Japan

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REGULATORY OVERVIEW

1. Please give a brief overview of the regulatory framework for medicinal products/pharmaceutical products/drugs (as they are called in your jurisdiction), including the key legislation and regulatory authorities.

The Pharmaceutical Affairs Law (*yakuji hô*) (PA Law) is the primary law in Japan regulating drugs and other medical products. Under the PA Law, medical products are categorised into the following four product categories (medicinal products):

- Drugs (*iyaku hin*).
- Quasi-drugs (*iyaku bugai hin*).
- Cosmetics (*keshô hin*).
- Medical devices (*iryô kiki*).

Details of the pharmaceutical regulations are provided in cabinet orders and ministerial orders relating to the PA Law, and related administrative guidelines.

The main licences and approvals to manufacture or import and market medicinal products are as follows:

- Marketing business licence (*seizô hanbai gyô kyoka*).
- Manufacturing business licence (*seizô gyô kyoka*).
- Accreditation as a foreign manufacturer (*gaikoku seizô gyôsha no nintei*).
- Marketing approval (*seizô hanbai shônin*) for each of the medicinal products.

The Ministry of Health, Labour and Welfare (MHLW) (*see box, The regulatory authority*) is the governmental authority that issues almost all related ministerial orders and administrative guidelines, and prepares relevant cabinet orders. While MHLW is the principle regulatory authority for medicinal products, prefectural governments (for example, the Tokyo Metropolitan Government) are primarily responsible for overseeing pharmaceutical companies and so on, on behalf of MHLW. The Pharmaceuticals and Medical Devices Agency (*iyakuhin iryôkiki sôgô kikô*) (PMDA), a Japanese regulatory agency, also plays an important role.

PRICING AND STATE FUNDING

2. Please give a brief overview of the structure and funding of the national healthcare system.

Japan has had a universal healthcare system since 1961. Almost all legal residents are covered by the health insurance system. Costs for a substantial number of medical services provided, and prescription drugs sold, are covered by it. Costs for prescription drugs cannot be reimbursed unless such drugs are listed on the drug tariff (*yakka shûsai*).

Having their drugs listed on the drug tariff is economically very important for prescription drug manufacturers and marketing companies. The listing of drugs on the drug tariff and prices designated for each drug listed are determined by MHLW.

3. In what circumstances are the prices of medicinal products regulated?

Prices of medicinal products are only regulated if the costs of the products are reimbursed under the health insurance system. Hospitals and doctors providing medical services covered under the health insurance system are prohibited from using drugs other than those listed on the drug tariff (the drug tariff is used as a type of authorised product list). For prescription drugs, prices often match those listed on the drug tariffs.

4. When is the cost of a medicinal product funded or reimbursed by the state? Please briefly outline the procedure and pricing for state funding or reimbursement (for example, is the reimbursement paid to the producer, pharmacist or end-user)?

Reimbursements under the health insurance system are generally made through the benefit-in-kind (*genbutsu kyûfu*) system. The cost of drugs used for medical services are directly paid out from the health insurance to the hospitals or doctors providing the medical services. The amount of reimbursement is determined by the prices of the drugs specified on the drug tariff (the drug tariff basically acts as a price list when determining the amount of reimbursement).

Hospitals and doctors in Japan profit from the difference between the reimbursement prices listed on the drug tariff and the purchase price of the drug or product designated by the pharmaceutical companies, or drug distributors or retailers. The price of a drug offered by pharmaceutical companies to the hospitals or doctors is usually lower than the reimbursement price provided under the drug tariff.

MANUFACTURING

5. Please give an overview of the authorisation process to manufacture medicinal products. In particular:

- **To which authority must the application be made?**
- **What conditions must be met to obtain authorisation?**
- **Are there specific restrictions on foreign applicants?**
- **What are the key stages and timing?**
- **What fee must be paid?**
- **How long does authorisation last and what is the renewal procedure?**

Application

There are two kinds of business licences related to the manufacture of medicinal products:

- Manufacturing business licence, which is required to manufacture the medicinal product (if a manufacturer of an imported product is located outside Japan, an accreditation as a foreign manufacturer is required).
- Marketing business licence, which is required for the initial marketing of a manufactured or imported medicinal product in Japan.

A company which has obtained a manufacturing business licence but not a marketing business licence cannot distribute medicinal product (manufactured or imported by the company) to others, such as a wholesaler. In general, applications for these business licences are submitted to the relevant local prefectural government.

