International
Comparative
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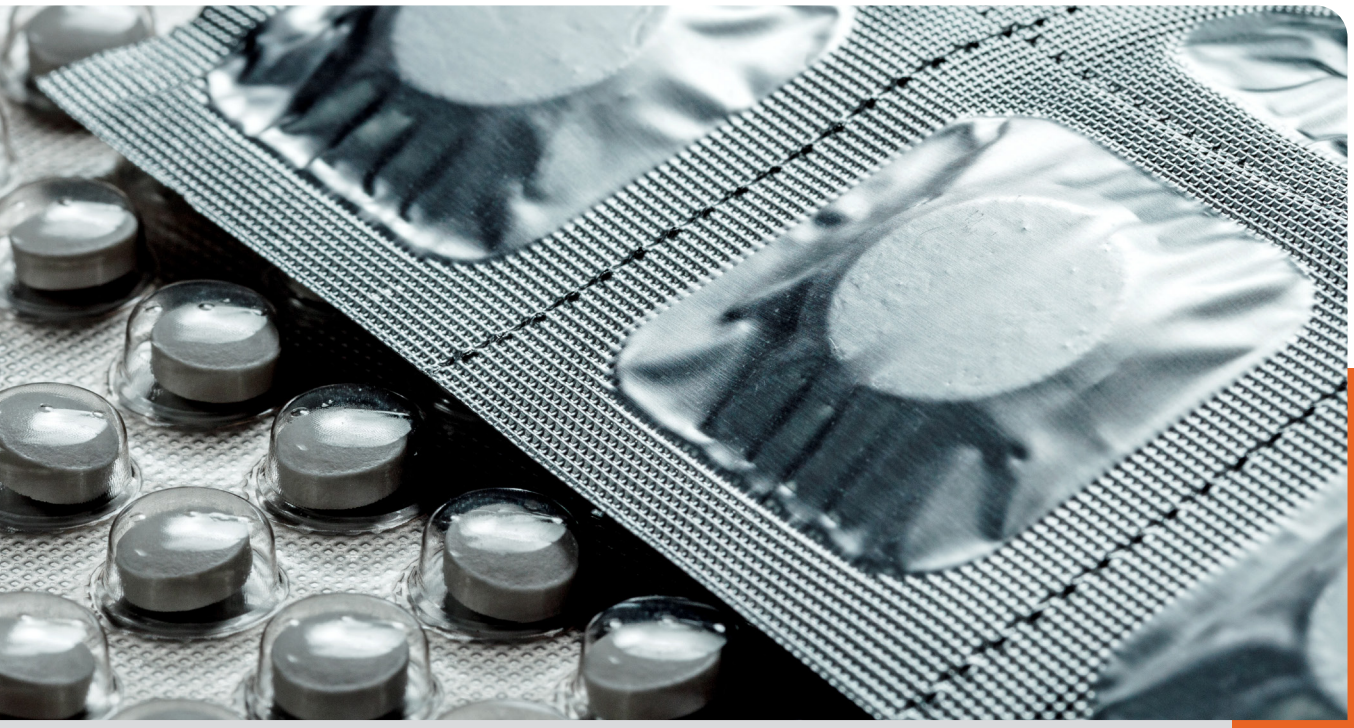

Pharmaceutical Advertising

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1 General – Medicinal Products

1.1 What laws and codes of practice govern the advertising of medicinal products 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) ("PMD Act") and other relevant laws and ordinances, including the Order for Enforcement of the PMD Act ("PMD Act Enforcement Order"), regulate drug marketing activities. The PMD Act, supplemented by administrative notices and guidelines issued by the Ministry of Health Labour and Welfare ("MHLW"), sets basic standards for drug advertising. The guidelines include the Standards for Fair Advertising Practices concerning Pharmaceuticals, etc. (PSEHB Notification No. 0929-4 of 29 September 2017) ("Fair Advertising Standards") and the Commentary on the Guidelines (PSEHBCND Notification No. 0929-5 of 29 September 2017). These Standards prohibit the advertising of prescription drugs to the public. They include specific restrictions on advertisements and limit the use of premiums, prizes and rewards. The Guidelines regarding the Provision of Marketing Information on Prescription Drugs (PSEHB Notification No. 0925-1 of 25 September 2018) ("Guidelines on Marketing Information") cover the provision of information for sales promotion and apply to marketing authorisation holders and their contractors, partners and wholesalers.

