Guidelines on Marketing Information allow the provision of information on unapproved drugs or off-label use only if requested by HCPs or other non-HCP persons, patients or organization and if certain strict conditions are satisfied:

- information on unapproved drugs and off-label indications is separated from other ethical drug promotion activities;
- the information is only provided to those who have requested it (and it is not more than what has been requested);
- the information must not be provided under the false pretence of being requested by the HCPs, patients, etc.
- comprehensive and accurate information based on scientific and objective evidence is provided, without exaggerations or misleading statements;
- information relating to clinical trials involving a pharmaceutical company is only provided if the study is conducted in accordance with the Good Clinical Practice Ministerial Ordinance (MHW Ordinance No. 28 of 1997), the Clinical Research Act (Act No. 16 of 2017, as amended) or other applicable regulations;
- negative information, such as information on risks of adverse effects or inconclusive clinical trials results, is provided in a proper manner;
- the fact that the efficacy and indication, dosage or method of administration of the ethical drug covered by the information have not been approved must be clearly explained; and
- records of the information contents, background and recipients should be prepared and maintained.

The commentary of the JPMA Promotion Code states that member companies must refrain from starting promotional activities until the marketing approval is granted; however, the commentary also clarifies that this prohibition should not deprive medical and pharmaceutical experts (or the general public) of the right to know about scientific advancements. For

example, the Code does not restrict:

- The appropriate exchange of scientific information about a drug through the presentation of research findings in a meeting of an academic society or in a scientific journal.
- The display of scientific exhibition materials about a drug yet to be approved in Japan (but approved in another country) in accordance with separate guidelines at a meeting of an international academic society.
- The supply of peer-reviewed scientific literature, such as the reprint of a research paper at a doctor's request.
- The lawful disclosure of medical information on products under development to the pharmaceutical company's shareholders. This also applies to off-label information.

However the JPMA Promotion Code does not allow the provision of information on unapproved drugs at seminars sponsored by pharmaceutical companies.

The supply of information or explanatory materials concerning medical data or a drug manufactured by a company to healthcare professionals is not prohibited by the Fair Competition Code (Article 5(2)).

9. Please provide an overview of the rules that apply to advertising to the general public for prescription only medicines and over the counter medicines, an indication of the information that must or must not be included.

With respect to the advertising of prescription drugs to the general public, the PMD Act and the PMD Act Enforcement Order only prohibit advertising of drugs for specially designated diseases (treating cancer, sarcoma and leukemia). However, the Fair Advertising Standards prohibit the advertising of prescription drugs to the general public. Advertisements regarding prescription drugs may only target HCPs. In addition, the Fair Advertising Standards prohibit misleading representations in advertisements targeting consumers to the effect that the use of a particular drug, without a diagnosis or treatment by medical practitioners, will cure cancer, diabetes, hyper-lipidaemia, heart diseases, hepatitis or other diseases that generally require a medical practitioner's diagnosis and treatment.

By contrast, OTC drugs can be freely advertised in Japan like other consumer goods. This is because OTC drug advertising is regarded as an important means of conveying useful health-related information to the general public. This relative freedom is subject to strict compliance with certain regulatory and voluntary checks. Advertisements for non-prescription drugs must comply with the PMD Act and the Fair Advertising Standards, etc. (e.g., no misleading or false information on efficacy and safety, no unproved claim, no use of expressions guaranteeing effectiveness, no encouragement leading to abuse or overdose, no reference to endorsements by HCPs, compliance with special restrictive rules applicable to e-detailing, sponsored TV and radio programmes and programmes targeting children). OTC drug advertising control in Japan has two key features:

- Control is carried out post-publication or post-broadcast (not a unique feature as the same applies to other drugs).
- Voluntary guidelines are well established and strictly observed by the industry (*see Question 2*).

10. Are there any restrictions on interactions between patients or patient organisations and industry (e.g., consultation, sponsorship)? If so, please describe those briefly.

There is no specific restriction placed by laws or ordinances. The JPMA Code of Practice provides that member companies must act ethically and respect the independence of patient groups in all types of collaboration with patient organisations. Member companies collaborating with patient organisations must establish internal guidelines based on the Guidelines on Collaboration with Patient Organisations and the Guidelines for Transparency of Relationship between Corporate Activities and Patient Organisations ("Patient Group Transparency Guidelines") issued by the JPMA. Each member company is recommended, in order to ensure transparency, to include in its internal guidelines to clarify the fact that it is involved with patient organisations and when providing financial support to patient organisations, to secure written consent for the objectives and keep records.