Conditions

An applicant for a manufacturing business licence must meet certain facility, staffing and other standards, as provided under the ministerial order of MHLW. There are several classes of manufacturing business licences. The standards to be met may differ, depending on the medicinal product to be manufactured. Also, a manufacturer must comply with the Good Manufacturing Practice (GMP) regulations, which are set out in a MHLW order.

An applicant for a marketing business licence must meet:

- Standards for maintaining quality assurances, as provided under Good Quality Practice (GQP) regulations (stated in a MHLW order).
- Standards for post-marketing safety management, as provided under the Good Vigilance Practice (GVP) regulations (stated in a MHLW order).
- Standards provided under other ministerial orders of MHLW.

Additionally, a marketing business operator must comply with the Good Post-marketing Surveillance Practice (GPSP) regulations, which are set out in a MHLW order.

Restrictions on foreign applicants

A foreign manufacturer of medicinal products must distribute its products in Japan through a licensed marketing business operator. Requirements for accreditation as a foreign manufacturer are basically the same as those to acquire a Japanese manufacturing business licence (*see above, Conditions*). Filing an application for accreditation as a foreign manufacturer can be delegated by the foreign applicant to a marketing business operator in Japan.

Key stages and timing

Before formal submission of an application for the business licences, an applicant usually submits a draft of the application to the relevant prefectural government for informal discussions. Once the application is formally submitted, MHLW and/or the prefectural government review the application, and in most cases conduct an on-site inspection of the applicant's office or factory.

In Tokyo it can take about 35 business days, from the time of formal submission of the application, to obtain the business licence, depending on:

- The nature of the applicant's business.
- The type of medicinal product to be manufactured or distributed.
- The applicant's preparation for the application.
- Other relevant factors and circumstances.

Fee

The amount of the application fee for a business licence is determined by the relevant local prefectural government, and typically differs depending on the nature of the applicant's business and the type of medicinal product. If the application is filed in Tokyo, the application fee for a:

- Drug manufacturing business licence ranges from JPY46,500 (about US$518) to JPY88,200 (about US$983).
- Drug marketing business licence ranges from JPY128,500 (about US$1,431) to JPY146,200 (about US$1,629).

Period of authorisation and renewals

Depending on the applicant's business and the type of medicinal product, business licences are generally effective for five years, and can be renewed every five years.

6. What powers does the regulator have to:

- **Monitor compliance with manufacturing authorisations?**
- **Impose penalties for a breach of a manufacturing authorisation?**

The main Japanese regulator is MHLW. However, a substantial amount of MHLW's authority is delegated to local prefectural gov-

ernments and the PMDA. The regulator can monitor a licensed business operator's business operations, to ensure compliance with regulations under the PA Law. The regulator can take the following actions (in addition to other actions) in relation to licensed business operators:

- Inspect the office or factory.
- Order disposal, recall or other appropriate treatment that the regulator deems necessary to protect public health.
- Require access for an inspector designated by the regulator, who is responsible for investigation.
- Temporarily shut down the pharmaceutical business operations.
- Order replacement of certain key personnel relevant to the pharmaceutical business.
- Cancel the business licence or accreditation which it previously granted.
- Request a report that includes data about adverse reactions to the medicinal product, recall information, and so on.

Additionally, criminal sanctions can be imposed for violations of regulations applicable to pharmaceutical business operators.

CLINICAL TRIALS

7. Please give an overview of the regulation of clinical trials. In particular:

- **Which legislation and regulatory authorities regulate clinical trials?**
- **What authorisations are required and how is authorisation obtained?**
- **What consent is required from trial subjects and how must it be obtained?**
- **What other conditions must be met before the trial can start (for example, the requirement for a sponsor and insurance cover)?**
- **What are the procedural requirements for the conduct of the trial (for example, using certain medical practices and reporting requirements)?**

The PA Law and the GCP ministerial order issued by MHLW are the principal items of legislation regulating clinical trials. MHLW and PMDA are the main regulatory authorities regulating clinical trials.

To conduct a clinical trial, a pharmaceutical company must register a protocol (*chiken jisshi keikaku sho*) with MHLW (*see below*). An applicant (a pharmaceutical company) usually consults informally with PMDA about its draft protocol, before formally registering the protocol with MHLW.

