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Transparency guidelines and disclosure payments in the pharmaceutical industry

Abstract

Based on the “Transparency Guidelines for the Relationship between Corporate Activities and Medical Institutions” established by the Japan Pharmaceutical Manufacturers Association (published on January 19th, 2011 and revised on March 21st, 2013, below “Transparency Guidelines”), the pharmaceutical industry is being requested to disclose information on payments to doctors and healthcare institutions.

The first year for which companies in Japan are to provide disclosure is FY2012, and as of October 15th, 2013, of the 70 companies in the JPMA, 64 large and medium-sized companies have completed their disclosure. Upon analysis of the disclosed information, the circumstance of each company’s R&D and sales promotion activities, as well as the differences in the way each company has responded to disclosure guidelines can be seen. Furthermore, similar information is requested in the US as a result of the Physician Payment Sunshine Act. Because this might also have effects on the Japanese pharmaceutical industry, it should be examined.

I. 2012 Information disclosed based on the Transparency Guidelines

Analysis of funding given to healthcare institutions

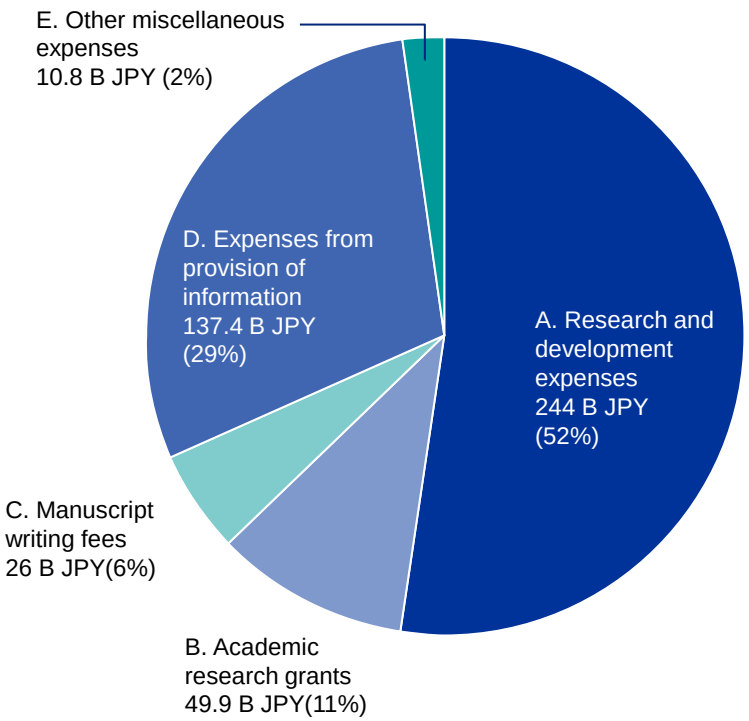
Based on 2012 disclosure information, the largest amount funding amount was given by Takeda, exceeding 40 B JPY. Daiichi Sankyo, Pfizer, Novartis, and other enterprises with large sales volume followed Takeda. Each company's funding amount is approximately 4% - 8% of domestic sales.

As shown in Figure 1 (Data Point A), funding for research and development comprised approximately half of the total funding amount. By company, R&D comprised over 60% of funding for Takeda, Daiichi Sankyo, Shionogi, and Janssen, and for these companies, expenses due to provision of information (Data Point D), were only below 20%. Also, for Eli Lilly, R&D funding comprised over 60% of total funding, but the portion of funding comprised by academic research grand expenses (Data Point B) and manuscript writing fees (Data Point C) were very low.

Conversely, for Astellas, MSD, Novartis, Kyowa Hakko Kirin, and other companies, the portion of funding comprised by R&D was low (approximately 40%), and the portion comprised by information provision expenses was high. Furthermore, for Chugai, Dainippon Sumitomo, MSD, and others, the portion comprised by academic research grand expenses exceeded 20%.

For Kyowa Hakko Kirin, Ajinomoto, Nippon Shinyaku, and other companies, other miscellaneous expenses (Data Point E) exceeded 5%. Conversely, miscellaneous expenses did not reach 5 M JPY for AstraZeneca, and for Chugai and Nippon Boehringer Ingelheim, they did not even reach 1%.

