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Medical Devices & Consumer Health Products 2021

Japan
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Law and Practice

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1. APPLICABLE PRODUCT SAFETY REGULATORY REGIMES

1.1 Medical Devices

The Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Pharmaceuticals Act) is the primary law in Japan which regulates drugs, medical devices and other medicinal products.

Under the Pharmaceuticals Act, drugs, medical devices and other medical products are categorised into the following product groups and each group is subject to different regulations:

- pharmaceuticals;
- quasi-pharmaceutical products;
- medical devices;
- cosmetics; and
- regenerative medicine products.

Blood products, personal protective equipment and medical instruments do not constitute an independent category under the Pharmaceuticals Act, but they are classified in one of the categories listed above.

Marketing a Medical Product

In general, in order to import or market a "medical product" (meaning all of the above, including medical devices; the same meaning is used throughout this chapter unless the context requires otherwise), which falls into any of the above categories, into Japan:

- the initial marketing entity is required to obtain a marketing business licence (*Seizō hanbai-gyō kyoka*) for the category into which the product falls; and
- a marketing authorisation (*Seizō hanbai shōnin*) is required to be obtained for each product based on a review and assessment of the efficacy and safety risk of the product.

Such review and assessment of the product is conducted by the Pharmaceuticals and Medical Devices Agency (*Iyakuhin Iryōkiki Sōgō Kikō*) (PMDA) and the final authorisation is granted by the Ministry of Health, Labour and Welfare (MHLW).

However, such marketing authorisation is not required for certain pharmaceuticals and quasi-pharmaceutical products and medical devices that have a limited safety risk as well as most cosmetics, so long as a prior notification is filed by the person seeking to market the product with the MHLW. For medical devices with an intermediate safety risk, the person seeking to market the medical device is required to obtain certification of the medical device from specified registered certification bodies (RCBs).

The Order for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Cabinet Order) provides a list of medical devices. This list includes 84 types of medical appliances and instruments, six types of medical supplies (including X-ray film, surgical sutures and surgical gloves) and three types of medical computer programs (including mediums installed with such programs). Thus, certain personal protective equipment and medical instruments are classified and subject to regulation as medical devices.

Reporting and Surveillance

Under the Pharmaceuticals Act, product suppliers, as the marketing authorisation holders, are required to report to the PMDA any side effects and other safety information related to their medical products. This reporting obligation is broader for pharmaceuticals and medical devices than for quasi-pharmaceutical products and cosmetics, meaning that non-serious side-effect shall be reported under certain conditions. If suppliers learn of the occurrence or spread

of hazards in health and hygiene suspected to be caused by their product, they are required to dispose of, recall, and discontinue selling such product; provide specified information to MHLW on such product; and take any other necessary measures.

In addition, for certain medical products, suppliers are required by ministerial order to perform post-marketing surveillance to collect information regarding the efficacy and safety of the medical product obtained in a real clinical environment. Based on such post-marketing safety information, certain pharmaceuticals and regenerative medicine products must be re-examined by the MHLW after four to ten years from the commencement of their marketing in Japan, depending on the nature of the product. Similarly, the results of usage in Japan of medical devices designated by the MHLW must be re-evaluated by the MHLW based on survey reports to be submitted by the suppliers.

Blood Products

Blood products, no matter which of the above categories they fall into, can be designated by the MHLW as biological products (*seibutsu yurai seihin*) and subject to additional regulation. These additional requirements include:

- special labelling requirements;
- obligation of the supplier to record the name, address and other information of the persons or entities who purchased or leased these products and to maintain such records for ten to 30 years depending on the type of product; and
- obligation of the supplier to periodically (usually every six months) report the results of evaluations based upon findings obtained from the latest papers and other sources on infectious diseases.

In the case of certain types of blood products (*tokutei seibutsu yurai seihin*, most of which are manufactured from human blood), physicians must obtain informed consent from their patients prior to using the blood product on them and hospitals must maintain records of usage of the product for twenty years.

1.2 Healthcare Products

Cosmetics

As mentioned in **1.1 Medical Devices**, regulations on cosmetics are few and less onerous than compared to other medical product categories. For example, marketing authorisations are not required for cosmetics as long as the names of all the components of the cosmetic are listed on the label. This, in turn, makes governmental oversight limited to adequately monitoring cosmetics after they have been released onto the market. However, if a cosmetic product contains any active ingredient with medicinal efficacy, the supplier is required to obtain marketing authorisation for such cosmetic product as a quasi-pharmaceutical product (or, in some cases, as a pharmaceutical).

