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Japan
Life Sciences

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

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Japan: Life Sciences

1. Please briefly summarize your country's legislative framework for medicinal products (including biologicals), medical devices, food, and food supplements

The main law governing medicinal products (including biologicals) and medical devices in Japan is the *Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices* ("Pharmaceuticals Law"), together with related cabinet and ministerial ordinances. The Food Sanitation Act, the Food Labeling Act, and the Health Promotion Act, and related cabinet and ministerial ordinances are the primary laws governing food and food supplements in Japan.

Medicinal products subject to regulations in the Pharmaceuticals Law are defined as products, which are not equipment or instruments, that are (i) listed in the Japanese Pharmacopoeia established and published by the Japanese government, (ii) intended for use in the diagnosis, treatment or prevention of disease in humans or animals, or (iii) intended to affect the structure or functions of the body of humans or animals. Medical devices are defined under the Pharmaceutical Law as appliances, instruments or similar items that are intended for use in the diagnosis, medical treatment or prevention of disease in humans or animals, or intended to affect the structure or functioning of the bodies of humans or animals, and that are specified by cabinet ordinance of the Pharmaceuticals Law.

To market medicinal products or medical devices, the Pharmaceutical Law requires that the initial marketing entity hold a marketing business license and a marketing authorization for each of the relevant medicinal products and devices. "Marketing" in this context means manufacturing or importing medicinal products or medical devices, and then selling, leasing or distributing them.

In order to obtain a marketing business license, the applicant must establish that it qualifies as an entity responsible for the quality, efficacy and safety of medicinal products.

Food safety regulations are primarily provided in the Food Sanitation Act. The Ministry of Health, Labour and Welfare ("MHLW") formulates various food safety standards in relation to residual agricultural chemicals, food additives, bacteria contained in food, and other food-related matters. The sale, manufacture, processing or import of any food that does not meet such standards is prohibited in Japan. Unlike medicinal products or medical devices, food suppliers generally are not allowed to sell their products by claiming that they have a function related to health. However, if the food product is approved by the Consumer Affairs Agency ("CAA"), an administrative agency of the Cabinet Office of Japan, as a *Food for Specified Health Use*, its health function can be claimed on packaging or in product advertisements. Suppliers can also choose to sell their food products as *Foods with Functional Claims*, based on self-certification of the efficacy and safety of the food product either based on the results of clinical trials or a systematic review of peer-reviewed academic papers, and filing the necessary documentation with the CAA.

2. With regards to medicinal products and medical devices, how is the regulatory process structured in your jurisdiction from R&D through market approval until post-marketing vigilance, and what rules does it follow? Please briefly describe.

In order to obtain a marketing authorization for a medicinal product or a medical device, the marketing authorization applicant is required to submit the information and materials listed in the cabinet ordinance addressing marketing authorization. The information and materials listed as being required for marketing authorization differ slightly depending on whether the product for which the marketing authorization is sought is a medicinal product or a medical device. If the marketing authorization is for a medical device, the results of either the clinical trials or the clinical evaluations may be submitted. However, if the marketing authorization is for a medicinal product, the results of only the clinical trials may be submitted and such results cannot be replaced by the results of the clinical evaluations.

An application for marketing authorization must be submitted to the MHLW, or in the case of certain medicinal products and all medical devices, to the relevant prefectural government or a particular registered certification body. With regard to an application for

marketing authorization for a medicinal product or medical device that is to be submitted to the MHLW, the application must be submitted through the Pharmaceuticals and Medical Devices Agency ("PMDA"). The MHLW's review of applications for marketing authorization for new medicinal products is substantially outsourced to the PMDA.

Completion of the procedures for modification of approved items is required in order to change any approved items after marketing authorization has been granted. Even if the change is only a partial change to an approved item, if such change is considered an essential change that would result in a material change in the identity of the medicinal product or the medical device, a new marketing authorization approval must be obtained for the product or device which would be considered a separate product from the original approved medicinal product or medical device. On the other hand, in the case of a partial change to an approved item that is not considered an essential change as described above, only an approval for the partial change is required; and in the case of a minor change, an approval for the change is not required and it is sufficient to submit a written notification of the change to the relevant agency after the change is implemented.

