The Life Sciences Law Review

second Edition

Editor
Richard Kingham

Law Business Research

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THE LAW REVIEWS

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THE PRIVATE COMPETITION ENFORCEMENT REVIEW

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EDITOR'S PREFACE

The second edition of the *Life Sciences Law Review* provides an overview of legal issues of interest to pharmaceutical, biotechnology and medical device companies in 30 jurisdictions. As before, each chapter contains information on legal requirements relating to the key stages in the life cycle of a regulated product, from discovery, through the clinical development process, registration, manufacturing and promotion, plus other issues of special interest, such as pricing and reimbursement, special liability regimes, competition and commercial transactions in the context of the medical products business. Each of the chapters has been prepared by a recognised expert in the relevant jurisdiction, and the resulting work product will assist industry lawyers, regulatory affairs staff and others who need to have an understanding of the issues in each major market.

This edition also includes a new chapter on international harmonisation, which plays an increasingly important role in the regulation of pharmaceuticals and medical devices. In particular, the guidelines adopted by the International Conference on Harmonisation (ICH) have been incorporated into the national requirements for pharmaceuticals in the European Union, United States, Japan and most other developed countries, and are increasingly influential in developing countries. Readers may find it useful to review this chapter before consulting the national chapters, because it is often key to understanding many of local requirements.

Once again, I wish to thank all of the lawyers who contributed to this reference work. It is a pleasure to be associated with them.

Richard Kingham
Covington & Burling LLP
Washington, DC
March 2014

Chapter 17

JAPAN

Kenji Utsumi and Kensuke Suzuki[1]

I INTRODUCTION

The Pharmaceutical Affairs Act, soon to be renamed the Act concerning Ensuring Quality, Efficacy and Safety of Drugs, Medical Devices, Etc. (the PA Act), is the primary law that regulates medicines, medical devices and other medical products. Supplemental information regarding pharmaceutical regulations is provided in cabinet orders and ministerial orders relating to the PA Act, as well as in other related administrative orders.

The following are the main licences and approvals necessary for the manufacture or importation and marketing of medical products in Japan:

a marketing business licence;
b manufacturing business licence;
c accreditation as a foreign manufacturer, for products manufactured outside Japan; and
d marketing authorisation, required for each medical product.

The Ministry of Health, Labour and Welfare (MHLW) is the principal regulatory authority over medical products. Prefectural governments, however, (for example, the Tokyo metropolitan government) are primarily responsible for overseeing pharmaceutical companies, on behalf of the MHLW. The Pharmaceuticals and Medical Devices Agency (PMDA), a Japanese regulatory body, also plays an important role.

1 Kenji Utsumi and Kensuke Suzuki are partners at Nagashima Ohno & Tsunematsu.

II THE REGULATORY REGIME

i Classification

Types of medical products

Products subject to the PA Act are categorised into the following four product categories (medical products):

a medicines;
b quasi-medicines;
c cosmetics; and
d medical devices.

Medicines

Medicines are defined as the products that are listed in the Japanese pharmacopoeia, in addition to certain other materials that, *inter alia*, are used for the diagnosis, treatment or prevention of disease. Distinguishing between medicines, quasi-medicines and foods is sometimes a practical issue that depends on the advertisement and promotion methods utilised for the relevant product, including statements of the product's virtues. Medicines are further classified into prescription medicines and over-the-counter medicines. After enforcement of the new PA Act, tissue-engineering medicines will be categorised separately, and expeditious approval of such products will be the aim in order to meet the high expectations for innovative medicines in this category.

Medical devices

Medical devices are defined as those products that are listed in the Cabinet Order of the Pharmaceutical Affairs Act. Medical devices are divided into three classes (specifically, controlled medical devices (basically equivalent to Class III and IV devices under international classification by the GHTF), controlled medical devices (Class II) and ordinary medical devices (Class I)), depending on the magnitude of the risk to human health and life posed by the subject device. Furthermore, the type of business licence that is required for manufacturing, marketing or distributing a medical device depends on which of the above classes the subject device falls under. After enforcement of the new PA Act, software used for data processing for X-ray, CT, MRI, PET-CT and other medical device hardware will also be categorised as a medical device.

ii Non-clinical studies

In applying for a marketing authorisation for a medicine, an applicant must attach data on the medicine obtained through a laboratory study performed in compliance with the Ministerial Order for Good Laboratory Practice (the GLP Order). The GLP Order provides, *inter alia*, requirements for trial facilities, equipment and trial plans, as well as rules for animal care and breeding in relation to experimentation on animals.

iii Clinical trials

The PA Act and the Ministerial Order for Good Clinical Practice (the GCP Order) are the principal items of legislation regulating clinical trials. The MHLW and the PMDA are the main regulatory authorities regulating clinical trials.