Biocides

Biocides used for preventing human disease are typically categorised as pharmaceuticals or quasi-pharmaceutical products and are subject to regulation as such. On the other hand, biocides used for other purposes, including protecting crops or wooden structures from insects or rodents, are subject to different laws such as the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, Etc and the Agricultural Chemicals Regulation Act.

Food and Nutrition

Food safety regulations are primarily provided in the Food Sanitation Act. The MHLW also formulates various food safety standards in relation to residual agricultural chemicals, food additives, bacteria contained in food and other food-relat-

ed matters. The sale, manufacture, processing or import of any food that does not meet such standards is prohibited in Japan.

Unlike drug companies who must obtain licences and authorisations for marketing pharmaceuticals, food suppliers are not generally allowed to sell their products claiming that they have a function related to health. However, if the food product is approved by Consumer Affairs Agency (CAA) as a Food for Specified Health Use (*tokutei hoken-yō shokuhin*), its health function can be claimed on packaging or in advertisements. This approval is granted by the CAA based on the assessment of the efficacy and safety of the food product, which itself is usually based on a review by the CAA of peer-reviewed papers in research journals. Suppliers can also choose to sell their food products as Foods with Functional Claims (*kinōsei hyōji shokuhin*), based on self-certification of the efficacy and safety of the food product either by clinical trial or systematic review of peer-reviewed academic papers, and filing the necessary documentation with the CAA.

1.3 New Products/Technologies and Digital Health

Apps and Programs

As mentioned in **1.1 Medical Devices**, certain medical programs are classified as medical devices. Therefore, medical apps will be regarded as medical devices if they meet the following criteria provided in the Pharmaceuticals Act and relevant Cabinet Orders:

- used for diagnosis, treatment or prevention of human or animal disease;
- designed to influence the structure or function of human or animal tissue; and
- excluding programs with little potential risk to human or animal life and health in the event of a side effect or malfunction occurring.

Further, a recent HMLW guideline explains that whether or not a program used by health care professionals is regarded as a medical device is to be determined by evaluation of two factors: (i) the extent of the contribution of the result obtained from the program to the diagnosis and treatment of human life or health, and (ii) the extent of potential risk to human life or health in the event of malfunction of the program. Based on such evaluation, typically, applications/programs for the purpose of record-keeping, data processing (unless used for diagnosis), staff training, patient communication, maintenance of medical devices and daily personal health care do not fall under the definition of medical device and are not subject to the regulations.

Wearables

In addition, wearables such as glasses, shirts with sensors, etc, can be classified as medical devices. The criteria for such classification varies depending on whether the wearable in question is first characterised as a medical program or medical appliance/instrument. For example, if the wearable is first characterised as a medical appliance/instrument, the exclusion of low-risk programs from the definition of a medical device will not apply.

Telemedicine

The Medical Practitioners' Act provides that no medical practitioner shall provide medical care or issue a medical certificate or prescription without personally performing an examination of the patient. However, under MHLW guidelines, telemedicine is allowed in certain situations, as long as the practitioner can obtain substantially equivalent information as would be obtained through face-to-face examination. Such situations include:

- cases where the examination is not the initial examination nor where the patient is in an acute phase of ill-health;

- cases where the patient cannot receive adequate medical care without telemedicine; and
- cases of smoking cessation treatment or emergency contraception.

Medical programs used for telemedicine can be classified as medical devices under the criteria explained above.

CBD

The Cannabis Control Act prohibits anyone from:

- importing or exporting cannabis (meaning the cannabis plant and its products, excluding grown stalks and seeds and products manufactured from them) without permission;
- giving treatment with medicines manufactured from cannabis or distributing them for treatment;
- receiving treatment with medicines manufactured from cannabis; and
- possessing, cultivating, receiving or transferring or performing research using cannabis without permission from a local government.

Medical use of cannabis is not allowed even with permission from a local government.

Thus, only cannabidiol (CBD) extracted from the grown stalks and seeds of the cannabis plant can be legally possessed or transferred in Japan without permission granted pursuant to the Cannabis Control Act. Such permission is granted by a local government only for purpose of cultivating the cannabis plant to extract fibre or seeds from it or for research purposes. As a result, in order for a person without such permission to import CBD products into Japan, they would be required to submit to Japanese Customs a certificate and evidence that the CBD product was made from the grown stalks and seeds of the cannabis plant.

