Healthcare Enforcement & Litigation 2022

Contributing editors
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Getting The Deal Through

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Mintz

Lexology Getting The Deal Through is delighted to publish the seventh edition of *Healthcare Enforcement and Litigation*, which is available in print and online at www.lexology.com/gtdt.

Lexology Getting The Deal Through provides international expert analysis in key areas of law, practice and regulation for corporate counsel, cross-border legal practitioners, and company directors and officers.

Throughout this edition, and following the unique Lexology Getting The Deal Through format, the same key questions are answered by leading practitioners in each of the jurisdictions featured. Our coverage this year includes a new chapter on European Union.

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Every effort has been made to cover all matters of concern to readers. However, specific legal advice should always be sought from experienced local advisers.

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Japan

Atsushi Okada, Yo Uraoka and Yurika Inoue
Mori Hamada & Matsumoto

OVERVIEW

Healthcare funding

1 | In general terms, how is healthcare, including access to medicines and medical devices, funded in your jurisdiction? Outline the roles of the public and private sectors.

In Japan, under the universal healthcare insurance system designed by the government, all Japanese citizens are covered by public health insurance. Under this system, Japanese citizens receive high-quality medical treatments at relatively low costs, from healthcare providers and facilities of their choice. While there are several types of public health insurance systems, the Employees' Health Insurance (EHI) and the National Health Insurance (NHI) are the most commonly used systems. The EHI covers employees employed by the public sector and private entities and the NHI covers individual businesses (including the self-employed) and the unemployed.

The universal healthcare insurance system is funded by insurance premiums, subsidies from central and local governments, and co-payments from patients. Patients generally pay 10 cent to 30 per cent of their medical costs.

Delivery

2 | In general terms, how is healthcare delivered in your jurisdiction? Outline the roles of the public and private sectors.

The type of healthcare insurance system or the health insurer a resident decides to use does not limit the choice of healthcare provider. Healthcare for Japanese residents is provided by both public and private hospitals. Under the universal health insurance system, Japanese citizens are free to choose their healthcare providers and facilities.

Key legislation

3 | Identify the key legislation governing the delivery of healthcare and establishing the regulatory framework.

The Health Insurance Act and the Mutual Aid Association Act govern EHI, and the National Health Insurance Act governs NHI. The Minister of Health, Labour and Welfare has the authority to decide the Uniform Fee Schedule, which provides for the fees that the health insurance system will pay to a healthcare provider for each healthcare service. The minister, in consultation with the Central Social Insurance Medical Council, revises the Uniform Fee Schedule every two years.

The Medical Practitioners' Act and the Medical Care Act are the two key pieces of legislation that regulate the provision of healthcare. The Rules for Professionals in Charge of Healthcare Services under the Health Insurance Programs are also relevant, as they provide for the rules applicable to healthcare providers which are covered by the health insurance system.

Responsible agencies

4 | Which agencies are principally responsible for the enforcement of laws and rules applicable to the delivery of healthcare?

The Ministry of Health, Labour and Welfare (MHLW), is responsible for the enforcement of the laws and rules applicable to the delivery of healthcare. The public health centres established by local governments also play important roles in maintaining public health and in regulating on the provision of healthcare.

Scope of enforcement

5 | What is the scope of their enforcement and regulatory responsibilities?

Generally, MHLW deals with nationwide issues, while public health centres deal with regional and local public issues.

Regulation of pharmaceutical products and medical devices

6 | Which agencies are principally responsible for the regulation of pharmaceutical products and medical devices?

The MHLW is responsible for the regulation of pharmaceutical products and medical devices. Some of its power and activities have been delegated to the local governments (such as prefecture governors) and the Pharmaceuticals and Medical Devices Agency (PMDA).

Scope of enforcement

7 | What is the scope of their enforcement and regulatory responsibilities?

The MHLW deals with nationwide issues relating to pharmaceutical products and medical devices and local governments deal with regional and local issues regarding the same. The PMDA deals with or assists the MHLW in:

- the review of applications for marketing approval for drugs, medical devices, and cellular and tissue-based products;
- implementing post-marketing safety measures; and
- providing relief services for adverse health effects that were caused by reactions to pharmaceuticals.