3. What is the regulatory process for food supplements, from first notification to the competent authorities until post-marketing vigilance in your country, and what regulations are applicable here? Please briefly describe.

The term *food supplement* is not legally defined in Japanese law, and there are no special regulations addressing food supplements. Therefore, in general, foods supplements are treated in the same way as foods, and therefore, among other things, cannot be labeled as affecting the structure or functioning of the body in a particular way. However, if a particular food supplement is categorized as a *Food for Specified Health Use*, *Food with Functional Claims,* or *Nutritional Functional Food*, it is exceptionally allowed to indicate in such food supplement's label the specific health or nutritional functions associated with such product to a limited extent.

Products in the *Nutritional Functional Foods* category are those of which the function of nutritional components contained therein such as vitamins and minerals is indicated in the product label, and for which individual permission or notification to the competent authority is not required. Products in the *Food with Functional Claims* category can be labeled as having certain functional properties by notifying the CAA of the scientific rationale for safety and functionality of the product together with other information, prior to marketing. The scientific basis for the functionality must be clarified through the reporting of results from clinical trials or an explanation that is based on a systematic review of relevant literature. Products in the *Foods for Specified Health Uses* category are foods that have been approved, on the basis of scientific evidence, as being useful for maintaining and improving health, and for which labeling such as "suppresses the absorption of cholesterol" is permitted. The labelled effects and safety are to be examined by the CAA, and individual approval for each food product by the CAA is required.

4. What are the ongoing obligations in your country after a marketing authorization for medicinal products has been obtained or a conformity assessment been carried out for medical devices?

After the marketing of a medicinal product or a medical device commences, the marketing authorization holder is required to conduct post-marketing pharmacovigilance and technovigilance in accordance with applicable law. If any issue relating to the effectiveness or safety of the marketed medicinal product or medical device is discovered during the post-marketing authorization surveillance period, the marketer must conduct a medicinal product or medicinal device recall campaign, report the discovery to the PMDA, issue public notices if the issue is important, and take other appropriate measures to prevent users or potential users of the relevant product or device from suffering injury, damage or losses.

5. Which are the competent national authorities having the regulatory oversight over medicinal products, medical devices, food, and food supplements and what are their respective responsibilities?

The MHLW is the principal regulatory body for medicinal products and medical devices. The MHLW is the national governmental body that issues most of the Pharmaceuticals Law-related ministerial ordinances and administrative guidelines and drafts relevant cabinet ordinances. Prefectural governments are primarily responsible for monitoring medicinal products and medical device marketers, manufacturers and distributors in their respective jurisdictions on behalf of the MHLW.

The PMDA, a Japanese independent administrative agency that receives financial support from the Japanese government to cover its operational costs, also plays a key role in reviewing marketing authorization applications for new medicinal products and medical devices. The MHLW is also the competent national authority overseeing food regulations (especially those established to ensure food safety), while the CAA maintains authority over food labeling regulations and food supplements.

6. Please briefly describe the procedure of challenging regulatory decisions (e.g., denial of marketing authorization) made by the competent regulatory authority in relation to medicinal products, medical devices, and food supplements.

If a pharmaceutical or medical device company violates the Pharmaceuticals Law or any related regulation, the MHLW or the relevant prefectural government may issue an administrative order such as an improvement order, an operation suspension order, a discontinuation order, or an order for change of marketing director. The recipient may challenge the administrative order through an administrative complaint review process provided under the Administrative Complaint Review Act. A pharmaceutical or medical device company served with an administrative order may also commence a legal action for the nullification of the administrative order with a competent court in accordance with the Administrative Case Litigation Act. These challenge procedures are also generally applicable in cases involving issuance of administrative orders for violations of laws concerning other regulated products.

7. Please briefly describe the legal framework and the relevant regulatory procedure (e.g., application process, requirements, approval, denial) that applies in your jurisdiction to clinical trials for medicinal products and medical devices.

In Japan, when conducting clinical trials for the purpose of obtaining marketing authorization for a medicinal product or medical device, compliance with the relevant provisions of the Pharmaceuticals Law and the Ministerial Ordinance for Good Clinical Practice ("GCP Ordinance") is required. Such clinical trials can be divided into two types: (i) "company-initiated clinical trials" in which the drug or medical device manufacturer entrusts a medical institution to conduct the clinical trials, and (ii) "investigator-initiated clinical trials" in which physicians plan, design and conduct the clinical trials on their own, and take full responsibility for such clinical trials.

