Life Sciences

In 25 jurisdictions worldwide

Contributing editor
Alexander Ehlers

2015

GETTING THE DEAL THROUGH

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Law Business Research

THE QUEEN'S AWARDS FOR ENTERPRISE: 2012

Published by
Law Business Research Ltd
87 Lancaster Road
London, W11 1QQ, UK
Tel: +44 20 7908 1188
Fax: +44 20 7229 6910

First published 2010
Sixth edition
ISSN 2042-4329

Printed and distributed by
Encompass Print Solutions
Tel: 0844 2480 112

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Japan

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Organisation and financing of health care

1 How is health care in your jurisdiction organised?

In Japan, two systems coexist: the national health insurance system (NHIS) and private health insurance, the latter being taken out voluntarily by individuals.

The NHIS, a public health-care system that covers the entire country, was established in 1961. Under the NHIS, the country is, in principle, entitled to all types of medical care services (including medical treatments and drugs) provided by medical institutions. Patients (insured) pay a portion of the medical fees to medical institutions on each visit (see question 2). Being a public health-care system, the NHIS allows every patient to freely choose, without any restrictions, the medical institution that will provide the medical treatment. It is worth noting that medical fees in Japan are almost the same in all medical institutions that provide the same kind of medical services.

In addition to the NHIS, private health insurance provided by insurance companies is also available. It is taken out voluntarily by individuals to cover the portion of the medical fees they bear under the NHIS (see question 2). Private health insurance is typically important in cases of prolonged hospitalisation or medical treatments requiring high costs, such as surgical operations.

In Japan, medical costs have been rapidly increasing primarily due to the steep rise in the ageing population, which could potentially contribute to a future collapse of the NHIS. To partly address this issue, a new health-care system designed for those aged 75 and over, called the 'health-care system for the latter-stage elderly', was established on 1 April 2008.

2 How is the health-care system financed in the outpatient and in-patient sectors?

The NHIS is financed by insurance payments made by the general public and public funds from the national and local governments. In addition, patients (insured) bear a portion of the costs of medical care as follows:

- 10 per cent (or 30 per cent for those with income above a certain level) for those aged 75 and over;
- 20 per cent (or 30 per cent for those with income above a certain level) for those aged 70 to 74. This percentage has been tentatively reduced to 10 per cent by a government welfare policy, but those who reach the age of 70 after 1 April 2014 shall bear the 20 per cent portion;
- 30 per cent for those aged six to 69; and
- 20 per cent for those aged five and below.

Under the NHIS, there is no distinction between the outpatient and in-patient sectors. However, private health insurance is financed by the insurance premiums paid by the insured, and the coverage of such insurance (ie, whether both outpatient and in-patient services are covered) depends on the type of insurance obtained by the insured.

Compliance – pharmaceutical manufacturers

3 Which legislation governs advertising of medicinal products to the general public and health-care professionals?

The Pharmaceutical Affairs Act (PAA) governs the advertising of medicinal products to the general public and health-care professionals.

In addition to the PAA, the 'Notice of Fair Advertisement Criteria for Medical Products' (Advertisement Criteria) was issued by the chair of the Pharmaceutical Affairs Bureau of the Ministry of Health, Labour and Welfare (MHLW) on 9 October 1980 to set out certain guidelines in respect of advertising medical products.

4 What are the main rules and principles applying to advertising aimed at health-care professionals?

The rules and principles provided in the PAA and the Advertisement Criteria do not make any distinction between advertising aimed at health-care professionals and advertising aimed at the general public, except for the following: the use of expressions in advertisements aimed at the general public that imply a certain disease may be cured without any medical treatment by a doctor is strictly prohibited.

This means that, other than the above point, the specific rules and principles applicable to advertising aimed at the general public (see question 5) also apply to advertising aimed at health-care professionals. Please note, however, that a certain portion of such applicable rules and principles varies depending on the nature of the medicinal products, namely, prescription drugs or non-prescription drugs including over-the-counter (OTC) drugs. Non-prescription drugs may be advertised to the general public while, in respect of prescription drugs, advertising aimed at the general public is prohibited.

