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Japan
Pharmaceutical Advertising

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

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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 Products Including Pharmaceuticals and Medical Devices (the "**PMD Act**")

In Japan, the PMD Act is the primary law that regulates the advertising of medicines. The following are the main rules set forth under the PMD Act regarding pharmaceutical advertising:

- Prohibition of false or exaggerated advertising (whether explicitly or implicitly) regarding the name, manufacturing process, efficacy and effects of pharmaceuticals (Article 66);
- Restrictions on advertising certain scope of drug products targeting the general public (Article 67); and
- Prohibition of advertising unapproved pharmaceuticals (Article 68).

Ministerial notices under the PMD Act

The Ministry of Health, Labour and Welfare (the "MHLW") has issued several ministerial notices to provide further details of the rules under the PMD Act, including the following:

- The Standards for Fair Advertising Practices Concerning Medicinal Products; and
- The Guidelines for Sales Information Provision Activities for Ethical Drugs.

The Act against Unjustifiable Premiums and Misleading Representations (the "**Unjustifiable Premiums Act**")

The Unjustifiable Premiums Act is also relevant in that the stipulations under this law include general rules on advertising of goods and services that business entities must comply with, such as a prohibition on misleading representations.

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?

Fair Competition Codes

Under Article 31 of the Unjustifiable Premiums Act, trade associations may agree on and establish a set of rules to self-regulate the relevant industry. Such rules, upon obtaining authorization from the Prime Minister and the Fair Trade Commission, constitute an industrial Fair Competition Code. In the drug industry, trade associations in the Ethical Drugs Marketing Industry and the Ethical Drugs Wholesaling Industry have established the Fair Competition Code Concerning Restriction on Premium Offers for each industry.

Other self-regulatory codes of practice

There are several other self-regulatory rules, codes and/or guidelines for advertising of medicines that are set forth by voluntarily organizations, such as:

- "The JPMA Code of Practice" (which includes "the Ethical Drugs Promotion Code" in it as a chapter) and multiple other guidelines established by the Japan Pharmaceutical Manufacturers Association (the "JPMA"), a leading voluntary association in the pharmaceutical industry;
- "The JGA Code of Practice" and other guidelines established by the Japan Generic Medicines Association; and
- "The OTC Drug Advertising Guidelines" established by the Japan Self-Medication Industry (the "JSMI").

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

The above-mentioned codes, namely, the Fair Competition Codes and other self-regulatory codes, are intended to regulate the member companies of the industry organizations and the associations that establish the relevant codes, and are therefore applicable to the member companies of such industrial organizations.

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

Fair Competition Codes are legally binding under the Unjustifiable Premiums Act for the participating member companies in the codes, while it is not for non-member companies. By complying with the relevant Fair

Competition Code, the companies can avoid legal risks, as compliance with the code ensures that with the relevant laws and regulations.

Other self-regulatory codes are not legally binding, while they help foster trust among consumers and society by encouraging voluntary adherence to ethical advertising practices and transparent behavior. They also help to maintain overall fair and healthy transactions throughout the industry, mitigating the legal compliance risks and reputation risks that could negatively affect each company or the industry as a whole.

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?

The MHLW notice "On the Applicability of Advertisements for Pharmaceuticals and Related Products Under the Act," dated September 29, 1998, provides criteria for determining what constitutes advertising. When any one or more of the following requirements are fulfilled, it is considered to be and regulated as an advertisement:

- When the intention of inducing customers (i.e. increasing their intention to purchase) is clear;
- When the product name of the specific drug has been made clear; and/or
- When the statement or the act is recognizable by ordinary people.

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

Any document or activity can be considered as an advertisement as long as it fulfills the above-mentioned criteria. Therefore, for example, patient information leaflets, catalogues, disease awareness campaigns and any correspondence, regardless of its format – be it an email, letter, brochure, or otherwise – could be considered an advertisement.