General laws include:

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

The AUPMR regulates premiums and representations relating to transactions of goods and services to ensure fair competition and protect consumers. It prohibits unjustifiable premiums and misleading representations, including through advertisements.

In addition, various industry self-regulations apply to the marketing of drugs. The Japan Pharmaceutical Manufacturers' Association ("JPMA") is a voluntary industry group representing large pharmaceutical companies. Members must comply with its code of practices for the promotion of prescription drugs to healthcare professionals ("Promotion Code"). This code is part of the JPMA Code of Practice ("JPMA Code") 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 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 ("FCC"). This Code (along with corresponding guidelines and interpretive commentary) has been approved by the Japan Fair Trade Commission ("JFTC") and the JFTC can step in to prevent or put an end to violations. The Japan Generic Medicines Association has adopted its own code of practice for the promotion of generics. The Japan Federation of Self-Medication Industries ("JSMI") has issued Guidelines for the Proper Advertising of Over-the-Counter Medicines.

1.2 How is "advertising" defined?

Advertising under the PMD Act is defined in a notice issued by the Pharmaceutical Safety Bureau of the 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 public.

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

The Guidelines on Marketing Information require companies to have standard operating procedures dealing with the supply of information when promoting prescription drugs and to set

up a promotion oversight department responsible for monitoring promotional activities and reviewing materials. It must be separate from the sales and marketing divisions. The JPMA Code requires its members to establish internal verification procedures and to appoint a "Promotional Materials Officer" responsible for the management of product information brochures for prescription drugs and a "Practical Operations Supervisor" in charge of practical operations regarding product information brochures for prescription drugs. In practice, all pharmaceutical companies have their own in-house verification procedures.

1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?

See question 1.3.

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

No such approval is required. Companies can consult with regulatory or industry bodies to confirm that their promotional materials comply with applicable laws and codes of practice.

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

The PMD Act does not expressly vest powers in the authorities to stop a breach. In practice, the Minister of the MHLW or Prime Minister will issue a recommendation asking the pharmaceutical company to cease or cure the illegal conduct and if it does not comply, an administrative disposition may be taken. For example, the Minister of the MHLW or competent prefectural governor may: order a violator 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 company advertising a product before obtaining a marketing approval to end the breach and take measures to prevent future violations (Article 72-5 of the PMD Act); or revoke the company's manufacturing or marketing licence or suspend all or part of its operations for a certain period (Article 75 of the PMD Act). Following PMD Act amendments effective on 1 August 2021, violations of the prohibition against false or exaggerated advertising (Article 66-1 of the PMD Act) can be the basis of an order requiring the suspension of the violations or the implementation of measures to prevent recurrence of those advertisements and public announcements relating to the implementation of those measures. See question 1.7.

1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases, please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?

Penalties. Breaches of the PMD Act and rules governing advertising are subject to administrative sanctions by the MLHW. Serious breaches can trigger criminal sanctions: imprisonment with work for 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). The Minister of the MHLW can 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 product sales during the period of unlawful advertising subject to a three-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). The Minister of the MHLW or competent prefectural governor can issue cease-and-desist orders (renamed "administrative orders concerning unlawful advertisements") against pharmaceutical companies to correct advertising in breach of Articles 66(1) and 68.

A business that has made misleading representations to consumers on the quality or standard of goods, price and other business terms and conditions may be liable to pay an administrative fine under the AUPMR (Articles 5 and 8). A cease-and-desist order may also be issued, and non-compliance is punishable by: imprisonment with work for up to two years, and/or a fine not exceeding JPY3 million (Article 36(1)); and a fine of up to JPY300 million for companies (Article 38).