The Patient Group Transparency Guidelines also include spend disclosure obligations applicable to members. Members must publicly release data on donations, grants and benefits in kind or other support provided to patient organisations. The Patient Group Transparency Guidelines recommend that members should disclose their financial contributions to these organisations for the past fiscal year on their website.

11. Which information must advertising directed at healthcare professionals contain, and which information is prohibited? For example can information about clinical trials, or copies of journal be sent?

The Fair Advertising Standards do not specifically require specific information to be included in advertising targeting HCPs. However, now defunct guidelines published by the former MHLW in 1980 did list the minimum information to be provided to HCPs, including:

- The product's name for distribution.
- The generic classification name.
- The product's indications and effects.
- The method of administration.
- Information regarding adverse reactions, precautions and contraindications, and dosage.
- A contact address for further information.
- The date of preparation of the advertisement.

In addition, the JPMA sets out a list of information fairly consistent with the above that must appear in advertisements of prescription drugs targeting HCPs via professional journals (including conference brochures and publications by pharmaceutical companies) in its 2013 Guidelines for the Preparation of Product Information Brochures for Prescription Drugs. This includes:

- Product brand name and generic name.
- Therapeutic category.
- Indications and usage.
- Regulatory classification.
- Dosage and administration.
- Precautions.
- National Health Insurance (NHI) price listing.
- Marketing authorisation holder's contact details.

12. May pharmaceutical companies offer gifts to healthcare professionals and are there any monetary limits?

In certain special circumstances, gifts and promotional items can be offered to HCPs but they must comply with good ethical practices and remain within the limits of decency imposed by the pharmaceutical industry and its core objectives. In accordance with the Fair Competition Code, inappropriate financial benefits or benefits in kind should not be offered to medical practitioners to induce them to prescribe drugs. This does not preclude the supply of after-sales services in the ordinary course of business. Article 3 of the Fair Competition Code provides that a Japanese marketing authorisation holder cannot provide premiums to HCPs, such as hospitals or pharmacies, as a means of unjustly inducing transactions.

The JPMA Promotion Code generally prohibits its members from offering any gift or cash that could potentially affect the appropriate use of drugs to HCPs. The impact of the gift or cash offering must be considered, in particular whether the practice may:

- Affect the proper use of drugs.
- Be perceived by the public as interfering with neutral, independent and scientifically based prescription methods and consequently undermine the social role of drugs.

The JPMA Promotion Code requires member companies to set clear standards for gifts and cash offerings in their own in-house codes and strictly observe them in accordance with the principles of the JPMA Promotion Code and the IFPMA Code of Practice. Seasonal gifts must not be offered even when they are customary because, depending on value and frequency, they can be seen as interfering with the independence of an HCP's decision to prescribe, recommend or purchase drugs. In the same vein, member companies should refrain from offering congratulatory money because the intention behind the payment and the range of congratulatory events are difficult to assess.

Yet, the JPMA Promotion Code commentary states that reasonable condolence money (about JPY10,000) for funerals is permitted as unlikely to have any bearing on prescription practices or the proper use of drugs. According to the Enforcement Rules and Operating Standards of the Fair Competition Code, the following gifts are permissible as not being considered to unduly affect an HCP's decision to prescribe, recommend or purchase medicinal products:

- gifts having a small value not exceeding appropriate levels in light of ordinary commercial customs (about JPY3,000); and
- modest gifts offered at seminars organized for one's own products or memorial events (about JPY5,000).

Bribery: If a pharmaceutical company makes inappropriate gifts or donations of money to, or entertains, a Japanese medical practitioner who is also a public official, the pharmaceutical company and the medical practitioner may be charged with bribery under the Criminal Code or the National Public Official Moral Code. Under the Unfair Competition Prevention Act, the provision of gifts, travel expenses, meals or

entertainment to foreign public officials can be treated as bribery in the same way as the provision of cash or any other benefits (see Question 20).