In the case of company-initiated clinical trials, the regulatory procedure is as follows. The sponsoring drug manufacturer or medical device manufacturer (the "Sponsor") prepares a clinical trial plan and submits notification of such plan to the regulatory authority (i.e., the PMDA). Then, the clinical trial protocol and patient informed consent form ("ICF") need to be approved by the Internal Review Board ("IRB") of each medical institution where the clinical trials are to be conducted, and a clinical trial agreement needs to be executed between the Sponsor and each such medical institution. The Sponsor and each medical institution can enter into the clinical trial agreement from the 31st day after the Sponsor's submission of the clinical trial plan notification. Informed consent must be obtained from each participant using the IRB-approved ICF. During each clinical trial, the Sponsor must continuously monitor the clinical trial to ensure that it is being conducted appropriately and in accordance with GCP regulations and approved protocols. After the clinical trial is completed, a summary report should be prepared based on the acquired and analyzed clinical trial data for the application for marketing authorization for the relevant medicinal product or medical device. The records from each clinical trial must be retained for a certain period of time for subsequent audits and other purposes.

As for clinical trials conducted for purposes other than obtaining marketing authorization for a medicinal product or medical device, the Clinical Trials Act or the Ethical Guidelines for Medical and Biological Research Involving Human Subjects (the "Ethical Guidelines") will apply, depending on the nature of the clinical trial in question.

8. Is there a public database for clinical trials in your country, and what are the rules for publication?

The following three public databases for clinical trials exist in Japan: (i) the UMIN Clinical Trials Registry managed by University Hospital Medical Information Network, (ii) the JAPIC Clinical Trials Information managed by Japan Pharmaceutical Information Center, and (iii) the Japan Registry of Clinical Trials ("jRCT") managed by the MHLW. Information regarding clinical trials conducted under (i) the Pharmaceuticals Law and the GCP Ordinance or (ii) the Clinical Trials Act is required to be registered with and published through jRCT. Information regarding clinical trials conducted under the Ethical Guidelines is required to be registered with and

published through any of the above-mentioned three public databases.

9. Please briefly summarize the rules that must be observed in your jurisdiction when using data from clinical trials?

Data from clinical trials generally falls under the category of sensitive personal information (*yōhairyo-kojin-jōhō*) as defined by the Act on the Protection of Personal Information ("APPI"). Consequently, the APPI requires that when acquiring and using data from clinical trials, the purpose of use (e.g., to support an application for marketing authorization for a medicinal product) be specified, each participant in the clinical trial be notified of such contemplated use and purpose for use of the data, and consent from each clinical trial participant be obtained in advance. In addition, when providing acquired clinical trial data to a third party, with certain exceptions, the APPI requires that the consent of each clinical trial participant to such data transfer be obtained in advance. In particular, when providing clinical trial data to a third party located outside of Japan (e.g., the parent company of the Sponsor which is located in a foreign country, or the licensor of the subject medicinal product which located in a foreign country), except in certain cases, it should be noted that (i) the personal information protection legislation in the country where the recipient is located and (ii) the measures that have been taken by the recipient to protect personal information, must be explained to the clinical trial participants in advance of obtaining consent from such participants. In practice, it is common to include the consent for the acquisition and handling (including the transfer to third parties) of sensitive personal information pursuant to the APPI in the informed consent form based on the GCP Ordinance, the Clinical Trials Act, or the Ethical Guidelines as applicable.

In relation to the acquisition, storage, and use of clinical trial data, the APPI requires that the responsible company implement and maintain adequate safety management measures to prevent the occurrence of security breach incidents involving personal information. When the handling of clinical trial data is outsourced to a third party (such as a contract research organization), the APPI requires that the responsible company also ensure and observe that proper safety management measures are taken by such third party.

10. Are there any trends and/or legislative proposals in your country on digitizing the process of conducting clinical trials (e.g., digitalization of the application process, decentralization of clinical trials)?