Prior registration with the authority
Prior to conducting a clinical trial, a sponsor must prepare a protocol and have it reviewed by the institutional review board of a hospital, of which at least one member must be independent. The applicant must then register the reviewed protocol with the MHLW. Applicants usually consult informally with the PMDA about draft protocols before formally registering with the MHLW.

Compensation and insurance for injuries
If a clinical trial results in any adverse effects, the sponsor is generally liable for all damages and losses suffered by any affected trial subjects. Due to the potential risk associated with this type of liability, sponsors engaging in clinical trials always obtain insurance coverage before a trial commences.

Informed consent
Doctors and hospitals must provide a written explanation to all trial subjects describing the details of the clinical trial, including the expected benefits and adverse effects of the trial medicine, and the trial subject's right to stop participating in the trial. Consent from a trial subject must be obtained in writing.

Safety reporting
Clinical trial results must be recorded at the hospitals at which the clinical trial is being conducted, and all serious adverse effects from the trial medicine must be reported to the MHLW.

Investigator-initiated studies
Investigator-initiated studies are accepted. A part of the GCP requirements is not applicable to marketer-initiated studies. This type of study is typically used for medicines that have already been authorised in another country, but have not been subject to a clinical study in Japan for cost reasons.

iv Named-patient and compassionate-use procedures

General prohibition against marketing without authorisation
Medicines and medical devices may not generally be distributed without a marketing authorisation.

Special procedure for importing medicines or medical devices
The PA Act provides for a special procedure for importing a medicine or medical device that has received a foreign marketing authorisation when all of the following requirements are met:

a the foreign marketing authorisation has been obtained in a country that has a marketing authorisation system equivalent to that in Japan;
b immediate use of the medicine or medical device is necessary to prevent a disease that can cause death or serious harm to the health of Japanese citizens from rising to the level of a pandemic; and

c the medicine or medical device is specifically designated through an administrative order.

This special procedure was once applied to the importation of a flu vaccine produced by foreign manufacturers. Any disease, disorder or death that is supposedly related to the medicine or medical device subject to this special procedure must be reported to the MHLW.

v Pre-market clearance

In order to market medicines or medical devices, the initial marketing entity (which generally must hold a marketing business licence) must generally obtain a marketing authorisation for each of the medicines or medical devices it intends to market.

Application

An application for a marketing authorisation must be submitted to the MHLW or, in certain cases (for certain limited medicines and medical devices other than Class IV medical devices), to the relevant prefectural government or a specified registered certifying agency. Where an application for a medical product must be addressed to the MHLW or a prefectural government, the application must be submitted through the PMDA.

Authorisation conditions

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

a quality;
b effectiveness;
c safety;
d the applicant's marketing business licence;
e the proposed manufacturer's manufacturing business licence or accreditation as a foreign manufacturer; and
f whether the manufacturer complies with good manufacturing practice (GMP).

Other conditions

The marketing of a medicine must be conducted by a party that has obtained both proper authorisation to market the medicine and a marketing business licence. If the medicine is distributed through wholesalers or retailers, the wholesalers and retailers participating in the distribution must obtain business licences in their respective categories.

Applicants located outside Japan

Foreign marketing authorisations are not generally recognised in Japan. If a foreign manufacturer intends to export a medical product to Japan, the manufacturer must, in principle, obtain a marketing authorisation for a foreign-manufactured medical product. To obtain such a marketing authorisation, a foreign manufacturer must file an application through a company located in Japan that has a marketing business licence.

Fee

The amount of the application fee for a marketing authorisation differs, depending on the type of medical product. The application fee for a marketing authorisation for a new medicine ranges from approximately ¥2 million to ¥50 million.

Standard review time and special procedures

Although dependent on factors such as the type of medical product, the standard time period for reviewing an application for a new medicine approval is one year after the official application filing.

There is an abridged procedure for generic medicines for which the examination of an application mainly focuses on:

a the similarity between the new medicine and the generic medicine;
b the adequacy of the data attached to the application; and
c the proposed manufacturing facility's compliance with GMP.