Provision of hospitality: Various industry self-regulations apply to promotional activities relating to pharmaceutical products and medical devices. The JPMA Promotion Code requires that seminars for members' products be held at appropriate venues and, if food and drinks or any social event or gift is offered in conjunction with a seminar, they must not be lavish and extravagant. The IFPMA Code of Practice provides that refreshments and meals incidental to the event can be offered only when they are restrained and reasonable by reference to local standards. The FTC-EDMI has prepared its own rules for "*settai*" (wining and dining) to serve as guidance for its members. For instance (per each HCP):

- for buffets following information-sharing lectures or meetings concerning the pharmaceutical company's products, food and drinks should not exceed JPY20,000;
- food and drinks provided to participants of meetings related to conference management, should not exceed JPY20,000;
- food and drinks offered to guest speakers at in-house workshops and seminars or guest speakers at symposia or other promotional events in recognition of their services should not exceed JPY20,000;
- food and drinks in connection with the activities of medical representatives should not exceed JPY5,000; and
- *bento*-lunch boxes and snacks and a cup of tea offered at in-house briefing meetings or drug explanatory meetings held by medical representatives should not exceed JPY3,000.

13. Are pharmaceutical companies allowed to provide samples to healthcare professionals?

Samples of pharmaceutical products may be provided to HCPs (with the product information) provided the pharmaceutical company has obtained a marketing authorization for the product.

The provision of free drug samples is permitted under the JPMA Promotion Code and the Japan Generic Medicines Association Promotion Code. The JPMA Promotion Code specifies that only the minimum requisite number of samples should be supplied (with information on the product).

The Fair Competition Code contains detailed provisions on the supply of samples. A pharmaceutical company is prohibited from providing free medicinal drugs as a means of inducing a medical institution to buy drugs (*Article 4(2)*). However, the provision of free "trial-use samples" is permitted for clinical trial purposes to test the quality, effectiveness, safety, and characteristics of a medicinal product prior to clinical use. Free "product samples" can also be supplied to medical institutions to allow medical staff to become familiar with the formulation, colour, taste, appearance or other characteristics of the product prior to use (*Article 5(3) of the Fair Competition Code and Article 2(1) of the Enforcement Rules of the Fair Competition Code*).

14. Is sponsorship of scientific meetings or congresses and/or attendance by healthcare professionals to these events? If so, which restrictions apply? Do additional restrictions apply to events taking place abroad?

Pharmaceutical companies are allowed to sponsor scientific meetings or congresses attended by HCPs provided they comply with the Fair Competition Code and the JPMA Promotion Code.

With respect to seminars for HCPs concerning a pharmaceutical company's own drugs, the company can provide non-extravagant articles or services and can bear some related expenses. For example, companies may provide tea and snacks or lunch boxes, hold small social gatherings, cover transportation and accommodation expenses and compensate the lecturer. The seminar should be held in an appropriate venue in light of its purposes – it would be sensible to avoid a resort, a place for sightseeing or a location overseas for this reason (the JPMA Promotion Code expressly provides that pharmaceutical companies should, in principle, hold such seminars in Japan). Even if such seminars are permitted to take place abroad, the payment of travel expenses must be limited to the travel expenses of HCPs who will provide information on the company's drugs to all participants. Where a pharmaceutical company hosts a seminar unrelated to its own drugs, only meeting expenses may be paid.

15. What are the restrictions on the organisation of cultural, sports or other non-scientific events in relation to scientific conferences by pharmaceutical companies?

Under the Fair Competition Code and interpretative commentary on gifts and hospitality, the approach is

restrictive with limited exceptions based on customs and common sense. As such no stand-alone entertainment and no after-parties (*nijikai*), no recreational or social activities can be provided to healthcare professionals. By way of example, providing entertainment such as karaoke, golf and other games, baseball or kabuki tickets, sightseeing, etc. is prohibited. For wining and dining, see Question 12.

16. Is it possible to pay for services provided by healthcare professionals and if so, which restrictions apply?

The Fair Competition Code provides for:

- The payment of compensation and costs and expenses for medical or pharmaceutical studies/research that are entrusted to a medical institution (for example, post-marketing surveillance studies, clinical trials, other medical or pharmaceutical research) (*Article 5(4)*).
- The donation of equipment or supply of services to medical institutions (as long as they are not luxurious or excessive) for use in lectures relating to the company's own drugs (*Article 5(5)*).

Pharmaceutical companies must comply with the Operating Standards of the Fair Competition Code (in particular the Standards for Premiums and Standards for Donations) issued by the JFTC and the Consumer Affairs Agency. Under Article 5(5) of the Fair Competition Code, it is possible to:

- Pay reasonable *honoraria* (payment given for professional services that are rendered nominally without charge).
- Reimburse out-of-pocket expenses (for example, travelling and accommodation) for conference speakers and presenters.
- Bear some of the expenses of an attending medical practitioner.