5 What are the main rules and principles applying to advertising aimed at the general public?

Article 66 of the PAA prohibits, inter alia, false or exaggerated advertisements and advertisements implying abortion or using obscene writings or images. Further, article 67 of the PAA provides that advertisements of drugs for certain diseases stipulated in article 64 of the relevant cabinet order may be restricted by ministerial ordinance. The Enforcement Order of the PAA and the MHLW ordinance restrict advertising of drugs for cancer, sarcoma and leukaemia by only allowing advertisements of such ailments to be aimed primarily at medical professionals. Furthermore, article 68 of the PAA prohibits advertisement of medical products prior to marketing approval. Under the PAA, a violation of article 66 or article 68 is subject to imprisonment for up to two years or a fine of up to ¥2 million (or both), and a violation of article 67 and the related MHLW ordinance is subject to imprisonment for up to one year or a fine of up to ¥1 million (or both).

In addition to the PAA, the Advertisement Criteria:

- set forth the purpose of the Advertisement Criteria (ie, to prevent false or exaggerated advertisements and to rectify inappropriate advertisements);
- oblige the advertiser to communicate correct information; and
- provide for detailed guidelines regarding the advertisement of medical products in respect of the following matters:
  - restrictions on the use of product names;
  - restrictions on expressions relating to manufacturing methods;
  - restrictions on expressions relating to efficacy and safety;
  - prohibitions against advertisements that may lead to abuse;
  - prohibitions against advertisements of prescription drugs aimed at the general public;
  - restrictions on expressions used in advertisements aimed at the general public (where such advertisement implies that certain diseases may be cured without medical treatment by doctors);
  - cautionary notes for addiction-forming drugs;
  - notice of precautions, if necessary;

- prohibitions against dyslogistic advertisement of other companies' products;
- prohibitions against endorsements by health-care professionals;
- restrictions on advertisements for prize promotions;
- prohibitions against intimidating advertisements, especially by e-mails;
- guidelines on advertising of medical products on television or radio shows;
- prohibitions against emphasising the use of medical products for cosmetic or food purposes; and
- prohibitions against advertisement that injures the integrity or credibility of medical products.

6 What are the most common infringements committed by manufacturers with regard to the advertising rules?

One of the most common infringements committed by manufacturers with regard to the advertisement rules and principles is the advertising of nutritional fortification products that declare efficacy not shown in the relevant marketing approval (these are considered to violate the Advertisement Criteria regarding restrictions on expressions relating to efficacy and safety; see question 5).

7 Under what circumstances is the provision of information regarding off-label use to health-care professionals allowed?

Provision of information regarding off-label use is not prohibited as long as it is only aimed at health-care professionals.

It should be noted that in Japan, off-label use is allowed at the discretion of the doctor, despite the official position of the MHLW being that drug manufacturers should obtain marketing approval for such use.

8 Which legislation governs the collaboration of the pharmaceutical industry with health-care professionals? Do different rules apply regarding physicians in the outpatient and in-patient sectors?

To ensure fair competition, the Act against Unjustifiable Premiums and Misleading Representations prohibits, inter alia, the inducement of customers by means of unjustifiable premiums to ensure fair competition. Based on this Act, the Restrictions on Premium Offers in the Ethical Drugs Industry, Medical Devices Industry, and Hygienic Inspection Laboratory Industry (Restrictions on Premium Offers) and the Fair Competition Code concerning Restriction on Premium Offers in the Ethical Drugs Industry (Fair Competition Code), the latter being a form of self-regulation by the industry, have been promulgated. These rules govern the collaboration of the pharmaceutical industry with health-care professionals.

In addition, the National Public Service Ethics Act (NPSEA) also governs such collaboration to some extent as most important health-care professionals are national public officers in Japan. There is no difference between the outpatient and in-patient sectors.

9 What are the main rules and principles applying to the collaboration of the pharmaceutical industry with health-care professionals?

