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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 voluntarily by people.

The NHIS, a public health-care system that covers the entire country, has been established since 1961. Under the NHIS, the country is, in principle, entitled to all types of medical care service (including medical treatment and drugs) provided by medical institutions. Patients (insured) pay a portion of the medical fees to the medical institutions on each visit (please 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 providing the same kind of medical services.

In addition to the NHIS, private health insurance provided by insurance companies is also available. It is taken voluntarily by people to cover the portion of the medical fees they bear under the NHIS (please 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 rising 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. However, this new system has been strongly criticised by the media and political parties in Japan primarily because part of the elderly population is required to bear a larger share of the medical costs, and such system also encourages discrimination based on age. Recently, the Democratic Party of Japan (which has become the ruling party after the House of Representatives election in September 2009) announced the abolition of the system. The current situation relating to this new system remains unpredictable.

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

The NHIS is financed by insurance payments made by the general public and public funds from the national and local governments. In addition, (insured) patients 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;
- 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 inpatient 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 inpatient services are covered) depends on the type of insurance obtained by the insured.

Compliance – pharmaceutical manufacturers

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

The Pharmaceutical Affairs Act (the 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' (the Advertisement Criteria) was issued by the chairman of the Pharmaceutical Affairs Bureau of the Ministry of Health 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 that 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 vary 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 false or exaggerated advertisements and advertisements implying abortion or using obscene writings or images, among other things. Further, article 67 of the PAA provides that advertisements of drugs for certain diseases may be restricted by cabinet order. The Enforcement Order of the PAA restricts advertising of drugs for cancer, sarcoma and leukaemia by only allowing such advertisement to be aimed at medical professionals. Furthermore, article 68 of the PAA prohibits advertisement of medical products prior to marketing approval. Under the PAA, any violation of

these provisions is subject to imprisonment of up to two years or a fine of up to ¥2 million (or both) or imprisonment of 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;
- 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;
 - prohibition against advertisement 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;
 - prohibition against dyslogistic advertisement to other companies' products;
 - prohibition against endorsements by health-care professionals;
 - restrictions on advertisements for prize promotions;
 - prohibitions against intimidating advertisements;
 - 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
 - prohibition 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 advertisement rules?

According to the Bureau of Social Welfare and Public Health of the Tokyo metropolitan government, one of the most common infringements committed by manufacturers with regard to the advertisement rules is the advertising of nutritional fortification products that declares efficacy not included in the admitted efficacy as shown in the relevant marketing approval (these are considered to violate the Advertisement Criteria regarding restrictions on expressions relating to efficacy and safety; please 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.

Please note that in Japan, off-label use is allowed at the discretion of the doctor, although the official position of the MHLW is that drug manufacturers should obtain marketing approval for such use.

- 8** Which legislation governs the collaboration of the pharmaceutical industry with health-care professionals?

The Act against Unjustifiable Premiums and Misleading Representations prohibits, among other things, the inducement of customers by means of unjustifiable premiums, in order to ensure fair competition. Based on the above law, the Restrictions on Premium Offers in the Ethical Drugs Industry, Medical Devices Industry, and Hygienic Inspection Laboratory Industry (the Restrictions on Premium Offers) and the Fair Competition Code concerning Restriction on Premium

Offers in the Ethical Drugs Industry (the 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 (the NPSEA) also governs such collaboration to some extent as most important health-care professionals are national public officers in Japan.

- 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, or other benefits or entertainment that they receive from business operators. Pursuant to the NPSEA, the National Public Service Ethics Code has been promulgated to, among other things, 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 (the 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 (the 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 as such collaboration is not common in Japan. We do note, however, that the JPMA provides symposia, workshops, educational campaigns and other supports 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) is an organisation officially authorised by the JFTC 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, the FTC 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 injunction is allowed under the Anti-Monopoly Act. While this is theoretically possible, no actual case has been filed to date. Please note, however, that the filing of any claims for damages by a private party through the anti-monopoly procedure is not allowed under the Anti-Monopoly Act. Nonetheless, private litigation based on tort liability is possible.

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, please 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 product. The minister of health, labour and welfare (the 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 have been undertaken by the relevant prefectural governor.

In order to obtain approval for marketing medicinal products, roughly 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 products.