1.4 Borderline Products

The treatment of so-called "combination products" (ie, medical products that contain aspects of more than one of the medical product categories listed in **1.1 Medical Devices**), and of in vitro diagnostic products (IVD), under the Pharmaceuticals Act may make them considered borderline products in Japan.

A combination product can be treated as a pharmaceutical, medical device or regenerative medicine product, even if its components fall under more than one of these categories. Whether a combination product is treated as a pharmaceutical, medical device or regenerative medicine product is determined by its main function and purpose. For example, an asthma drug with an inhaler is treated as a pharmaceutical, while a drug-eluting stent is treated as a medical device.

In Japan, unlike other countries, IVDs are classified as pharmaceuticals, not medical devices. However, to harmonise Japanese IVD regulations with international standards, the regulations on IVDs are far less strict than those for other pharmaceuticals and are almost identical to those for medical devices.

The distinction in Japan between foods and pharmaceuticals is also important. MHLW guidelines provide that this distinction is determined by whether the purpose of ingesting the product is the same as is typical for pharmaceuticals, and whether a reasonable person would consider that the product functions as a pharmaceutical. The guidelines add that such ingesting purpose is to be determined by overall evaluation of the ingredients contained in the product, as well as the product form, effect and efficacy, dosage and administration, sales methods and advertisements. The guideline further lists the ingredients that are "exclusively used as pharmaceuticals" in its Appendix. A product which contains any ingredient listed in the Appendix

will be regulated as a pharmaceutical, with some minor exceptions. On the other hand, if a product does not include any of the ingredients in that list, then it will not be considered as a pharmaceutical unless the advertisement or package indicates medicinal efficacy, or there is any other factor (eg, type of container or description of dosage and administration) which would cause a reasonable person to misunderstand that the product is a pharmaceutical.

2. COMMERCIALISATION AND PRODUCT LIFE CYCLE

2.1 Design and Manufacture

Persons engaged in the manufacture of medical products as a business must obtain a manufacturing business licence (*Seizō-gyō kyoka*) (in the case of pharmaceuticals, quasi-pharmaceutical products and cosmetics) from, or register (in the case of medical devices) with, the MHLW for each manufacturing site.

"Manufacturing" includes, in the case of pharmaceuticals, the manufacture of the active pharmaceutical ingredient (API), formulation, packaging, and labelling of legally required items, and, in the case of medical devices, design, assembly, sterilisation and storage of the final product in Japan.

In order to obtain a licence to manufacture pharmaceuticals, the following requirements must be satisfied:

- the manufacturing site must be equipped with structural facilities that enable appropriate manufacturing and quality control of pharmaceuticals; and
- the applicant (the manufacturing corporation and its responsible officers) must not have been subject to any disqualifying circumstance (such as having had a licence or registration revoked within the past three years, or having been sentenced to imprisonment).

The standards for structural facilities are set forth in the Structural Facilities Regulations (*kōzō setsubi kisoku*), and inspections are conducted to assess conformity with such standards. For manufacturing facilities that do not actually manufacture pharmaceuticals, quasi-pharmaceutical products or cosmetics but only store products, it is possible to register them instead of obtaining a licence, and conformity to the structural facilities standards is unnecessary if only registration is required.

For the manufacture of medical devices, unlike pharmaceuticals, since the components handled in the manufacturing process are not dangerous, registration is sufficient and there is no need to obtain a licence. The only requirement for registration as a manufacturer of medical devices is that the applicant not fall under any of the above stated disqualifying circumstances, and compliance with the standards for structural facilities is not required.

2.2 Corporate Social Responsibility, the Environment and Sustainability

In Japan, there are no legal obligations on companies regarding corporate social responsibility, the environment or sustainability specifically related to product life cycles, although studies are underway on the disclosure of information on environmental, social and governance (ESG). Companies are, on an individual level, promoting corporate social responsibility, as well as the environmental and sustainability aspects of their products according to their own circumstances, such as ethical considerations in animal experiments, respect for the human rights of subjects in clinical trials, development of pharmaceuticals in areas with high unmet medical needs, reduction of medical costs through widespread use

of generic drugs, and promotion of carbon-free activities.

2.3 Advertising and Product Claims

The Pharmaceuticals Act prohibits both explicit and implicit 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 pharmaceuticals and medical devices before marketing authorisation has been obtained for them is also prohibited. The Guidelines for Adequate Advertisement of Pharmaceuticals (*Iyakuhin to tekisei kōkoku kijun*) have been issued by the MHLW to clarify interpretation of the Pharmaceuticals Act related regulations in this area. For example, under these Guidelines, advertisements in relation to prescription pharmaceuticals cannot be presented directly to the general public (they can only be presented directly to doctors and hospitals).