The Restrictions on Premium Offers provide that the pharmaceutical industry shall not offer, as a means of unjustifiably inducing transactions involving ethical drugs, medical devices or hygienic inspection, any premiums to medical institutions and other similar institutions beyond that which is necessary for the use of ethical drugs, medical devices or hygienic inspection, or reasonable in light of normal business practice.

The Fair Competition Code also provides that the pharmaceutical industry shall not offer premiums to medical institutions and other similar institutions as a means of unjustifiably inducing transactions involving ethical drugs.

Under the NPSEA, health-care professionals who are national public officers of a certain rank are obliged to report and disclose certain gifts of money, articles, entertainment or other benefits that they receive from business operators. Pursuant to the NPSEA, the National Public Service Ethics Code has been promulgated to, inter alia, prohibit such officers from receiving certain gifts from those who have any interests in the performance of their duties.

In addition to the above rules and principles, the Promotion Code for Ethical Drugs (Promotion Code) has also been promulgated by the Japan Pharmaceutical Manufacturers Association (JPMA), a voluntary organisation of drug makers. The Promotion Code provides that JPMA members should abide by the PAA, the Act on the Prohibition of Private Monopolisation and Maintenance of Fair Trade (Anti-monopoly Act), the Fair Competition Code and other applicable laws and regulations.

10 What are the most common infringements committed by manufacturers with regard to collaboration with health-care professionals?

The provision of excessive entertainment by manufacturers is the most common infringement. However, it is often difficult to clearly determine to what extent entertainment is considered acceptable as far as professional behaviour goes, and to what extent it may be considered beyond the bounds of socially accepted norms.

11 What are the main rules and principles applying to the collaboration of the pharmaceutical industry with patient organisations?

There are currently no rules or principles applying to the collaboration of the pharmaceutical industry with patient organisations. Such collaboration is therefore not common in Japan. We do note, however, that the JPMA provides symposia, workshops, educational campaigns and other support to patient organisations.

12 Are manufacturers' infringements of competition law pursued by national authorities?

Yes. Such infringements are pursued by the Japanese Fair Trade Commission (JFTC) and the Consumer Affairs Agency. Insofar as infringements of the Act against Unjustifiable Premiums and Misleading Representations are concerned, the Fair Trade Council of the Ethical Pharmaceutical Drugs Marketing Industry (FTC of the EPDMI) is an organisation officially authorised by the JFTC and the Director-General of the Consumer Affairs Agency to conduct self-regulation regarding restrictions on the provision of unjustifiable premiums. In practice, as long as a manufacturer is a member of the FTC of the EPDMI, it exercises preliminary supervision over such manufacturer regarding the provision of unjustifiable premiums on the basis of such membership.

13 Is follow-on private antitrust litigation against manufacturers possible?

For certain violations by manufacturers of the Anti-monopoly Act, private litigation seeking injunctions or claiming for damages are allowed under the Anti-monopoly Act and the Civil Code. Note, however, that these litigations are private and based on tort liability, not through the anti-monopoly procedure. In addition, as to litigation seeking injunctions, while this is theoretically possible, no actual case has been filed to date.

Compliance – medical device manufacturers

14 Is the advertising of medical devices and the collaboration of manufacturers of medical devices with health-care professionals and patient organisations regulated as rigorously as advertising and collaboration in the pharmaceuticals sector?

Yes. The advertising of medical devices is regulated as rigorously as the advertising of medicinal products (see questions 3 to 5). Except for article 67 of the PAA, which only applies to medicinal products for designated special diseases, the pertinent provisions on advertising under the PAA also apply to the advertising of medical devices.

In the same manner, the collaboration of manufacturers of medical devices with health-care professionals is also regulated as rigorously as the collaboration in respect of medicinal products (see questions 8 and 9).

As regards collaboration with patient organisations, see question 11.

Pharmaceuticals regulation

15 Which legislation sets out the regulatory framework for granting marketing authorisations and placing medicines on the market?

The PAA (together with the orders, regulations, notices and guidelines issued pursuant thereto) sets out the regulatory framework for granting marketing authorisations and placing medicines on the market.