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

The definition basically applies equally to all advertising, regardless of its target audience or population.

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)?

While press releases regarding pharmaceuticals are not prohibited, they may be considered to constitute an advertisement if they meet the relevant criteria and may therefore be subject to regulations and restrictions under the aforementioned laws, relevant ministry notices, and/or voluntary regulations, as applicable.

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

There is no specific internal process required under the law in order for companies to approve their pharmaceutical advertisements.

However, the MHLW notice "Guidelines for Sales Information Provision Activities for Ethical Drugs" under the PMD Act provides that marketing authorization holder companies of ethical drugs should have an internal division to monitor the companies' activities of providing drug information (including, but not necessarily, sales promotions). The guidelines require that the companies have the information materials be reviewed and approved by such monitoring division before they are used for the information provision activities.

Additionally, even if a company is not marketing ethical drugs, pharmaceutical companies are still generally expected to take necessary measures to ensure that their advertisements comply with the law and align with relevant voluntary standards. Establishing an appropriate internal review and approval process would therefore be a reasonable expectation.

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

No prior approval from the MHLW or any other regulatory authority is required for the release of advertising materials.

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

While comparative advertising for pharmaceuticals is not entirely prohibited, it is subject to strict guidelines and

precautions.

First, the PMD Act prohibits false or exaggerated advertisements for pharmaceuticals (Article 66). In line with this, the Standards for Fair Advertising Practices concerning Medicinal Products, an MHLW notice, prohibits expressions that guarantee the efficacy, effectiveness, or safety of pharmaceuticals.

Additionally, the Unjustifiable Premiums Act prohibits misleading representations. Misleading representations include:

- Quality Misrepresentation: Representations that falsely portray a product or service as being significantly superior in quality, specification, or other attributes compared to the actual features or those of competitors. Claiming effects of a product without reasonable grounds is also one type of quality misrepresentation.
- Benefit Misrepresentation: Representations that falsely portray a product or service as offering significantly greater advantages in terms of price or transaction conditions compared to the reality or competitors.

Taking these regulations into account, the Standards for Fair Advertising Practices Concerning Medicinal Products provide the following rules for comparative advertising for pharmaceuticals:

- Even when making an abstract comparison, this must be handled with caution, as it risks violating the prohibition on guaranteeing efficacy, effectiveness, or safety.
- Comparative advertisements for pharmaceuticals are permissible only when the company compares among its own products and when the name of the product being compared is explicitly identified. Sufficient explanations and grounds must be provided. Comparison with other companies' products (whether explicit or implied) is prohibited.

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?

Advertising of unapproved drugs is specifically and explicitly prohibited under Article 68 of the PMD Act. This prohibition also covers advertising of unauthorised indications.

Please note that, according to the MHLW notice "Guidelines for Sales Information Provision Activities for Ethical Drugs", it is permissible to "provide information" about unapproved drugs, off-label indications or dosages/administration to medical professionals, patients, patient organisations or other people upon their request, subject to the following restrictive conditions. As you may see, this is not supposed to be an advertisement, but rather a genuine provision of information:

- This provision of information must be separated from usual sales activities;
- The content and recipients must be limited to what was specifically requested;
- You must not disguise a request for information;
- You must ensure that the information is accurate and based on scientific evidence. There must not be any falsehoods or exaggeration, and you must not summarize, omit, or emphasize certain parts;
- The disclosure must be in compliance with applicable regulations (e.g., the GCP or the Clinical Research Act) in the case where the company was involved in the relevant clinical studies;
- Negative information must also be included;
- You must explicitly state the fact that the product, etc. has not yet been approved; and
- There should be recordkeeping of the details about the information provision.

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, and include the information that must or must not be included.

According to the MHLW notice "Standards for Fair Advertising Practices concerning Medicinal Products", it is prohibited to advertise prescription only medicines to the general public.