Commencing from 2023, clinical trial plan notifications and responses to inquiries from the regulatory authority (i.e., the PMDA) can be submitted online. In addition, the MHLW is now developing regulations to promote the use of decentralized clinical trials ("DCT"). For example, in March 2023, the MHLW issued a guidance clarifying the points to be considered when adopting the so-called "eConsent" procedure (a structure and process by which participants of a clinical trial (i) will be informed of relevant information regarding the clinical trial by, among other ways, having information and videos available for viewing through a mobile device application and/or participating in video calls over the Internet), and (ii) will consent to participation in the clinical trials, which consent may be indicated by the participants' electronic signatures. In addition, when providing medical care services online during clinical trials, the physicians performing such services must comply with the MHLW's telemedicine guidelines which were originally issued in 2018 (and amended periodically thereafter). The MHLW is expected to issue other related guidance going forward.

11. What are your country's legal requirements for the authorization of manufacturing plants for medicinal products, medical devices, food, and food supplements? Please briefly describe.

Under the Pharmaceuticals Law, operators of manufacturing sites where medicinal products are to be produced in Japan (the domestic drug manufacturers) must possess a manufacturing business license from the relevant municipal government and operators of manufacturing sites where medical devices are to be produced in Japan (the domestic device manufacturers; and together with domestic drug manufacturers, the "domestic manufacturer") must secure manufacturing business registration with the MHLW. In order to obtain and maintain such license/registration, a domestic manufacturer is required to take appropriate actions to maintain certain facility standards as well as to appoint a statutory officer who has certain credentials and will be responsible for the manufacturing and quality management at each manufacturing site. Operators of manufacturing sites located outside of Japan that manufacture medicinal products to be marketed in Japan must receive foreign manufacturer accreditation from the MHLW, and operators of manufacturing sites located outside Japan that manufacture medical devices to be marketed in Japan must secure foreign manufacturer

registration from the MHLW. All manufacturing sites of medicinal products and medical devices must comply with the GMP/QMS regulations set forth in the relevant ministerial ordinances in relation to their manufacturing/quality control activities.

Under the Food Sanitary Act, operators of manufacturing sites for food and food supplements in Japan may be required to possess a manufacturing business license from the relevant municipal government depending on the nature of the manufactured foods or food supplement. In order to obtain and maintain such license, the operator of a manufacturing site is required to take appropriate actions to maintain certain facility standards as well as to appoint a statutory officer who has certain credentials and will be responsible for the manufacturing and quality management at each manufacturing site. Except for certain types of manufacturing sites, all the manufacturing sites must implement general sanitary control measures as well as sanitary measures based on principles of HACCP.

12. Please briefly describe the typical process of distributing medicinal products, medical devices, and food supplements in your country, encompassing, if applicable, the wholesale distribution of products.

In Japan, once medicinal products and medical devices are manufactured and/or imported, those products typically will be sold by the marketing authorization holder to a specialized wholesale distributor. Under the Pharmaceuticals Law, each wholesale distributor of medicinal products and/or medical devices must possess the relevant category of distribution business license for each of its distribution centers and sales offices in order to distribute and sell drugs or to sell or lease certain high-risk medical devices to the customers (such as hospitals, pharmacies and patients) as well as to other distributors. A distributor who sells or leases certain moderate-risk medical devices must submit to the relevant municipal government a distribution business notification for each of such distributor's distribution centers and sales offices. A distributor who sells or leases only low-risk medical devices does not need to obtain such business license or submit such notification.

Ordinarily, food supplements are also distributed initially through a wholesale distributor who purchases the supplements from the marketing authorization holder. A distributor of food supplements usually is not required to possess a sales business license under the Food Sanitary Act, which can be required for the distribution and sales of certain types of foods.

13. Please briefly describe the pricing and reimbursement rules, if any, for medicinal products, medical devices, and food supplements in your jurisdiction?

With respect to over-the-counter ("OTC") drugs and food supplements, there are no specific pricing and reimbursement rules established under applicable law; therefore, manufacturers may freely set prices for their products as they deem appropriate so long as such products do not fall under the category of prescription pharmaceuticals. On the other hand, prices for prescription pharmaceuticals are listed on the drug tariff (i.e., a listing of NHI (National Health Insurance) prices for prescription pharmaceuticals, the amounts of which are decided not by manufacturers but by the MHLW and applied uniformly throughout the country) and reimbursements of the cost of prescription pharmaceuticals used for medical services are made directly to the relevant medical services providers through Japan's universal healthcare system by which almost all of Japanese residents are covered. Medical devices are broken down into many categories, and costs for certain medical devices may or may not be reimbursed by Japan's universal healthcare system depending on the category to which such medical devices belong.

