Pricing & Reimbursement

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Japan

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Abstract

Market introduction/overview

National Health Insurance System

Japan maintains a national health insurance system called the "Universal Health Insurance Coverage System". The characteristics of such system are: (i) covering all citizens through public medical insurance; (ii) freedom of choice of medical institution; (iii) high-quality medical services at a low cost; and (iv) being based on the social insurance system, which allows spending from the public subsidy to maintain universal health insurance coverage.

The Japanese health insurance market is the second-largest in Asia and the third-largest in the world. The most important issue currently facing the Japanese system is the fact that national medical expenditure has been expanding due to the increasing population of elderly people and expensive drugs.

Pharmaceutical pricing and reimbursement

Regulatory classification/outline of regulation

The manufacture and sale of drugs in Japan are regulated by the Minister of Health, Labour and Welfare (the "MHLW"). The MHLW issues Marketing Licences (defined below) and Licences for Manufacturing (defined below) through delegating to other government entities, as described below. Only someone who has obtained the proper Marketing Licence can market pharmaceuticals that are: (i) approved (as described below); or (ii) manufactured by someone who has obtained a Licence for Manufacturing (as defined below) or imported from an accredited Foreign Manufacturer (as described below).

Marketing Licence

A Marketing Licence is necessary to market drugs in Japan. A Marketing Licence may be obtained from the governor of the prefecture designated by the MHLW. Such licence allows the holder to engage in the business of marketing pharmaceuticals, quasi-pharmaceutical products or cosmetics (the "Pharmaceuticals, Etc.").[1]

Depending on the type of product, there are several kinds of Marketing Licence, such as the First-class Marketing Licence for Pharmaceuticals (for prescription pharmaceuticals), and the Second-class Marketing Licence for Pharmaceuticals (for non-prescription pharmaceuticals). In order to obtain the Marketing Licence: (i) the methods of quality control for the Pharmaceuticals, Etc., must comply with good quality practice (the "GQP") specified by the Ministerial Ordinance on Good Quality Practice for Pharmaceuticals, Quasi-pharmaceutical Products or Cosmetics;[2,3] and (ii) the methods of post-marketing safety

control for the Pharmaceuticals, Etc., must comply with the good vigilance practice (the "GVP") specified by the Ministerial Ordinance on Good Vigilance Practice After Marketing for Pharmaceuticals, Quasi-pharmaceutical Products, Cosmetics, Medical Devices or Regenerative Medicine Products.[4,5]

Licence for Manufacturing

A Licence for Manufacturing is necessary to manufacture Pharmaceuticals, Etc. in Japan. A Licence for Manufacturing may be obtained from the governor of the prefecture or the Director of the Regional Bureau of Health and Welfare designated by the MHLW.[6] The Licence for Manufacturing shall be granted in accordance with the categories of: (i) biological preparations, pharmaceuticals manufactured using a genetically-modified technique, etc.; (ii) radioactive pharmaceuticals; (iii) aseptic pharmaceuticals; (iv) any products other than (i), (ii) and (iii); and (v) only the packaging, labelling and storing of the products set forth in (iii) and (iv). Generally, the Pharmaceuticals and Medical Devices Agency (the "PMDA") designated by the MHLW will conduct an investigation regarding any application for a Licence for Manufacturing.[7]

Additionally, a foreign manufacturer intending to manufacture Pharmaceuticals, etc. that are exported to Japan can be accredited by the MHLW.[8] Generally, the PMDA designated by the MHLW will conduct an investigation regarding such accreditation.[9]

Application for approval for marketing brand name pharmaceuticals

Any person who intends to market pharmaceuticals[10] must obtain approval from the MHLW for each such item.[11] Such person must hold a Marketing Licence[12] and such pharmaceuticals must be manufactured by the holder of a Licence for Manufacturing or imported from an accredited foreign manufacturer.[13] The methods to control manufacturing, or the quality of the pharmaceuticals[14] at that manufacturing facility, must comply with the good manufacturing practice (the"GMP") specified by the Ministerial Ordinance on Standards for Manufacturing Control and Quality Control for Drugs and Quasi-drugs.[15,16] In addition, any person engaged in manufacturing, etc. of pharmaceuticals in foreign countries (the "Foreign Manufacturer") may apply for approval for marketing pharmaceuticals from the MHLW through a holder of a Marketing Licence designated thereby.[17]