The Pharmaceuticals Act also provides that advertisements regarding pharmaceuticals for cancer, sarcoma (*nikushu*), leukemia (*hakketsubyō*) or such other pharmaceuticals specifically designated by the MHLW cannot be presented directly to the general public (they can only be presented directly to doctors and hospitals). In addition, the MHLW has issued Guidelines for Sales Information Provision Activities of Prescription Pharmaceuticals (*Iryō-yō iyakuhin no hanbai jōhō teikyō katsudō ni kansuru* guidelines), which expressly state that company 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 of prescription pharmaceuticals.

Furthermore, the Act against Unjustifiable Premiums and Misleading Representations also applies to advertisements of medical products that are directed at the general public. Under this Act, the following advertisements are prohibited:

- advertisements that indicate that the product is significantly more effective than it actually is;
- advertisements that falsely claim that the product has a significantly superior efficacy or effectiveness to that of similar products of other companies;
- advertisements that mislead general consumers into believing that the price or other terms and conditions are significantly more favourable to general consumers than they actually are; and
- advertisements that mislead general consumers into believing that the terms and conditions are significantly more favourable to general consumers than those of other companies' products.

2.4 Marketing and Sales

To market pharmaceuticals, quasi-pharmaceutical products, cosmetics or medical devices, the initial marketing entity is required to hold a marketing business licence and a marketing authorisation for each of the relevant products. "Marketing" in this context means manufacturing (including outsourcing manufacturing to others but excluding manufacturing entrusted to others) or importing pharmaceuticals (excluding pharmaceuticals that are APIs), quasi-pharmaceutical products, cosmetics or medical devices, and then selling, leasing or providing them, respectively.

In order to obtain a marketing business licence, the applicant must be qualified as an entity responsible for the quality, efficacy and safety of medical products. The following requirements must be met in order to obtain such a licence:

- the quality control method must conform to the GQP (Good Quality Practice) Ordinance for pharmaceuticals, quasi-pharmaceutical products and cosmetics, or the QMS (Quality Management System) Ordinance for medical devices;
- the post-marketing safety control method must conform to the GVP (Good Vigilance Practice) Ordinance; and
- the applicant must not fall under any of the disqualifying circumstances.

Marketing business licences are granted by the prefectural government of the prefecture in which the office of the applicant that conducts the marketing business is located. Once the application for a marketing business licence is formally submitted, the prefectural government reviews the application and, in most cases, conducts an on-site inspection of the applicant's office or factory.

Marketing business licences are generally valid for five years from the date of issue although the actual validity period will depend on, among other things, the applicant's business and the type of pharmaceutical or medical device to be distributed. Wholesalers and retailers of pharmaceuticals and medical devices are further required to obtain a distribution business licence.

There are two types of marketing business licences for pharmaceuticals: Type 1 and Type 2.

- A Type 1 pharmaceutical marketing business licence is required for marketing prescription pharmaceuticals.
- A Type 2 pharmaceutical marketing business licence is required for marketing other pharmaceuticals (ie, non-prescription ethical pharmaceuticals and over-the-counter pharmaceuticals).

There are three types of marketing business licences for medical devices: Type 1, Type 2 and Type 3.

- A Type 1 medical device marketing business licence is required for marketing medical devices with a GHTF classification of class III or IV.
- A Type 2 medical device marketing business licence is required for marketing medical devices with a GHTF classification of class II.
- A Type 3 medical device marketing business licence is required for marketing medical devices with a GHTF classification of class I.

2.5 Internationalisation

When importing or exporting medicinal products into or from Japan, both the Pharmaceuticals Act of Japan as well as the applicable laws of the country into which the products are imported or from which they are being exported must be complied with. Thus, in order to market imported medicinal products in Japan, it is necessary to obtain marketing authorisation for such products under the Pharmaceuticals Act. On the other hand, the importation into Japan of medicinal products for purposes other than marketing in Japan, such as for personal use, is not subject to the Pharmaceuticals Act and, therefore, no marketing authorisation is required for such importation. However, in order to prevent the marketing in Japan of medicinal products that have not been confirmed through the marketing authorisation procedures as safe, there is a process whereby the MHLW can confirm in advance that the importation of the medicinal products is for purposes other than marketing in Japan.