To obtain an authorisation through the abridged procedure for generic medicines, all of the following conditions (among others) must be met:

a the re-examination period for the original medicine must have expired;
b the quality, effectiveness and safety of the generic medicine must be equivalent to those of the original medicine;
c the generic medicine must be capable of being a substitute for the original medicine; and
d the patent for the original medicine must have expired.

The review of an application for an orphan medicine, curing a rare but serious disease, can be expedited and prioritised over applications for new medicines if the orphan medicine is found to contribute to an apparent improvement in the quality of medical care for the subject disease.

vi Regulatory incentives

Patent protection

Medical products and related substances can be protected by substance patents as well as process patents. Patent protection lasts for 20 years from the date of application; this term cannot be renewed. Payment of an annual fee is required to maintain the patent registration.

Extending protection

For medical products, the term of a patent can be extended at the request of the patent holder. The term of the extension, which may not exceed five years, is generally equivalent to the period during which the patent holder was prevented from implementing the patented product while waiting for the medical product registration required under the PA Act.

Protection under the PA Act

In Japan, there is no explicit 'data exclusivity' system. Depending on the type of medical product, however, approval of a new medicine is generally subject to re-examination six

years after the initial authorisation. As a matter of practice, an applicant for a generic product cannot apply for a marketing authorisation under the PA Act until the expiration of the original medicine's re-examination period (see generic drug requirements in Section II.v, *supra*). In substance, this re-examination system has an effect that is equivalent to that of data exclusivity. To encourage new orphan drug development, the re-examination period for an orphan drug is set between six and 10 years. To encourage generic product market share expansion for a medicine that is only different from another already authorised medicine in terms of its effectiveness, the re-examination period is shorter than six years.

vii Post-approval controls

Post-marketing commitments and pharmacovigilance obligations

After the marketing of a medicine starts, the authorisation-holding marketer must conduct post-marketing surveillance. If any issue relating to the effectiveness or safety of the marketed medicine is discovered during the post-marketing surveillance, the marketer must:

a conduct a medicine recall campaign;
b report the discovery to the PMDA;
c issue public notices if the issue is important; and
d take other appropriate measures to prevent further damage or loss to patients.

Period of authorisation and renewals

The effective period of a marketing authorisation for a medical product is not permanent. Subject to the type of medical product, an approval for a new medicine is generally subject to re-examination six years after its initial authorisation. Additionally, the MHLW will occasionally conduct a re-evaluation of a medicine.

Amendment to, transfer of and cancellation of marketing authorisations

Any amendment to a product subject to marketing authorisation (except for minor amendments) generally requires approval from the MHLW, while a minor amendment can be made upon notification to the MHLW. Marketing authorisations can generally be transferred to another marketer that holds an adequate marketing business licence, after prior notice of such transfer is submitted to the MHLW. Criminal sanctions can be imposed, or a product recall administrative order or an order cancelling a marketing authorisation or marketing business licence, can be issued, in response to a violation of a marketing authorisation. After enforcement of the new PA Act, any amendment to the medical packaging insert accompanying a medicinal product must be reported to the MHLW, and the amended insert must also be uploaded to the marketer's website.

viii Manufacturing controls

Application

There are two types of business licence related to the manufacture of medical products:

a a manufacturing business licence, which is required to manufacture the medical product (if a manufacturer of an imported product is located outside Japan, accreditation as a foreign manufacturer is required); and

b a marketing business licence, which is required for the initial marketing of a manufactured or imported medical product in Japan.

A company that has obtained a manufacturing business licence, but not a marketing business licence, cannot distribute medical products (manufactured or imported by the company) to others, for example, a wholesaler. After enforcement of the new PA Act, a manufacturer of a medical device will merely be subject to a prior registration requirement, while such manufacturer has previously been required to obtain a manufacturing business licence.

Conditions

An applicant for a manufacturing business licence must meet certain facility, staffing and other standards, as set out under a ministerial order of the MHLW. The manufacturer must comply with the GMP regulations, which are set out in another MHLW order.

In addition, an applicant for a marketing business licence must meet:

a standards for maintaining quality assurances, as provided under good quality practice (GQP) regulations (stated in an MHLW order);

b standards for post-marketing safety management, as provided under the good vigilance practice (GVP) regulations (stated in an MHLW order);

c standards provided under other ministerial orders of the MHLW; and

d further, a marketing business operator must comply with the good post-marketing surveillance practice (GPSP) regulations, which are set out in an MHLW order.