As for over-the-counter (OTC) drugs, advertising targeting the general public is permissible. The advertising must comply with general rules of drug advertising, such as prohibitions of false or exaggerated advertising and misleading representations. Expressions in the advertisement must be within the scope of and in accordance with the granted approval. While there is no specific mandatory information that must be included in OTC drug advertising, the advertisement has to be properly understood as being for a pharmaceutical product, and information on special precautions in use, such as contradictions, need to be provided when

applicable. The JSMI's "OTC Drug Advertising Guidelines" set out detailed explanations of permissible and non-permissible expressions for OTC drug advertisements under the PMD Act and the relevant ministerial notices.

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 are no specific laws or regulations that expressly restrict interactions between patients or patient organisations and the industry.

However, the JPMA Code of Practice outlines certain rules for member companies regarding such interactions. The companies are required to disclose sponsorships provided to patient organisations. The purpose and scope of the sponsorship must be mutually agreed upon in writing and properly documented. In addition, companies shall not, either directly or indirectly, provide goods or monetary benefits that could unduly influence the decision-making of stakeholders in the healthcare sector, including patient organisations. Additionally, the company must establish and adhere to internal policies based on the "Guidelines on Collaboration with Patient Organisations" and the "Transparency Guidelines for Relations between Corporate Activities and Patient Organisations," both issued by the JPMA.

11. Which information must advertising directed at healthcare professionals contain, and which information is prohibited? For example, can companies provide information about clinical trials, or reprints of scientific journal articles?

There are no specific laws or regulations that explicitly provide what information must be included in pharmaceutical advertising directed to healthcare professionals ("HCPs").

However, the Guidelines for Preparation of Ethical Drug Product Information Summaries, a self-regulatory code established by the JPMA, provide specific rules for professional journal advertisements of ethical drugs targeted at HCPs. For instance, general advertisements with the product's characteristics and data must include the following information:

- Name (brand name and generic name);
- Therapeutic category;
- Regulatory classification;
- Indications;
- Dosage and administration;
- Warnings and precautions, including contraindications and other relevant information;
- Whether the product is listed in the National Health Insurance (NHI) price list;
- Name of the marketing authorisation holder (including contact information for requesting references and inquiries);
- Notes on insurance coverage (if applicable);
- Approval conditions (if applicable); and
- Date of preparation.

On the other hand, regarding prohibited information, the PMD Act stipulates that no person shall explicitly or implicitly advertise, describe or disseminate the name, manufacturing process, indications or performance of a drug using false or exaggerated statements. The Standards for Fair Advertising Practices Concerning Medicinal Products provide more detailed guidelines to enforce this rule.

Additionally, the Guidelines for Sales Information Provision Activities for Ethical Drugs (an MHLW notice) and the JPMA Code of Practice (an industry self-regulation) outline certain rules regarding advertising directed toward HCPs, including:

- Providing not only efficacy information but also safety information, such as details on adverse reactions;
- Ensuring a fair balance between benefit and risk information;
- Ensuring that the provided information is based on scientific and objective evidence, which must be verifiable by a third party or subjected to third-party review for appropriateness;
- Avoiding the promotion of one's own products by disparaging or defaming competing products; and
- Avoiding excessively emphasizing disease symptoms in a way that unnecessarily induces anxiety.

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

The rules governing interactions between pharmaceutical companies, HCPs and healthcare institutions are outlined in the Fair Competition Code Concerning Restriction on Premium Offers in the Ethical Drugs Marketing Industry, along with its enforcement regulations and its operational standards (collectively, referred to as the "Ethical Drugs Fair Competition Codes"). These self-regulatory codes were established by the Fair-Trade Council of the Ethical Drugs Marketing Industry.

The Ethical Drugs Fair Competition Codes provide examples of permitted gift-giving activities, including:

- Items or services necessary for the use of or to enhance the benefits of ethical drugs;
- Medical or pharmacological information on ethical drugs, as well as materials and explanatory information related to the company's drugs;
- Small-value premiums that do not exceed the reasonable scope recognized under normal commercial practices; and
- Gifts or entertainment provided during customary social gatherings or commemorative events for companies or healthcare institutions, as long as they are neither extravagant nor excessive by societal standards.