Such person shall make an application by attaching data concerning the results of clinical studies and other pertinent data to their written applications.[18,19] The type of data that must be attached depends on the type of pharmaceuticals: in the case of brand-name prescription pharmaceuticals, (i) data concerning the results of clinical studies collected by clinical trials,[20] which must be conducted in accordance with the good clinical practice (the "GCP") specified by the Ministerial Ordinance on Good Clinical Practice for Drugs;[21] and (ii) data collected and compiled in accordance with the good laboratory practice (the "GLP") specified by the Ministerial Ordinance on Good Laboratory Practice for Nonclinical Safety Studies of Drugs.[22,23]

Application for approval for marketing generics, biosimilars and non-prescription drugs

The approval process for generic drugs, biosimilars and non-prescription drugs is similar to that for brand-name pharmaceuticals. However, the data that must be attached to such application is different. In case of generic drugs, after such brand-name drugs are re-examined as described later, data concerning bioequivalence are needed instead of most of such data described above.[24] In case of a biosimilar, however, data concerning the results of clinical studies collected by clinical trials must be attached, though certain data regarding toxicity do not need to be attached. In case of non-prescription drugs, excluding those with

new active components, etc., such data do not need to be attached.

Application process for marketing approval

Generally, the PMDA designated by the MHLW will conduct an examination regarding an application for marketing approval.[25] The MHLW may prioritise an examination for orphan drugs, etc.[26] This includes drugs designated under the Precursor Designation Scheme. In order to be designated, the drug must satisfy the following four requirements: (i) it constitutes a breakthrough; (ii) its indication is serious; (iii) it has a very high efficacy for its indication; and (iv) the party has the intention and system to develop and apply for marketing such drug in Japan earlier than the rest of the world, which means that it is advisable to conduct the First-in-Human test and the Proof Of Concept test in Japan. The target periods for examination are nine months for the 80th percentile of orphan drugs, etc. and 12 months for the 80th percentile of other pharmaceuticals with new active components, etc. (the "New Pharmaceuticals").

In cases where the MHLW receives an application for approval for marketing of the New Pharmaceuticals, the MHLW shall hear the opinions of the Pharmaceutical Affairs and Food Sanitation Council in advance.[27]

A person who has received approval for marketing the New Pharmaceuticals shall apply for re-examination by the MHLW within three months after the certain investigation period.[28] In the case of orphan drugs, etc., such investigation period shall be ten years, and in the case of ordinary brand-name drugs, such investigation period shall be eight years.

Licence for Sale

Generally only a proprietor of a pharmacy, or one who has obtained a licence for sale of pharmaceuticals (the "Licence for Sale") may engage in the business of selling pharmaceuticals.[29] As mentioned above, however, a holder of a Marketing Licence may sell pharmaceuticals to a proprietor of a pharmacy, and a holder of a Licence for Sale and a holder of a Licence for Manufacturing may sell pharmaceuticals to a holder of a Marketing Licence.

A pharmacy means a place where a pharmacist is engaged in the dispensing of medicine for the purpose of the sale of such pharmaceuticals,[30] and anyone who establishes a pharmacy must obtain a licence from the governor of the prefecture.

There are three kinds of Licences for Sale: (i) a Licence for Store-based Distribution; (ii) a Licence for Household Distribution; and (iii) a Licence for Wholesale Distribution.[31] The Licence for Store-based Distribution shall be obtained from the prefectural governor for each store.[32] The Licence for Household Distribution shall be obtained from the prefectural governor for each prefecture that includes the area where the intended household distribution will take place.[33] The Licence for Wholesale Distribution shall be obtained from the prefectural governor for each business office. The holder of the Licence for Wholesale Distribution can sell pharmaceuticals only to proprietors of pharmacies, holders of a Marketing Licence, a Licence for Manufacturing or a Licence for Sale, as well as proprietors of hospitals, clinics, or clinics for domesticated animals, etc.[34]

A pharmacy can sell all kinds of pharmaceuticals, though it can sell prescription pharmaceuticals only those who hold a prescription.[35] A holder of a Licence for Store-based Distribution can sell only Pharmaceuticals Requiring Guidance, which means behind-the-counter pharmaceuticals, and over-the-counter ("OTC") Pharmaceuticals.[36] A holder of a Licence for Household Distribution may sell only certain OTC Pharmaceuticals.[37]

Health insurance – who are the payers?