Doctors, hospitals and so on must explain in writing to a trial subject details about the clinical trial, including the expected benefits and adverse effects of the trial drug, and the trial subject's right to be removed from the trial. Consent from a trial subject must be obtained in writing, after the trial subject has received a thorough explanation.

The material procedural requirements under the GCP are as follows:

- To prepare a protocol.
- To have the protocol reviewed by an Institutional Review Board (*chiken shinsa iin kai*) of the hospital, at least one member of which must be an outside independent person.
- To register the protocol with MHLW.
- To obtain informed written consent from the trial subject.
- To report all serious adverse effects of the trial drug to MHLW.
- To properly monitor the operation of its clinical trial.

MARKETING

8. Please give an overview of the authorisation process to market medicinal products. In particular:

- **To which authority must the application be made?**
- **What conditions must be met to obtain authorisation?**
- **What are the key stages and timing?**
- **What fee must be paid?**
- **How long does authorisation last and what is the renewal procedure?**

To market drugs and other medicinal products, the initial marketing entity (which must hold a marketing business licence (*see Question 5*)) must obtain a marketing approval (*seizô hanbai shônin*), for each of the medicinal products it intends to market.

Application

An application for a marketing approval must be submitted to MHLW or, in certain exceptional cases (applications for certain limited products), to a relevant prefectural government. Where an application for a medicinal product must be submitted to MHLW, the application must be submitted through PMDA.

Conditions

In reviewing an application, key consideration is given to the following:

- Quality.
- Effectiveness.
- Safety.
- The applicant's marketing business licence.
- The proposed manufacturer's manufacturing business licence or accreditation as a foreign manufacturer.
- GMP compliance by the manufacturer.

Key stages and timing

Review of applications for marketing approval for new medicinal products is substantially outsourced to PMDA. Once PMDA is satisfied with the application, the application is forwarded to MHLW. MHLW then obtains a recommendation from the Council of Pharmaceutical and Food Sanitation (*yakuji shokuhin eisei shingikai*) before approving such application.

Although dependant on factors such as the type of medicinal product, the standard time period for reviewing an application for new drug approval is one year after the official application filing.

Fee

The amount of the application fee for a marketing approval differs, depending on the type of medicinal product. The application fee for a marketing approval for a new prescription drug ranges from JPY10,578,200 (about US$118,000) to JPY30,347,700 (about US$338,000).

Period of authorisation and renewals

The effective period of an approval for a medicinal product is not permanent. Subject to the type of medicinal product, an approval for a new drug is basically subject to reexamination (*sai shinsa*) after six years have passed since the initial approval.

9. Please briefly outline the abridged procedure for obtaining marketing authorisations for medicinal products. In particular:

- **Which medicinal products can benefit from the abridged procedure (for example, generics)?**
- **What conditions must be met?**
- **What procedure applies and what information can the applicant rely on?**

There is an abridged procedure for generic drugs (*kôhatsu iyakuhin*). The examination of an application mainly focuses on the identity between the new drug and the generic drug, adequacy of data attached to the application, and the proposed manufacturing facility's compliance with GMP if, among other factors:

- The reexamination period (*see Question 8*) for the original drug has expired.
- The level of quality, effectiveness and safety of the generic drug is equivalent to those of the original drug.
- The generic drug is capable of being a substitute for the original drug.
- The patent for the original drug has expired.

Additionally, the review of an application for an orphan drug (*kishô shippei yô iyakuhin*), curing a scarce but serious disease, can be expedited and prioritised over applications for new drugs, if the orphan drug is found to apparently contribute to an improvement in the quality of medical care for the disease.

10. Are foreign marketing authorisations recognised in your jurisdiction? If so, please briefly outline the recognition procedure.

Foreign marketing authorisations are not recognised in Japan. If a foreign manufacturer intends to export its medicinal product into Japan, the manufacturer must obtain a marketing approval for a foreign manufactured medicinal product (*gaikoku seizô iyakuhin tô no seizô hanbai no shônin*). To obtain the marketing approval, a foreign manufacturer must file an application through a company in Japan that has a marketing business licence (*see Question 5*).

The PA Law provides for a special procedure for importing a drug or medical device that has received a foreign marketing authorisation, if:

- The foreign marketing authorisation was obtained in a country with a marketing approval system equivalent to the system in Japan;
- Immediate use of the drug or medical device is necessary to prevent a pandemic disease which may cause death or serious harm to the health of Japanese citizens; and
- The drug or medical device is specifically designated under an administrative order.