Local governments are also given authority over certain matters, for example, licensing and supervision of pharmacies, and monitoring of compliance with regulations on drugs and devices.

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Other agencies

8 Which other agencies (eg, competition or securities regulators, prosecutors) have jurisdiction over healthcare, pharmaceutical and medical device cases?

The Act on Securing the Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (the PMD Act) provides for criminal penalties for certain violations. Therefore, prosecutors have the primary authority in deciding whether to prosecute criminal cases for violations of this act.

Competition and securities regulators also have jurisdiction over business activities related to pharmaceuticals and medical devices, to the extent that these business activities violate relevant competition and other laws.

Simultaneous investigations

9 Can multiple government agencies simultaneously conduct an investigation of the same subject? Does a completed investigation bar another agency from investigating the same facts and circumstances?

The answer to this question depends on each case. In Japan various government agencies typically act in close consultation and cooperation with each other.

REGULATION OF PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES

Monitoring powers

10 What powers do the authorities have to monitor compliance with the rules on drugs and devices?

The Act on Securing the Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (the PMD Act) authorises the Ministry of Health, Labour and Welfare (MHLW), itself or through the Pharmaceuticals and Medical Devices Agency (PMDA), to require marketing authorisation holders and manufacturers to submit reports and, more importantly, issue inspection orders to marketing authorisation holders and manufacturers. The MHLW (or the PMDA) carries out inspections of marketing authorisation holders and manufacturers' facilities, offices and other sites where the companies carry out business, interview employees, inspect books and records, and test drug samples to monitor compliance with the laws and regulations.

The MHLW also has the power to issue orders to marketing authorisation holders and manufacturers to improve their manufacturing controls, quality controls or post-marketing safety controls, or to suspend their operations until a required improvement is implemented.

In certain cases, local governments, such as prefectural governors and city or ward mayors, have the authority to require certain marketing authorisation holders, manufacturers, sellers of drugs and devices (such as pharmacies and store-based distributors) and clinics and hospitals to submit reports, and to conduct site inspections, interview employees, inspect books and test drug samples. In certain cases, the prefectural governors may issue orders for these entities to improve their facilities if those facilities fail to meet certain standards.

Investigation time frames

11 How long do investigations typically take from initiation to completion? How are investigations started?

There is no typical length of time for investigations as they depend on the facts of each case. Investigations are usually initiated by regulators, especially in areas which are considered important to Japanese society or government priorities, or when regulators receive information of wrongdoing from whistle-blowers or complaints from consumers.

Access to investigation materials

12 What rights or access does the subject of an investigation have to the government investigation files and materials?

Generally, under the Act on Access to Information Held by Administrative Organisations, the subject of an investigation has the right to access administrative documents, such as documents relating to an administrative investigation. The administrative authority that receives a request for disclosure of administrative documents is obligated to disclose those documents, unless they fall within information specifically excluded by article 5 of the act. Excluded information includes personal information concerning individuals, and information that, if made public, may pose a threat or risk to state security, prevention or investigation of crimes, maintenance of prosecutions and other matters concerning public safety and public order.

Investigations abroad

13 If pharmaceutical products or medical devices are made in a foreign country, may the authorities conduct investigations of the manufacturing processes in that other country?

Yes, the MHLW has the authority to conduct the same investigations it can conduct on domestic authorisation holders and the MHLW conducts investigations outside Japan from time to time.

Enforcement proceedings

14 Through what proceedings do agencies enforce the rules?

The regulators hold their own proceedings and investigations, which are administrative in nature. They do not need to apply to the courts before initiating and carrying out those investigations.

However, with respect to certain violations that are punishable by criminal penalties, then investigations are initiated by a prosecutor's office as they are criminal in nature. Generally, prosecutors do not need to apply to the courts to conduct their investigations, although they need to apply to the courts for warrants to conduct searches.

Sanctions

15 What sanctions and other measures can the authorities impose or seek in enforcement actions against drug and device manufacturers and their distributors?