With respect to international regulatory harmonisation, the MHLW participates in the Medical Device Single Audit Program (MDSAP) with the regulatory authorities of USA, Australia, Brazil and Canada. This program permits an MDSAP-recognised auditing organisation to conduct a

single regulatory audit of a medical device manufacturer to check whether the medical device satisfies the requirements of MDSAP-participating regulatory authorities. Both the MHLW and the PMDA accept MDSAP audit reports in QMS (Quality Management System) conformity assessments, where the procedures are streamlined by switching from on-site surveys to documentary surveys and by reducing the number of documents to be submitted in such documentary surveys.

2.6 Post-marketing Obligations – Including Corrective Actions and Recalls

After the marketing of pharmaceuticals, quasi-pharmaceutical products, cosmetics or medical devices commences, the marketing authorisation holder (MAH) is required to conduct post-marketing pharmacovigilance and technovigilance in accordance with the GVP (Good Vigilance Practice) Ordinance. If any issue relating to the effectiveness or safety of the marketed pharmaceuticals, quasi-pharmaceutical products, cosmetics or medical devices is discovered during the post-marketing authorisation surveillance period, the MAH must conduct a recall campaign, report the discovery to the PMDA, issue public notices and take other appropriate measures to prevent further damage or losses suffered by patients. The PMDA publicly discloses on its website case reports on the side effects of medical products.

3. REGULATOR ENGAGEMENT AND ENFORCEMENT

3.1 Regulatory Authorities

The MHLW is the governmental authority that issues most of the related ministerial orders and administrative guidelines, and drafts relevant cabinet orders.

Although the MHLW is the principal regulatory authority for medical products, a substantial part of its authority is delegated to local prefectural governments (for example, the Tokyo Metropolitan Government) and the PMDA (*Iyakuhin Iryōkiki Sōgō Kikō*), a Japanese regulatory agency.

More specifically, prefectural governments are primarily responsible for overseeing licensed business operators and related matters on behalf of the MHLW. The PMDA plays an important role in reviewing new drug applications.

In general, a company which seeks to obtain a marketing business licence or manufacturing business licence must file an application to the prefectural government in which the factory or office of the applicant is located. For example, the Tokyo Metropolitan Government for an applicant company that has its factory or office in Tokyo. Foreign companies which seek to obtain accreditation as a foreign manufacturer (*Gaikoku seizō gyōsha no nintei*) or marketing authorisation for each of the medical products it desires to market in Japan must submit an application to the PMDA.

3.2 Regulatory Enforcement Mechanisms

As explained in **3.1 Regulatory Authorities**, although the main regulator is the MHLW, a substantial part of the MHLW's authority is delegated to local prefectural governments and the PMDA.

The regulator (ie, the MHLW directly and/or either or both of the relevant prefectural government and the PMDA) can monitor the business operations of holders of marketing business licences and/or manufacturing business licences and can take any of the following actions (in addition to others) with respect to such licence holders to ensure compliance with the Pharmaceuticals Act and related regulations:

- inspect any office or factory of the licence holder (including examination of relevant facilities and records);
- order disposal, recall or other appropriate treatment that the regulator deems necessary to protect public health;
- require access to such offices, factories, facilities and records for an inspector designated by the regulator, who is responsible for investigation;
- temporarily stop the pharmaceutical business operations of the licence holder;
- order replacement of certain key personnel relevant to the pharmaceutical business of the licence holder;
- cancel any licence, registration or accreditation/approval which the regulator previously granted;
- request a report from the licence holder that includes data on adverse reactions to the medical product, recall information, and similar matters; and
- impose administrative monetary penalties against false or misleading advertising.

Furthermore, criminal sanctions can be imposed by a court against a licence holder (including the responsible individuals) for violations of the laws and regulations applicable to marketing business licence holders and manufacturing business licence holders. The judgment of a court of first instance that imposes criminal sanctions against the licence holder can be appealed to appellate courts.

4. LIABILITY

4.1 Product Safety Offences

In general, any natural person who violates the Pharmaceuticals Act and any corporation on whose behalf or for whose benefit that natural person made the violation are liable to criminal imprisonment (only for natural persons) and/or criminal fine.

For example, an off-label promotion violates Article 66, paragraph 1 of the Pharmaceuticals Act, which forbids anyone from advertising false, exaggerated or misleading statements in relation to medical products. An employee of a pharmaceutical company who violates this provision is subject to criminal imprisonment for up to two years and/or a criminal fine of up to JPY2 million (approximately USD20,000), and the pharmaceutical company in relation to the business of which the employee made the violation is liable to a criminal fine with the same upper limit.