17 What are the relevant procedures?

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

Clinical trials must be performed in order 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 the approval to market such 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?

According to the PDMA, no licence has been invalidated due to the fact that the relevant medicinal products have not been marketed within a certain time limit. Please note, however, that 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.

19 Which medicines may be marketed without authorisation?

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

- medicinal products with standards specified and designated by the minister (please note 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 What, according to the legislation and case law, constitute medicinal products?

In general, products are classified as medicinal products based on their function. In particular, under the PAA, the following articles constitute medicinal products:

- any item recognised under the Japanese Pharmacopeia;
- any item (excluding quasi-drugs) that is intended to be used in the diagnosis, treatment or prevention of disease in humans or animals, and which is not a device; and
- any item (excluding quasi-drugs and cosmetics) that may affect any structure or function of the human or animal body but is not a device.

Pricing and reimbursement of medicinal products

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

The medical examinations and treatment 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, (insured) patients

pay 10 per cent, 20 per cent or 30 per cent (depending on age; see question 2) of the price of health insurance treatment to the medical institutions on each visit. There is no distinction between the outpatient and inpatient sectors.

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

The cost of medicines is not, in principle, reimbursed to patients. As stated in question 21, the price of health insurance treatment is entirely determined by law or regulation, and patients are only required to pay 10 per cent, 20 per cent or 30 per cent (depending on, among other things, age; see question 2) of the price of health insurance treatment to the medical institutions on each visit. Similarly, there is no distinction between the outpatient and inpatient sectors.

However, notwithstanding that the burden on patients is limited to 10 per cent, 20 per cent or 30 per cent (depending on, among other things, age; see question 2) of the cost of health insurance treatment, payment may become extraordinarily high due to extensive hospitalisation or advanced and complicated treatment. In such cases, patients are reimbursed for the amount exceeding a certain level.

On the other hand, 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 use of unapproved medical drugs, off-label use of approved medical drugs, ordinary orthodontics, cosmetic surgery, and normal pregnancy and parturition (please note that normal pregnancy and parturition are not deemed injury or disease).

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

23 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 MHLW. The MHLW 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 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 due to business negotiations between the suppliers (ie, manufacturing companies and distributors) and the users (ie, medical institutions and pharmacies), the MHLW conducts research into such actual price. Based on the outcome of such research, the MHLW revises the price of the medicinal products paid by the NHIS to medical institutions and pharmacies once every two years in principle. In relation to generic drugs, the price is set at 70 per cent of the corresponding original drug price when the generic version is first approved. If other generic versions have been already approved, the price is set to the lowest among the other generic versions available in the market.

The competent body for decisions regarding reimbursability (ie, whether the products are covered by the NHIS) is the Health Insurance Claims Review & Reimbursement Services (the HICRRS). The review committee of the HICRRS examines whether individual uses of the medicinal products are covered by the NHIS from its medical perspective. In this regard, off-label uses of approved medicinal products are, in principle, not covered by the NHIS. However, there are some exceptions, and the review committee has so far publicly announced 156 specific cases where certain off-label uses can be 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 above 156 cases should not be used as precedents.

Update and trends

Except for the possible abolition of the 'health-care system for the latter-stage elderly' (please see question 1), no legislative changes are presently expected that will have a major impact on the current legal environment with regard to medicine or medical devices in Japan. In general, however, the Japanese government has been working toward reducing medical costs. One such initiative is the MHLW focusing on the promotion of generic drugs in order to increase the market share of generic drugs (currently 20.2 per cent based on the number of units sold as of September 2009) to at least 30 per cent by fiscal year 2012.

24 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

25 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)) or the Unfair Competition Prevention Act (for (iii)).

The owner of the patent, registered trademark or well-known mark is entitled to seek 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 (impossible on individual offenders, ie, employees) and a fine of up to ¥300 million (impossible on the employer company).

In addition, the manufacture and marketing of unapproved medicines are 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).

26 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 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, 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.

27 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 the marketing approval. Since then, several changes of the system have been made, and 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 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, in which the effectiveness and safety of an approved medicine is re-examined in view of the data that

are 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 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 (GPSP Ordinance) and Good Vigilance Practice Ordinance (GVP 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.

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