If an entrepreneur violates Article 4 or 5 of the AUPMR, the Prime Minister (or Secretary General of the Consumer Affairs Agency ("CAA") by delegation) can:

- Order the entrepreneur to stop the violation (Article 7).
- Order the entrepreneur to pay surcharges (administrative fines) (Article 8).
- Take measures to prevent the reoccurrence of the violation (such as delegating powers to the JFTC or Minister supervising the entrepreneur's business) (Article 33).

This is in addition to the right to request compliance reports from the offender, conduct on-site inspections and interrogate the staff. The prefectural governor can instruct the entrepreneur to take certain measures. If an entrepreneur is subject to an administrative sanction for breach and the punishment is illegal or unreasonably harsh, he can appeal the decision.

In case of breach of voluntary standards set by industry organisations, corrective measures or disciplinary sanctions can be taken against members. For example, the Promotion Code Committee of the JPMA can take action against breaches of the JPMA Code. The Fair Trade Council of the FTC-EDMI, the JFTC and the CAA can take measures to stop or prevent FCC breaches. The FTC-EDMI can issue warnings and, in case of non-compliance, impose penalties of up to JPY1 million, order the violator's expulsion or ask the CAA to take administrative action against the violator.

Enforcement. The distribution of drugs to consumers is supervised by the Minister of the MHLW and the competent prefectural governor. The Minister of the MHLW, the CAA, prefectural governors and the Personal Information Protection Commission (data protection watchdog) are responsible for the supervision of marketing activities to consumers. Self-regulatory codes typically establish an organ in charge of enforcing the code, e.g., the JPMA Code Compliance Committee for the Promotion Code and the FTC-EDMI for the FCC.

1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?

See question 1.7 (Enforcement). The procedures before the self-regulatory authority and courts/competent authorities are generally conducted separately. However, the regulatory authorities can still investigate a matter already assessed by a self-regulatory body.

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

Pharmaceutical companies can initiate proceedings against competitors before the courts for advertising infringements under the UCPA. Companies whose business interests have been infringed by a competitor's "act of using a description of goods or services, in an advertisement, or in trade documents or electronic correspondence, 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, […]" or a competitor's "false allegations that harm business reputation" may seek an injunction against the competitor to stop or prevent the infringement. They can also claim damages for wilful or negligent infringement with respect to unfair trade practices.

Companies can initiate legal proceedings based on tort, e.g. for defamation or disparagement. Preventing competitors from entering, or operating in, a market is another form of unfair competition that includes conduct like boycotting or offering unreasonably low prices.

2 Providing Information Prior to Authorisation of Medicinal Product

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

Article 68 of the PMD Act prohibits advertising 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 organisations, and subject to strict conditions:

- information on unapproved drugs and off-label indications is separated from other ethical drug promotion activities;
- information is only provided to those who have requested it and is limited to what has been requested;
- information must not be provided under the false pretense of being requested by 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) 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 information content, background and recipients should be kept.

The Promotion Code commentary states that members must refrain from starting promotional activities until the marketing approval is granted; however, this prohibition should not deprive medical and pharmaceutical experts (or the 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 at an academic society meeting 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 an international academic society meeting.
- 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 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 HCPs is not prohibited by the FCC.

2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?

See question 2.1.

2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. mainstream public media), please specify.

Press releases about unapproved pharmaceutical products and off-label indications for promotional purposes are prohibited under the PMD Act. However, press releases not intended to advertise a product or disseminate off-label information may be permitted (e.g., shareholder information). The JPMA Code 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 scrutinised "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".

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

See question 2.1. 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 organisations and under strict conditions.

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

This is not applicable to our jurisdiction.

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

Doing so may be in breach of the prohibition against the advertising of unapproved pharmaceuticals.

2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?

No guideline has been issued on market research of medicinal products; however, research should not be used to circumvent the prohibition against the advertising of unapproved pharmaceuticals.