Under the amended Pharmaceuticals Act, an administrative monetary penalty (*kachōkin*), which is not a criminal penalty, may also be imposed on the company for a violation of Article 66, paragraph 1 of the Pharmaceuticals Act (advertising exaggerated or false statements in relation to medical products). The amount of this monetary penalty is equal to 4.5% of the sales figures of the relevant medical product during the period which such violation occurred. This part of the amended Pharmaceuticals Act came into effect on 1 August 2021.

There are many instances where companies and persons are charged and convicted for selling pharmaceuticals which are not granted any marketing authorisation.

4.2 Product Liability

In general, the product categories listed in **1. Applicable Product Safety Regulatory Regimes** are subject to the product liability suit mechanisms of Japan. These product liability suit mechanisms are mainly tort (including claims under the Product Liability Act) and contract.

Tort

The general principle of tort in Japan, which is provided in Article 709 of the Civil Code, is that any person who intentionally or negligently infringes another person's right or legally protected interest is liable to compensate that other person for any loss or damage caused by that infringement. Tort liability under Article 709 of the Civil Code requires the following four conditions to be met:

- violation of the plaintiff's right or legally protected interest by the defendant;
- an intentional or negligent act by the defendant;
- the occurrence of damage to the plaintiff; and
- a causal relationship between the violation and the damage.

In the case of product liability claims, a special rule to the above general principle of tort is added by Article 3 of the Product Liability Act. The special rule is that a person who is injured by defects in a product can demand compensation from the manufacturer and other specified involved parties without having to prove intent or negligence (ie, the second condition above is not required to be met) which, in effect, makes a claim against the manufacturer or specified involved parties one of strict liability.

Product liability under Article 3 of the Product Liability Act requires the following seven conditions to be met.

- The defendant corresponds to
  - (a) any person who manufactured, processed, or imported the product as a business;
  - (b) any person who indicates their name, trade name, trade mark or other similar indication (below referred to as "Name Representation") on the product as the manufacturer of the product, or any person who indicates their Name Representation on the product which makes others misunderstand that they are the manufacturer; or
  - (c) except for the cases outlined in the two points above, any person who indicates a Name Representation on the product such that, in terms of the manufacturing, processing, importing or selling of the product, and other circumstances, such name is recognised as the substantive manufacturer of the product (a person corresponding to any of these three bullet points will be referred to as the "Manufacturer").
- Delivery of the product, which shall be movable, by the defendant.
- Damage being caused by the product which, at the time of delivery by the defendant, had been manufactured or processed.
- A defect in the product which existed at the time of delivery.
- Infringement of the plaintiff's right or legally protected interest.
- The occurrence of damage.
- A causal relationship between the defect in the product and the damage.

Software

As stated above, to attract liability under the Product Liability Act, the product must be movable. Therefore, as a software program is not movable, a software program itself is not subject to the Product Liability Act and, consequently, a medical app by itself is not subject to the Product Liability Act. However, a device which incorporates a software program such as a medical app is subject to the Product Liability Act and therefore, if a defect in a medical app leads to a malfunction of a device thereby causing damages, the device incorporating the medical app is subject to the Product Liability Act.

Contract

Buyers of defective products may, in accordance with contract law under the Civil Code, make a claim against the seller for compensation for damages, repair of the defect, or delivery of a substitute product.

Contractual liability requires the following five conditions to be met:

- the entering into of a contract;
- a defect in the product;
- the cause of that defect being attributable to the defendant;
- the occurrence of damage; and
- a causal relationship between the defect and the damage.

4.3 Judicial Requirements

The Japanese courts have general jurisdiction over an action that is brought (i) against a corporation whose principal office or business office is located in Japan, and (ii) against a corporation whose representative or other person principally in charge of its business is domiciled in Japan, if the corporation does not have a business office or other office in Japan, or if the location of business office or other office is unknown.

In addition, the Japanese courts have additional jurisdiction in the following cases depending on the grounds of the claim.

Tort

Japanese courts have jurisdiction if the place where the wrongful act was committed or the place where the consequences thereof occurred are in Japan (except where the consequence of a wrongful act committed in a foreign country have occurred within Japan but it would not ordinarily have been possible to forecast that such consequences could have occurred within Japan).