In order for the price of a pharmaceutical product to be listed on the drug tariff, the holder of the marketing authorization for such product needs to file an application pursuant to the Health Insurance Act of Japan after obtaining the marketing authorization under the Pharmaceutical Law.

14. What legislative framework applies to the advertising for medicinal products, medical devices, and food supplements in your country?

The Pharmaceuticals Law prohibits false, exaggerated or misleading advertisements, descriptions and circulations in relation to the name, manufacturing method, efficacy, effects, or performance of pharmaceuticals, quasi-pharmaceutical products, cosmetics, and medical devices. Advertisements for unauthorized pharmaceuticals and medical devices are also prohibited until and unless marketing authorizations have been obtained therefor. In addition, pharmaceuticals for the treatment of certain diseases such as cancer cannot be advertised directly to the general public. Although food

supplements basically are not subject to the Pharmaceuticals Law, if certain expressions are adopted, such as expressions relating to ingredients, dosage form, dosage and administration, or efficacy, an advertisement for food supplements may violate such prohibition.

The MHLW has issued the Code of Fair Practices in the Advertising of Drugs and Related Products (*iyakuhintō tekisei kōkoku kijun*) in order to clarify and interpret the relevant provisions of the Pharmaceuticals Law and related regulations. For example, this Code stipulates that advertising of prescription pharmaceuticals directly to the general public is prohibited.

In addition, the MHLW has issued its Guidelines on Sales Information Provision Activities for Prescription Pharmaceuticals (*Iryō-yō iyakuhin no hanbaijōhō teikyō katsudō ni kansuru guidelines*), which expressly state that a company's management is responsible for all business actions related to sales information, and that companies are required to establish sales information supervision departments and monitor their promotion activities.

Furthermore, the Act against Unjustifiable Premiums and Misleading Representations applies to advertisements of medicinal products and other products that are directed at the general public.

15. What laws apply to patents and trademarks for medicinal products, medical devices, and food supplements in your country?

The Patent Law of Japan applies to patents to be registered in Japan and the Trademark Law of Japan applies to trademarks to be registered in Japan. There are no special or additional requirements for patent registration or trademark registration that are exclusively applicable to patents and trademarks for medicinal products, medical devices, and food supplements; however, under the Patent Law of Japan, with respect to patented pharmaceuticals for which market authorization is granted, the term of the patent may be extended by a period of not more than five years. The length of the extended patent term is considered generally equivalent to the period of time during which the patent holder was prevented from exploiting the subject invention due to the fact that the market authorization for the relevant patented medicinal product had not been granted in accordance with the Pharmaceuticals Law.

Furthermore, the MHLW's relevant circular (i.e., a published notice issued by the MHLW to local governments, etc. providing guidance on the interpretation of the law with respect to a particular matter, etc.) provides for a kind of “patent linkage" system which purports to consider the interest of the innovator (i.e., the holder of the patent(s) applicable to the relevant medicinal product; the “Innovator”) and the interest of the company producing a generic version of such medicinal product. The PMDA performs a limited review, based on information they possess or find from public information sources and information they receive from the Innovator, to determine whether a generic version of a patented medicinal product infringes the Innovator's patent, and if they determine that it does, they do not grant marketing authorization for such generic product to the applicant company.

16. Please briefly describe how patent infringements in relation to medicinal products and medical devices are addressed in your jurisdiction, including possible defense strategies and legal proceedings against patent infringements.

There are no distinctive features or procedures that specifically or exclusively apply to patent infringements in relation to medicinal products and medical devices in our jurisdiction. That is to say, as with other patent infringement cases, if a patent holder believes that the patent is infringed, the patent holder may seek injunctive relief to force the infringing party to cease and desist the infringement, and to destroy the infringing articles. The patent holder can also assert a monetary compensation claim against the infringing party for damages incurred by the patent holder due to the infringement.

