The Impact of Unfair Trade Restrictions on Corporate Behavior and Financial Performance of Pharmaceutical Companies: The Dual Punishment System in Korea

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ABSTRACT

This study aims to evaluate the effectiveness of the dual-punishment system by analysis of the financial performance of pharmaceutical companies before and after introduction of the dual-punishment system. This study analyzed the business performance of 136 pharmaceutical companies from 2009 to 2011. The results from paired t-tests found that sales, operating cost, and EBITDA showed significant differences in performance, and, according to the variance analysis, the five groups obtained through a hierarchical cluster analysis differed from each other in sales, operating cost, EBITDA, and research and development cost. Differences in financial performance among the groups seem to be related to the strategy for response to the regulation. The introduction of the dual-punishment system is generally acknowledged to have had positive effects on the pharmaceutical industry. However, some companies appear to be continuing kickback practices.

Key words*: Corporate Behavior, Dual Punishment, Kickback, Pharmaceutical Company, Policy Change.*

1. INTRODUCTION

According to analysis of key indicators in the 2014 Organization for Economic Co-operation and Development (OECD) Health Data, the ratio of total national health expenditure to GDP increased from 6.4% in 2007 to 7.6% in 2012 in Korea [1]. While this is lower than the 2012 OECD average of 9.3%, the average annual growth rate of 6.6% from 2007 to 2012 in Korea is significantly higher than the OECD average of 2.3% and highest among the organization's member countries. In order to curb such rapid growth of medical expenses, the Korean government is enacting various measures to improve healthcare policies and institutions. The government is focusing its efforts on limiting the growth of pharmaceutical expenditures, which account for a larger proportion of health expenditures compared to those in other countries. As a result of these efforts, the percentage of drug expenses relative to total health expenditure decreased from 22.7% in 2007 to 19.8% in 2012.

Since November 2010, the Korean government has had a dual punishment system for pharmaceutical kickbacks to help limit medical price increases. A kickback is an illegal reward or an unjust profit paid to medical institutions or health professionals from pharmaceutical or medical equipment manufacturers or distributers to encourage the use of certain drugs or devices [2]. According to the Fair Trade Commission of Korea (2009), approximately 20% of the total sales of pharmaceutical companies are used for paying kickbacks, and the amount exceeds 2.5 billion dollars [3]. The Korean government had implemented multiple regulatory measures to eliminate kickback practices even before 2010, but without any visible effect. For that reason, the dual punishment system punishing both the provider and recipient of kickbacks was introduced. In the past, due to the ambiguity of regulations and the complexity of procedures, punishment for kickbacks had been imposed only on the providers, not the recipients [4]. With the dual punishment system, the Korean government aimed to address medical institutions and health professionals and to eliminate practices of giving and receiving kickbacks.

With the introduction of the dual punishment system, some health professional organizations insisted that the money provided by medical equipment companies and pharmaceutical companies could be considered as legal expenses for sales promotion or as support for academic research; therefore, introduction of the dual punishment system was excessive regulation [5]. This reaction seems to start from the notion that the dual punishment system is an indiscriminate measure to regulate the majority of health professionals because of the misconduct of a few [6]. On the other hand, pharmaceutical companies did not have significant objections and displayed a positive external reaction including the declaration of kickback eradication and reinforcement of staff education on fair trade [6]. However, despite the official positions or reactions of pharmaceutical companies, cases of kickback payment have been consistently exposed and reported in the media even after the introduction of the system [2].