The JPMA Code of Practice prohibits member companies from providing HCPs or healthcare institutions with any items or money that could affect the proper use of drugs or undermine their dignity.

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

The Ethical Drugs Fair Competition Codes outline specific rules for the provision of ethical drug samples (including investigational drugs) to HCPs, including provisions stating that:

- The number of units contained in one package must not exceed the designated amount determined by the dosage form;
- The number of packages provided shall be the minimum necessary for the purpose, typically one or two packages per physician;
- Ethical drug samples provided through wholesalers must be directed to healthcare institutions designated by the pharmaceutical company;
- Pharmaceutical companies are required to provide the relevant drug information to recipient HCPs;
- Investigational ethical drug samples must only be provided upon written request by a physician; and
- Investigational ethical drug samples must not be provided to pharmacies or through wholesalers.

The JPMA Code of Practice requires member companies to provide only the minimum amount of samples with the relevant drug information.

14. Are pharmaceutical companies permitted to sponsor 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?

The Ethical Drugs Fair Competition Codes outline certain rules for sponsoring scientific meetings or congresses attended by HCPs and related to the sponsor company's drugs, including provisions stating that:

- Non-extravagant gifts or services, such as a light meal and drinks, as well as social gatherings, can be provided;
- Attendance expenses typically for speakers, including travel expenses, accommodation costs, and compensation, may be covered; and
- Meetings or congresses must be held in venues appropriate for their purposes and should not take place in resorts or tourist attractions.

The JPMA Code of Practice expressly states that pharmaceutical companies should, in principle, hold such meetings or congresses in Japan, and that payments for travel expenses, accommodation costs and speaking fees can only be made to individuals who play a role in the events.

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

The Ethical Drugs Fair Competition Codes prohibit pharmaceutical companies from providing entertainment or hospitality to HCPs (including invitations to or special treatment regarding movies, musicals, sports events, and travel) as a means of unjustly inducing drug transactions.

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

The Ethical Drugs Fair Competition Codes allow pharmaceutical companies to pay remuneration and expenses to HCPs for post-marketing surveillance and testing of ethical drugs, clinical trials, and other surveillance and studies, as well as medical case reports and presentations at meetings or conferences. Such payments must meet the criteria provided in such Codes.

The JPMA Code of Practice allows member companies to pay remuneration and expenses to HCPs for

presentations, studies, research, meeting attendance, and article writing, provided that the fees are not excessively high in relation to the nature of the work.

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?

The Ethical Drugs Fair Competition Codes prohibit pharmaceutical companies from providing donations to HCPs or healthcare institutions as a means of unjustly inducing drug transactions, such as donations for expenses which HCPs or healthcare institutions should normally pay, and donations for regular medical activities carried out by HCPs or healthcare institutions.

However, donations not associated with transactions (including donations in response to disasters and those made by industrial organizations), donations for research activities, and donations for scientific meetings or conferences are, in principle, permissible.

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?

The Clinical Research Act requires pharmaceutical companies and their subsidiaries to disclose certain transfers of value to HCPs, healthcare institutions and other covered recipients in connection with specified clinical research. This is a legal requirement. Specified clinical research refers to clinical research funded by pharmaceutical companies, clinical research on unapproved drugs, or clinical research concerning off-label use of a drug; however, it does not include a clinical trial for a new drug conducted under the PMD Act. Transfers of value that must be disclosed on the company's website in the following fiscal year include:

- Research funds for specified clinical research;
- Donations made during the term of or within two years after such research; and
- Fees for services such as article writing, giving presentations or other activities provided during the term of and within two years after the research.