With respect to a possible defense, Article 69, paragraph 1 of the Patent Law of Japan provides that a patent holder's infringement protection rights are not effective against the exploitation of the patented invention for experimental or research purposes. Since the results of various types of experiments and research are necessary to file an application for market authorization of medicinal products and medical devices, this provision of the Patent Law is often cited as a defense to a claim of patent infringement with respect to medicinal products and medical devices.

17. Does your jurisdiction provide for restrictions on the use of trademarks for medicinal products, medical devices, food, and food supplements?

Our jurisdiction does not provide for specific restrictions on the use of trademarks for medicinal products, medical

devices, food, and food supplements. However, there is a court precedent in which the court found that even if a certain ingredient of medicinal products is registered by a pharmaceutical company as a trademark and another pharmaceutical company sells medicinal products under the name which is subject to such trademark, the trademark holder may not exercise its trademark protection rights against such other pharmaceutical company since the other company used the trademark to indicate the relevant raw material contained in its products and did not use it in a manner that induces consumers to believe that the products are manufactured or distributed by the trademark holder.

18. Please briefly describe the product liability regime for medicinal products, medical devices, and food supplements in your country.

There is no specific product liability regime that exclusively applies to medicinal products, medical devices, and food supplements in Japan.

Product liability may be pursued based on tort claims (including claims under the Product Liability Act) and/or contract claims.

Tort Liability

The general principle of tort in Japan is that any person who intentionally or negligently infringes another person's right or legally protected interest is liable to compensate for any loss or damage incurred by such another person as a result of the infringement. In order to establish tort liability in relation to the defendant, the plaintiff needs to demonstrate that the following four requirements are met:

- violation of the plaintiff's right or legally protected interest by the defendant;
- such violation is caused by the willful misconduct or negligence of the defendant;
- the occurrence of damage to the plaintiff; and
- a causal relationship between the violation and the damage.

In relation to product liability claims, a special rule to the above general principle of tort is created by Article 3 of the Product Liability Act. The special rule is that a person who is injured by a defect in a product can demand compensation from the manufacturer of such product, among others, without having to prove willful misconduct or negligence of the defendant (i.e., the second requirement above need not be met), which, in effect, makes the claim one of strict liability.

Contract Liability

Purchasers of defective products may, in accordance with contract law under the Civil Code of Japan, make a claim against the seller for damage compensation, repair of the defect, or delivery of a substitute product, price deduction, or cancellation of the contract.

19. Please provide a short overview of risks of liability (criminal liability, serious administrative / civil liability) and enforcement practice with regards to medicinal products (including biologicals), medical devices, foods, and food supplements.

Any natural person who violates the Pharmaceuticals Law will be subject to criminal imprisonment and/or a criminal fine in accordance with the Pharmaceuticals Law, and any legal entity (e.g., a corporation) for whom or for whose benefit that natural person made the violation, will be liable for a criminal fine in accordance with the Pharmaceuticals Law.

Furthermore, after August 1, 2021, an administrative monetary penalty (*kachōkin*), which is not a criminal penalty, may also be imposed on a company which commits a violation of Article 66, paragraph 1 of the Pharmaceuticals Law (prohibition of false, exaggerated or misleading advertisements, descriptions and circulations in relation to medicinal products). The amount of this administrative monetary penalty would be equal to 4.5% of the total gross sales amount for the relevant medicinal product during the period in which such violation occurred.

20. Does your jurisdiction provide for a specific legislative and regulatory framework for digital health applications (e.g., medical apps)? If yes, please briefly describe the relevant framework.

There is no specific legislative or regulatory framework for digital health applications (e.g., medical apps) in Japan. However, certain digital health applications will be classified as medical devices if they meet the following criteria provided in the Pharmaceuticals Law:

- the application is used for diagnosis, treatment or prevention of human or animal disease;
- the application is designed to influence the structure or function of human or animal tissue; and
- programs that pose little potential risk to human or animal life and health in relation to side effects or in

the event of malfunction, are excluded.

If a digital health application is classified as medical device, the following licenses and approvals will be necessary for the manufacture and marketing of the digital health application in Japan:

- Marketing business license;
- Manufacturing business registration;
- Accreditation as a foreign manufacturer, for products manufactured outside of Japan; and,
- Marketing authorization, which is required for each application.