16 Which authorities may grant marketing authorisation in your jurisdiction?

As a general rule, any person intending to market a medicinal product must obtain approval for marketing such a product. The Minister of the MHLW (Minister) has the authority to grant the approval for marketing medicinal products, although the prefectural governors may exercise such authority in certain circumstances (such as approval for cold medicines). This occurs after review and examination in respect of the approval for marketing medicinal products, performed by the Pharmaceuticals and Medical Devices Agency (PMDA), except where such review and examination has been undertaken by the relevant prefectural governor.

To obtain approval for marketing medicinal products, generally speaking, there are two steps involved:

- the manufacturing establishment of the medicinal products must obtain a licence for the manufacture of such products; and
- the person intending to market a medicinal product must obtain a licence for marketing such a product.

17 What are the relevant procedures?

In brief, the procedure for obtaining the approval for marketing medicinal products (as mentioned in question 16) is as follows.

Clinical trials must be performed to collect data that is necessary for the application. In essence, clinical trials performed before the application consist of phase I (for a small number of healthy adults); phase II (for a small number of patients); and phase III (for a large number of patients).

After clinical trials, any person intending to market a medicinal product must file an application with the PMDA for approval to market such a product. The PMDA then reviews and examines such application, and reports the results of such review to the Minister. The Minister then decides whether to grant the approval to market the products based on the report of the PMDA.

As regards licences for manufacturing or marketing, applications must be filed for the issuance of such licences with the Minister or prefectural governors (as the case may be).

18 Will licences become invalid if medicinal products are not marketed within a certain time? Are there any exceptions?

Under article 74-2(3)(vi) of the PAA, the Minister may cancel any approval issued in respect of medicinal products, or order partial changes to any such approval if the relevant medicinal products have not been manufactured or marketed for three consecutive years without justifiable reasons. In practice, when the relevant medicinal products have not been manufactured or marketed for three consecutive years, the Minister would urge the companies to voluntarily withdraw the approval, and these companies tend to comply with the Minister's request for withdrawal of approval.

For commercial supply to occur, in addition to a marketing approval, ethical drugs must be listed on the National Health Insurance Drug Price Standard (NHI Drug Price Standard), which is provided by the Minister in accordance with the Health Insurance Act. The listed drugs need to be commercially provided within three months after their listing on the NHI Drug Price Standard. If the manufacturer fails to abide by this timeline, it will receive an administrative inquiry and advice or direction from the MHLW regarding the reason for not providing the products. However, this does not mean that the marketing licence or approval is cancelled or invalidated.

19 Which medicines may be marketed without authorisation?

The following medicinal products may be marketed without the authorisation described in questions 16 and 17:

- medicinal products with standards specified and designated by the Minister (it should be noted that medicinal products recognised in the Japanese Pharmacopeia can be included in such medicinal products designated by the Minister); and
- in vitro diagnostic reagents specified and designated by the Minister (in lieu of authorisation, such diagnostic reagents should have been certified to be marketable by the registered certification body).

20 Are any kinds of named patient programmes in place? If so, what are the requirements for pre-launch access?

In Japan, there is no generally available system or programme equivalent to a named patient programme. However, there are three actual cases in which pre-approved drugs were provided under the supervision of the government authority from a humanitarian point of view as these drugs were for the treatment of life-threatening diseases for which there were no alternative therapeutic measures. Tropical disease drugs and AIDS curative drugs are being provided free of cost to a study group by the MHLW. For the treatment of leprosy, pre-approved curative drugs were obtained by the government and provided at national sanatoria (leprosy was covered by off-label use after 2008 when thalidomide was approved for other diseases).

A report of a working group at the MHLW issued in 2007 stated that:

- the current approval system should be maintained continuously;
- nevertheless, the necessity of a compassionate use system is recognised for serious diseases with no effective therapeutic measures; and
- compassionate use should be introduced as long as it does not interfere with the current approval system.

At present, the system is under discussion, although the government takes a relatively conservative position on it.