3 Advertisements to Healthcare Professionals

3.1 What information must appear in advertisements directed to healthcare professionals?

The Fair Advertising Standards do not require specific information to be included in advertising targeting HCPs. However, past MHLW guidelines published 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.

The JPMA's Guidelines for the Preparation of Product Information Brochures for Prescription Drugs list information that must appear in prescription drug advertisements targeting HCPs via professional journals (including conference brochures and publications by pharmaceutical companies):

- 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.

3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to: (a) studies not mentioned in the SmPC; or (b) studies which have not been published either in peer-reviewed journals or at all ("data on file")?

The JPMA Code includes basic principles regarding materials (brochures, adverts in medical journals, websites targeting HCPs, audiovisual materials) and provides that statements contained therein 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 efficiency and safety data, including adverse reactions.
- Comparisons with other drugs must be based on scientific data, in principle, using generic names.
- Competitors or their 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 advertisement must include the information mentioned in question 3.1.
  (a) Advertisements may refer to clinical studies not mentioned in the SmPC, although such references are limited by general advertising rules under the PMD Act and by self-regulatory codes.
  (b) Reference to data on file in advertisements to HCPs is subject to rules set forth under the JPMA's Guidelines for the Preparation of Product Information Brochures for Prescription Drugs. The studies must be published in a peer-reviewed journal.

3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?

The PMD Act prohibits advertisements, descriptions or the circulation of statements giving the false impression that a medical doctor or other person has endorsed the efficacy or performance of a drug.

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

No, there is no such requirement.

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

The AUPMR does not prohibit comparative advertising. However, in accordance with the CAA's Guidelines for Comparative Advertising under the AUPMR, the following forms of advertising are considered misleading and likely to affect product selection by consumers:

- Comparison by indicating matters not demonstrated and incapable of being demonstrated.
- Comparison based on unfair grounds, e.g., by putting the emphasis on aspects inconsequential to product selection by consumers, or on an arbitrary selection of products being compared.
- Advertising that disparages competitors or products.

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

The JPMA Code 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. Its commentary stresses that comparing new drugs with existing drugs is important. 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. The drug being compared against must be referred to using its generic name (the use of rival manufacturers' logos or brands is prohibited without their consent).

3.6 What rules apply to environmental "green" claims made in relation to specific products in promotional material?

There is currently no legislation or guidance regarding green claims in relation to pharmaceutical products, but the sanctions described in questions 1.6 and 1.7 for false or exaggerated claims under Article 66-1 of the PMDA may be applicable.

3.7 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?

See question 2.1. The JPMA Code commentary allows the supply of peer-reviewed scientific literature, such as reprints of a research paper or medical journals at a doctor's request. However, the distribution of scientific papers or proceedings of congresses should not be used to circumvent advertising prohibitions.

3.8 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?

Teasers are not expressly regulated as such. The JPMA Code prescribes that where advertisements are aimed mainly at promoting only the name of a drug, they must include the brand name, therapeutic category (product title), regulatory classification, non-proprietary name, NHI price listing status and contact details for further information.

3.9 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?

Combination products are treated as one and this situation should theoretically not arise. Combinations have to be mentioned in the company's SmPC (essentially label information under Article 52 of the PMD Act) to avoid off-label use.

4 Gifts and Financial Incentives

4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?

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

The provision of free samples is permitted under the Promotion Code and the Japan Generic Medicines Association promotion code. The Promotion Code specifies that only the minimum requisite number of samples should be supplied. The FCC contains detailed provisions on samples. A company is prohibited from providing free medicinal drugs as a means of inducing a medical institution to buy drugs. However, the provision of free "trial-use samples" is permitted for clinical trial purposes. Free samples can be supplied to medical institutions to allow medical staff to become familiar with the formulation, colour, taste, appearance or other characteristics of the product before use.