Product Liability Act

In line with the above principle applying to tort, the Japanese courts have jurisdiction over a product liability case if the place where the wrongful act was committed or the place where the consequences occurred was within Japan. In relation to a product liability case, "the place where the wrongful act was committed" is interpreted as the place of manufacture of the product.

Contract Law

Japanese courts have jurisdiction if the place of performance of the obligation under the contract is within Japan, or if it is determined that the place of performance of the obligation is within Japan in accordance with the law of the place selected under the contract. In the case of an action regarding a contract entered into between a consumer and a business, which is brought by the consumer against that business, the Japanese courts have jurisdiction if the consumer is domiciled in Japan at the time when the action is brought or at the time the consumer contract is entered into.

4.4 Costs

The general rule is that court costs are borne by the losing party. In the case where the plaintiff has partially succeeded, the court determines, at its own discretion, the burden of the court costs on each party. However, depending on the circumstances, the court can order one of the parties to bear all the court costs. Court costs include, among other things, filing fees, travel expenses, daily allowances, and the fees of any court-designated expert witnesses. Court costs do not include legal costs for counsel. In general, each party bears its own legal counsel fees. However, part of the prevailing party's legal costs can be awarded as part of the damages, for claims under the Product Liability Act and tort claims based on the Civil Code. For breach of contract claims, the legal costs for counsel can-

not be included as part of the damages awarded to the prevailing party.

There are no special measures that are available to protect against cost orders. For example, there are no "without prejudice save as to costs" settlement offers or the like in Japan, and therefore, even if a settlement offer by the defendant has been rejected by the plaintiff and the amount ordered in the judgment is less than that stated in the rejected settlement offer, the courts do not consider such rejection of the settlement offer prejudicially to the plaintiff.

4.5 Product-Related Contentious Matters

To prevent the occurrence or spread of health and hygiene-related hazards caused by medical products the Minister of the MHLW and the governor of the relevant prefecture exercising jurisdiction are vested with authority to implement various measures, including issuing an order to dispose of, recall, or take other measures to prevent the occurrence of hazards in health and hygiene. Such orders can be disputed by filing a request for review under the Administrative Complaint Review Act. Furthermore, a person may generally file an action for judicial review of an administrative disposition with the Japanese courts.

4.6 Mass Tort Litigation

The Act on Special Measures Concerning Civil Court Proceedings for the Collective Redress of Property Damage Incurred by Consumers (the Collective Recovery Act) came into force on 16 October 2016. Under the Collective Recovery Act, only certified consumer organisations can bring opt-in consumer collective actions. However, the scope of such collective actions does not include claims concerning the Product Liability Act, nor claims concerning product defect-related torts. Consequently, individuals who have sustained injuries or incurred damage due to a defective product who wish to initiate a joint action with other persons who have been similarly injured by or have incurred damage from the same defective product, are constrained to file parallel product liability lawsuits against the same defendant manufacturer and not a class action.

4.7 Class Actions, Representative Actions or Co-ordinated Proceedings?

The Collective Recovery Act establishes a two-tiered system for collective redress for property damage incurred by consumers. In the first tier, a specified qualified consumer organisation files an action for a declaratory judgment on common obligations. This is an action seeking a declaratory judgment that a defendant company owes monetary obligations to consumers based on factual and legal causes that are common to the consumers (except where the individual consumer has no grounds to receive money due to circumstances that are specific to the consumer) where property damage is incurred by a considerable number of consumers in connection with consumer contracts.

In the second tier, if the claim for declaratory judgment on common obligations is successful in the first tier, simplified proceedings to determine the presence or absence and the contents of a claim for the payment of money are held before the district court that made the final judgment in the first tier for the declaratory judgment on common obligations.

A specified and qualified consumer organisation can file an action for a declaratory judgment on common obligations with regard to monetary payment obligations regarding a consumer contract:

- for the performance of a contractual obligation;
- pertaining to unjust enrichment;

- for damages based on the non-performance of a contractual obligation; and
- for damages based on tort (this is limited to claims made under the Civil Code).

However, the action cannot be filed if the damage incurred by the consumer is due to:

- loss or damage to property other than goods, rights, or any other object of a consumer contract resulting from the non-performance of a contractual obligation or a tort;
- loss of profit that would have been gained through the disposition or use of the object of a consumer contract if the object had been provided;
- loss or damage to property other than the service that is the object of a consumer contract resulting from the non-performance of a contractual obligation or a tort;
- loss of profit that would have been gained through the use of a service under a consumer contract if the service had been properly provided;
- harm done to the life or body of a person; and
- mental suffering.