These payments must be kept at a modest level.

The JPMA Code of Practice provides that member companies may engage HCPs for services such as research, clinical studies, post-marketing surveys, consultant and adviser duties, participation in the planning of meetings, chairing or lecturing at seminars, and training instructor duties, where such participation involves fees such as honoraria. However, when making arrangements for these services, member companies must enter into a written agreement that fulfils all of the following criteria:

- A written contract must be agreed which specifies the purpose of the service to be provided and the basis for payment of those services.
- A legitimate need for the services must be clearly identified in advance.
- The contractor must be directly related to the identified need and must have the expertise necessary to provide the service.
- The number of persons to be contracted must be reasonable to meet the specified need.
- The hiring must not be an inducement to prescribe, purchase, or recommend any specific drug.
- The compensation for the services is reasonable and reflects the fair value of the services provided.

The JPMA Promotion Code requires that any remuneration must be appropriate in relation to the services provided by HCPs.

17. Are pharmaceutical companies permitted to provide grants or donations to healthcare professionals or healthcare institutions? Does it matter if the grant or donation is monetary or in kind?

Pharmaceutical companies may generally provide grants or donations to healthcare professionals or healthcare institutions subject to certain restrictions. The Fair Competition Code prohibits pharmaceutical companies from offering premiums to healthcare institutions, etc., that unjustifiably induce drug transactions. Donations should be made to serve the interests of society as a whole and not for commercial purposes. Whether they have such purposes is decided based on criteria provided in the Operating Standards of the Fair Competition Code.

The Standards on Donations provide that even if the donation is made "free of charge", if in fact the manufacturer of prescription drugs is promised to be treated advantageously in return for the donation or the manufacturer responds to a request of donation that is excessive compared to what is socially acceptable, such donations are deemed to be means of improperly inducing a transaction and therefore restricted. Examples of donations prohibited by the Standards include, for example, complying with donation requests where a certain target amount is set for each manufacturer or making donations in response to hints that the manufacturer will be treated disadvantageously if it rejects the request.

The following are general examples of donations that the Standards on Donation do not deem to be associated with the prescription of drugs and thus not prohibited by the Fair Competition Code:

- Donations widely accepted by society
- Donations by industry organizations which are widely acknowledged in society
- Donations in response to disasters (e.g. relief money, consolation payment, free supply of prescription drugs)
- Donations by medical institutions to other businesses (e.g. educational or research facilities) managed by the same legal entity
- Other donations where neither the medical institutions nor HCPs are involved, the supply of prescription drugs not associated with a transaction such as overseas support

With respect to donations to medical institutions or HCPs, the Standards on Donation provides detailed guidelines on what is prohibited by the Fair Competition Code or not. Examples of donations that are prohibited as a means of improperly inducing transactions of prescription drugs are:

- Donation made by assuming certain costs that should be borne by the medical institutions/HCPs;
- Donations for ordinary medical services performed by the medical institutions/HCPs;
- When the manufacturer (donator) is promised that it will profit from making the donation;
- When the requested donation is compulsory or such that a certain target amount is allocated among manufacturers, and a manufacturer makes the donation considering the consequences it may have on its future transactions; and
- Donations that are deemed excessive compared to what is socially acceptable.

Examples of donations that are acceptable under the Code are:

- Donations for research activities (however, support for clinical research on the manufacturer's own medicinal products is prohibited);
- Donations for lectures targeting the general public or HCPs that do not belong to the medical institutions receiving the donations; and
- Other donations that are not deemed to be means of inducing transactions (e.g. donating funds to build a new hospital when the local municipality invites such investment, providing prescription drugs for free to educate students in response to requests by universities, donations for educational, training or scholarship funding purposes).

Under the JPMA Promotion Code, pharmaceutical companies must not provide donations to healthcare professionals or healthcare institutions which may affect the proper use of drugs.

18. Are pharmaceutical companies required to disclose details of transfers of value to healthcare professionals or healthcare institutions? If so, please indicate whether this is a legal requirement or not, and describe briefly what the companies must report and how. Do these transparency requirements apply to foreign companies and/or companies that do not yet have products on the market?

Disclosure obligations regarding the details of transfers of value to HCPs or healthcare institutions is basically left to self-regulation by the pharmaceutical companies except in relation to clinical trials.

