The Pharma Legal Handbook

Japan

Regulatory, Pricing and Reimbursement Overview · Preclinical and Clinical Trial Requirements · Marketing, Manufacturing, Packaging and Labeling Advertising · Traditional Medicines and OTC Products · Product Liability · Patents and Trademarks · Regulatory Reforms · Cannabinoid Drugs, Medicinal Cannabis and Opioid Drugs · Orphan Drugs and Rare Diseases · Localization · Biosimilars and Biologics

PHARMA BOARDROOM

Japan

The Pharma Legal Handbook answers essential questions about this environment for pharmaceuticals in Japan.
It is a must have for any company operating in the country or looking to enter the market.

Prepared in association with Nishimura & Asahi, Japan's largest international law firm, it should answer any questions linked to Regulation, Pricing, Clinical and Preclinical Trials, Marketing, Manufacturing, Trademarks and Patents.

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**including Associate and Alliance offices*

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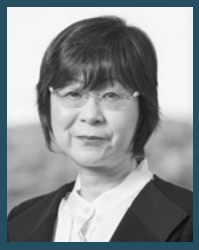
Nishimura & Asahi
Otemon Tower
1-1-2 Otemachi
Chiyoda-ku
Tokyo 100-8124
Japan

Tel: +81 3 6250 6200
Fax: +81 3 6250 7200
Email: info@nishimura.com
Web: https://www.nishimura.com/en

THE AUTHORS



MARIKO MIMURA

Mariko Mimura is an Of Counsel of Nishimura & Asahi. She rejoined Nishimura & Asahi in 2018 and serves as leading counsel for the Life Science and Healthcare practice group of N&A.

Before rejoining N&A, she was the Vice President, General Counsel and Board Member of GlaxoSmithKline K.K., leading Legal, Compliance, Government Affairs, Public Policy and Patient Advocacy from 2015.

From 2010 to 2015, she was a Director, Country General Counsel, and the Head of Legal/Intellectual Property Department, at Novartis Holding Japan K.K., and has managed the legal affairs and IP of all the Novartis Group Companies in Japan, including Novartis Pharma K.K. Her responsibilities as an in-house counsel in the Novartis Group spanned a wide array of work, from general corporate legal affairs to M&A and IP litigation.

She held tenure as a Corporate Officer and General Counsel at GE Healthcare Japan Corporation (manufacture and sale of medical devices and Bio products) from 2005 to 2009, taking on responsibility for legal affairs, IP and compliance across the board. She has also assumed the position of General Counsel of Asia Pacific to oversee legal affairs and compliance in the APAC region. Furthermore, Mariko was appointed as an outside statutory auditor at Nihon Medi-Physics Co., Ltd. (manufacture and sale of pharmaceutical products), an affiliate of GE Healthcare Japan, continuing to hold the position until she left GE Group in 2009.

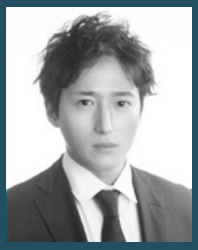
Following registration with the Japanese Bar Association in 1992, Mariko joined Nishimura & Partners (currently Nishimura & Asahi) in 1995, with expertise in intellectual property, entertainment,

general corporate, bankruptcy, and civil rehabilitation. During her tenure at Nishimura & Partners, she was seconded to Gibson, Dunn & Crutcher LLP, a US law firm, as well as working at a US medical device company as Vice President & General Counsel. After returning to Nishimura & Partners, she became a partner in 2003 and served until she became an in-house counsel of GE Healthcare Japan Corporation until 2005.

She leads N&A Life Science and Healthcare Practice Team, which recently published a book detailing a Japanese law designed to secure the quality, efficacy, and safety of pharmaceutical, quasi-pharmaceutical, cosmetic products and other medical stuff. This book provides basic and detailed explanations of these matters, as well as a minute description of relevant laws and regulations, ministry notifications and industry rules, making it one of the most comprehensive and aspirational illustration of pharmaceutical affairs in Japan to date. She was the editors' representative for this book and was responsible for its overall supervision based on her accumulated experience in this area.

Thus, she is an in-house counsel pioneer in the Japanese healthcare industry. She was selected as one of the top 100 Corporate Counsel in Asia Pacific in the GC Powerlist of the Legal 500 in 2014.