The dual punishment system aims to encourage fair trade of medicine and ultimately limit the increase of drug expenditures; however, its impact and effectiveness have yet to be properly evaluated. Prohibition of kickback practices may affect the management and performance of pharmaceutical companies. Historically, pharmaceutical companies have utilized kickbacks as an important tool for sales or marketing [7]. Offering kickbacks has been prohibited and punished by law even before the introduction of the dual punishment system, but providing and receiving kickbacks has been widely accepted as a practice in the industry. With the introduction of the dual punishment system, the Korean government proclaimed its intentions to eliminate kickbacks, and society's heightened interest in the issue made it difficult to continue kickback practices. It was thus expected that there would be significant changes in marketing strategies, sales activities, and the ethical management of pharmaceutical companies and, consequently, to management performance. The purpose of the study was to comparatively analyze the financial performance of pharmaceutical companies before and after the introduction of the dual punishment system, understand the companies'

response strategies, and indirectly evaluate the effectiveness of the dual punishment system.

2. METHODS

2.1 Data and Subjects

We used data from the Data Analysis, Retrieval, and Transfer System (DART) disclosed by the Financial Supervisory Service in Korea. DART is an electronic disclosure system that allows companies to submit disclosures online, where it becomes immediately available to investors and other users (http://dart.fss.or.kr/). Data were collected from financial statements of 136 pharmaceutical companies listed in the manufacture of pharmaceutical goods other than medicaments of the Korean Standard Industrial Classification every year from 2009 to 2011.

2.2 Variables

The dataset consisted of values of seven financial variables (1. sales: S; 2. operating cost: OC; 3. operating profit: OP; 4. net income: NI; 5. operating revenue: OR; 6. earnings before interest, taxes, depreciation and amortization: EBITDA; 7. research and development cost: R&D) divided by assets. We consider the seven generic and influential aspects of the kickback regulation on financial performance according to type of pharmaceutical company.

To determine the significant variables that most closely associate with financial performance according to kickback regulation, a paired t-test of the seven variables was performed using SPSS 22.0 (SPSS, Inc., Chicago, IL, USA)between 2009 (two years before kickback regulation) and 2011 (one year after kickback regulation). Three variables (S, OC, and EBITDA) were shown to be statistically significant variables (Table 1). Another paired t-test of the seven variables between 2010 (one year before kickback regulation) and 2011 (one year after kickback regulation) demonstrated statistically significant results for OC, OP, as shown in Table 1.

2.3 Statistical Analysis

To perform a cluster analysis using those statistically significant variables, we used hierarchical cluster (HC) analysis through the Ward method by XLminer. Cluster analysis helps to understand the target group and make efficient use of the target group by dividing target subjects into corresponding groups. An HC method to build a hierarchical structure of internally similar groups, clustering the measured data according to class, involves various techniques to create clusters, including single linkage, complete linkage, centroid linkage, and Ward's method [8]. This research utilized Ward's method, which is useful for reducing the difference in standard deviations of explanatory variables [9]. To evaluate the characteristics of the clusters in detail, we set the number of clusters to five. A series of descriptive analyses collected from five clusters were conducted to examine their characteristics.

We performed variance analysis to evaluate the financial effect of management performance according to type of pharmaceutical company following the kickback regulation.

Duncan's multiple range test was performed on the seven financial variables described in the above section, which were significantly different according to SPSS 22.0.

Table 1. Paired t-test of financial variables

Variable		Paired Differences					t	P-value
		Mean	SD	SE	95% CI			
Between 2009 and 2011								
Pair 1	sales	.063	.215	.018	.027	.100	3.432	.001
Pair 2	operating cost	.056	.215	.018	.019	.092	3.017	.003
Pair 3	operating profit	.013	.104	.009	-.005	.030	1.414	.160
Pair 4	net income	.004	.190	.016	-.028	.036	.246	.806
Pair 5	operating revenue	.016	.101	.009	-.001	.033	1.878	.063
Pair 6	EBITDA	.018	.103	.009	.000	.035	1.983	.049
Pair 7	R&D cost	.001	.050	.004	-.008	.009	.209	.835
Between 2010 and 2011								
Pair 1	sales	.057	.155	.013	.031	.083	4.282	.000
Pair 2	operating cost	.054	.158	.014	.027	.081	3.969	.000
Pair 3	operating profit	.020	.088	.008	.005	.034	2.579	.011
Pair 4	net income	-.004	.157	.013	-.031	.022	-.325	.745
Pair 5	operating revenue	.012	.099	.008	-.005	.028	1.366	.174
Pair 6	EBITDA	.016	.100	.009	-.001	.033	1.846	.067
Pair 7	R&D cost	-.002	.053	.005	-.011	.006	-.544	.588