Kinds of health insurance

Under the Health Insurance Act, certain workers employed at certain places of business[38] are insured by the Japan Health Insurance Association (the "JHIA") and health insurance societies.[39] An employer who has one or more certain places of business, regularly employing a certain number or more of such workers or employees, may establish a health insurance society.[40] Employers who jointly employ a certain number or more of such workers at several such places of business can also join together to jointly establish a health insurance society.

Workers who are not members of a health insurance society are insured directly by the JHIA. Such workers may continue to be insured for two years after he/she loses the eligibility therefor.[41] Under certain mutual aid association laws, such as the National Public Servants Mutual Aid Association Act, certain workers are insured by mutual aid associations. Under the National Health Insurance Act, municipalities shall generally insure any other persons domiciled in the area of such municipality other than insured persons under the Health Insurance Act or any mutual aid association laws.[42]

Contributions to health insurance

The above insurance providers receive contributions from the insured persons, employees and the national government. Please note, however, that the elderly aged 75 and over are insured through extended associations for medical insurance specifically for such group under the Act on Assurance of Medical Care for Elderly People.[43] Such insurance through extended associations receive contributions from the insured persons, the national government, prefectures, municipalities, the JHIA, health insurance societies and mutual aid associations.

Use of drug price standard prices for prescription pharmaceuticals

A physician or dentist providing treatment covered by health insurance shall prescribe pharmaceuticals as listed in the Drug Price Standard,[44,45] and a pharmacy providing services covered by health insurance shall fill a prescription with pharmaceuticals listed in the Drug Price Standard.[46,47]

How payment is made under the Drug Price Standard

The pharmaceuticals listed in the Drug Price Standard are paid in the following manner: (i) patients (insured persons and their dependents) partially pay the Drug Price listed in the Drug Price Standard for such pharmaceuticals;[48] and (ii) payment agencies such as the Social Insurance Medical Fee Payment Fund and the Federation of National Health Insurance Associations, pay the rest of the cost to pharmacies upon being billed therefor,[49] and (iii) health insurance providers pay to the payment agency upon being billed therefor.[50]

Please note that the drug price paid between a holder of a Marketing Licence and a holder of a Licence for Wholesale Distribution, or the drug price paid between a holder of a Licence for Wholesale Distribution and a pharmacy, or any drug price other than the price to be paid partially under the health insurance system, is not regulated at all, though the price paid by the pharmacy shall be considered upon revision of the Drug Price listed in the Drug Price Standard as described below.

Patients pay for any other pharmaceuticals, such as OTC Pharmaceuticals and Pharmaceuticals Requiring Guidance, by themselves.

Application for listing in the Drug Price Standard

The MHLW lists pharmaceuticals in the Drug Price Standard, and the holders of a

Marketing Licence of New Pharmaceuticals and generic drugs may apply for listing of such pharmaceuticals in the Drug Price Standard.

An application for listing of New Pharmaceuticals shall be made within one week of the granting of approval for marketing such drugs.[51] As a practical matter, the MHLW hears opinions from the applicant before each application. Thereafter, the MHLW hears opinions from the Japan Medical Association, the Japan Dental Association and the Japan Pharmaceutical Association, and decides whether to list such pharmaceuticals in the Drug Price Standard. Here, it is practically decided whether to list such pharmaceuticals.

Pharmaceuticals inappropriate for health insurance treatment, such as "Viagra", OTC Pharmaceuticals and Pharmaceuticals Requiring Guidance, are not listed. "Re-up", a hair regrowth product of which the active component is Minoxidil, was successfully launched as a Pharmaceutical Requiring Guidance. Therefore, the likelihood of success for an application for listing in the Drug Price Standard is very high.

The MHLW consults with the Central Social Insurance Medical Council (the "CSIMC") regarding the listing of such pharmaceuticals.[52] Then, the MHLW prepares a draft listing of such pharmaceuticals, including the price, and lets the internal organisation of the CSIMC decide upon the draft, and notifies the applicant of the draft. If the applicant is satisfied with the draft, the MHLW lets the CSIMC approve the draft and lists such pharmaceuticals in the Drug Price Standard according to the draft.