Pricing and reimbursement of medicinal products

21 To what extent is the market price of a medicinal product governed by law or regulation?

Medical examinations and treatments covered by the NHIS are known as 'health insurance treatment'. The cost of health insurance treatment, which consists of compensation for medical services given by medical institutions, the price of medical drugs and medical materials, is determined entirely by the National Health Insurance Act and related regulations. As previously mentioned, patients (insured) pay 10, 20 or 30 per cent (depending on, inter alia, age; see question 2) of the price of health insurance treatment to medical institutions on each visit. There is no distinction between the outpatient and in-patient sectors.

The (official) price of a medicinal product is determined by the NHI Drug Price Standard (see question 18). The NHI Drug Price Standard governs the price of medicinal products, which is paid by the NHIS (and individual patients who pay the said percentage of the price) to medical institutions and pharmacies. The NHI Drug Price Standard does not regulate the market price between manufacturers and wholesalers, and between wholesalers and medical institutions or pharmacies. Usually, manufacturers provide their medical products to medical institutions and pharmacies at a price lower than the price in the NHI Drug Price Standard. The NHI Drug Price Standard is reviewed periodically (currently every two years) in keeping with the diminishing market price.

22 Must pharmaceutical manufacturers negotiate the prices of their products with the public health-care providers?

The price of medicines and medical treatments are determined by the NHIS (see question 24), and medicines and medical treatments are provided to the patients at such listed price.

Pharmaceutical manufacturers do not negotiate the price of their products with public health-care providers (such as medical institutions and pharmacies). Usually, pharmaceutical manufacturers distribute their products to medical institutions through pharmaceutical wholesalers. The negotiation for a wholesale price (including rebate and allowance) is conducted between pharmaceutical manufacturers and pharmaceutical wholesalers in consideration of the price determined by the NHIS.

Pharmaceutical manufacturers not only sell their products to wholesalers, but also send their own medical representatives to medical institutions to provide information about their products and to collect feedback from physicians and pharmacists. However, manufacturers should not negotiate the prices of their products, because if the manufacturers negotiate the retail price with medical institutions, they might be held liable for unfair resale price maintenance, which is prohibited under the Antimonopoly Act.

23 In which circumstances will the national health insurance system reimburse the cost of medicines?

The price of medicines and medical treatments covered by the NHIS is determined by the NHI Drug Price Standard and Central Social Insurance Medical Council. Patients are required to pay only a portion of the price (10 , 20 or 30 per cent, depending on, inter alia, age; see question 2) to medical institutions on each visit as long as the patient shows his or her insurance card. In that sense, it is not a reimbursement system, but the patients are only required to pay a portion of the price. There is no limit

to the health insurance treatment under the NHIS. In addition, if payment exceeds a certain level in the same month at the same medical institution due to extensive hospitalisation or advanced and complicated treatment, patients are reimbursed for all or 99 per cent of the amount exceeding that level (the reimbursement is calculated based on the patient's household income). There is no distinction between the outpatient and in-patient sectors.

If patients use medical services not covered by the NHIS, they shall bear the entire cost of such medical services. Medical services not covered by the NHIS include the use of unapproved medical drugs, off-label use of approved medical drugs, ordinary orthodontics, cosmetic surgery, and normal pregnancy and parturition (because normal pregnancy and parturition are not deemed to be injuries or diseases).

For reference, off-label use of approved medical drugs may be covered by the NHIS under exceptional circumstances.

24 If applicable, what is the competent body for decisions regarding the pricing and reimbursability of medicinal products?

The competent body for decisions regarding the price of medicinal products is the Minister. The Minister provides the NHI Drug Price Standard, which determines the price of new medicinal products paid by the NHIS to medical institutions and pharmacies by reference to, in principle, the price of existing similar medicinal products. As the actual market price of medicinal products sold from the manufacturing companies or distributors to medical institutions or pharmacies usually differs from the price paid by the NHIS, the Minister conducts research into such actual market price. Based on the outcome of such research, the Minister revises the NHI Drug Price Standard once every two years, in principle. In relation to generic drugs, the price is set at around 60 to 70 per cent of the corresponding original drug price when the generic version is first approved. If other generic versions have already been approved, the price is set to the lowest among the other generic versions available in the market.