Figure 1: Total funding of 64 companies by disclosed expense type



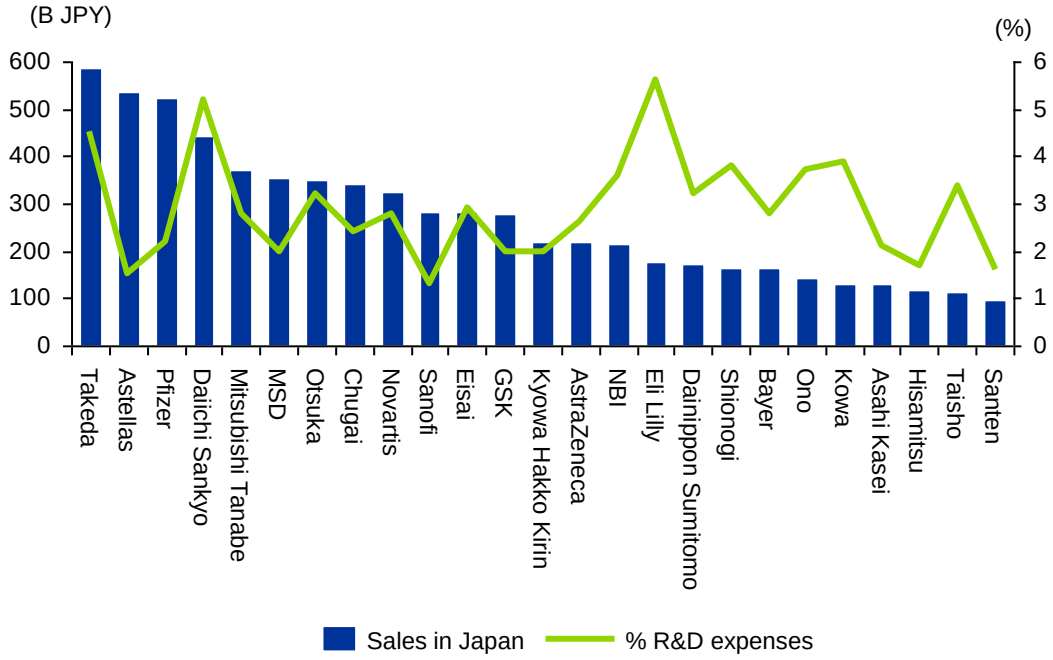
Further analysis of the features of each company for Data Types A and E are below.

A. Research and development expenses

In Figure 2, for the top 25 companies by 2012 Japan sales, 2012 Japan sales and R&D expenses as a percentage of 2012 sales are shown. In the pharmaceutical industry, because there is a fixed base cost for research and development activities which is not related to the scale of company sales and which cannot be avoided, for companies with lower overall sales, there is a tendency for the ratio of research and development costs with sales to be higher.

On the other hand, without increasing too much, the ratio is also high for Takeda, Daiichi Sankyo, and Eli Lilly. For many pharmaceutical companies faced with the so-called “patent cliff”, after 2010, many high-sales products lost their patents, and there was the potential for sharp decrease in revenue. At that time, these companies, in order to create new revenue sources, enthusiastically advanced research and development activities, and research and development costs exceeded 30% of total sales.

Figure 2: Japan sales and R&D expenses as a %of sales

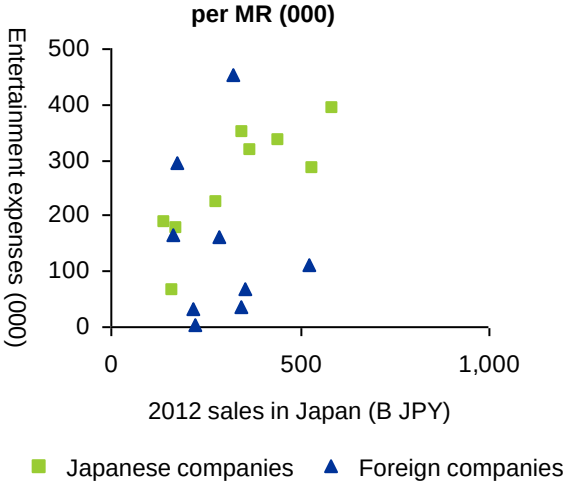


E. Miscellaneous expenses

In Figure 3, for the top 20 companies by 2012 Japan sales, disclosed amounts for miscellaneous expenses are divided by the number of MRs, and the relationship between per-MR entertainment expenses and Japan sales is shown.