In 2019, she received an award as a Corporate and M&A lawyer by Best Lawyers® 10th Edition of The Best Lawyers in Japan (2020).



HARUHI ABE

He works as an associate at Nishimura & Asahi (N&A), practicing in the areas of General Corporate, Crisis Management (compliance and investigation of white-collar crimes), Antitrust, Mergers and Acquisitions, Life Science, Entertainment and Litigation among others.

He is also a member of N&A Life Science and Healthcare Practice Team, where he engages in a wide variety of legal activities, such as conducting investigations into manufacturing errors at pharmaceutical companies. He is also involved in M&A cases dealing with pharmaceutical and cosmetic products.

N&A Life Science and Healthcare Practice Team recently published a book detailing a Japanese law designed to secure the quality, efficacy, and safety of pharmaceutical, quasi-pharmaceutical, cosmetic products and other medical stuff. In this volume, as a member of the practice team, he took charge of the chapters on quasi-pharmaceutical, cosmetic products and regenerative medicine and other products.

He obtained his LL.M. (Master of Laws) from University of California, Berkeley, School of Law in 2021, Juris Doctor degree from the University of Tokyo, Graduate Schools for Law and Politics in 2013, and Bachelor of Laws from Kyoto University in 2011. Since September 2021, he has belonged to Technology, Media and Telecommunications Law LL.M. (Master of Laws) at Queen Mary, University of London, for the study and research of the following areas of law: Life science law (protection and regulation of medicines with patent-related matters); International copyright law; Digital piracy law; Entertainment law (video game law, fashion law and esports law); Animal law; Media reputation law (defamation and privacy); and E-commerce regulations.

TAKESHI YAMAMOTO

Takeshi is an associate at Nishimura & Asahi (N&A), where he has handled various domestic and cross-border corporate scandals, business regulation matters mainly related to manufacturing, infrastructure, telecommunications, and healthcare business sectors and the casino industry.

He also has rich experience in Japanese pharmaceutical industry cases, such as handling whistleblower hotlines for pharmaceutical company employees and handling corporate scandal cases involving advertising regulations for pharmaceutical companies.

He graduated in 2014 from the University of Tokyo with a bachelor's degree in law and was admitted to the Japanese bar in 2017.

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*including Associate and Alliance offices

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01 REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

1. What are the regulatory authorities with jurisdiction over drugs, biologicals, and medical devices in your country?	The Ministry of Health, Labour and Welfare (the "MHLW") and the Pharmaceuticals and Medical Devices Agency (the "PMDA").
2. What is the regulatory framework for the authorization, pricing, and reimbursement of drugs, biologicals, and medical devices?	Authorization is governed by the Pharmaceuticals and Medical Devices Law (the "PMD Act") of Japan. Pricing of drugs and biologicals is governed by the National Health Insurance. Drug Pricing Standards are established by the MHLW under the Health Insurance Act. The method of calculation of drug pricing and the price of each drug are announced by the MHLW after consultation with the Central Social Insurance Medical Council. Pricing of medical devices is included in the Medical Fee, which is also established by the MHLW under the Health Insurance Act, and the calculation method and price thereof are announced by the MHLW after consultation with the Central Social Insurance Medical Council. Reimbursement is governed by the Health Insurance Act.
3. What are the steps to obtaining authorization to develop, test, and market a product?	To develop and test a product, it is necessary to obtain a manufacturing/marketing business license, depending on the type of business. To market a product, in addition to the above, the license holder must obtain marketing authorization for each such product.
4. What are the approximate fees for each authorization?	The fee for a manufacturing/marketing license varies depending on the type of license, but is approximately 100,000 to 150,000 yen. The fee for marketing authorization for each product varies depending on the product.
5. For how long are marketing authorizations/registrations valid? How are marketing authorizations/registrations renewed?	Manufacturing/marketing licenses are valid for five years, and the license holder must renew the relevant license(s) every five years. Marketing authorizations are valid until and unless withdrawn by the government for appropriate reasons or abandoned by the authorization holder, both of which are rare.
6. How does the authorization process differ between brand-name products and generic products? Are there differences for local manufacturers versus foreign-owned manufacturers?	Clinical trial data is required to obtain authorization for brand-name products. Normally, product creators spend more than 10 years from basic research to obtaining authorization. For generic products, only stability tests and bioequivalence tests are required, as opposed to clinical trials. Thus, generic products can obtain authorization in a short time, normally 2 years from the start of testing.