Abbreviations: SD, Standard Deviation; SE, Standard Error; CI, Confidence Interval; EBITDA, Earnings before Interest, Taxes, Depreciation and Amortization; R&D, Research and Development

Table 2. Characteristics of the five groups extracted by hierarchical cluster (HC) analysis

Group		Explanation
Group 1	A company with slightly above average R&D cost	A company in group 1 had the lowest operating profit, though its R&D cost was above the average of all other companies.
Group 2	A company with slightly below average R&D cost	A company in group 2 appeared to have the lowest average R&D cost and EBITDA of all companies.
Group 3	A company in pursuit of stability	A company in group 3 showed the lowest R&D cost but the highest net income, operating revenue, and EBITDA. Therefore, having established a stable financial condition in its business operation, the company pursues high operation efficiency.
Group 4	A company seeking a breakthrough	A company in group 4 showed the lowest sales, net income, operating revenue, EBITDA, but highest R&D costs. As a low performing company, the company stresses R&D in hopes of a breakthrough.
Group 5	An aggressive company	While the company in group 5 had the highest operating profit, its R&D cost was the lowest. The company maintains or expands its market share rather than investing in R&D.

Abbreviations: EBITDA, Earnings before Interest, Taxes, Depreciation and Amortization; R&D, Research and Development

3. RESULTS

All characteristics collected from the five clusters are described in Table 2, and Table 3 shows the descriptive statistics (mean) per cluster according to year. The five groups obtained through HC analysis were different from each other in S, OC, EBITDA, and R&D (Table 3).Companies with slightly above average R&D were named group 1 and showed the lowest OP. Companies with slightly below average R&D represent group 2, and their EBITDA was far below average. Group 1 had higher S, OC, EBITDA, and R&D than group 2. Companies in pursuit of stability belong to group 3, showing the lowest R&D and the highest NI, OR, and EBITDA. Group 3 has very high S and OC. However, R&D was the lowest in 2010 and 2011 in group 3. Companies seeking breakthrough belong to group 4, whose S, NI, OR, and EBITDA are the

lowest, but R&D is the highest. Aggressive companies belong to group 5 and show the highest OP but the lowest R&D. S and OC in group 5 were lower than those in group 3, but still much higher than those in group 1, group 2, and group 4. R&D in group 5 increased from 2009 to 2011 (Table 3).

As a result, the five classified groups demonstrated different performances in S, OC, EBITDA, and R&D. Characteristics from the classified groups according to Duncan analysis of 2009 are shown in Table 4. The result of comparing the average S among the groups based on F verification showed a meaningful difference among groups. Group 5 had the highest average at 1.2012, while the lowest average was recorded at 0.8910 in group 4. Average OC was also quite different among groups, with group 3 showing the highest average at 1.1146, and group 4 demonstrating the lowest average at 0.8514. EBITA and R&D, however, were meaningfully different only when comparing group 4 with the other groups. EBITA in group 4 was the lowest of all groups, while R&D in this group was the highest (Table 4). The results of comparing the data in 2010 and 2011 are similar to the results of 2009.

4. DISCUSSION

Medicine is essential in disease treatment and health promotion. Generally, medicine is more regulated and controlled than other goods or services in the healthcare industry, putting a cost burden on pharmaceutical companies and distributors and limiting sales. In particular, the usage and price in the manufacture and supply of drugs covered by health insurance are regulated, which affects the sales and profits of related organizations. Korean pharmaceutical companies actively utilized kickbacks in order to maximize sales and profits in this regulatory context [7].