Restrictions on foreign applicants

A foreign manufacturer of medical products must distribute its products in Japan through a licensed marketing business operator. Accreditation requirements for a foreign manufacturer are basically the same as those to acquire a Japanese manufacturing business licence. The filing of an application for accreditation as a foreign manufacturer can be delegated by the foreign applicant to a marketing business operator in Japan.

ix Advertising and promotion

Restrictions

The PA Act prohibits false, excessive or misleading adverts in relation to the name, manufacturing method, effectiveness, etc., of medical products, communicated either explicitly or implicitly. In its effort to regulate adverts, the MHLW has issued Guidelines for the Adequate Advertisement of Medicines, etc., together with official commentary, that provide detailed examples of adverts that the MHLW considers to be false, excessive or misleading.

Internet advertising

These advert-related regulations apply equally to advertising over the internet. Internet web pages of advertisers containing hyperlinks to other web pages are considered together as a single advert in determining whether a violation of the advert-related regulations exists (even where each internet web page on its own may not explicitly violate these regulations).

x Distributors and wholesalers

Wholesaler and retailer business licences

The marketing of medicines and medical devices must be done by a marketer that holds both a marketing authorisation and a marketing business licence. Wholesalers and retailers of medicines or medical devices are subject to separate business licence requirements. Business licences for wholesalers and those for retailers are different, and a party can apply for both types of licence.

Marketing through internet or mail order

After enforcement of the new rules under the amended PA Act, almost all non-prescription medicines will be able to be marketed through the internet and by mail order, except for certain potent medicines and non-prescription medicines that had previously been considered prescription medicines but have recently been re-classified as non-prescription. Such internet or mail order retailers will be required to have at least one 'real' store where they can receive orders from consumers via internet or mail.

xi Classification of products

Prescription medicine and over-the-counter medicine

Among the medicines authorised in the market, the MHLW designates certain medicines that may not be distributed or sold without a prescription. The MHLW designates prescription medicines on a case-by-case basis upon the granting of the relevant marketing authorisation in consideration of its prescription medicine designation standard. In order to market a prescription medicine, a marketer is required to obtain a marketing business licence for marketing a prescription medicine. Advertising prescription medicines is generally prohibited.

Prescription medicine designation standard

Based on the standard, the MHLW designates the following types of medicines as prescription medicine:

a medicines that cannot be used effectively or safely without proper selection based on a doctor's diagnosis;

b medicines that require periodic medical checks in order to avoid serious adverse effects; or

c medicines that can be used for other improper purposes (e.g., recreational addictive use).

xii Imports and exports

Licences and authorisation for imports

For the importation and sale of a medicine or medical device into Japan, generally, the following business licences and authorisations are required:

a accreditation as a foreign manufacturer by an offshore manufacturing factory for the products being imported;

b a manufacturing business licence held by a domestic factory (if a part of the manufacturing process, such as packaging of the imported products, is conducted in Japan before marketing);

c a marketing business licence held by a marketer, for marketing the imported products;
d a marketing authorisation held by a marketer, for marketing the imported products; and
e an import report from a marketer, for customs clearance.

Licences and authorisation for exports
For the exportation of a medicine or medical device from Japan, the following business licences and authorisations are required:
a a manufacturing business licence held by a domestic factory, for manufacturing products for export; and
b an export report from a domestic factory for product export.

Domestic factory manufacturing products for export must be subject to GMP compliance review by the MHLW, even if the products are solely for export and distribution outside Japan.

xiii Controlled substances

Narcotics and psychotropic drugs are heavily controlled substances in Japan. The Narcotics and Psychotropic Control Act regulates the import, export, manufacturing, sale and purchase, possession, use and disposition of narcotics and psychotropic drugs. Doctors, importers, exporters, manufacturers, wholesalers, retailers, hospitals and research institutions are required to obtain special permission in order to handle narcotics or psychotropic drugs.

xiv Enforcement

Monitoring compliance
The main regulator is the MHLW, but a substantial amount of its authority is delegated to local prefectural governments and the PMDA. The regulator can monitor a licensed business operator's business operations, to ensure compliance with the regulations provided under the PA Act. The regulator can monitor and oversee medical products that are subject to marketing authorisation. New medicines are subject to re-examination after a certain period of time. In addition, an applicant that receives authorisation must have its medical product re-evaluated upon an MHLW order.