Because this data also includes congratulations and condolence costs and transportation fees, it is not strictly limited to MR-generated expenses, but still the trend across companies for per-MR expenses can be seen. For Japanese companies, it can be seen that if sales increase then MR expenses also increase, showing the importance of MR activities. On the other hand, for foreign companies, unlike Japanese companies, this proportional relation is not seen. Excluding Novartis and Eli Lilly, MR expenses are low, and there appears to be a reduction in MR activity.

Figure 3: Entertainment expenses per MR (000)



Reactions of each company to disclosure

There is no significant difference in the granularity of disclosure information across companies, and each company published their information in accordance with the transparency guidelines, but there are some differences in small details.

- Handling of taxes
  As far as consumption tax, depending on the company, Daiichi Sankyo, Shionogi, and other companies omitted taxes, but Eisai, Mitsubishi Tanabe, and other companies included taxes in their disclosure amounts. Some companies included taxes only for some of the disclosure items, such as Takeda and Astellas. Eisai, Daiichi Sankyo, and many other companies included withholding income tax in their disclosures. Furthermore, there are some companies for which it is not clear how they handled taxes.

- Units of measure in which disclosure amounts are expressed
  Takeda, Daiichi Sankyo, and 49 other companies expressed their disclosure information in Japanese yen, but GlaxoSmithKline (GSK), and 7 other companies expressed their disclosure amounts in thousands of Japanese yen, and NBI expressed in units of 10,000 Japanese yen. Furthermore, Astellas, Eisai and 7 other companies expressed their disclosure information in millions of Japanese yen.

- Disclosure related to provision of samples and other in-kind items
  In the case of providing in-kind items Pfizer calculated and disclosed the financial value. Takeda, Astellas, Mitsubishi Tanabe, MSD, and 12 other companies also disclosed the types and amounts of in-kind materials.

- More detailed classifications
  Sanofi has shown the form of payment for manuscript writing fees, and GSK has shown the contents of its expenses for other miscellaneous expenses. Pfizer, AstraZeneca, Bayer and 5 other companies added items which did not fall into one of the other categories to other miscellaneous expenses.

II. The US Sunshine Act and transparency systems in other countries

The Physician Payment Sunshine Act in the US is one part of the law which President Obama has driven through to completion in March 2010. It is a reform to the method of provision of health care (The Patient Protection and Affordable Care Act of 2010, below, the PPACA). In the US, it is said that there are 50 million people without health insurance, and the PPACA is intended to create an environment in which these people have access to appropriate medical care. In order to implement and help with healthcare costs, and because there might be a connection with drug price increases, pharmaceutical manufacturers and medical device manufacturers are requested to disclose payments to doctors. It is called The Sunshine Act because it exposes to daylight the payments from pharmaceutical and medical device makers to doctors.

Although Japan's transparency guidelines are an act of self-regulation by the JPMA, non-compliance with the Sunshine Act carries a penalty and due to the detailed information requested by the guidelines, pharmaceutical companies are struggling to comply. Since the Sunshine Act covers payments to doctors made in the United States, Japanese pharmaceutical companies have left this matter to their subsidiaries in the US, regarding it as a problem only for the subsidiaries. However, a guideline released in February 2013 stated that all the expenses paid to doctors with American medical licenses and medical institutions in the US must be reported. This means that companies outside of the US which sell products prescribed under the American medical system must disclose the payments as well. It is no longer a problem only for American subsidiaries, but is also an urgent matter that parent companies in Japan should address.