Table 3. Descriptive statistics (mean) of financial variables per cluster by year

Variable	Group	2009	2010	2011	Mean
Sales	Group 1	0.9384	0.9373	0.8847	0.9201
	Group 2	0.9372	0.9265	0.8395	0.9011
	Group 3	1.0101	0.9416	0.9238	0.9585
	Group 4	0.8910	0.9284	0.8432	0.8876
	Group 5	1.2012	1.2027	1.2165	1.2068
	Mean	0.9564	0.9498	0.8930	0.9331
Operating cost	Group 1	0.8688	0.8708	0.8040	0.8478
	Group 2	0.8756	0.8543	0.8048	0.8449
	Group 3	1.1146	1.1761	1.1107	1.1338
	Group 4	0.8514	0.8244	0.8338	0.8411
	Group 5	0.8614	0.8813	0.8376	0.8555
	Mean	0.8831	0.8812	0.8274	0.8639
Operating profit	Group 1	0.3255	0.3264	0.3098	0.3206
	Group 2	0.3251	0.3407	0.3236	0.3298
	Group 3	0.3612	0.3832	0.3848	0.3764
	Group 4	0.3530	0.3175	0.3046	0.3251
	Group 5	0.4957	0.5478	0.4522	0.4986
	Mean	0.3406	0.3475	0.3280	0.3387
Net income	Group 1	0.0402	0.0272	0.0311	0.0328
	Group 2	0.0253	0.0530	0.0467	0.0417
	Group 3	0.1002	0.0815	0.0542	0.0786
	Group 4	-0.0005	-0.0306	-0.0296	-0.0202
	Group 5	0.0421	-0.0407	0.0666	0.0227
	Mean	0.0388	0.0304	0.0348	0.0346
Operating revenue	Group 1	0.0696	0.0665	0.0645	0.0669
	Group 2	0.0617	0.0721	0.0347	0.0562
	Group 3	0.1486	0.1172	0.0862	0.1173
	Group 4	0.0396	0.0471	0.0095	0.0321
	Group 5	0.0866	0.0266	0.1046	0.0726
	Mean	0.0733	0.0687	0.0570	0.0663
EBITDA	Group 1	0.0944	0.0921	0.0854	0.0906
	Group 2	0.0882	0.1029	0.0628	0.0846
	Group 3	0.1786	0.1427	0.1118	0.1444
	Group 4	0.0634	0.0962	0.0438	0.0678
	Group 5	0.1052	0.0452	0.1221	0.0908
	Mean	0.0986	0.0969	0.0810	0.0922
R&D cost	Group 1	0.0408	0.0428	0.0436	0.0424
	Group 2	0.0388	0.0271	0.0305	0.0321
	Group 3	0.0012	0.0013	0.0010	0.0012
	Group 4	0.0592	0.0450	0.0673	0.0572
	Group 5	0.0174	0.0121	0.0040	0.0112
	Mean	0.0368	0.0334	0.0359	0.0353

Abbreviation: EBITDA, Earnings before Interest, Taxes, Depreciation and Amortization; R&D, Research and Development

However, kickbacks provided in the distribution process not only seriously undermined the drug distribution system, but also resulted in a burden on National Health Insurance finances by increasing medicine costs. For this reason, the Korean government introduced the dual punishment system to eliminate kickback practices. This study aimed to identify how pharmaceutical companies reacted to the implementation of the dual punishment system by analyzing changes in their financial performance.