4.2 Are there any restrictions on the value of payments or benefits that may be provided to healthcare professionals or healthcare organisations for consultancy services? Is it necessary to obtain advance approval from the authorities for the arrangements?

Under the FCC, pharmaceutical companies may pay remuneration or expenses for research, certain studies, or post-marketing surveillance. These payments must comply with the FCC Enforcement Rules and Operating Standards. In particular, remuneration must be appropriate in light of the content of the relevant research.

Under the JPMA Code, member companies may engage researchers, HCPs, medical institutions, patient organisations, etc., for services such as research, clinical studies, post-marketing surveillance, 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. When making arrangements for these services, member companies must enter into a written agreement that satisfies certain criteria. In particular, the engagement must not be an inducement to prescribe, purchase, or recommend any specific drug and the compensation for the services must be reasonable and reflect the fair value of the services. There is no obligation to obtain any approval from the authorities.

4.3 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.

Gifts. In special circumstances, gifts and promotional items can be offered to HCPs, provided they comply with good ethical practices and remain within the limits of decency. Under the FCC, inappropriate financial benefits or benefits in kind should not be offered to medical practitioners to induce them to prescribe drugs, and a marketing authorisation holder cannot provide premiums to HCPs and healthcare institutions, such as hospitals or pharmacies, to unjustly induce transactions. The Promotion Code generally prohibits 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 or be perceived by the public as interfering with independent and scientifically based prescription methods and consequently undermine the social role of drugs.

JPMA members must set clear standards for gifts and cash offerings in their in-house codes. 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. Members should refrain from offering congratulatory money because the intention behind the payment and the range of congratulatory events are difficult to assess. The Promotion Code commentary states that reasonable condolence money (about JPY10,000) for funerals is permitted as it is unlikely to influence prescription practices. According to the FCC Enforcement Rules and Operating Standards, gifts having a small value not exceeding appropriate levels in light of ordinary commercial customs (about JPY3,000) and modest gifts offered at seminars organised for one's own products or memorial events (about JPY5,000) are permissible, as they are not considered to unduly affect an HCP's decision.

Grants and donations. Pharmaceutical companies may generally provide grants or donations to HCPs or healthcare institutions, subject to restrictions. The FCC prohibits the offering of 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 purpose is decided based on criteria provided in the FCC Operating Standards. The Standards on Donations under the FCC provide that even if a donation is "free of charge", if the manufacturer of prescription drugs is promised to be treated advantageously in return for the donation or the manufacturer responds to a donation request that is excessive compared to what is socially acceptable, it may improperly induce a transaction and should be restricted. Examples of prohibited donations include 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 the request is rejected. Examples of permissible donations not deemed to be associated with drug prescription include:

- Donations widely accepted by society.
- Donations by industry organisations widely acknowledged in society.
- Donations in response to disasters (e.g. relief money, 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 provide detailed guidelines on what is prohibited as improperly inducing prescription drug transactions:

- Donations through the assumption of costs that should be borne by the medical institutions/HCPs.
- Donations for ordinary medical services performed by the medical institutions/HCPs.
- When the manufacturer 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.
- Donations deemed excessive compared to what is socially acceptable.

Donations acceptable under the FCC include: donations for research activities (except for support for clinical research on the manufacturer's own medicinal products); donations for lectures targeting the public or HCPs that do not belong to the medical institutions receiving the donations; and other donations not deemed to induce transactions (e.g. donating funds to build a new hospital, providing prescription drugs for free to educate students in response to requests from universities, donations for educational, training or scholarship funding purposes).

4.4 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply? If monetary limits apply, please specify.

The principles in questions 4.3 and 4.5 apply. JPMA member companies can offer or provide items of medical utility if they are of modest value, do not offset routine business practices and are beneficial to the provision of medical services and patient care (different rules could apply to clinical trials). The cost of a nurse cannot be covered by a donation.