The Clinical Research Act (Act. No 16 of 14 April 2017) which came into force on 1 April 2018, requires pharmaceutical companies and their subsidiaries to disclose certain transfers of value to healthcare professionals and institutions in connection with specified clinical research (as defined in the Act). The Act requires a manufacturer with marketing approval for pharmaceuticals providing a person who conducts specified clinical trials with research funds or other benefits for specified clinical trials, to enter into an agreement specifying the amount and details of such research funds or other benefits, etc. The manufacturer must, in addition to information on the provision of research funds or other benefits for specified clinical trials, make information public on the provision of money or other profits (excluding research funds or other benefits) to a person who conducts specified clinical trials and other organisations that are in special relationships with such person such as medical or research institutions to which such person belongs, using the Internet. This information must be made public within one year after the end of each fiscal year and must be kept public for 5 years. The disclosure obligation under the Clinical Research Act applies to pharmaceutical companies that are licensed to market under the PMD Act.

The JPMA Guidelines for Transparency of Relationship

between Pharmaceutical Companies and Medical Institutions, etc. ("Medical Institutions Transparency Guidelines") require member companies to disclose certain information regarding transfers of value made to healthcare professionals or healthcare institutions. Each member company must prepare its own in-house transparency policy as a code of practice referring to the Guidelines. Transfers of value are disclosed on each company's website within one year of each fiscal year end. Fees and expenses to be disclosed in detail are broken down into five categories in the Guidelines:

- Research and development expenses, etc.: expenses required for research/surveillance, etc. conducted under public regulations and various policies such as the Clinical Trials Act and the PMD Act's Good Clinical Practice (GCP), Good Pharmacovigilance Practice (GVP) and Good Post-marketing Study Practice (GPSP) ministerial ordinances;
- Academic research support expenses: scholarship donations and general donations for promotion of academic research or research support, etc., and donations to academic societies, etc. and expenses of co-sponsored conferences, etc., as expenses to academic societies, etc. for supporting conferences.
- Manuscript/writing fees: for instance, fees for the provision of scientific information on the company's pharmaceutical products or fees, etc. paid for lectures and writing or supervision of the manuscript that are related to research and development, or commissioning of services including consulting contracts (such as fees for writing manuscripts containing scientific information regarding the pharmaceutical companies' own drugs);
- Expenses relating to the provision of information including spend for lecture meetings and explanation meetings, etc. for providing information, etc. relating to the company's pharmaceutical products to medical professionals (such as expenses for lectures and seminars); and

Other expenses (such as for hospitality as a matter of social courtesy).

19. When if at all with a competent authority have to get involved in authorising advertising? Is advertising on the internet (including social media) for medicinal products regulated, and if so, how? Should companies include access restrictions on websites containing advertising or other information intended for healthcare professionals?

No competent authority has to get involved in authorising advertising.

Advertising on the internet (including social media) for medicinal products is governed by the same laws, regulations and self-regulatory codes concerning the advertising of medicinal products as those applicable to other media, in particular the PMD Act and the Fair Advertising Standards. Advertising prescription-only medicines to the general public is therefore prohibited. When an unapproved drug is advertised on the internet, the MHLW or competent prefectural governor may request internet service providers to block the prohibited advertising pursuant to MHLW's guidelines on monitoring and guidance concerning internet advertisements in breach of the PMD Act (PSFSBCND Notification No. 1217-1 of 17 December 2014). Due to the advertising of unapproved drugs by certain importers on the internet, a notification was issued to provide guidance to, and control, individual importers, including in relation to drug advertising (PSFB Notification No. 0828014 of 28 August 2002).

The activities of pharmaceutical companies in relation to the promotion of prescription products to HCPs are self-regulated through industry associations. The JPMA Promotion Code commentary lays down specific rules concerning access restrictions to information on prescription-only medicines available on the internet. Pharmaceutical companies providing HCPs with product-related information concerning prescription-only medicines through the internet must restrict access to the relevant website and ensure that only HCPs can access the information. Although there is no need to set a password, the restricted nature of the information should be apparent and users should first confirm their HCP status before being able to access the site. The JPMA Promotion Code also contains detailed guidance on the use of social media (sponsor identification and responsibility for contents, extra care in the review and validation of the information and materials given the nature of social media).

Non-prescription drugs may be marketed on the internet but only if these drugs are also marketed at a real store with the relevant marketing business license.