However, in practice there is currently no such special procedure.

11. What powers does the regulator have to:

- **Monitor compliance with marketing authorisations?**
- **Impose penalties for a breach of a marketing authorisation?**

The regulator can monitor and oversee medicinal products that are subject to marketing approval. New drugs are basically subject to reexamination after a certain period of time (*see Question 8*). Additionally, an applicant which receives approval must have its medicinal product reevaluated (*sai hyôka*) if MHLW orders this.

Criminal sanctions can be imposed or a product recall administrative order can be issued for violation of a marketing approval.

12. Are parallel imports of medicinal products into your jurisdiction allowed? If so, please briefly outline what conditions must be met by the parallel importer. Can intellectual property rights be used to oppose parallel imports?

To commercially import medicinal products into Japan, both a marketing business licence (*see Question 5*) and a product marketing approval (*see Question 8*) are required.

An individual can import medicinal products for his personal use (for example, an individual's one month supply of a prescription drug, or two month supply of an over the counter (OTC) drug). It is not uncommon for parallel importers to fraudulently become an agent to import medicinal products under the personal use exception. The use of adverts to promote importation of a non-registered drug for personal use is considered illegal.

Intellectual property rights are sometimes asserted to oppose parallel imports of approved drugs and medicinal products.

13. Please briefly outline the restrictions on marketing practices such as gifts or "incentive schemes" for healthcare establishments or individual medical practitioners.

The Act against Unjustifiable Premiums and Misleading Representations (*futô keihin rui oyobi futô hyôji bôshi hô*) prohibits wrongful inducement of customers through provision of excessive gifts, incentives, and so on.

The Fair Trade Council of the Ethical Pharmaceutical Drug Marketing Industry (*iryôyô iyakuhin seizô hanbai gyô kôsei torihiki kyôgi kai*) has prepared, and Japan's Fair Trade Commission (JFTC) has authorised, the Fair Competition Code of the Ethical Pharmaceutical Drug Marketing Industry (*iryôyô iyakuhin seizô hanbai gyô kôsei kyôsô kiyaku*). This code:

- Sets guidelines in relation to gifts or incentives provided to hospitals or doctors.
- Provides detailed examples of excessive gifts or incentives which are not acceptable under the Act against Unjustifiable Premiums and Misleading Representations.

14. Please briefly outline the restrictions on marketing medicinal products on the internet, by e-mail and by mail order.

Historically, the marketing of drugs, except for prescription drugs, on the internet, by e-mail or by mail order, was generally permissible under the old PA Law. However, under the current PA Law, which was implemented in 2009, non-prescription drugs are classified into three categories (category 1 through to category 3), and only category 3 non-prescription drugs can be marketed on the internet, by e-mail or by mail order.

Because a substantial part of consumer healthcare drugs are categorised as category 1 or category 2, the volume of transactions by drug marketing business doing business via the internet, by e-mail or by mail order sales, will be substantially reduced.

ADVERTISING

15. Please briefly outline the restrictions on advertising medicinal products. In particular:

- **Which legislation applies and which regulatory authority enforces it?**
- **What types of medicinal product cannot be advertised?**
- **What restrictions apply to advertising that is allowed?**

The PA Law prohibits false, excessive or misleading adverts in relation to the name, manufacturing method, effectiveness and so on of medicinal products, communicated either explicitly or implicitly. In its effort to regulate adverts, the MHLW has issued its Guideline for Adequate Advertisement of Drugs, Etc (*iyakuhin tô tekisei kôkoku kijun*) and official commentary on it, which provide detailed examples of adverts which MHLW considers to be false, excessive or misleading.

Additionally, adverts in relation to drugs for cancer, sarcoma (*nikushu*), leukemia (*hakketsubyô*) or such other drugs specifically designated by MHLW cannot be presented directly to the general public (they can be presented directly to doctors and hospitals). Adverts for drugs or medical devices before marketing approval has been obtained are also prohibited. Adverts of health foods which may appeal to the public because of their claimed effectiveness to cure certain diseases may violate this regulation.