4.8 ADR Mechanisms

The Federation of Pharmaceutical Manufacturers' Associations of Japan has established the Pharmaceuticals PL Centre (Centre) at the time the Product Liability Act came into force to enhance the complaint-handling system in relation to pharmaceuticals. The Centre:

- accepts complaints from consumers in relation to pharmaceuticals (including quasi-pharmaceutical products);
- makes inquiries to pharmaceutical companies and asks them to address complaints from consumers;
- assists bilateral negotiations between consumers and pharmaceutical companies by providing information and similar assistance; and
- mediates disputes between consumers and pharmaceutical companies if agreement is not reached through such bilateral negotiations.

4.9 Interrelation between Liability Mechanisms

A "defect" as used in the Product Liability Act means a lack of safety which a product should normally have. In determining whether a defect exists, compliance of the product with relevant legislation is considered as one of the important factors. Although a product can be defective even if the product is in compliance with the legislation, compliance with the legislation typically implies the non-existence of a defect in the product.

5. POLICY AND LEGISLATIVE REFORM

5.1 Policy Development

There are no significant policy developments in relation to product safety and liability in Japan other than those which have been crystalised in the legislation set out in **5.2 Legislative Reform**.

5.2 Legislative Reform

The Pharmaceuticals Law was amended in 2019 (Amended Act). The Amended Act has progressively come into effect in parts on 1 April 2020, 1 September 2020 and 1 August 2021, with the remainder scheduled to come into effect on 1 December 2022. The more significant amendments introduced by the Amended Act are listed below.

The system has been improved, from development to post-marketing, which enables companies to provide pharmaceuticals and medical

devices in a more secure, expedient and efficient manner. This includes:

- an expedited approval procedure for innovative pharmaceuticals and medical devices;
- a conditional approval system for pharmaceuticals and medical devices which require a long clinical trial period (Conditional Early Approval System);
- a notification procedure for the change in manufacturing methods pursuant to a post-approval change management protocol (PACMP);
- an approval examination system for high-tech medical devices; and
- changes to the rules regarding package inserts requiring them to be provided and updated to reflect the latest information via electronic methods and to reduce paper usage.

Amendments have been made regarding the operation of pharmacists and pharmacies so that patients may use pharmaceuticals without concern.

A legal compliance system has been established for the purpose of regaining consumer trust and confidence. This involves:

- new obligations on licence holders to establish a legal compliance system regarding pharmaceutical related activities; and
- introduction of administrative monetary penalties against false or misleading advertising.

5.3 Impact of Brexit

There has been no significant impact made by Brexit on the regimes outlined in **1. Applicable Product Safety Regulatory Regimes** in Japan.

5.4 Impact of COVID-19

In Japan, in general, an in-person examination is required at least for the first visit to a doctor. However, in response to the spread of COVID-19, the MHLW has issued an announcement regarding temporary, exceptional measures as to diagnosis and consultation via telephone or other information communication equipment (such as videoconferencing via the internet) in response to the spread of COVID-19 (Announcement). The Announcement states that doctors may make their diagnosis and prescribe medicines via telephone or other information communication equipment, regardless of whether or not the patient has already visited the doctor in person in the past, as long as the doctor judges, in line with their professional responsibilities, that diagnosis, etc, via telephone or such information communication equipment is medically possible, excluding the prescription of narcotic drugs and psychoactive drugs.

According to media reports, the Japanese government recently decided at a Cabinet meeting that such temporary, exceptional measures will become permanent and that telemedicine will be permitted permanently from the first consultation with a doctor from 2022. It is likely that the Japanese government will announce more detailed rules regarding telemedicine before then.

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Nagashima Ohno & Tsunematsu is widely recognised as one of Japan's leading international law firms, specialising in all aspects of business and commercial law. The firm represents domestic and foreign clients involved in every major industry sector, including many of the largest and most influential companies, funds and organisations in Japan. The firm has structured and negotiated many of Japan's largest and most significant corporate and finance transactions, and has extensive expertise across all of its practice areas. The pharmaceutical and healthcare team consists of over 14 lawyers, including six partners, based in the Tokyo office. Key areas of the firm's practice relating to the life sciences sector include pharmaceutical and healthcare, risk and crisis management/compliance, corporate/M&A, data protection and privacy, intellectual property, antitrust/competition, consumer law (consumer litigation), dispute resolution, and labour and employment.

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