20. Are there any anti-bribery rules apply

to communications between pharmaceutical companies and healthcare professionals or healthcare organizations?

In Japan, various statutes prohibit bribery and classify it as a crime. The Criminal Code sets out a general prohibition regarding the bribery of Japanese public officers while the Unfair Competition Prevention Act prohibits the bribery of foreign public officers. The Criminal Code prohibits bribing public officials. In this Code, 'public official' means a national or local government official of Japan, a member of an assembly or committee, or other employees engaged in the performance of public duties for Japan. As a result of this definition, a director or an employee of an enterprise, generally, will not be considered as a public official, unless for a certain enterprise he/she is categorised under an applicable law as a "quasi-public official" (*minashi koumuin*) and therefore, regarded as a "public official" under the Criminal Code. For instance, the medical practitioners of a state-owned hospital are quasi-public officials. Offering bribes is punishable by imprisonment with work for up to three years or a fine of up to JPY2.5 million. Bid-rigging is also a crime and punishable by imprisonment with work up to three years or a fine up to JPY2.5 million.

The National Public Service Act (Act No. 120 of 21 October1947, as amended) sets out the employment and working conditions, evaluation and disciplinary actions and other general matters regarding national public servants. The National Public Service Ethics Act covers anti-corruption measures with respect to national public servants. The National Public Service Ethics Code (Cabinet Ordinance No. 101 of 2002, as amended) (also known as the Rules) provides standards of conduct and prohibited conduct of national public servants. By way of example, under this Code, personnel (i.e., a national public officer who belongs to the regular service (with limited exceptions)) are prohibited from:

- Receiving cash, goods or real estate from interested parties (i.e., counterparties in the personnel's duties);
- Accepting loans in cash by interested parties;
- Receiving free services from interested parties;
- Accepting entertainment from interested parties;
- Playing games or golf with interested parties; or
- Traveling with interested parties.

Exceptions are enumerated in the National Service Ethics Code. For example, accepting refreshments from interested parties in the form of a buffet at a party attended by a large number of people or accepting tea and cake provided by interested parties at meetings or other gatherings attended by personnel in the performance of their duty is not prohibited.

If personnel with the rank of assistant director or higher, receives any benefit or entertainment with a value greater than JPY 5,000 from any entrepreneur (i.e., organizations and individuals doing business), they must, pursuant to the National Public Service Ethics Act, after the end of each calendar quarter, report to the head of their department: (i) the value of the benefit; (ii) the date of receipt and reason for receiving such benefit; (iii) the name and address of the provider; (iv) the details of the benefit; (v) the relationship between the provider and the institutions to which the recipient belongs; and (vi) in case of entertainment, the name and address of the venue and number and professions of the attendees

Further, the National Public Service Ethics Code provides that if any personnel plans to dine with an interested party and the cost of their own meal (the interested party is prohibited from paying for the meal) is likely to exceed JPY10,000, then such personnel must give prior notice to an Ethics Supervisory Officer. The foregoing does not include buffet parties or meals with a person with whom the personnel has a private relationship subject to certain safeguards.

The Unfair Competition Prevention Act ensures fair competition among business operators. The Act provides various means to achieve fair competition such as civil actions or punishment, etc. Its Article 18 prohibits the bribery of foreign public officials, which is punishable by imprisonment with work up to five years and/or a fine up to JPY5 million. Companies may also be punished for the conducts of their representatives or employees, by a fine of up to JPY300 million.

21. What are the rules (whether statutory or self-regulatory) which govern the offering of benefits or inducements to healthcare professionals?

See Questions 1 and 2. Basically the rules are contained in the following laws, guidelines and self-regulatory codes:

- The PMD Act and its Enforcement Order
- The JPMA Code of Practice and JPMA Promotion Code
- The Guidelines on Marketing Information
- The Fair Advertising Standards
- The Fair Competition Code

- The Act on the Prohibition of Private Monopolisation and the Maintenance of Fair Trade
- The Unfair Competition Prevention Act
- The Act against Unjustifiable Premiums and Misleading Representations
- The Criminal Code
- The National Public Service Ethics Act

22. Which bodies are responsible for enforcing the rules on advertising and the rules on inducement? Please include regulatory authorities, self-regulatory authorities and courts.