Appeal process

If the applicant is dissatisfied with the draft listing, the applicant may make an appeal and the internal organisation of the CSIMC will hear opinions from the applicant and decide regarding the draft again. The MHLW then notifies the applicant of such draft. This time, the applicant cannot appeal.

Length of the application process

It takes about 60 days to 90 days at the latest from the grant of approval for marketing such New Pharmaceuticals to having them listed in the Drug Price Standard.

If marketing generic drugs is approved by either February 15 or August 15, an application for listing of such generic drugs must be made by March 10 or September 10, respectively.[53] Such generic drugs are normally listed in the Drug Price Standard in June and December, respectively.

Decision regarding the drug price for pharmaceuticals newly listed in the Drug Price Standard

In case there is any drug listed in the Drug Price Standard similar to the New Pharmaceuticals newly listed therein, the Similar Efficacy Comparison Method shall be used to determine the Drug Price of such pharmaceuticals. If such pharmaceuticals lack novelty, the Correction Premiums described below shall not be added, and the Foreign Price Adjustment shall not be made. If such pharmaceuticals are novel, the Correction Premiums, such as the Breakthrough Premium, the Usefulness Premium, Premium for Orphan Drugs and Drugs in Small Markets, the Pediatric Premium and the Premium for the Precursor Designation Scheme described above, if any, shall be applied, and the Foreign Price Adjustment shall be made. Finally, the Inter-specification Adjustment shall be applied in order to equalise the ratio of the Drug Price and the active components of such pharmaceuticals and that of similar drugs.

In case there is no drug listed in the Drug Price Standard similar to the New Pharmaceuticals newly listed therein, the Cost Accounting System shall be used to determine the price of such pharmaceuticals. Then, the Foreign Price Adjustment shall be applied.

In case there is no generic drug listed in the Drug Price Standard similar to the generic drug newly listed therein, the Drug Price of such generic drug shall be basically 50% of that of the New Pharmaceuticals. If such generic drug is a biosimilar, its Drug Price shall be basically 70% thereof, and may be increased by up to 10% depending on sufficiency of the clinical testing. In case such generic drug is an oral medicine and more than 10 of the same generic drugs are newly listed in the Drug Price Standard at the same time, the percentage shall be reduced by 10%.

In case there is any generic drug listed in the Drug Price Standard that is identical to the generic drug newly listed in the Drug Price Standard, the Drug Price of such generic drug shall be the same as such identical generic drug. In case that is any generic drug listed in the Drug Price Standard similar to the generic drug newly listed in the Drug Price Standard, the Drug Price of such generic drug shall be the same as such similar generic drug, and the Inter-specification Adjustment shall be applied in order to equalise the ratio of the Drug Price and the active components of such generic drug and that of such similar generic drug.

Revision of the Drug Price

The Weighted Average Market Price Plus Adjustment Range shall be used when revising the Drug Price listed in the Drug Price Standard. Here, the Market Price shall mean the price paid by pharmacies. Such revision is basically made once every two years. The MHLW may conduct a necessary survey to ensure the appropriateness of the Drug Price.[54]

The Drug Price of the New Pharmaceuticals[55] shall be lowered through a certain formula depending on the replacement rate of generic drugs, if such rate is lower than 80% after five years have passed since the first generic drug was listed in the Drug Price Standard. The Drug Price of the New Pharmaceuticals shall be lowered to the Drug Price of the generic drugs 10 years after the first generic drug is listed in the Drug Price Standard.

If any paediatric efficacy or performance, or orphan drugs efficacy or performance, is added or any true clinical usefulness is verified, the Drug Price shall be increased through a certain formula. In certain cases where: (i) the market is expanded; (ii) the principal efficacy or performance has changed; or (iii) the dosage or administration has changed, the Drug Price shall be reduced through a certain formula. In extraordinary cases described in (i) and (iii) above, such reduction shall be made four times a year.

The Drug Price of generic drugs shall be consolidated in three categories through a certain formula. The Drug Price of authorised generic drugs shall be consolidated to the Drug Price of other generic drugs.

There are special provisions to maintain the Drug Price for fundamental pharmaceuticals.

A certain amount shall be added through a certain formula to the Drug Price of certain New Pharmaceuticals listed in the Drug Price Standard before any generic drug is listed therein. Such New Pharmaceuticals include orphan drugs, drugs for which a Breakthrough Premium or a Usefulness Premium was applied when they were listed in the Drug Price Standard, etc.