According to the guidelines, gifts with a value over $10 must be reported. The specific items below must be reported:

- Consulting fees
- Rewards for services other than consulting
- Honoraria
- Gifts
- Entertainment expenses, meals, and travel fees
- Teaching fees
- Development fees
- Lecture fees
- Donations
- Royalties and licenses, interest payments, and other items of monetary value

To develop a system which can report properly, it is not only the data gathering process but also awareness in the sales, marketing, and research and development divisions which must be improved, and reforms in various parts of the organization are necessary. According to a survey which Deloitte conducted in the US, many companies think that they must recognize the importance of increasing transparency into payments to doctors and change the way they do business in order to comply with the Sunshine Act. After that, construction and maintenance of a database of doctor payments, collecting payment information using a third party to collect data, protecting personal information of doctors, and promotion of understanding inside and outside of the organization about these regulations are challenges which companies face.

When the report is submitted, the President, the CFO, and the Compliance Officer or a top management member bear responsibility for the report. Not only can there be fines levied on the company for inaccurate reporting, but since the report can have significant consequences on the reputation of the signer, it is necessary to build a strong reporting system which can ensure accuracy and completeness of the reports.

Increased transparency into payments to doctors has become a common issue for pharmaceutical and medical device makers across countries. Regulations similar to the Sunshine Act are being investigated throughout the world. As of October, 2013, France and Slovakia have adopted such laws. The main countries in which industrial regulations (rather than laws) have been adopted are UK, the Netherlands, and Australia. It has been announced that in 2015, the regulations of the European Federation of Pharmaceutical Industries and Associations (EFPIA) will be adopted in each member country. In order to efficiently provide reports in a sustainable way responding to this global movement for transparency, companies should consider adopting a global rather than local policy on how to provide this information.

III. Possible utilization of the disclosed information

Possible utilization of the disclosed information should be discussed and examined, considering the fact that all pharmaceutical companies are to disclose payments based on the same guidelines, and payments to individual physicians are anticipated to also be disclosed from next year, although there is no significant differences in the granularity of disclosure information. Analysis of competitors' information, for instance, might allow for optimization of sales and marketing activities and reinforcement of compliance.

Major items that can be benchmarked through analysis of disclosed information include:

- The industry average of honoraria for physicians
- Key opinion leaders (KOLs) by disease / region / event
- The average expense / number of events (product briefings, lectures, seminars at academic meetings, etc.)
- Number of recipients and number of donations and average donation amount in the industry

For sales and marketing functions, these benchmarking results will allow for review of investment in KOLs, which could optimize cost effectiveness and ultimately improve profits. Comparison of event-related expenses (cost per doctor) with those of competitors and the industry average enables the company to validate the investment (Figure 4), identify KOLs in areas for new entry and review the current targeting of KOLs.

It will be also possible to analyze competitors' R&D / product launch strategies (e.g. product positioning, marketing messages, target customers) and refine the company's own strategies, by identifying competitors' KOLs (based on the amount paid) and learn about the KOLs' research themes. Moreover, integrating the disclosed information into CRM (Customer Relation Management) data will allow for more accurate and consistent customer segmentation and targeting rather than analyzing / using the disclosed data in isolation.

The benchmarking could also reinforce the company's compliance if the payments are tracked over years to detect relationships with certain institutions and doctors that may breach codes and to check whether payments are appropriate or not compared with those of competitors (Figure 5).

Figure 4: Comparison of expense per event

Consider re-allocation of budget depending on the scale of events and cost per doctor

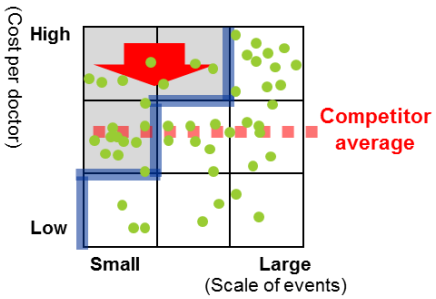
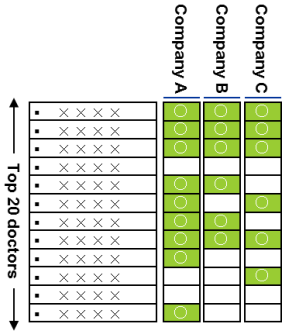


Figure 5: Comparison of KOLs

Check competitors' expenses to validate the company's own payments



Disclosure has just started from 2012 payments and obviously many efforts will be made to utilize this information. It will be crucial for the pharmaceutical industry to examine and validate the possible utilization of this data not only for compliance enhancement, but also for commercial efficiency improvement.

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