The distribution of drugs to consumers is supervised by the Minister of the MHLW and the competent prefectural governor. The following bodies are responsible for the supervision of marketing activities to consumers:

- The Minister of the Ministry of Health, Labour, and Welfare.
- The Consumer Affairs Agency.
- Prefectural governors, who are responsible for the supervision of marketing activities to consumers.
- The Information Protection Commission, which is the governmental agency acting as supervisory watchdog on issues of privacy protection under the Act on the Protection of Personal Information (the law that regulates data protection issues).

In addition, if an entrepreneur acts in violation of Articles 4 or 5 of the AUPMR, the Prime Minister (or the Secretary General of the Consumer Affairs Agency by delegation) can:

- Order that the entrepreneur stops the violating act (*Article 7*).
- Order that the entrepreneur pays surcharges (administrative fines) (*Article 8*).
- Take measures necessary to prevent the reoccurrence of the violation (such as delegating powers to the JFTC, minister supervising the violating entrepreneur's business, etc.) (*Article 33*).

This is in addition to the right to request compliance reports from the offender, conduct on-site inspections, and question staff. The prefectural governor can also give instructions to the entrepreneur on the necessary measures to be taken. If an entrepreneur is subject to an administrative sanction for a breach and the punishment is illegal or unreasonably harsh, the entrepreneur can appeal the decision.

Each self-regulatory code typically establishes an organ that is in charge of enforcing the code. The JPMA Code Compliance Committee is responsible for the enforcement of the JPMA Promotion Code and the FTC-EDMI is in charge of enforcing the Fair Competition Code.

23. On what basis and before which bodies or courts can companies initiate proceedings against competitors for advertising infringements?

Pharmaceutical companies can initiate proceedings against competitors before courts for advertising infringements under the UCPA. A company whose business interests have been infringed or are likely to be infringed by a competitor's "act of using an indication on goods or services, in an advertisement thereof, or in trade documents or electronic correspondence thereof, in a way that is likely to mislead as to the place of origin, quality, content, manufacturing process, purpose, or quantity of the goods, or the quality, content, purpose, or quantity of the services, […] (UCPA Article 2 (1) (xx)); or a competitor's "act of making or circulating false allegations that harm the business reputation of another person that is a business competitor" (UCPA Article 2 (1) (xxi)) may seek an injunction against the competitor suspending or preventing the infringement (UCPA Article 3 (1)). They can also claim damages for wilful or negligent infringement with respect to said competitor's unfair practices.

Companies can initiate legal proceedings based on tort against competitors (e.g. the defamation of competitors by falsely imputing to them dishonourable conduct, inability to perform contracts, questionable credit standing or the false disparagement of the quality and efficacy of their medicinal products with the tendency to mislead or deceive HCPs). The practice of paying commissions to physicians to prescribe certain drugs that harms the business interests of other players is not common in Japan but preventing competitors from entering or operating in a market is another form of unfair competition that can happen and includes conduct like boycotting or offering unreasonably low price levels aiming at commercially exhausting the competitor and pushing it out of the relevant market in the OTC sector.

24. What are the penalties, sanctions or measures that regulators or courts can impose for violating medicines advertising rules and rules on inducements to

prescribe in your jurisdiction?

Breaches of the PMD Act and the rules governing advertising are subject to administrative punishment by the MLHW. Serious breaches of the PMD Act can trigger the following criminal sanctions (*Article 85*): imprisonment with work for a term of up to two years or a fine of up to JPY2 million, or both, for certain offences, including:

- false and exaggerated claims and advertising (*Article 66*); and
- advertising before receiving a marketing approval (*Article 68*).

In practice, the Minister of the MHLW or the Prime Minister will issue a recommendation asking the pharmaceutical company to cease or cure the illegal conduct and if the company does not comply, an administrative disposition may be taken. For example, the Minister of the MHLW or the competent prefectural governor may order a violating pharmaceutical company to comply with a business improvement order (Article 72-4 of the PMD Act) which may include taking measures to improve advertising oversight procedures; order a pharmaceutical company that advertised a pharmaceutical product before obtaining the necessary marketing approval in breach of Article 68 to take certain measures to prevent any such violation in the future (Article 72-5); or revoke the pharmaceutical company's manufacturing and/or marketing licence or suspend all or part of its operations for a certain period, as determined by the Minister of the MHLW, for violations of the PMD Act (Article 75). In addition to the foregoing, recent amendments to the PMD Act which became effective on 1 August 2021 enable (i) the Minister of the MHLW to order the payment of administrative surcharges to sanction false or exaggerated advertising in violation of Article 66(1) at the rate of 4.5% of the revenues generated by the relevant product over the period during which the unlawful advertising has taken place subject to a 3-year maximum (no surcharge is imposed for sales below JPY50 million and a 50% reduction applies if the violator reports violations of the PMD Act before an investigation and if there is a surcharge payment imposed under the AUPMR for the same case, the surcharge rate will be reduced from 4.5% to 1.5%); and (ii) the Minister of the MHLW or the competent prefectural governor to issue cease and desist orders (renamed "administrative orders concerning unlawful advertisements") against pharmaceutical companies to correct advertising that are in violation of Article 66(1) or 68.