The Foreign Price Adjustment shall be applied for New Pharmaceuticals: (i) which are imported or which contain active ingredients that are imported; (ii) for which the Cost Accounting System was used when they were listed in the Drug Price Standard; (iii) for which there was no foreign price to be referred to when they were listed therein; and (iv) for which a foreign price is listed after they were listed therein.

Policy issues that affect pricing and reimbursement

Expanding national medical expenditure

The cost of healthcare was 10.9% of GDP in Japan in 2016 – not so high as in the United States and Switzerland, though expenditure on pharmaceuticals and other medical non-durables was 18.8% of expenditure on health in Japan in 2014, which was higher than in the United States and Switzerland. From this perspective, there might seem to be a case to hold down payments to pharmacies under the health insurance system.

But the percentage of elderly Japanese is increasing, even though the Japanese population is decreasing overall. Therefore, the amount of the nation's medical expenditure has been basically increasing. In order to maintain health insurance for elderly people, the new system – which is also contributed to by other insurance providers, as described above – was introduced. In addition, recently, the cost of developing New Pharmaceuticals has tended to increase and accordingly the Drug Prices of New Pharmaceuticals newly listed in the Drug Price Standard has tended to increase. Therefore, the national movement in Japan is toward promoting the following policies.

Promotion of generic drugs

The national government aims to achieve an 80% usage rate for generic drugs by September 2020 or earlier.[56] Therefore, the form of the prescription which a physician or dentist providing health insurance treatment writes must contain a column for generic drugs. If such physician or dentist does not check such column, a pharmacist may, without asking such physician or dentist, change the prescribed pharmaceuticals to generic drugs after consultation with the patient.

Lowering Drug Prices

Recently, the Drug Prices of some New Pharmaceuticals newly listed in the Drug Price Standard are very expensive according to the Cost Accounting System, such as direct-acting antivirals for hepatitis C and the "Opdivo", cancer immunotherapeutic. Therefore, if the markets for such New Pharmaceuticals are expanded, the Drug Prices shall be lowered as described above. On the other hand, in order to facilitate development of New Pharmaceuticals, the Drug Prices for certain New Pharmaceuticals shall be increased as described above.

In addition, the Drug Prices of New Pharmaceuticals which have not been replaced to a large extent by generic drugs shall be lowered, as described above.

Self-medication

The national government promotes self-medication in order to hold down medical expenditure under the health insurance system. Then, the government tries to switch prescription pharmaceuticals to Pharmaceuticals Requiring Guidance, such as pharmaceuticals of which the active component is a histamine-2 receptor antagonist. But there are not so many such pharmaceuticals.

Emerging trends

No new legislation is necessary to modify the Drug Price Standard. The MHLW may flexible enough to make such modifications by itself. Therefore, it is difficult to anticipate any regulation by the MHLW. The following systems might be introduced in the future: (i) a pharmacy would claim from an insurer the purchase price of pharmaceuticals and administration expenses; (ii) a national public corporation would purchase pharmaceuticals

necessary for providing services covered by health insurance; (iii) the reimbursement price would be decided beforehand and if a pharmacy claims more than that, a patient would pay the difference and if a pharmacy claims less than that, the price claimed by such pharmacy would be the price which an insured person would normally partially pay; and (iv) a claim can be made only if the clinical trial effect of a pharmaceutical is approved. Therefore, pharmaceutical companies should be prepared for the possibility of such changes.

Successful market access

Although international harmonisation of the Japanese market is proceeding through such measures as the GLP, the GCP, the GMP, the GQP and the GVP, Japanese pharmaceutical affairs are heavily regulated and the Japanese health insurance system is unique. Therefore, in order to enter the Japanese market, a foreign pharmaceutical company would be well advised to have a subsidiary in Japan and use it to obtain a Marketing Licence.

Actually, most major pharmaceutical companies already have subsidiaries in Japan. Most started by acquiring Japanese pharmaceutical companies or setting up joint ventures with Japanese companies. A foreign pharmaceutical may make a lot of sales in the large Japanese market, but it costs a lot to have a subsidiary with a Marketing Licence in Japan. If a foreign pharmaceutical company does not have a subsidiary in Japan for some reason, it should execute a licence with a Japanese pharmaceutical company with a Marketing Licence.