The competent body for decisions regarding reimbursement (ie, whether the products are covered by the NHIS) is the Health Insurance Claims Review & Reimbursement Service (HICRRS). The review committee of the HICRRS examines whether individual use of the medicinal products is covered by the NHIS from its medical perspective. In this regard, off-label use of approved medicinal products is, in principle, not covered by the NHIS. However, there are some exceptions, and the review committee publicly announces specific cases where certain off-label use is covered by the NHIS. It should be noted that the HICRRS states that each review is conducted on a case-by-case basis and, therefore, the announced cases should not be used as precedents.

25 Are manufacturers or distributors of medicinal products statutorily obliged to give a discount?

There is no such statutory obligation to give a discount under Japanese law.

Medicine quality and access to information

26 What rules are in place to counter the counterfeiting and illegal distribution of medicines?

If, for instance, (i) the active ingredients of any counterfeit medicines are patented, (ii) the product names of any counterfeit medicines are identical or similar to any registered trademark, or (iii) the product names of any counterfeit medicines are identical or similar to any well-known marks, the manufacture and distribution of such counterfeit medicines would be prohibited by the Patent Act (for (i)), the Trademark Act (for (ii)) and the Unfair Competition Prevention Act (for (iii)).

The owner of the patent, registered trademark or well-known mark is entitled to seek an injunction against the manufacture and distribution of the counterfeit medicines, destruction of the counterfeit medicines possessed by the counterfeiter, and damages caused by the illegal manufacture and distribution of the counterfeit medicines. In addition, violations of these acts are subject to criminal penalties. For instance, under the Patent Act, the infringer of a patent right is subject to imprisonment of up to 10 years or a fine of up to ¥10 million, or both (imposable on individual offenders, ie, employees) and a fine of up to ¥300 million (imposable on the employer company).

In addition, the manufacture and marketing of unapproved medicines is prohibited by the PAA. Any violation of the PAA in this regard is subject to administrative penalties (suspension of business) and criminal penalties (imprisonment or fine).

27 What recent measures have been taken to facilitate the general public's access to information about prescription-only medicines?

The PMDA provides an online database of the package inserts of medicines (both prescription-only and OTC medicines). In addition, the PMDA also discloses online the minutes of the deliberations on the approval of applied medicines online. Accordingly, the general public may access the PMDA website and obtain information regarding any medicines.

Further, under the general procedure for information disclosure, the general public may request the MHLW to disclose any documents and materials submitted in connection with the application for the approval of medicines. However, the major part of the disclosed documents is usually redacted for the protection of the trade secrets of the applicants, and the request usually takes several months to be acted upon. Due to the foregoing reasons, this alternative may not be a very effective way for the general public to access important information about medicines. The amended PAA stipulates that manufacturers should draft package inserts based on the latest knowledge available and notify them to the Minister. Immediately after the notification, the manufacturers must also announce the information concerning the package inserts through the PMDA website.

28 Outline major developments to the regime relating to safety monitoring of medicines.

Post-marketing surveillance (PMS) is required pursuant to the PAA to ensure the effectiveness and safety of approved medicines. It was first introduced in 1967, whereby marketing approval holders were required to report any adverse reactions for two years after obtaining marketing approval. Since then, several changes have been made to the system. The current PMS consists of three systems: the adverse reaction and infection reporting system, the re-examination system and the re-evaluation system.

As regards the adverse reaction and infection reporting system, where marketing approval holders have knowledge of any adverse reaction or infection relating to the approved medicines, they must generally notify the MHLW within 15 days or 30 days (depending on the severity thereof).

With respect to the re-examination system, new medicines must be re-examined after approval, with the effectiveness and safety of an approved medicine being re-examined in view of the data collected during the re-examination period, which lasts for eight years, in principle, after approval. If a problem is discovered during the re-examination, the marketing approval may be cancelled.

Regarding the re-evaluation system, marketing licence holders are required to perform a re-evaluation of the approved medicines in order to monitor the effectiveness and safety thereof upon instruction from the MHLW. Similar to the re-examination system, if a problem is discovered as a result of the re-evaluation, the marketing approval may be cancelled.