In certain cases, the MHLW and the local governments have the authority to issue orders to improve manufacturing control, quality control or facilities, and to suspend business operations of, or the use of facilities by, manufacturers and distributors until necessary improvements are made. They also have the authority to order manufacturers and distributors to dispose of, recall or take other measures to prevent hazards to public health and hygiene caused by drugs and devices that do not meet the required standards. More importantly, they have the power to cancel the authorisation given to manufacturers and distributors to provide pharmaceuticals, quasi-drugs, cosmetics, medical devices or regenerative medicine products.

The PMD Act imposes penalties consisting of fines or imprisonment, or both, on certain violations of the PMD Act and its regulations by manufacturers and distributors.

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Actions against employees

16 | Can the authorities pursue actions against employees as well as the company itself?

An officer or employee who directly violates the PMD Act is subject to fines or imprisonment, or both. Furthermore, the representative and employees of the company may also be subject to fines along with the company.

Additionally, under the PMD Act, the MHLW may order manufacturers and distributors to change certain supervisor-level employees if they are found to be inappropriate as supervisors or technical supervisors or if they are found to have violated the PMD Act. These supervisors include the marketing supervisor-general of pharmaceuticals or medical devices, manufacturing supervisors of pharmaceuticals, and technical supervisors of medical devices.

The MHLW may order pharmacies, or proprietors, sellers or lessors of drugs or devices to change the supervisors of pharmacies or certain managerial-level employees of such establishments, if these employees are found to be inappropriate or if they are found to have violated the PMD Act.

Defences and appeals

17 | What defences and appeals are available to drug and device company defendants in an enforcement action?

If a person is dissatisfied with an agency's decision, that person may file a request for a review or re-examination of this decision with that agency in accordance with the Administrative Complaint Review Act. If such a filing is made, the relevant agency will examine its decision-making process and whether any error was made in the process or in its decision.

If a person wishes to cancel an agency's decision, that person may file a suit in court against the agency to ask the court to cancel the decision in accordance with the Administrative Case Litigation Act.

Minimising exposure

18 | What strategies should companies adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

One recommendation is for companies to establish and implement internal policies and systems on regulatory compliance, and to have a robust system of regular checks and audits to make sure that these policies and systems are being complied with by everyone in the company. Companies are encouraged to have more open working environments to encourage employees and officers to report irregularities or possible violations of the standards and requirements of the PMD Act, any other laws and regulations.

Recent enforcement activities

19 | What have the authorities focused on in their recent drugs and devices enforcement activity and what sanctions have been imposed?

Regulators have issued orders for improvements, and have suspended certain business operations for failure to comply with these improvement orders in a timely manner.

Self-governing bodies

20 | Are there self-governing bodies for the companies that sell pharmaceutical products and medical devices? How do those organisations police members' conduct?

The major self-governing bodies include the Japan Pharmaceutical Manufacturers Association (JPMA) and the Japan Federation of Medical Devices Associations (JFMDA). These self-governing bodies and associations have issued practice standards, compliance guidelines, codes of practice, promotion codes, and transparency guidelines that the members are expected to follow.

The JPMA consists of around 70 companies, and is a member of the Federation of Pharmaceutical Manufacturers' Associations of Japan, which consists of 15 industrial organisations and 16 regional organisations. It deals with inquiries and complaints and imposes improvement measures on violating members in accordance with its internal regulations.

JFMDA consists of 21 associations (which represent about 4,280 companies), associate members' organisations and individual companies. If JFMDA receives complaints of possible violations of one of its codes by a member, it will investigate and examine whether a violation exists. If JFMDA determines that such a violation exists, it will notify the violating member to comply with the code. JFMDA's members are obliged to cooperate with investigations conducted by JFMDA's committees.

RELATIONSHIPS BETWEEN HEALTHCARE PROFESSIONALS AND SUPPLIERS

Relationship rules

21 | What are the rules prohibiting or controlling the financial relationships between healthcare professionals and suppliers of products and services?