	Currently, applications for authorization of generic products are accepted only twice a year, in February and August.
7. How are combination products (drug + drug, drug + biologic, drug + device, biologic + device, drug + biologic + device) regulated?	Basically, the same rules apply to combination products. To ensure the safety of combination products, the single drugs used in combination products must be in the market for one year or more, with exceptions for some special combination products (such as HIV drugs).
8. How is compliance with regulations monitored and evaluated? Is the regulatory regime comparable with the U.S. Food and Drug Administration or the European Medicines Agency expectations and requirements?	Compliance with regulations is monitored and evaluated by the PMDA and the local government of each prefecture. Basically, compliance with regulations is harmonized with the FDA and EMA.
9. What is the potential range of penalties for noncompliance?	Potential penalties include suspension of part or all of a business, cancellation of authorizations, or up to 3 years imprisonment or a fine of up to 3 million yen or both, depending on the type of noncompliance/misconduct.
10. Is there a national healthcare system? If so, how is it administered and funded?	There is a national healthcare system. Japan's universal insurance system began with introduction of the Health Insurance Act in 1961. This system ensures that all people's healthcare costs are covered by public insurance and that people have free access to any healthcare provider. People have to pay insurance fees to the health insurance program they join, and then, when the individual goes to a healthcare provider, the cost is covered by the National Health Insurance (other than a portion the individual patient must pay). The portion an individual must pay varies from 10% to 30% depending on the individual's age; in addition, if an individual's total payments exceed a certain amount, which is decided based on his or her income, the residual amount is covered by the National Health Insurance. People have an obligation to join a health insurance program. Company employees join the health insurance program their employer has joined. Most other people join the national health insurance program, although there are also several special insurance programs such as the public employee union program. The national healthcare system is funded primarily by insurance fees paid by the program members. For example, a company employee has an obligation to pay half of his/her insurance fee to the insurance program; the other half is paid by the employer. However, current healthcare costs are far beyond the total of insurance fees. Thus, there is an added public expense. Most recently, approximately one half of the total healthcare costs was covered by insurance fees, approximately 40% was covered as a public expense, and approximately 10% was covered by individual payment by the patients.

11. How does the government (or public) healthcare system function with private sector healthcare?

Most of the hospitals in Japan belong to the private sector (approximately 80%).

The basic functions of public sector and private sector hospitals are the same, but public sector providers have special missions, such as providing healthcare in remote places where no other hospitals exist, assisting patients as a safety net, and providing advanced healthcare based on advanced research and study.

12. Are prices of drugs and devices regulated and, if so, how?

Prices of drugs and devices are regulated under the Health Insurance Act.

Pricing of drugs and biologicals is governed by the National Health Insurance Drug Pricing Standard which is regulated by the MHLW under the Health Insurance Act. The methods of calculation of drug pricing and the prices for each drug are announced by the MHLW after consultation with the Central Social Insurance Medical Council.

The pricing of medical devices is included in the Medical Fee, which is also regulated by the MHLW under the Health Insurance Act, and the calculation methods and prices thereof are announced by the MHLW after consultation with the Central Social Insurance Medical Council.

13. How are the drugs and devices used by patients paid for? What roles do public and private payers play?

Drugs and devices prescribed by doctors and used by patients are covered by the National Health Insurance, other than the portion individual patients must pay under the Health Insurance Act.

14. Who dispenses drugs and devices to patients and how are those dispensers compensated?

Doctors prescribe the drugs and pharmacies dispense the drugs to patients. When a pharmacy dispenses a prescribed drug, the patient has to pay a portion of the total cost, and the other portion is reimbursed to the pharmacy by the National Health Insurance payer.

The cost of devices used by doctors for patients is reimbursed to the doctor by the National Health Insurance payer. Patients only pay the hospital a portion of the doctor fees, including service fees.

15. What are the professional and legal responsibilities of those who dispense drugs and devices? What role do they play in providing patient care, information, and safety?

Under the Health Insurance Act, a doctor must register as an insurance doctor. Only registered insurance doctors can prescribe drugs and dispense devices covered under the national insurance system.

Also, only a pharmacy that is designated as an insurance pharmacy under the Health Insurance Act can dispense drugs.

Insurance doctors and insurance pharmacies have obligations under the Health Insurance Act, and non-compliance may result in cancellation of their licenses.