It should be noted that the Clinical Research Act generally applies only to marketing authorisation holders. Therefore, foreign companies without any marketing authorization in Japan are not subject to this requirement.

The JPMA “Transparency Guidelines for Relations Between Corporate Activities and Healthcare Institutions” (the “Transparency Guideline”) require member companies to disclose certain information regarding transfers of value made to HCPs or healthcare institutions, and to create their own internal “transparency policy” based on the Transparency Guidelines. These are not legal requirements. Transfers of value categorized under the following matters must be disclosed in detail for each category in the following fiscal year through the company's website:

- Research and development expenses, including payments for clinical trials for new drugs;
- Academic support expenses, including payments to academic societies;
- Manuscript/writing fees, including payments for writing manuscripts containing scientific information about the companies' drugs;
- Information provision expenses, including payments for presentations; and
- other expenses, including payments for hospitality as a social courtesy.

The Transparency Guidelines only apply to members of the JPMA. Therefore, foreign companies that are not members of the JPMA are not subject to this requirement.

19. Are there any restrictions (whether by law or Codes of Practice) on advertising for medicines on social media directed to healthcare professionals or directed to the general public?

The restrictions and prohibitions under the PMD Act and other general laws and regulations equally apply to advertising on social media.

The JPMA Code of Practice provides the following instructions regarding the usage of digital communications on social media; and such communications may include, without limitation, advertising activities regarding pharmaceutical products:

- Compliance with the PMD Act and the Standards for

Fair Advertising Practices Concerning Medicinal Products;
- When the company plans or supports the use of social media, it is responsible for confirming the appropriateness of the content, including posts made by third parties. If any inappropriate information—such as unapproved use, slander or defamation of competitors' products, or any adverse events—is posted, the company must take appropriate measures at its own responsibility;
- Information disseminated by companies must be vetted by the appropriate department within the company; and
- If the company is sponsoring content, its name must be clearly stated.

20. Is advertising on the internet for medicinal products regulated, and if so, how? Should companies include access restrictions on websites containing advertising or other information intended for healthcare professionals?

The restrictions and prohibitions under the PMD Act and other general laws and regulations equally apply to advertising on the internet.

When companies provide product-related information through their websites, especially regarding ethical drugs, there are situations where access by non-HCPs (healthcare professionals) needs to be restricted in view of compliance with the MHLW notice and the Standards for Fair Advertising Practices Concerning Medicinal Products. Considering the nature of the internet which is basically designed to allow free access to anyone and to any information, the JPMA Code of Practice provides the guidance that, if the following conditions are met for the website, it may be deemed appropriate to provide information without requiring measures such as password protection, within the scope permitted under the laws and regulations (e.g., when it does not solicit patients or the general public):

- The company name and the fact that the information is intended for HCPs are both clearly indicated, and the website is structured so that only those who confirm that the information is intended for HCPs can access it;
- The content is appropriate for HCPs; and
- When linking from an HCP-targeted site to an external website, the content, destination, and other aspects of the link must be appropriate for HCPs, and the owner or creator of the linked site must be clearly identifiable.

Regarding the applicability of advertising on the internet, the MHLW provides some Q&As in a relevant notice to help understand the application of such notice, entitled "On the Applicability of Advertising for Pharmaceuticals and Related Products Under the Act", to activities on the internet.

21. Are there any anti-bribery rules that apply to communications between pharmaceutical companies and healthcare professionals or healthcare organisations?

There are no specific anti-bribery laws or regulations specifically governing communications between pharmaceutical companies and HCPs or healthcare organisations.

However, the Penal Code prohibits individuals from giving, offering or promising bribes to public officials, including HCPs working at national university hospitals. Bribery under the Penal Code extends beyond money or goods to any material or immaterial benefits that fulfil an individual's personal desires.

Additionally, the Unfair Competition Prevention Act prohibits individuals from giving, offering or promising benefits to foreign public officials to influence their actions or inactions in the performance of their official duties in order to gain an improper business advantage in connection with an international commercial transaction.