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

Notification No. 124 issued by the Cabinet dated 1 April 2016 on Restrictions on Premium Offers in the Ethical Drugs, Medical Devices and Hygienic Inspection Laboratory Industries under the AUPMR prohibits pharmaceutical companies from offering goods, services or other premiums to HCPs beyond what is necessary for the use of ethical drugs and commercially reasonable as a means of inducing unjust transactions. Under certain conditions, the FCC allows the supply of goods or services required for the proper use of the drugs or services that maximise the use of the product or its benefits. A market expansion would likely result from action beyond the pale.

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

Volume-related discounts are permissible, subject to general

competition law rules. If a company offers a volume-related rebate, it may have the effect of restraining the purchaser's dealings in competing products (exclusionary dealing). The FCC exempts "premiums that do not include any economic benefit such as discounts or after-sales services in light of normal business practices" from its premium restrictions.

4.7 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable? If so, what rules apply?

See question 4.5. The FCC does not prohibit package deals, but each deal should be reviewed on a case-by-case basis.

4.8 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?

There is no express prohibition against refund schemes, although, in practice, pharmaceutical companies typically go through wholesalers, who in turn sell drugs to medical institutions or pharmacies, and this may limit refund opportunities. These schemes are sometimes used for over-the-counter ("OTC") medicine like money-back guarantees for other consumer goods. There have been instances of pharmaceutical companies paying a refund to consumers when recalling ethical or OTC drugs.

4.9 Are more complex patient access schemes or managed access agreements, whereby pharmaceutical companies offer special financial terms for supply of medicinal products (e.g. rebates, dose or cost caps, risk share arrangements, outcomes-based schemes), permitted in your country? If so, what rules apply?

No specific rules apply to more complex schemes or agreements, and certain companies are exploring schemes to move away from volume-based pricing. Potential issues may involve sales below cost, patient data protection, insurance regulations, etc.

4.10 Is it acceptable for one or more pharmaceutical companies to work together with the National Health System in your country, pooling skills, experience and/or resources for the joint development and implementation of specific projects? If so, what rules apply?

No specific rules govern or restrict such cooperation.

4.11 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?

Please see question 4.3. This is permissible under the FCC, provided it does not improperly induce transactions.

4.12 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?

The Criminal Code prohibits bribing Japanese public officials. Medical practitioners of a state-owned hospital are quasi-public officials and regarded as public officials under the Criminal Code. Offering bribes is punishable by imprisonment with work for up to three years or a fine of up to JPY2.5 million.

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) provides standards of conduct. For example, personnel must not receive cash, goods or real estate, cash loans, free services from interested parties (i.e., counterparties in their duties), accept entertainment from them or play games or golf or travel with them. Exceptions include accepting refreshments in the form of a buffet at a party attended by many people or accepting tea and cake at meetings or other gatherings attended by personnel in the performance of their duties.

The UCPA ensures fair competition among business operators and the bribery of foreign public officials is forbidden under Article 18 (1), which prohibits any person from giving, offering or promising to give any money or other benefit to a foreign public official to have such foreign public official act or refrain from acting in relation to the performance of official duties, in order to make any unlawful gains in business with regard to international commercial transactions. The penalties for a violation of this article were substantially increased as a result of an amendment of the UCPA, which came into force on 1 April 2024,

An individual (e.g. an employee of a Japanese company) is punishable by imprisonment with labour for up to 10 years and/or a fine of up to JPY30 million. Companies may also be punished by a fine of up to JPY1 billion.

The National Police Agency and Public Prosecutors' Office are responsible for the supervision and enforcement of anti-bribery rules. They can investigate matters that may constitute both a breach of advertising rules and anti-bribery legislation, in circumstances where these are already being assessed by the competent pharmaceutical authorities or self-regulatory bodies.

5 Hospitality and Related Payments

5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?

The 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 FTC-EDMI has wining and dining rules serving as guidance for its members. For instance (for each HCP) the maximum value is:

- for buffets following information-sharing lectures or meetings concerning the company's products, food and drinks: JPY20,000;
- for food and drinks provided to participants of meetings related to conference management: JPY20,000;
- for 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: JPY20,000;
- for food and drinks in connection with the activities of medical representatives: JPY5,000; and
- for "bento"-lunch boxes and snacks and a cup of tea offered at in-house briefing meetings or drug explanatory meetings held by medical representatives: JPY3,000.