The means of implementation of PMS is stipulated under the Good Post-Marketing Study Practice Ordinance and Good Vigilance Practice Ordinance.

For reference, with respect to the re-examination system, since the data submitted at the time of the application for the approval of new medicines is not available to generic drug companies to support their applications for approval during the re-examination period, the re-examination system effectively works as a data exclusivity system in Japan.

Vaccination

29 Outline your jurisdiction's vaccination regime for humans.

Japan's modern government vaccination programme started after World War II. The programme was initially compulsory, and avoiding vaccinations without justifiable reason was subject to penalties. However, as infectious diseases decreased over time, vaccinations came to be viewed as less important, while their side effects were increasingly considered as social problems. As a result, in 1994, the legal obligation to have any vaccination was abandoned, and the Preventive Vaccination Act (Act) now only requires individuals to make efforts to have vaccinations that are designated by the Act and relevant rules and orders.

The Japanese vaccination system is administrated by the MHLW. (However, the register of vaccinations administered is maintained by local governments, which are generally required to keep such records for five years.) In 2013, the Act was reviewed and amended (2013 Amendment)

Update and trends

Amendments to the PAA
Two bills to amend the PAA were promulgated on 27 November 2013 (November Amendment) and on 13 December 2013 (December Amendment) respectively. The former will become effective on 25 November 2014 (as of October 2014), while the latter became effective from 12 June 2014. The concepts under the November Amendment are as follows:

Enhancing safety measures in relation to pharmaceutical drugs and medical devices
- Redefine the purpose of the PAA to clarify the position on the implementation of regulations to prevent the occurrence or spread of danger against health and hygiene (article 1).
- Impose responsibilities on the relevant parties (ie, the national and local governments, manufacturers, health-care professionals and citizens) in relation to maintaining the quality, validity and safety of pharmaceutical drugs, medical devices and regenerative medical products, etc, and the proper use of such products (articles 1–2 to 1–6).
- Pharmaceutical manufacturers must prepare package inserts based on the most up-to-date knowledge and notify the MHLW thereof. After the notification, the pharmaceutical manufacturers must release the information through the PMDA website (article 55-2).

Regulations regarding medical devices
- Separate the provisions for the sale and manufacture of medical devices from those for pharmaceutical drugs due to the distinct features of medical devices, such as that they are released to the market in short cycles, and that their efficiency is very dependent on the skills of health-care professionals. To reflect this policy, the title of the PAA has been changed to The Act regarding Quality, Efficacy and Safety of Medicinal Products and Medical Devices.
- Extend the authentication system handled by private organisations to cover high-level administrated medical devices (article 23-2-23).
- Stand-alone software programs will be included in the definition of medical devices and subject to approval and authentication.
- The manufacture of medical devices will be simplified and become subject to the registration system (article 23-2-3).
- Rationalise the examination of compliance of the manufacture and maintenance of medical devices. For instance, the examination will not be conducted for individual products but for similar product groups (article 23-2-5 (vii)).

Regulations regarding regenerative medical products
- Define 'regenerative medical products' and provide safety regulations in view of its nature (ie, its quality differs depending on the individual differences).
- Enable especially prompt grants of marketing conditional approval if the feasibility of a regenerative medical product is presumed and if the safety thereof is confirmed. For reference, Riken and the Foundation for Biomedical Research Innovation performed a retina transplant using iPS cells made from the patient's skin on 12 September 2014. This is the first case of transplant by means of iPS cells in the world.

The concepts under the December Amendment are as follows:

Regulations regarding the methods of marketing medical drugs
- This amendment reflects a Supreme Court decision of 1 January 2013. The Supreme Court ruled that a regulation prohibiting Category 1 and Category 2 OTC drugs was null and void. As a result of the decision, almost all non-prescription drugs can be sold through the internet, except powerful drugs and drugs that were prescription drugs less than three years ago.
- Impose responsibilities on pharmacists, such as requiring them to give purchasers correct information and to confirm the age of the purchasers.