PACKAGING AND LABELLING

16. Please briefly outline the regulation of packaging and labelling of medicinal products. In particular:

- **Which legislation applies and which regulatory authority enforces it?**
- **What information must the packaging and/or labelling contain?**
- **What other conditions must be met (for example, information being stated in the language of your jurisdiction)?**

The PA Law sets out certain regulations about the packaging and labelling of medicinal products. Under the PA Law:

- A drug container must identify, among other things, the:
  - name and address of the marketing company;
  - name of the drug and its serial number;
  - volume of drugs in the container;
  - ingredients used to create the drug; and
  - final date by when the drug should be used.
- An enclosed instruction document (*tenpu bunsho*) must be provided which describes, among other things:
  - how the drug is to be used;
  - dosage;
  - ingredients used to create the drug; and
  - information about the effectiveness of the drug, adverse effects, and the proper method of storage.

MHLW is the primary authority to enforce these regulations, although a substantial amount of its responsibilities are outsourced to prefectural governments.

If any information in the packaging or labelling of a medicinal product is changed (for example, a relocation of the marketing company's office, and a change of corporate name), all packaging and labelling must also be changed accordingly.

TRADITIONAL HERBAL MEDICINES

17. Please briefly outline the regulation of the manufacture and marketing of traditional herbal medicinal products in your jurisdiction.

Traditional herbal drugs are also subject to the marketing regulations (*see Question 8*).

PATENTS

18. What types of medicinal products and related substances and processes can be protected by patents and what types cannot be patent protected? What are the legal criteria to obtain a patent? Which legislation applies?

The Patent Act sets out the legal criteria for patentability of inventions, which also apply to patentability of medicinal

products and related substances. The essential criteria are that the invention must:

- Be new.
- Involve an inventive step.
- Be capable of industrial application.

Standards for determining whether these essential criteria are met are stated on the website of the Japan Patent Office (JPO) (see Examination Guidelines for Patent and Utility Model in Japan, at *www.jpo.go.jp/cgi/linke.cgi?url=/tetuzuki_e/t_tokkyo_e/1312-002_e.htm*).

There are a number of excluded categories for patent protection. For example, inventions that are likely to harm public order, good morals or public hygiene are barred from patentability. Discoveries, scientific theories, and mathematical methods are also not patentable.

19. How is a patent obtained? In particular:

- **To which authority must the application be made?**
- **What fee must be paid?**
- **What are the key stages and timing?**

The authority

Applications are made to the JPO (*www.jpo.go.jp/index.htm*).

Fee

In principle, fees relating to new patent applications are:

- Fee for a patent application: JPY15,000 (about US$167).
- Fee for requesting an examination of the patent application: JPY168,600 (about US$1,878), plus JPY4,000 (about US$45) per claim.
- Annual fee for patent registration: starts at JPY2,300 (about US$26), plus JPY200 (about US$2) per claim, and increases gradually to JPY61,600 (about US$686), plus JPY4,800 (about US$53) per claim in the patent's final year.

A schedule of fees can be found at the JPO website (*www.jpo.go.jp/cgi/linke.cgi?url=/tetuzuki_e/ryoukin_e/ryokine.htm*).

Process and timing

After a patent application is filed, a request for a full examination must also be filed with the JPO. This request can be filed with the application, or no later than three years after the filing date of the application. The JPO's full examination is commenced on receipt of this request and payment of the examination fee. Notice of the patent application is published 18 months after filing of the application (or earlier, on receiving an applicant's request for publication).

If an application is to be rejected, the applicant is notified in advance of the reason for the rejection, and can submit a written statement to support its application or amend the application before a formal rejection decision is given. If, after the examination, no reasonable basis for rejection is found, the patent is registered, on payment of an amount equal to the aggregate registration fees for the first three years. An announcement about the patent is published soon after it is registered. Details of the patent application process can be found at the JPO website (*www.jpo.go.jp/cgi/linke.cgi?url=/tetuzuki_e/t_gaiyo_e/pa_right.htm*).

The length of time to register a patent depends on various factors, including the nature of the invention. Generally, the time to process a straightforward examination is at least one to two years. In practice, the JPO provides an expedited process for certain applications, such as those for inventions for which a patent application has been filed outside Japan.

20. How long does patent protection last? How is a patent renewed or patent protection extended?

Patent protection lasts for 20 years from the date of the application, subject to payment of annual patent fees. For medicinal products, the term of the patent can be extended on request by the patent owner. The term of the extension, which cannot exceed five years, is generally equivalent to the period of time in which the patent holder, while awaiting medicinal product approval under the PA Law, was prevented from implementing the invention.

Payment of an annual fee is required to maintain the patent registration.