There are fair competition codes for drugs as well as for medical devices that aim to prevent unfair inducement of customers by restricting unjustifiable premium offers, and to ensure fair competition and order within the industry. As examples, the Japan Fair Trade Council of the Medical Devices Industry has issued the Fair Competition Code of the Medical Devices Industry in Japan; and for the pharmaceutical industry, the Japan Fair Trade Council of the Ethical Pharmaceutical Drugs Marketing Industry has issued the Fair Competition Code concerning Restrictions on Premium Offers in the Ethical Pharmaceutical Drugs Marketing Industry.

In addition, industrial groups, such as JPMA, also issue their own guidelines or codes of ethics and practice to guide their members. For example, JPMA has its Code of Practice, which provides the principal rules which pharmaceutical manufacturers must comply with in their activities, including the promotion of drugs. JPMA also issues 'Transparency Guidelines' that require pharmaceutical manufacturers to disclose certain financial relationships in research and development activities with medical institutions.

Enforcement

22 | How are the rules enforced?

Each industry's Fair Trade Council operates the relevant fair competition codes. The relevant industrial group enforces industry guidelines or best practice standards.

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Reporting requirements

23 What are the reporting requirements on such financial relationships? Is the reported information publicly available?

The Transparency Guidelines of JPMA require pharmaceutical companies to disclose financial relationships with medical institutions. In addition, under the new Clinical Research Law, which was enacted on 1 April 2018, pharmaceutical and medical device companies are required to disclose if they provide funding to clinical researches conducted on their products by medical institutions.

REGULATION OF HEALTHCARE DELIVERY

Authority powers

24 What powers do the authorities have to monitor compliance with the rules on delivery of healthcare?

Under the Medical Practitioners' Act, when the Minister of Health, Labour and Welfare finds that it is necessary to investigate whether a disposition should be made regarding a medical practitioner under the Act, he or she may seek the opinion of and collect reports from persons who are connected with the circumstances in question or from witnesses, may order owners of medical records or other articles to submit those records and articles, and may have its officials enter the hospital or any other location that is connected with the relevant circumstances and inspect medical records and other articles.

Investigation time frames

25 How long do investigations of healthcare providers typically take from initiation to completion? How are investigations started?

There is no typical length of time for investigations as they depend on the facts of each case. Investigations usually start upon the initiative of the regulators, especially in areas which are considered important to Japanese society or government priorities, or when regulators receive information of wrongdoing from whistle-blowers or complaints from consumers.

Access to investigation materials

26 What rights or access does the subject of an investigation have to the government investigation files and materials?

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However, with respect to certain violations that are punishable by criminal penalties, then investigations are initiated by a prosecutor's office as they are criminal in nature. Generally, prosecutors do not need to apply to the courts to conduct their investigations, although they need to apply to the courts for warrants to conduct searches.

Sanctions

28 What sanctions and other measures can the authorities impose or seek in enforcement actions against healthcare providers?

Under the Medical Practitioners' Act, if a medical practitioner acted in a way that damages his or her respectability as a medical practitioner, the Ministry of Health, Labour and Welfare (MHLW) may issue an order admonishing the medical practitioner, suspending him or her from medical practice for up to three years, or revoking his or her licence.

Additionally, it is necessary for healthcare providers to obtain insurance authorisation from the MHLW because healthcare insurance held by each patient only applies to services provided by healthcare providers who have that insurance authorisation. If a healthcare provider violates the Health Insurance Act and other laws and regulations related to insurance, the MHLW has the authority to cancel its insurance authorisation.

Criminal penalties consisting of fines or imprisonment may be imposed in the case of violation of certain provisions of the relevant laws.

Defences and appeals

29 What defences and appeals are available to healthcare providers in an enforcement action?

If a person is dissatisfied with an agency's decision, that person may file a request for a review or re-examination of this decision with that agency in accordance with the Administrative Complaint Review Act. If such a filing is made, the relevant agency will examine its decision-making process and whether any error was made in the process or in its decision.

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Recent enforcement activities

31 What have the authorities focused on in their recent enforcement activity and what sanctions have been imposed on healthcare providers?

The authorities have focused on improper billing and false claims under health care insurance, which are among the most common misconduct by healthcare providers.