The Korean government has been laying the groundwork for supporting the pharmaceutical industry by such means as expanding investments in research and development and simultaneously has strengthened regulations on drug manufacture, distribution, and sales [10]. Various policies for limiting drug price increases, such as the dual punishment of kickback practices introduced in November 2010 and the price cuts in the drug fee schedule in 2012, are considered to have had a serious impact on the business performance of pharmaceutical companies [11]. The operating profit to sales ratio — an indicator of the profitability of a company — of pharmaceutical companies continuously increased before the introduction of the dual punishment system. However, this index started to decline in 2011, the year following the implementation of the dual punishment regulation. In 2012, the total operating profit of all pharmaceutical companies in the country decreased by 27.4% compared to the previous year, amounting to 1.3 billion US dollars [10]. Research and development costs of pharmaceutical companies have increased every year since 2008 but showed the largest growth in 2011, after the introduction of the dual punishment system. However, the margin of increase started to diminish in 2012, when massive price cuts on drugs were instituted.

In the past, multiple small and mid-sized companies in the Korean pharmaceutical industry have excessively competed against each other primarily in the area of generic drugs and

mainly through advertisements and other sales promotion activities [11]. After the introduction of reform measures, such as dual punishment of kickback practices, reorganization of the drug price system, and advancement of the pharmaceutical industry, many pharmaceutical companies started to curb unnecessary cost waste and competition in sales promotion and concentrated efforts to improve their profit structure [11]. Some companies demonstrated positive changes, reducing expenses on sales promotion and increasing investment in research and development in order to improve their performance. A previous study that analyzed 74 pharmaceutical companies listed on the Korea Composite Stock Price Index and the Korea Securities Dealers Automated Quotation speculated that, due to the dual punishment system, expenditure on sales promotion (a direct sales cost) decreased and was replaced by investment in research and development as a long-term growth strategy [7]. However, considering that several pharmaceutical companies continue to be punished for offering kickbacks even after the introduction of regulation, it is difficult to conclude that the dual punishment system only brought positive results. In December 2014, a case that broke the record for the largest amount of kickback payment was exposed. Considering that the company in question was a mid-sized business with annual revenues of approximately 30 million dollars, it can be concluded that a significant number of small and mid-sized companies are continuing to offer kickbacks.

Table 4. ANOVA test of the financial variables in 2009

Variable	Group	N	Mean	F	Duncan`s multiple range test
Sales	Group 1	61	0.9384	187.915***	G3>G5>G1>G2>G4
	Group 2	30	0.9372		
	Group 3	7	1.0101		
	Group 4	12	0.8910		
	Group 5	26	1.2012		
Operating cost	Group 1	61	0.8688	178.109***	G3>G5>G1>G2>G4
	Group 2	30	0.8756		
	Group 3	7	1.1146		
	Group 4	12	0.8514		
	Group 5	26	0.8614		
EBITDA	Group 1	61	0.0944	11.083***	G5=G1=G3=G2>G4
	Group 2	30	0.0882		
	Group 3	7	0.1786		
	Group 4	12	0.0634		
	Group 5	26	0.1052		
R&D cost	Group 1	61	0.0408	5.315***	G4>G3=G1=G5=G2
	Group 2	30	0.0388		
	Group 3	7	0.0012		
	Group 4	12	0.0592		
	Group 5	26	0.0174		

*** $p < .001$

Abbreviations: EBITDA, earnings before interest, taxes, depreciation, and amortization; R&D, research and development: G, group

In the past, changes in policies related to the pharmaceutical industry affected the companies' corporate behavior and management performance, and the responses were different foreach company according to the company's core values and strategies [11]. This study divides pharmaceutical companies into several groups according to the management performance of the companies and their reaction strategies deduced from performance analysis after the introduction of the dual punishment system. The first group was companies that actively invested in technology development as a result of the regulation. The second group was comprised of companies that did not have the resources for investment in technology development under poor profit conditions. The third group was companies whose overall management status was stable and that were able to consistently seek management efficiency without being affected by regulations. The fourth group consisted of companies whose current management performance was poor and that were seeking a breakthrough by increasing investment in technology development. The fifth group was aggressive companies that focused on expanding their market share.