21. In what circumstances can a patent be revoked?

The validity of a patent can be challenged in proceedings before the JPO brought by any person. A registered patent can be invalidated for a number of reasons, including that:

- The patent exceeds the scope of protection stated in the patent application.
- The criteria for patentability are not met (*see Question 18*).
- The specification of the patent is not sufficiently clear or complete for it to be implemented by a person who is skilled in the subject field to which the patent relates.
- The patent holder is not entitled to the patent.

22. When is a patent infringed? How is a claim for patent infringement made and what remedies are available?

A registered patent is infringed when a person exploits the patented invention during the term of the patent without the patent holder's permission. This includes, for example, producing, using, selling, importing and exporting a patented product.

If a patent is infringed, the patent holder can seek injunctive relief, to cause the infringing party to cease and desist the infringement and to destroy all infringing articles. The patent holder can also assert a monetary compensation claim against the infringing party for damages that it incurred from the infringement.

The Patent Act provides special measures to facilitate the patent holder's ability to seek damages based on an infringement. For example, a person who infringes a patent is presumed to have acted negligently in relation to the infringement. This shifts the

burden of proof from the patent holder to the infringing party, and the infringing party must prove that there was no negligence on its part relating to the infringement.

Further, the following special measures are provided in the Patent Act, to address how damages incurred by the patent holder due to the wilful or negligent acts of a patent infringer are calculated:

- The patent holder can claim, as the total amount of damages it incurred from the infringement, the amount obtained by multiplying the number of infringing products that were sold by the infringing party, by the amount of lost profit per relevant product incurred by the patent holder, subject to adjustment based on the sales capability of the patent holder.
- The patent holder is presumed to have incurred damages equivalent to the amount of profit gained by the infringing party.
- The patent holder can use the amount equivalent to the royalty payment to be paid for use of the patented invention, as a base factor in calculating the minimum amount of damages incurred from the infringement.

TRADE MARKS

23. Can a medicinal product brand be registered as a trade mark? What are the legal criteria to obtain a trade mark? Which legislation applies?

A medicinal product brand can be registered as a trade mark under the Trade Mark Act. The Trade Mark Act stipulates a number of legal criteria to be met to register a trade mark, including that a sign (that is, letters, figures, signs or three-dimensional shapes, or any combination of these and colours):

- Is capable of distinguishing the subject goods or services from those of other manufacturers or merchants.
- Is legally distinguishable from signs used to identify widely recognised brands, and from other trade marks which were filed earlier.
- Is not deceptive or contrary to public policy.

24. How is a trade mark registered? In particular:

- **To which authority must the application be made?**
- **What fee is payable?**
- **What are the key stages and timing?**

The authority

Applications are made to the JPO (*www.jpo.go.jp/index.htm*).

Fee

The fee for a trade mark registration application filed in Japan is JPY3,400 (about US$38), plus JPY8,600 (about US$96) per classification of goods or services to be covered in the application.

The fee for registering the trade mark is JPY37,600 (about US$419) per classification of goods or services.

A schedule of fees related to trade mark registration can be found at the JPO website (*www.jpo.go.jp/cgi/linke.cgi?url=/tetuzuki_e/ryoukin_e/ryokine.htm*).

Process and timing

Once an application for trade mark registration is filed, an announcement of the filing is published and the application is examined at the JPO. If an application is to be rejected, the applicant is notified in advance of the reason for the rejection, and can submit a written statement to support its application or amend the application before a formal rejection decision is made. If after the examination no reasonable basis for rejection is found, the trade mark is registered on payment of the registration fee. On registration, notice of the trade mark is published. Details of the trade mark application process can be found at the JPO website (*www.jpo.go.jp/cgi/linke.cgi?url=/tetuzuki_e/t_gaiyo_e/tr_right.htm*).

The length of time to register a trade mark depends on various factors, including whether a similar trade mark or brand name exists. Generally, the time to process a straightforward application is about six to eight months from the application filing date.

25. How long does trade mark protection last? How is a trade mark renewed?

A trade mark is valid for ten years. Trade mark registration can be renewed every ten years, subject to payment of renewal fees.

26. In what circumstances can a trade mark be revoked?

A registered trade mark can be invalidated for a number of reasons, including:

- Non-use of the trade mark for three consecutive years without a proper reason.
- Use of the trade mark by the trade mark owner in a manner that is misleading to the public in relation to the quality of goods/services, or that causes confusion with the goods/services covered by another party's trade mark.