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Self-governing bodies

32 | Are there self-governing bodies for healthcare providers? How do those organisations police members' conduct?

Yes, the Japan Medical Association (JMA), which is the largest physicians' organisation in Japan. It has about 167,000 members or about 60 per cent of all licensed physicians in Japan. Under its internal regulations, JMA may expel any member who violates JMA's ethical standards or internal regulations.

Remedies for poor performance

33 | What remedies for poor performance does the government typically include in its contracts with healthcare providers?

Not applicable.

PRIVATE ENFORCEMENT

Causes of action

34 | What private causes of action may citizens or other private bodies bring to enforce a healthcare regulation or law?

Enforcement actions in case of breach of healthcare regulations are generally conducted by either the MHLW or the prosecutor's office. Citizens or other private bodies may file civil actions against healthcare providers only in accordance with the framework of tort or a breach of contract if they are directly affected by the healthcare providers' acts, negligence or decisions.

Framework for claims

35 | What is the framework for claims of clinical negligence against healthcare providers?

Civil actions for medical injury against healthcare professionals may be based on either tort or non-performance of contract, both of which are provided for under the Civil Code. In order to prove liability, a patient must establish the doctor's negligence, the damage to the patient's life, body or property, and the causation between the negligence and the damage.

The applicable standards are essentially the same under either theory. Japanese courts generally consider the standard of care that is expected of a healthcare professional to be the standard prevailing in clinical medical practice at the time of the treatment, considering various circumstances such as the specialisation, size, functions or resources of the relevant medical facility and its personnel.

Damages awarded in medical injury cases are standardised in accordance with levels of severity of injuries, out-of-pocket medical expenses incurred or will be incurred, the present amount of expected earnings of the injured person, and a standardised amount for mental suffering. Punitive damages are not available under Japanese law.

Seeking recourse

36 | How and on what grounds may purchasers or users of pharmaceuticals or devices seek recourse for regulatory and legal infringements?

Purchasers or users of pharmaceuticals or medical devices may seek liability against any person who manufactured, processed or imported the pharmaceuticals or the devices if they can establish the defect in the product, the damage to their life, body or property, and the causation between the defect and the damage. The injured person is not required to prove negligence with respect to the defect. 'Defect' is defined under the Product Liability Act as a lack of safety that the product ordinarily should provide, considering the nature of the product, the ordinarily foreseeable manner of use of the product, the time when the product was delivered and other circumstances concerning the product. There are three categories of defects, defect in manufacture, defect in design; and defect in instructions or warnings.

Compensation

37 | Are there any compensation schemes in place?

The PMDA has drawn up a compensation scheme called the Relief System for Adverse Drug Reactions, which provides for relief benefits and compensation relating to damage to one's health, body and life, such as diseases and disabilities requiring hospitalisation that were caused by adverse reactions to prescription drugs, over-the-counter drugs and certain other products, even if the drugs were properly used. This scheme started in May 1980 and covers medical expenses and allowances, disability pensions, funeral expenses and bereaved family compensation.

Class and collective actions

38 | Are class actions or other collective claims available in cases related to drugs, devices and provision of care?

In Japan, the concept of class litigation does not have a long history. However, in October 2016, the Act on Special Measures concerning Civil Court Proceedings for the Collective Redress for Property Damage Incurred by Consumers came into force. This Act introduced a new type of litigation that allows for the filing of certain collective consumer actions to seek damages.

Under this Act, a specified qualified consumer organisation (SQCO) may file a lawsuit that demands the declaration of payment obligations commonly owed by a business operator to consumers in certain categories of cases. If the SQCO prevails, then the SQCO may file a petition for a special proceeding to obtain an order from the court regarding the substance and amount of each claim of target consumers. However, damage to property other than the subject matter of the consumer contract, lost profits, personal injury, and mental suffering are expressly excluded from the scope of claim that can be brought by an SQCO. Therefore, this collective action will have limited influence on the practice of bringing legal actions in cases related to drugs, medical devices and the provision of care.

Review

39 | Are acts, omissions or decisions of public and private institutions active in the healthcare sphere subject to judicial or administrative review following a complaint from interested parties?