Given the challenge of obtaining the necessary licenses and approvals, companies not specializing in medical device manufacturing often explore options to ensure their applications are not classified as medical devices.

21. Does your jurisdiction provide for laws or certain legal measures to ensure the supply of medicinal products and medical devices, or are such rules envisaged in the future? If yes, please briefly describe those rules.

There are currently no explicit laws to ensure the supply of medicinal products and medical devices in Japan, however the Pharmaceuticals Law is currently being in the process of amendment. The Pharmaceutical and Medical Devices System Subcommittee of the Health Science Council has been discussing a proposed amendment to the Pharmaceuticals Law, and in December 2024, a proposal was made regarding the direction of the amendment.

The proposal suggests that the establishment of the following obligations in the Pharmaceuticals Law for marketing authorization holders of ethical pharmaceuticals, with the aim of ensuring a stable supply system for ethical pharmaceuticals:

i. The appointment of a "Director for the Management of a Stable Supply System (tentative name)" is to be made; and
ii. The implementation of necessary measures to ensure a stable supply (e.g., the preparation of "Procedures for Ensuring a Stable Supply System (tentative name)").

In addition, the following provisions are to be established in the Pharmaceuticals Law under the said proposal, in order to ensure operational measures for a stable supply of ethical pharmaceuticals:

i. Marketing authorization holders of ethical pharmaceuticals are obliged to notify the Minister of Health, Labour and Welfare of supply status reports and supply instability reports;
ii. The Minister of Health, Labour and Welfare may request a marketing authorization holder or wholesale distributor to report on the status of manufacturing, marketing, etc. when there is a possibility of a supply shortage; and
iii. The Minister of Health, Labour and Welfare may request necessary cooperation from marketing authorization holders, wholesale distributors, medical institutions or pharmacies, etc. when there is a possibility of supply shortage.

22. Are there any specific compliance standards in your jurisdiction for the marketing of medicinal products and medical devices (e.g., codes of conducts of industry associations, etc.)? If yes, please give a brief overview of the relevant standards.

JPMA Code of Practice

This code was established in 2013 by the Japan Pharmaceutical Manufacturers Association, an organization consisting of research-oriented pharmaceutical companies, ("JPMA") in line with the IFPMA (International Federation of Pharmaceutical Manufacturers & Associations) Code of Practice. JPMA member companies are required to comply with this code when interacting with their respective directors, officers, and employees, as well as with researchers, medical professionals, and patient groups.

JFMDA Medical Device Industry Promotion Code

This code was established in 1997 by the Japan Federation of Medical Devices Associations ("JFMDA"), a group consisting of medical device associations whose members are manufacturers and suppliers of medical devices and other items and materials. This code clarifies the compliance standards to be observed by member companies when promoting medical devices.

Fair Competition Code

With regard to the marketing of medical devices and prescription pharmaceuticals in Japan, business operators need to comply with *The Fair Competition Code of the Medical Devices Industry* issued by the Japan Fair Trade Council of the Medical Devices Industry and *The Fair Competition Code of the Ethical Pharmaceutical Drugs Industry* issued by the Fair Trade Council of the

Ethical Pharmaceutical Drugs Marketing Industry, respectively. Under these codes, business operators are prohibited from offering premiums to medical institutions and other similar institutions as a means of unjustifiably inducing transactions of medical devices and prescription pharmaceuticals.

23. Please state 3-5 key decisions by courts or regulatory authorities that have been issued recently and that are relevant for the life sciences sector.

Supreme Court decision addressing the definition of "advertisement" under the Pharmaceuticals Law

As mentioned in the response to question number 14, Article 66, paragraph 1 of the Pharmaceuticals Law prohibits false, exaggerated or misleading advertisements, descriptions and circulations in relation to the name, manufacturing method, efficacy, effects or performance of pharmaceuticals, etc. With regard to this provision, the Supreme Court has held (i) that the words "advertisements, descriptions and circulations" should be construed as informing unspecified or many persons of the matters prohibited under Article 66, paragraph 1 of the Pharmaceuticals Law as a means of promoting the purchase or prescription of the relevant drug, etc. concerned; and (ii) that whether or not such notifications can be regarded as a means of promoting the purchase or prescription of a specific drug, etc. should be determined objectively in light of the content, nature, and mode of the notification (Supreme Court, June 28, 2021; *Keishu*, Vol 75, No.7, p.666).