It is difficult to say that regulation affects all pharmaceutical companies the same way, in the way government intended. Each pharmaceutical company tries to maximize its profit by establishing the most suitable management strategy and bringing behavioral changes under a

given policy. Some large pharmaceutical companies that have the capacity for technology development are reacting by enhancing their long-term competence, increasing investments in development of new drugs or biosimilars. Companies that are relatively less competent in technology development, on the other hand, are reacting by establishing different strategies including process improvement, cost reduction, diversification of business in areas other than specialized pharmaceuticals, expansion to overseas markets, and merger and acquisition [12]. However, some companies that have not been able to determine proactive response strategies are continuing to provide kickbacks, if not in monetary form, then by offering other unjust privileges and benefits [13].

The main OECD countries have attempted various cost containment methods in order to suppress the medical expenses that have been steadily increasing since the 1990s [14]. Many countries are implementing such policies as establishment of ex-factory prices and encouragement of generic drug use in order to curb pharmaceutical expenditures [6]. Regulation of kickback practices to establish order in distribution of pharmaceuticals and to stifle unreasonable cost growth is being implemented in many countries, but the details differ by country. The United States prohibits and punishes acceptance of kickbacks with regard to Medicare and Medicaid services based on the federal Anti-Kickback Statute [15]. In Japan, there is no regulation against the provision and receipt of unjust profit for sales promotion purposes, but doctors of public hospitals are open to punishment as civil servants in cases of bribery [15]. Similar to Korea's dual punishment system, France prohibits not only public health professionals, but also private practitioners from receiving kickbacks. The French Public Health Code, enacted in 1993, limits the amounts of money and valuables doctors can receive and serves as a system for overall control of monetary support within the healthcare industry [15]. In Germany, kickback practices are punishable by criminal law as acceptance of bribery, since there are no general regulations that prohibit kickbacks [16].

These kinds of direct and indirect regulations of drug prices and of kickback practices are known to affect pharmaceutical company performance [11]. This study also focuses on the impact of reinforcement of anti-kickback regulations on pharmaceutical companies' financial performance. After the policy of drug price reduction was implemented, the management performance of pharmaceutical companies appears to have improved overall, despite the concerns. However, not all pharmaceutical companies' performances have improved. In some companies, sales and operational profits have decreased [11]. As shown by our results, differences in the performances of pharmaceutical companies can be attributed to the distinct ways in which individual companies responded to regulation.

This study has several limitations. Changes in societal structure including in the accounting system and overall economic environment, as well as changes in policies and institutions other than the dual punishment system that could have directly and indirectly affected management performance of pharmaceutical companies in the 2009 to 2011 analysis period were not taken into account. Since sales management costs of pharmaceutical companies include not only expenses for kickback payments, but also expenses for a broader range of sales management activities such as lawful advertisements, the results can be interpreted in different ways.

5. CONCLUSIONS

This study demonstrates that, in some pharmaceutical companies, sales management costs decreased and research and development costs increased with the implementation of the dual punishment system against kickback practices. This indirectly confirms the effect of implementing dual punishment of kickback practices to advance the pharmaceutical industry and mitigate pressure on National Health Insurance finances. Not all pharmaceutical companies actively demonstrated positive corporate behavior changes, and a number of companies are assumed to be continuing to offer kickbacks in covert and indirect ways or to be maintaining passive response strategies without any clear changes. It will be difficult to eliminate kickback practices in a short period of time with the dual punishment system alone and to achieve the ultimate goals of improvement of the medicine distribution system, enhanced competitiveness of pharmaceutical companies, elimination of the pharmaceutical price bubble, and improvement of the National Health Insurance finances. Remedying the limitations of the dual punishment system, addition of regulations for the advancement of distribution and trade in the pharmaceutical industry, and various supporting measures such as tax benefits for pharmaceutical companies' investment in research and development need to be considered.

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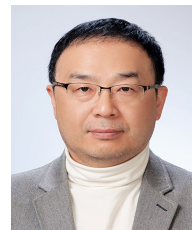
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