In addition, a trade mark registration can be declared invalid if it is determined that the registration does not satisfy the criteria for registration (*see Question 23*).

27. When is a registered trade mark infringed? How is a claim for trade mark infringement made and what remedies are available?

A registered trade mark is infringed when a person exploits a sign which is identical (or similar) to another's registered trade mark on the designated or similar goods/services, without permission of the trade mark owner. Exploiting includes placing the violating sign on a product or packaging of a product (Infringing Product), and selling, exhibiting for sale, importing or exporting the Infringing Product.

If a registered trade mark is infringed, the trade mark owner can seek injunctive relief to cause the infringing party to cease and

desist the infringement and to destroy all infringing articles. The trade mark owner can also assert a monetary compensation claim against the infringing party, for damages that it incurred from the infringement.

The Trade Mark Act provides special measures to facilitate the trade mark owner's ability to seek damages based on an infringement. For example, a person who infringes a trade mark is presumed to have acted negligently in relation to the infringement. This shifts the burden of proof from the trade mark owner to the infringing party, and the infringing party must prove that there was no negligence on its part relating to the infringement. Further, the following special measures are provided in the Trade Mark Act, to address how damages incurred by the trade mark owner due to the wilful or negligent acts of a trade mark infringer are calculated:

- The trade mark owner can claim, as the total amount of damages it incurred from the infringement, the amount obtained by multiplying the number of infringing products that were sold by the infringing party, by the amount of lost profit per relevant product incurred by the trade mark owner, subject to adjustment based on the sales capability of the trade mark owner.
- The trade mark owner is presumed to have incurred damages equivalent to the amount of profit gained by the infringing party.
- The trade mark owner can use the amount equivalent to the royalty payment to be paid for use of the registered trade mark, as a base factor in calculating the minimum amount of damages incurred from the infringement.

28. Is your jurisdiction party to international conventions on patent and trade mark protection?

Japan is party to the (among others):

- WIPO Paris Convention for the Protection of Industrial Property 1883 (Paris Convention).
- WIPO Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks 1989 (Madrid Protocol).
- WTO Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPS).
- WIPO Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks 1957.
- Patent Cooperation Treaty 1970.
- Strasbourg Agreement Concerning International Patent Classification 1971.
- Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure 1977.
- Trade Mark Law Treaty 1994.

PRODUCT LIABILITY

29. Please give an overview of medicinal product liability law, in particular:

- **Under what laws can liability arise (for example, contract, tort or statute)?**
- **What is the substantive test for liability?**
- **Who is potentially liable for a defective product?**

Legal provisions

Product liability claims relating to medicinal products are typically based on:

- The Product Liability Act.
- Tort principles (*Article 709, Civil Code*).
- Contract provisions (non-performance of contractual duties under Article 415 of the Civil Code).

Substantive test

Product Liability Act. The plaintiff (claimant) bears the burden of proving:

- A defect in the product.
- Damage suffered by the claimant.
- A reasonable connection between the defect and damage.

The Product Liability Act reduces the claimant's burden of proof by imposing strict liability on manufacturers or importers.

Tort. The claimant bears the burden of proving:

- An intentional or negligent act (or omission) by the person committing the tort.
- Damage suffered by the claimant.
- A reasonable connection between the act and damage.

Negligence is a violation of a duty of care. As it is often difficult for a consumer, who typically has only limited resources, to prove that a manufacturer intentionally or negligently caused the consumer to sustain damages, a presumption of negligence which shifts the burden of proof from the consumer to the manufacturer has been established, in some cases, through court precedents.

Contract. The claimant bears the burden of proving:

- A party's non-performance of contractual duties.
- Damage suffered by the claimant.
- A reasonable connection between the non-performance and damage.

Unlike in a tort action, the burden of proof is placed on the manufacturer/seller to prove that it was not negligent in its actions.

Liability

Product Liability Act. Claims can be asserted against "manufacturers or importers", which include:

- Persons engaged in the business of manufacturing, processing or importing the product.
- Persons who represent or misrepresent themselves as a manufacturer by putting their name, trade mark or other similar proprietary markings on the product.

Tort. If the substantive requirements are met (*see above, Substantive test*), there is no limitation on who may be liable for a tort claim. Tort claims for a defective medicinal product are typically made against manufacturers, importers and sellers. Hospitals, doctors, nurses, pharmacies and pharmacists can also potentially be liable.