Supreme Court decision addressing the definition of "medical practice" under the Medical Practitioners' Act

Under Article 17 of the Medical Practitioners Act, no person except a medical practitioner may engage in medical practice. With regard to this provision, the Supreme Court has held (i) that the term "medical practice" means the practice of medical care and health guidance, which is likely to cause harm to public health and hygiene unless performed by a medical practitioner and (ii) that it is appropriate to judge whether or not an act constitutes a "medical practice" in the light of socially accepted ideas, taking into account not only the method and action of the act, but also the purpose, the relationship between the offender and the other party, the specific circumstances in which the act is conducted, and the actual situation and the perception in society (Supreme Court, September 16, 2020; *Keishu*, Vol 74, No. 6, p.581).

Tokyo District Court decision addressing whether provision of information under the patent linkage system violates the Unfair Competition Prevention Act

Under Article 2, Paragraph 1, Item 21 of the Unfair Competition Prevention Act, "the act of making or circulating false allegations that harm the business reputation of a business competitor" falls under the definition of "unfair competition".

In this case, under the patent linkage system (please see the response to question number 15 for details of the patent linkage system), an innovator (the "Innovator") informed the MHLW that the relevant generic product infringes the Innovator's patent. The plaintiff (the manufacturer of the generic product) filed a lawsuit against the Innovator arguing that such provision of information to the MHLW falls under "unfair competition."

The Tokyo District Court judged that the information provided by the Innovator to the MHLW was false, but dismissed the plaintiff's claims, finding that such provision of information is not extremely unjustifiable in light of purpose of the patent linkage system. It is noteworthy that the court made a judgment on whether the relevant generic product infringes the Innovator's patent in the course of drawing the above conclusion (Tokyo District Court, October 28, 2024).

24. What, if any, are the key legal and regulatory trends in your jurisdiction with regards to the digitalization of the local healthcare system and with regards to the use of artificial intelligence in the life sciences sector? Please briefly describe.

Digitalization of the local healthcare system

The MHLW has decided to establish the National Medical Information Platform which is a nationwide platform for sharing and exchanging information on all aspects of medical care, such as electronic prescriptions and municipal health checkups. This platform will facilitate smooth information exchange among emergency, medical, and nursing care providers.

Artificial intelligence in the life sciences sector

The Government of Japan established the Improvement Design within Approval for Timely Evaluation and Notice ("IDATEN") system. Before the IDATEN system was established, medical device manufacturers had to apply for approval from the PMDA for partial alterations to their medical devices (for which they obtained marketing authorization) each time they made an improvement to

their medical devices, which took several months. On the other hand, under the IDATEN system, if manufacturers obtain prior approval of their alteration plan from the PMDA, they can proceed with improving their medical devices by simply submitting reports on the partial alterations made to their medical devices (i.e., without additionally obtaining separate approval for each partial alteration) so long as such alterations fall within the scope of the alteration plan.

25. Please briefly highlight 3-5 key developments or trends in your jurisdiction with regards to the life sciences sector as you consider them relevant. This may include legislative proposals, market activity, etc.

Promotion of utilization of anonymously / pseudonymously processed information.

Contrary to the APPI's basic principle, the Next Generation Medical Infrastructure Act ("NGMIA") allows an opt-out process instead of opt-in consent for the collection and provision by medical institution of medical information to a certified entity performing anonymous processing of medical information to enhance the utilisation of Anonymously Processed Information in medical fields. The 2023 amendment thereto enacted in 2024 applies similar regime to Pseudonymously Processed Information in medical fields.

Telemedicine

In Japan, the regulation on the telemedicine has historically been governed by the MHLW's administrative notices and the legal grounds thereof has not been so clear. The MHLW is planning to submit a bill for amendment of Medical Care Act, which provides the explicit framework of telemedicine regulation.

Revitalization of generic drug industry

In May 2024, MHLW published a report on policy measures discussed by their review committee to revitalize the generic drug industry, which has encountered substantial supply shortage originally triggered by business suspension orders for cGMP violation of multiple generic drug manufacturers.

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