* * *

Endnotes

1. Article 12 (1) of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 145 of 1960)(the "Law") and Article 80 (2) of the Order for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Cabinet Order No. 11 of 1961) (the "Order").
2. Ordinance of the Ministry of Health and Welfare No. 136 of 2004.
3. Article 12-2 (i) of the Law.
4. Ordinance of the Ministry of Health and Welfare No. 135 of 2004.
5. Article 12-2 (ii) of the Law.
6. Article 13 (1) of the Law.
7. Article 13-2 (1) of the Law.
8. Article 13-3 (1) of the Law.
9. Article 13-3 (3) and Article 13-2 (1) of the Law.
10. With certain exceptions.
11. Article 14 (1) of the Law.
12. Article 14 (2)(i) of the Law.
13. Article 14 (2)(ii) of the Law.
14. With certain exceptions.
15. Ordinance of the Ministry of Health and Welfare No. 179 of 2004.
16. Article 14 (2) (iv) of the Law.

17. Article 19-2 of the Law.
18. Article 14 (3) of the Law.
19. Article 40 (1) of the Regulation for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Order of the Ministry of Health, Labour and Welfare No. 1 of 1961) (the "Regulation").
20. Article 2 (17) of the Law.
21. Ordinance of the Ministry of Health and Welfare No. 28 of 1997.
22. Ordinance of the Ministry of Health and Welfare No. 21 of 1997.
23. Article 43 of the Regulation.
24. Article 40 (2) of the Regulation.
25. Article 14-2 of the Law.
26. Article 14 (7) of the Law.
27. Article 14 (8) of the Law.
28. Article 14-4 of the Law.
29. Article 24 (1) of the Law.
30. Article 2 (12) of the Law.
31. Article 25 of the Law.
32. Article 26(1) of the Law.
33. Article 30(1) of the Law.
34. Article 25 (iii) of the Law.
35. Article 49 (1) of the Law.
36. Article 27 and Article 4(5)(ii), (iii) and (iv) of the Law.
37. Article 31 of the Law.
38. Article 3(1) of the Health Insurance Act.
39. Article 4 of the Health Insurance Act.
40. Article 11 of the Health Insurance Act.
41. Article 38 of the Health Insurance Act
42. Article 5 of the National Health Insurance Act.
43. Article 48 of the Act on Assurance of Medical Care for Elderly People.
44. Article 70 (1), Article 72 (1) of the Health Insurance Act, Article 40 of the National Health Insurance Act, Article 19 of the Rules for Health Insurance-covered Medical Facilities and Medical Practitioners.
45. With certain exceptions.
46. Article 70 (1), Article 72 (1) of the Health Insurance Act, Article 40 of the National Health Insurance Act, Article 9 of Rules for Health Insurance-covered Dispensing Pharmacies and Pharmacists.
47. With certain exceptions.
48. Article 74, Article 76 (2) of the Health Insurance Act, Article 42, Article 45 (2) of the National Health Insurance Act.
49. Article 76 (4), (5) of the Health Insurance Act, Article 45 (4), (5) of the National Health Insurance Act.

50. Article 76 (1), (2) of the Health Insurance Act, Article 45 (1), (2) of the National Health Insurance Act.
51. With certain exceptions.
52. Article 82 (1), 76 (2) of the Health Insurance Act.
53. With certain exceptions.
54. Article 77 of the Health Insurance Act.
55. With certain exceptions.
56. Basic Policy on Economic and Fiscal Management and Reform 2015 and 2017.

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Mr. Kobayashi has wide-ranging experience in corporate, M&A, compliance, intellectual property, antitrust, international transactions, product liability and dispute resolution. Mr. Kobayashi has conducted due diligences and prepared share purchase agreements, etc. in the health care industry. He has also handled investment in a foreign company and acquisition of Japanese company's business by a foreign company in the health care industry. Mr. Kobayashi has prepared and negotiated international licence agreements of pharmaceuticals. As defence attorney for pharmaceutical companies, he has handled many cases of alleged contaminated medicines. Mr. Kobayashi has advised on pharmaceutical affairs not only Japanese companies but also foreign companies. He has handled establishing foreign capital's entities and advising on their operations in Japan. Mr. Kobayashi has handled dispute resolutions in which foreign companies are involved.

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