Imposing penalties
The regulator can take the following actions (among others) against licensed business operators:
a inspect offices and factories;
b order the disposal, recall or other appropriate treatment necessary to protect public health;
c require that access be granted to the inspector designated by the regulator, who is responsible for the subject investigation;
d temporarily shut down pharmaceutical business operations;

e order the replacement of certain key personnel relevant to the pharmaceutical business;
f cancel a business licence or accreditation it had previously granted; and
g demand a report that includes data about adverse reactions to the medical product, recall information, etc.

Further, criminal sanctions can be imposed in response to violations of the regulations applicable to pharmaceutical business operators.

III PRICING AND REIMBURSEMENT

Japan has had a universal health-care system since 1961, under which most legal residents are currently covered. Costs for a substantial number of medical services provided and prescription drugs sold, as well as certain medical supplies, are covered by this system. Costs for prescription drugs may only be reimbursed if the subject drugs are listed on the national health insurance price list. Costs for medical services provided using a medical device are reimbursed if such services are covered by the national health insurance. In addition, costs for certain expendable medical supplies can also be reimbursed if they fall within one of the classifications of the medical supplies that are listed on the price list. In the case of large medical equipment and non-expendable medical devices, however, the costs of the devices themselves are not reimbursed. The scope of the medical services, drugs and medical supplies covered by the national health insurance, and the prices designated for each, are determined by the MHLW.

Reimbursement under the national health insurance system is generally made through a benefit-in-kind system. A large portion of the cost of the medical services, drugs and medical supplies covered by the health insurance is directly paid by the health insurance to the hospitals, doctors or pharmacists providing the services, drugs or supplies to patients. The amount of reimbursement is determined based on the prices of the medical services, drugs and medical supplies specified on the respective price list. The patient is required to pay the hospital, doctor or pharmacist a small portion of the cost of such services, drugs or supplies, which is not reimbursed under this system.

IV ADMINISTRATIVE AND JUDICIAL REMEDIES

An administrative disposition made by an administrative agency (such as an administrative remedial order or a revocation of a licence) may generally be subject to an appeal to an administrative agency, in accordance with the Administrative Appeal Act; or a Japanese court, in accordance with the Administrative Case Litigation Act.

Under the Administrative Appeal Act, a person affected by an administrative disposition may file an application for review with the administrative agency that is superior to the agency that made the disposition, or, if no such superior agency exists, file an objection with the administrative agency that made the disposition. Such appeals must be filed within 60 days of the day that the affected person became aware of the subject disposition. In the case where an administrative agency renders a written disposition which is subject to these appeals, the agency rendering the disposition must inform the

recipient in writing of the agency to which an appeal may be filed and the time limit for filing an appeal. The trial procedures resulting from an appeal are stipulated in the Administrative Appeal Act and are not as formal as court proceedings; therefore, the process is generally considered to be easier and faster than litigating in court.

In addition to appeals pursuant to the Administrative Appeal Act, a person affected by an administrative disposition may also dispute the disposition by bringing suit in a Japanese court pursuant to the Administrative Case Litigation Act. The Administrative Case Litigation Act provides for various types of administrative litigation, including an action for a revocation of disposition and an action for a declaration of nullity. In general, an action for a revocation of disposition must be filed, absent reasonable grounds, within the earlier of six months from the day that the affected person became aware of the subject disposition or one year from the day of the subject disposition.

V FINANCIAL RELATIONSHIPS WITH PRESCRIBERS AND PAYORS

The Act against Unjustifiable Premiums and Misleading Representations (the Premiums Act) prohibits the wrongful inducement of customers through the provision of excessive gifts, incentives and other benefits. Pursuant to the authority granted to the Japan Fair Trade Commission (JFTC) and the Secretary General of the Consumer Affairs Agency (CAA) under the Premiums Act, the Fair Trade Council of the Ethical Pharmaceutical Drugs Marketing Industry (the Drugs FTC) has established the Fair Competition Code Concerning Restriction on Premium Offers in the Ethical Pharmaceutical Drugs Marketing Industry, and the Japan Fair Trade Council of the Medical Devices Industry (the Devices FTC) has established the Fair Competition Code Concerning Restriction on Premium Offers in the Medical Devices Industry. These codes set guidelines in relation to gifts or incentives provided to physicians and medical institutions, and provide examples of excessive gifts or incentives that are not acceptable under the Premiums Act. The Drugs FTC and the Devices FTC have each issued more detailed standards on permissible gifts and incentives, including specific upper limit amounts for entertainment expenses. If a gift or incentive is offered to physicians or medical institutions in violation of these rules, the JFTC and CAA would likely consider such offer to be a violation of the Premiums Act.