Not applicable.

Whistle-blowers

40 | Are there any legal protections for whistle-blowers?

The Whistle-blower Protection Act protects persons who expose information pertaining to certain criminal conduct or statutory violations from unfair treatment as a result of their disclosure. Under this Act, whistle-blowers who uncover information of criminal or unlawful acts at their place of employment and inform their employers of the information are protected from retribution in the form of dismissals, demotions, salary cuts, termination of dispatch arrangement and other disadvantages. If whistle-blowers expose such information to a third party, they only enjoy statutory protection if they meet certain conditions, such as where evidence is likely to be destroyed or when the employer fails to notify the whistle-blower within 20 days that it will investigate the complaint.

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41 | Does the country have a reward mechanism for whistle-blowers?

There is no reward mechanism for whistle-blowers.

42 | Are mechanisms allowing whistle-blowers to report infringements required?

There are no legal requirements for the establishment and implementation of such mechanisms. However, the Whistle-blower Protection Act imposes certain mandatory obligations upon private and public organisations upon receipt of a report from a whistle-blower. Employers must notify the whistle-blower in writing, without delay, what steps it will take to remedy the problem or whether there is insufficient evidence to support the complaint. Government agencies must respond by investigating the whistle-blower's complaint and taking any necessary remedial action.

CROSS-BORDER ENFORCEMENT AND EXTRATERRITORIALITY

Cooperation with foreign counterparts

43 | Do prosecutors and law enforcement authorities in your country cooperate with their foreign counterparts in healthcare cases?

The Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) collaborate with foreign authorities, such as the US Food and Drugs Administration and the European Medicines Agency, on various activities such as Good Manufacturing Practice inspections.

Triggering investigations

44 | In what circumstances will enforcement activities by foreign authorities trigger an investigation in your country?

The MHLW and PMDA collaborate with foreign authorities when necessary. Memorandums and confidentiality arrangements have been executed by Japan with certain countries for effective collaboration. This collaboration includes the exchange of information between the Japanese authorities and their foreign counterparts.

Pursuing foreign entities for infringement

45 | In what circumstances will foreign companies and foreign nationals be pursued for infringements of your country's healthcare laws?

The Act on Securing the Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, in principle, does not apply outside Japan. However, if a foreign company is a holder of a marketing approval or authorisation in Japan, such approval or authorisation may be cancelled and it or its distributor can no longer manufacture or distribute its products in Japan.

UPDATE AND TRENDS

Key developments of the past year

46 | What are the authorities' enforcement priorities likely to be in the coming year? Are there any noteworthy cases pending? Are there any current developments or emerging policy or enforcement trends that should be noted?

Major revisions to the Drugs and Medical Devices Act was passed by the Diet in December 2019, and the first set of revision took effect in the autumn of 2020, subsequently, the second set in 2021 and the last is due in 2022.

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While the revisions cover various topics, one of the revisions receiving a lot of attention is the requirement of constructing the internal governance structure in drugs and medical device companies for the purpose of complying with the regulations applicable to drugs and medical devices.

Coronavirus

47 | What emergency legislation, relief programmes and other initiatives specific to your practice area has your state implemented to address the the pandemic? Have any existing government programmes, laws or regulations been amended to address these concerns? What best practices are advisable for clients?

The Ministry of Health, Labour and Welfare (MHLW) released several policy guidance in order to cope with the current pandemic.

For example, traditionally, the use of telehealth and telemedicine by doctors has been strictly regulated in Japan. However, owing to the emerging strong demand to receive healthcare services at home where possible, MHLW has released policy guidance that enables much easier access to telehealth and telemedicine services.

Another example is an expedited process for the issuance of the marketing authorisation of new drugs and medical devices. While we do not have the official regulatory framework of the emergency use authorisation, the Ministry of Health, Labour and Welfare and the Pharmaceuticals and Medical Devices Agency have issued marketing authorisations in surprisingly short periods of time for certain new drugs and medical devices, such as coronavirus test kits and artificial intelligence for diagnosis, to cope with the pandemic.

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