The code rules also apply to hospitality offered overseas and the JPMA Code commentary explains that even for activities taking place overseas, members must abide by the JPMA Code while at the same time conforming to local laws and regulations, in addition to whatever pharmaceutical organisation codes exist, or to the IFPMA Code in the absence of a code. There is no requirement regarding company affiliate consent.

5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?

HCPs can be paid in connection with attending scientific meetings, subject to restrictions under the FCC and Promotion Code. The Promotion Code provides that members should hold seminars in appropriate locations and venues (i.e., avoiding resorts) and, in principle, in Japan. It authorises the reimbursement of nominal expenses, including travel expenses and accommodation and the payment of lecture fees to HCPs providing genuine services as guest speakers or presenters. Should a seminar take place abroad, the payment of travel expenses is limited to those of HCPs providing information on the company's drugs. Where a company hosts a seminar unrelated to its own drugs, only meeting expenses may be paid.

5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?

A company is responsible for the contents and hospitality arrangements at meetings it directly sponsors or organises. For independent meetings, responsibility will be assessed on a case-by-case basis.

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

The FCC 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). Pharmaceutical companies must comply with the FCC guidelines (in particular, the Standards for Premiums) issued by the JFTC and CAA. It is possible to pay reasonable honoraria, reimburse out-of-pocket expenses (e.g., travelling and accommodation) for conference speakers and presenters. These payments must be kept at a modest level.

The Promotion Code and commentary clarify that JPMA members may engage HCPs for services such as lectures, writing papers, conducting surveys or research, taking part in meetings held by members, or providing training, etc., where such participation involves fees such as honoraria. Fees should not be excessive in light of the services. A written contract must be agreed, which specifies the purpose of the services and basis for payment. A legitimate need for the services must be identified, and the HCP must have the relevant expertise.

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

See question 5.4.

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

See question 5.4.

6 Advertising to the General Public

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

They can be freely advertised like other consumer goods. OTC drug advertising is regarded as an important means of conveying useful health-related information to the public. Advertisements for non-prescription drugs must comply with the PMD Act and the Fair Advertising Standards (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).

JSMI's Guidelines for the Proper Advertising of Over-the-Counter Medicines deal with OTC drug distribution (see question 1.1).

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

The PMD Act and its Enforcement Order only prohibit advertising of drugs for specially designated diseases (treating cancer, sarcoma and leukemia) but the Fair Advertising Standards prohibit the advertising of prescription drugs to the public. Such advertising may only target HCPs. In addition, they 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, hyperlipidaemia, heart diseases, hepatitis or other diseases that generally require a medical practitioner's diagnosis and treatment.

6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?

In principle, disease awareness campaigns do not qualify as advertising unless they satisfy the definition of advertising (see question 1.2). They should not promote a particular drug. The Guidelines on Marketing Information apply to campaigns focusing on diseases treated with prescription-only medicines. Extra caution is needed where there is only one treatment option or medicine available.

6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?

Press releases concerning medicines are not prohibited, but if a press release falls under the definition of advertising (see question 1.2), advertising restrictions under the PMD Act and the Fair Advertising Standards will apply.

6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?

Should the product information and pipeline fall within the definition of advertising, the advertising regulations will apply. Under the JPMA Code, if the information disclosed to shareholders concerns a product under development, members must ensure it is not used for promotional activities and that it will not be perceived as information for investors.