A business that has made the following misleading representations may be liable to pay an administrative fine pursuant to the AUPMR (*Articles 5 and 8*):

- Where the quality or standard of goods is portrayed to general consumers as being much better than that of the actual goods, or much better than those supplied by other businesses.
- If the price or any other trade terms of the goods can be misunderstood by general consumers to be much better than those otherwise applicable to the actual goods supplied, or to be much better than those applicable to goods supplied by other businesses.

A cease and desist order may also be issued to a business that has made misleading representations such as the above, and violation of such order is punishable by:

- Imprisonment with work for a term of up to two years, and/or a fine not exceeding JPY3 million (*Article 36(1)*)
- A fine up to JPY300 million (for companies) (*Article 38*)

The following can take measures to stop or prevent breaches of the Fair Competition Code:

- The Fair Trade Council of the Ethical Pharmaceutical Drugs Marketing Industry ("FTC-EDMI")
- The Japan Fair Trade Commission
- The Consumer Affairs Agency

In case of breach of voluntary standards set by industry organisations, corrective measures or disciplinary sanctions can be taken by the industry organisations against their respective members. For example, for breaches of the JPMA Code of Practice, the Promotion Code Committee of the JPMA can take action (within the limits of its authority as a self-governing regulatory body).

For breaches of the Fair Competition Code, the FTC-EDMI can (*Article 10 of the Fair Competition Code*):

- Issue a warning;
- In the event of non-compliance with the warning, impose a penalty up to JPY1 million, or order the expulsion of the violator; or ask the Consumer Affairs Agency to take administrative action against the violator.

If the FTC-EDMI decides to impose a penalty or order the expulsion of a member company, it must first submit its decision as a draft to the company. The company then

has ten days to file an objection (*Article 11(2) of the Fair Competition Code*). The FTC-EDMI will give the company the opportunity to submit its own arguments before making a final decision on the measures to be taken (*Article 11(3) of the Fair Competition Code*).

25. What is the relationship between procedures before or measures taken by the self-regulatory authority and the procedures before or measures taken by courts/government competent authorities?

The procedures before or measures taken by the self-regulatory authority and the procedures before or measures taken by courts/government competent authorities are generally conducted separately.

26. Are there any recent enforcement trends in relation to pharmaceutical advertising in your jurisdiction? Please report any significant (publicly known) enforcement actions in the past two years.

Japan is following international trends. The advertising of medicines is subject to tighter controls as medicines have the potential to have harmful effects if not used appropriately and over the last few years, the MHLW has been stepping up its enforcement activities in relation to the advertising of medicinal products.

As indicated in Question 24, amendments to the PMD Act became effective on 1 August 2021 which enable (i) the Minister of the MHLW to order the payment of administrative surcharges to sanction false or exaggerated advertising in violation of Article 66(1) at the rate of 4.5% of the revenues generated by the relevant medicinal product over the period during which the unlawful advertising has taken place subject to a 3-year maximum (no surcharge is imposed for sales below JPY50 million and a 50% reduction applies if the violator reports violations of the PMD Act before an investigation and if there is a surcharge payment imposed under the AUPMR for the same case, the surcharge rate will be reduced from 4.5% to 1.5%); and (ii) the Minister of the MHLW or the competent prefectural governor to issue cease and desist orders (renamed “administrative orders concerning unlawful advertisements”) against pharmaceutical companies to correct improper advertising that are in violation of Article 66(1) or 68.

Contributors

Shinya Tago
Managing Partner
stago@iwatagodo.com

Landry Guesdon
Registered Foreign Attorney
lguesdon@iwatagodo.com

Minako Ikeda
Counsel
minako.ikeda@iwatagodo.com