If a public servant (eg, a physician at a government-managed hospital) receives excessive gifts, incentives or other benefits in relation to his or her official function and capacity, he or she can be criminally prosecuted for bribery and the party offering the bribe may also face criminal penalties for the violation. If an act of bribery (eg, payment of money or an offer of excessive gifts) occurs in Japan, and the bribe is offered to a public servant of another country, the party offering the bribe may also face criminal penalties under Japanese law.

In January 2011, the Japan Pharmaceutical Manufacturers Association (JPMA), a voluntary organisation formed by pharmaceutical companies, issued a guideline in regard to disclosure of certain payments made to physicians and medical institutions. This guideline recommended that in 2013, all JPMA members disclose all such payments made in fiscal year 2012. The Japan Federation of Medical Devices

Association, a voluntary organisation formed by medical device companies, issued a similar guideline in January 2012. This guideline recommends that in 2014, members disclose all payments made in fiscal year 2013.

VI SPECIAL LIABILITY OR COMPENSATION SYSTEMS

Product liability claims relating to medicines or medical devices are typically based on the Product Liability Act, tort principles or non-performance of contractual duties.

The PMDA provides certain relief services for adverse health effects arising from medical products. These services are funded by contributions from the pharmaceutical industry and are partially subsidised by the Japanese government. The PMDA provides relief benefits relating to health damage, such as diseases and disabilities requiring hospitalisation, that were caused by adverse reactions to prescription drugs prescribed at hospitals or clinics as well as over-the-counter drugs purchased at pharmacies or drug stores. Health damage caused by adverse reactions to certain anti-cancer and immunosuppressant drugs is not eligible for these benefits. The PMDA also provides relief benefits to patients who have suffered health damage, such as diseases and disabilities requiring hospitalisation, caused by infections acquired through biological products. These benefits are available in cases where the relevant drugs or products were properly used and are not available if the drugs or products were improperly used. Furthermore, these relief benefits are supplementary to any damages awarded under civil liability, in that if a pharmaceutical business is held liable for the injuries caused by the use of a drug or biological product, the PMDA will not provide relief benefits or such benefits will be reduced by the amount awarded. The PMDA does not provide relief benefits for adverse health effects resulting from statutory vaccinations, for which a different public relief system is available.

In addition to the above relief services, the PMDA provides the following relief benefits:

a health-care allowances and nursing-care expenses for subacute myelo-optico-neuropathy patients with respect to whom a settlement has been reached in court;

b health-care expenses or health-care allowances for patients who have become infected with HIV due to treatment with blood products; and

c financial assistance in accordance with the Act on special measures concerning the payment of benefits to assist individuals affected by hepatitis C through specified fibrinogen products and specified blood coagulation factor IX products contaminated by the hepatitis C virus.

VII TRANSACTIONAL AND COMPETITION ISSUES

i Competition law

Among the various restrictions provided under the Antimonopoly Act, prohibition against resale price maintenance often becomes an issue for drug manufacturers of prescription drugs. In the case where a prescription drug is supplied from a drug manufacturer to a distributor, and then to a wholesaler, the respective sales price of the drug is generally determined based on the price of the drug specified on the price list (see also Section III,

supra). The price list is reviewed periodically (typically every two years), and the price for a prescription drug may be lowered if, for example, the price at which wholesalers purchase and sell the drug decreases during the two-year period. Accordingly, in order to prevent the drug price in the price list from being lowered, drug manufacturers have an interest in maintaining the price at which wholesalers purchase and sell their drugs.