Contract. A claim based on breach of contract can only be made against a party which has a contractual relationship with the claimant. A consumer or patient is not usually able to claim for breach of contract against the manufacturer or importer, due to the lack of a contractual relationship.

30. What are the limitation periods for bringing product liability claims?

Product Liability Act

The limitation period to bring a claim is:

- Three years from the date when the injured party became aware of both the damage and the identity of the party liable for the damage.
- Ten years from the date of delivery of the product by the manufacturer or importer.

For latent injuries or damages, evidence of which is only detected after a certain period, the starting date for the ten year limitation period is the date on which the damages first appear.

Claims under the Product Liability Act can only be made for products delivered by manufacturers on and after 1 July 1995.

Tort

The limitation period to bring a tort claim is:

- Three years from the date when the injured party became aware of both the damage and the identity of the party liable for the damage.
- 20 years from the date the tortious act was committed.

Contract

The limitation period for a contract claim is ten years (five years for a business contract claim) from the date when the injured party is first able to make a claim.

31. What defences are available to product liability claims?

In product liability cases, a defendant usually argues the non-existence of one or more of the elements required to establish a product liability claim (for which the burden of proof lies with the claimant) (*see Question 29*). In addition, the following defences are also available.

THE REGULATORY AUTHORITY

Ministry of Health, Labour and Welfare

T +81 3 5253 1111
F Not publicly disclosed.
E Not publicly disclosed.
W *www.mhlw.go.jp/english/index.html*

Main areas of responsibility. The Pharmaceutical and Medical Safety Bureau of the Ministry of Health, Labour and Welfare implements measures for securing the efficacy and safety of drugs/quasi-drugs and medical devices.

Product Liability Act

Manufacturers are not liable for damages if they can prove either of the following:

- It was impossible for the manufacturer to detect the defect in the product, based on the level of scientific or technical knowledge available at the time of delivery by the manufacturer.
- For a product (component product) used as a component or part of another product (final product), the defect is only created after the manufacturer of the component product has strictly complied with instructions for the component product's design or specifications given by the manufacturer of the final product, and the component product manufacturer was not negligent in creating the defect.

Tort

For tort claims, some court precedents have adopted a presumption of negligence standard, which shifts the burden of proof from the consumer to the manufacturer. In such cases, the manufacturer is not liable for damages, if it can prove that it was not negligent in its actions.

Contract

Manufacturers/sellers are not liable for damages if they can prove that they were not negligent in their actions.

32. What remedies are available to the claimant?

The claimant can request monetary compensation for damages that would ordinarily arise from the defect. Damages that would not ordinarily arise but have in fact arisen through special circumstances may also be awarded, if the parties foresaw or could have reasonably foreseen such special circumstances.

The courts determine the actual scope of damages on a case-by-case basis, giving consideration to such matters as the:

- Type of product.
- Nature of the defect.
- Circumstances under which the product was manufactured, distributed and consumed.

Subject to the existence of reasonable causation relating to the damage sustained, the scope of possible damages could include

actual damage, mental suffering, prospective and consequential damage. Punitive damages are not allowed under Japanese law.

33. Are class actions allowed for product liability claims? If so, are they common?

Class actions (as they are known in the US) are not permitted in Japan. The Civil Procedure Act of Japan allows claimants to join their cases if their claims and their grounds for bringing such claims are the same or similar. Generally, each claimant in a joint action remains an independent party.

REFORM

34. Please summarise any proposals for reform and state whether they are likely to come into force and, if so, when.

A scheduled reform that may have substantial impact on the pharmaceutical industry is an amendment to the Antimonopoly Act, scheduled to take effect on 1 January 2010. The amendment will expand the scope of antimonopoly violations subject to administrative monetary penalty by the JFTC, to include certain unfair trade practices such as:

- Discriminatory pricing.
- Unjust low price sales.
- Abuse of superior bargaining position.

This may result in an enhanced risk of expedited administrative sanctions being imposed by JFTC, depending on the trade practices used by pharmaceutical companies.

The amendment also introduces a prior notification system for share acquisitions that meet minimum threshold requirements. In principle, a 30 day waiting period must be observed under the proposed notification system, which will be a serious change from the current post facto filing requirement. This may substantially impact scheduling and structuring of M&A transactions involving the acquisition of a Japanese pharmaceutical company.

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