Enhancing safety measures in relation to designated drugs
- Give drug agents the same powers as police officers to crack down on designated drugs, also known as 'law-evading drugs', in reaction to the recent spread of designated drugs (article 76-9).
- Prohibit the possession of designated drugs other than for medical purposes (article 76-4).

in response to the swine flu pandemic in 2011. Two of the main purposes of the 2013 Amendment are to give flexibility to the government vaccination programme by allowing the Minister of the MHLW to formulate a Preventative Vaccination Basic Plan and to review it every five years; and to resolve the 'vaccination gap' problem, where the number of vaccines supported by the Japanese government is lower than in other developed countries by adding haemophilus influenza type b, pneumococcal and HPV to the government vaccination programme.

The government vaccination programmes
The diseases targeted by the government vaccination programmes are classified into 2 groups; Category A and Category B.

Category A diseases are defined as 'diseases which should be included in the vaccination programme in order to prevent their occurrence and transmission, taking into consideration (i) their capability of being transmitted from one person to another; and (ii) their severity or potential severity', and include the following diseases: diphtheria, pertussis, polio, tetanus, measles, rubella, Japanese encephalitis, BCG, haemophilus influenza type b, pneumococcal, HPV and smallpox.

Category B diseases are defined as 'diseases which should be included in the vaccination programme in order to prevent individual pathogenesis or severe symptoms, as this will prevent the transmission of such diseases', and include influenza.

The government vaccination programme involves two types of vaccinations: routine vaccination and temporary vaccination. In addition, there is also voluntary vaccination, which exists outside of the government vaccination programmes in terms of funding.

Routine vaccination
Routine vaccination is carried out on a routine basis against predetermined individuals who may be affected by the relevant Category A or Category B disease (excluding smallpox). The individuals that are subject to routine vaccination and the date or period for being vaccinated are preliminary determined by the governors of the local government. If such governors recommend individuals to receive a routine vaccination, such individuals or their guardians should make reasonable efforts to have the vaccination administered. However, it is not mandatory to receive a routine vaccination.

Temporary vaccination
If the governors of the local governments find that there is an urgent necessity for vaccinations to prevent the transmission of a Category A or Category B disease, they may recommend designated individuals to receive temporary vaccinations at a designated time or period. If such a recommendation is made, the designated individuals or their guardians should make reasonable efforts to have the vaccination administered. However, it is not mandatory to receive a temporary vaccination.

Voluntary vaccination
Individuals can voluntarily receive vaccinations for diseases that are not listed as Category A and Category B diseases, provided they must bear all expenses. Further, vaccinations for Category A and Category B diseases that are received outside the designated date or period are considered to be voluntary vaccinations and the recipients of such vaccinations must bear all expenses.

Costs for vaccinations
Most of the costs for routine and temporary vaccinations are covered by public financial support, and some local governments even provide them for free. However, the costs for voluntary vaccinations must be fully borne by recipients.

Under the Act, it is provided that if any damage to health is caused by routine or temporary vaccinations, the governors of local governments shall provide relief measures. With respect to voluntary vaccinations, individuals may receive relief through the relief system provided by the PMDA for injuries to health caused by pharmaceutical products with adverse effects.

Reporting obligations

All medical agencies that provide routine and temporary vaccinations, individuals that receive vaccinations, and their guardians shall report any damage to health caused by routine or temporary vaccinations (or both) to the MHLW.

If the MHLW receives such a report, it may ask the PMDA to investigate the case. Based on the investigation results of the PMDA, the MHLW, in close cooperation with the National Institute of Infectious Diseases, will organise all information concerning the adverse effects of the vaccination, report such information to each local government and recommend necessary measures to be taken to prevent the adverse effects.

WHO targets for vaccination

As of 1 August 2013, the WHO recommends routine vaccinations against the following diseases: BCG, hepatitis B, polio, DTP, haemophilus influenza type b, pneumococcal, rotavirus, measles, rubella and HPV.

The above-mentioned 2013 Amendment to the Act added haemophilus influenza type b, pneumococcal and HPV to the list of Category A diseases as of April 2013, and, as a result, the government vaccination programmes now cover all the routine vaccinations recommended by the WHO, except for hepatitis B and rotavirus vaccinations.

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