In this connection, the Antimonopoly Act prohibits a business entity from supplying goods to another party while, without justifiable grounds, causing the said party to maintain the selling price of the goods as determined by the business entity, or otherwise restricting the said party's ability to freely decide on the sales price of the goods. Indicating a non-binding reference price is generally considered not to violate such prohibition; however, if the manufacturer seeks to restrict the resale price of the distributors by causing them to comply with the reference price, the manufacturer may be regarded as having violated the Antimonopoly Act. Whether resale prices have been restricted is generally determined based on whether any artificial means are taken to effectively ensure that the distributors will comply with the sales price indicated by the manufacturer. Such artificial means may include, for example, imposing, or suggesting the imposition of, an economic disadvantage if sales are not made at the manufacturer's indicated price. Price indications by a manufacturer may be made not only by indicating a specific price, but also by indicating a specific price range or by requiring that a resale price be approved by the manufacturer in advance.

ii Transactional issues

The JFTC has established guidelines setting out its views on antitrust aspects relating to joint R&D, and use of intellectual property such as patents. It is important to be mindful of the provisions in these guidelines in conducting licensing and collaboration transactions in respect of drugs and medical devices in Japan.

The Guidelines concerning Joint Research and Development under the Antimonopoly Act (the Joint R&D Guidelines) are applicable to transactions that may affect the Japanese market, irrespective of whether the participants are domestic or foreign business entities. According to the Joint R&D Guidelines, if an arrangement made in respect of an implementation of a joint R&D project unjustly restricts the business activities of a participant, which may thereby impede fair competition, the arrangement may constitute an unfair trade practice prohibited under the Antimonopoly Act. For example, in the case of contractual arrangements imposing restrictions on R&D with third parties, it is generally not considered an unfair trade practice to restrict R&D with third parties on the same theme as the joint R&D project during the implementation period of the joint R&D project. Restrictions on R&D after completion of the joint R&D project are, however, in principle, considered to be impermissible under the Antimonopoly Act because they would unjustly restrict the R&D activities of the participants and may significantly impede fair competition. Having said that, such restrictions may be permissible if the subject restriction is imposed on the same theme only for a reasonable period after completion of the joint R&D project, provided that the restriction is necessary to prevent a breach of faith or to ensure acquisition of rights.

The Guidelines concerning Use of Intellectual Property under the Antimonopoly Act are applicable to intellectual property related to technology, such as those technologies

protected by patents and copyrights under Japanese law. These Guidelines stipulate the principles by which the Antimonopoly Act is applied to restrictions pertaining to the use of technology, including, *inter alia*, grant back and assignment back arrangements under licensing agreements.

VIII CURRENT DEVELOPMENTS

During the extraordinary session of the Diet held from October to December 2013, bills containing substantial amendments to the current regulatory regime set out under the PA Act were adopted. First, there is an amendment introducing new rules to regulate the sale of non-prescription drugs on the internet. These new rules will replace the current rules, which have been rendered void by a recent Supreme Court judgment. This amendment is scheduled to take effect within six months of 13 December 2013, on a date to be specified by cabinet order.

Second, there is another amendment that will restructure the current regulatory regime related to medical devices under the PA Act; this includes changing the title of the PA Act to 'the Act concerning Ensuring Quality, Efficacy and Safety of Drugs, Medical Devices, Etc.' and allows for reduced business licensing and product approval requirements for medical devices. The amendment will also introduce new rules to regulate regenerative medical products, and enhance various safety measures concerning medicines and medical devices, such as a new requirement to file package inserts with the regulator. This amendment is scheduled to take effect within one year of 27 November 2013, on a date to be specified by cabinet order.

Appendix 1

ABOUT THE AUTHORS

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Kenji Utsumi is a partner of Nagashima Ohno & Tsunematsu. He represents domestic and foreign clients in a wide variety of transactions related to pharmaceutical matters. He regularly acts as main legal counsel to various domestic and foreign pharmaceutical companies in domestic and cross-border M&A and joint venture transactions, and provides advice on a variety of legal and compliance matters. His expertise encompasses pharmaceutical and life science regulations.

Mr Utsumi is a graduate of the University of Tokyo (LLB, 1992) and of the University of Pennsylvania Law School (LLM, 1999). He was admitted to the Japan Bar in 1994 and worked as a visiting attorney at Paul, Hastings, Janofsky & Walker (Los Angeles) from 1999 to 2000. He is fluent in Japanese and English.

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Mr Suzuki is a graduate of the University of Tokyo (LLB, 1999) and Stanford Law School (LLM, 2006). He was admitted to the Japan Bar in 2000 and worked as a visiting attorney at Kirkland & Ellis (Chicago) from 2006 to 2007. He also worked at the Financial Services Agency of Japan from 2007 to 2009, where he worked on various Japanese financial regulation reforms. He is fluent in Japanese and English.

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