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

Article 4 of the Unjustifiable Premiums Act empowers the Prime Minister to regulate the provision of premiums. Under this authority, the "Restrictions on the Providing of Premiums in the Ethical Drugs, Medical Devices and Sanitation Inspection Industries" were established. This notice prohibits pharmaceutical companies from offering items, services or other benefits to HCPs or healthcare institutions as a means of inducing improper transactions that exceed what is considered appropriate under normal business practices.

Additionally, as noted above, the Ethical Drugs Fair Competition Codes regulate the provision of benefits to HCPs or healthcare organisations. Similar rules are found in the JPMA Code of Practice, which also prohibits the provision of inappropriate benefits to HCPs or healthcare

institutions. These are self-regulatory codes.

23. 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 MHLW is the ministry responsible for overseeing the PMD Act and issuing the relevant administrative notifications. Meanwhile, the Consumer Affairs Agency is the governmental agency responsible for the enforcement of the Unjustifiable Premiums Act and the relevant rules and regulations.

The self-regulatory codes explained in paragraph 2 above are established and managed by each relevant industry association, such as the JPMA.

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

As explained in paragraph 25 below, advertising that infringes upon the relevant laws and regulations would be subject to surcharges, criminal penalties, and administrative orders. Competitors can alert the relevant regulatory authority to the facts regarding such illegal activities and request that appropriate measures be taken.

If advertising causes damage to the business interests of a competitor and the advertisement constitutes an act of unfair competition under the Unfair Competition Prevention Act (e.g., using false statements in comparative advertising that harm the business credibility of the competitor), then the competitor may file a civil lawsuit to seek an injunction or claim damages based on the act. Claims for general tort liability under civil law may also be pursued.

25. 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?

The PMD Act prohibits false or exaggerated advertisements and advertising of unapproved pharmaceuticals. Violations of these provisions may result in criminal penalties, including imprisonment for up to two years and/or fines of up to two million Japanese yen. The same applies to violations of the PMD Act regarding the prohibition of advertising for prescription drugs targeting specific diseases, with penalties of up to one year imprisonment and/or fines of up to one million yen.

Additionally, the Minister of Health, Labour and Welfare or the prefectural governor may issue orders to take the necessary measures to stop the violations and prevent public health risks arising therefrom, such as notifying HCPs and consumers of the violation and implementing measures to prevent the recurrence thereof.

Furthermore, regarding the prohibition of false or exaggerated advertisements, the Minister of Health, Labour and Welfare may order violators to pay a surcharge equivalent to 4.5% of the sales revenue of the product during the violation period.

Similarly, advertising that violates regulations under the Unjustifiable Premiums Act may also result in surcharges, criminal penalties (imprisonment and/or fines), and administrative orders from the Prime Minister (in practice, the Consumer Affairs Agency by delegation from the Prime Minister) to take the necessary corrective measures.

26. 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 and measures taken by the relevant self-regulatory associations are not legally binding and are distinct from the legal measures imposed by courts (whether criminal penalties or civil remedies in private lawsuits between competitors) or governmental authorities (such as administrative orders to implement preventive measures or the imposition of surcharges).

27. 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.

The introduction of a surcharge system under the PMD Act was recently introduced in August 2021. This reflects the government's strict stance on and increasing social

needs for the regulation of such inappropriate advertisements.

Recently, a pharmaceutical company was issued an administrative order under the Unjustifiable Premiums Act to implement preventive measures following improper advertising tied to the stealth marketing of supplements (which are primarily classified as food in Japan). Additionally, the MHLW has recently revised its guidelines on medical service advertising, driven by concerns over the increasing number of incidents involving the improper use of diabetes medications for weight loss purposes.

While these may not be specifically related to pharmaceutical advertisements in the strict legal sense, they reflect a broader trend in the authorities' efforts to ensure appropriate advertising practices and promote proper use of medicines.

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