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

There is no specific regulation. The JPMA Code provides that members must act ethically and respect the independence of patient groups. Those collaborating with patient organisations must establish internal guidelines based on the JPMA's Guidelines on Collaboration with Patient Organisations and the Guidelines for Transparency of Relationship between Corporate Activities and Patient Organisations ("Transparency Guidelines"). Members are advised to include in their internal guidelines the need to clarify their involvement with patient organisations and, when providing financial support, to secure written consent for the objectives and keep records. The Transparency Guidelines include spend disclosure obligations. Members must publicly release data on donations, grants and benefits in kind or other support provided to patient organisations. The Guidelines recommend that members' financial contributions for the past fiscal year be disclosed on their website.

6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?

The advertising of prescription drugs to consumers is prohibited (see question 6.2); however, the restrictions do not apply to non-prescription drugs, and gifts and benefits can be provided to patients and consumers as part of a marketing strategy, subject to the rules on premiums under the AUPMR. The benefits should be reasonable and should not lead to overconsumption.

6.8 What are the rules governing company funding of patient support programmes?

See question 6.6.

7 Transparency and Disclosure

7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?

There is no such obligation in the legislation. To ensure transparency of information on clinical studies, JPMA members must publicly disclose clinical study information in conformity with the Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases adopted by major international industry associations. A publicly accessible clinical trial registry contains basic information on ongoing clinical trials, other than exploratory, sponsored by members, including brief title, description, trial phase, type, status and purpose (e.g., treatment, diagnosis, prevention), intervention type (e.g., drug, vaccine), condition or disease and eligibility criteria. A publicly accessible clinical trial results database summarises the results of completed clinical trials, other than exploratory trials, conducted on a drug approved for marketing and commercially available in at least one country, regardless of outcome. Trial results from exploratory trials of a significant importance should be disclosed.

7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?

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

The Clinical Research Act requires pharmaceutical companies and their subsidiaries to disclose certain transfers of value to HCPs 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 five years. The disclosure obligation under the Clinical Research Act applies to pharmaceutical companies that are licensed to market under the PMD Act.

7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?

The JPMA Guidelines for Transparency of Relationship between Pharmaceutical Companies and Medical Institutions, etc. require members to disclose information regarding transfers of value made to HCPs or healthcare institutions. Members must prepare their 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 are broken down into five categories:

- 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, Good Pharmacovigilance Practice and Good Post-marketing Study Practice 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., for lectures and writing or supervision of a 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 companies' own drugs).
- Expenses related to the provision of information including spend for lecture meetings and explanation meetings, etc., for providing information, etc., related to the company's pharmaceutical products to medical professionals (such as expenses for lectures and seminars).
- Other expenses (such as for hospitality as a matter of social courtesy).

7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?

See question 7.2 on Clinical Research Act obligations. Transfers of value are typically made on the condition that disclosure is authorised by the HCP.

8 Digital Advertising and Social Media

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

Advertising drugs on the Internet is governed by the same laws, regulations and self-regulatory codes 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 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 importers on the Internet, a notification was issued to provide guidance to 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 Promotion Code commentary lays down specific rules concerning access restrictions to information on prescription-only medicines available on the Internet. 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 accessing the site. The 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 licence.

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

See question 8.1.

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

Responsibility should be considered on a case-by-case basis. Companies may be held responsible for the advertising content of an independent website or platform accessed from a company-sponsored site or in case of reverse linking arranged by them.

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

See question 8.1.

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

The rules in question 8.1 would also apply.

8.6 Are there any restrictions on social media activity by company employees using their personal accounts, including interactions with third parties through "likes", "applauds", etc.?

There are no express restrictions. Clearly, responsible employees should show some restraint depending on the circumstances, and in-house rules and policies can be adopted.

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

No, there are no specific rules.

9 Developments in Pharmaceutical Advertising

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

There have not been any significant developments in the last year.

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

No significant developments are expected in the next year.

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

Japan is following international trends. The advertising of medicines is subject to tighter controls for a variety of reasons (e.g., the fact that the advertising of OTC products via social media and the Internet has skyrocketed, thereby increasing risks of abuse, fraud, or overmedication, the need to protect a more vulnerable aging population and rising healthcare costs). Over the last few years, the MHLW has been stepping up its enforcement activities in relation to drug advertising.

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