

New Anti-Rebate Legislation in South Korea

Su-Yeon Yu · Bong-Min Yang · Jin-Hyun Kim

Published online: 4 May 2013
© Springer International Publishing Switzerland 2013

Abstract The South Korean Government recently announced a reform in the drug anti-rebate law, with the purpose of eradicating pervasive, unethical, and illegal rebate practices in pharmaceutical marketing. The main objective of this reform is to have the ability to bring criminal charges against doctors and pharmacists for receiving illegal kickbacks from drug companies. Previously, provision of illegal kickbacks by drug companies led to criminal punishment of the drug companies alone, leaving doctors and pharmacists unpunished as the recipients. With the introduction of the “Dual Punishment System (DPS)” reform, criminal punishment for illegal rebates is extended to those receiving illegal kickbacks. Although bitter controversy erupted among stakeholders when the reform was first drafted, a civic group participated in the reform process and effectively influenced the legislative process to a successful end. Some interim outcomes from the DPS in terms of bringing illegal practices to account have already been reported since the policy’s implementation in November 2010. The reform background, goals, potential issues, and policy implications are explored in this study with the objective of providing further insight into drug policy for other countries that face similar challenges in the area of drug marketing.

S.-Y. Yu · B.-M. Yang (✉)
Graduate School of Public Health, Seoul National University,
Seoul, Korea
e-mail: bmyang@snu.ac.kr

J.-H. Kim
School of Nursing & The Research Institute of Nursing Science,
Seoul National University, Seoul, Korea

Key Points for Decision Makers

- All past government administrations have showed strong interest in cracking down on drug-related illegal rebates, and stakeholders and civic groups at the heart of the issue have had countless heated debates on numerous aspects of it.
- The DPS debate had its own politics and power struggles entangled with drug distribution and consumption.
- For ultimate prescription efficiency in Korea, additional demand and supply side measures could be added to the current DPS.

1 Introduction

In South Korea (hereafter, Korea), it has been an established business practice that some doctors and pharmacists receive extra payment or gifts from pharmaceutical companies and distributors in exchange for business favors, which are considered as unethical and illegal drug rebates¹ in Korea. The Korea Fair Trade Commission (KFTC) estimated the kickbacks to amount to around US\$1.70

¹ Drug-related rebates come in various forms. Some rebates are legally authorized while others are against the law. For example, in a risk-sharing scheme within a drug reimbursement system, rebates in the form of payback to payers are legally approved and are often even required. However, rebates in the form of covering expenses of academic conference participation, providing material gifts or discounts, and supporting various events organized by prescribers, dispensers, and medical institutions, are considered unethical and illegal by the Pharmaceutical Affairs Acts. The rebates that are the subject of this study are the illegal ones.

billion in 2009 alone [1]. The Korea–US Free Trade Agreement (FTA) in 2007, which finally became effective in both nations on 15 March 2012, also addressed the need for appropriate measures in both countries to prohibit improper inducement of healthcare professionals or institutions for formulary listing, purchasing, or prescribing of pharmaceutical products by pharmaceutical manufacturers and suppliers [2].

With the objective of halting such illegal rebate practices, which was rampant in the Korean pharmaceutical industry, regulation reform has been seriously pursued by the Korean Ministry of Health and Welfare (MOHW). The MOHW formed a taskforce called “Taskforce for Advancement of Pharmaceutical Pricing and Distribution” in July of 2009 and worked on legislation against illegal rebates. Taskforce members were drawn from the KFTC, the National Health Insurance Corporation (NHIC), the Korean Medical Association (KMA), the Korean Pharmaceutical Association, the Korea Pharmaceutical Manufacturers Association (KPMA), the Korean Research-Based Pharmaceutical Industry Association (KRPIA, an official group of global drug makers), and the Korea Pharmaceutical Wholesalers Association. In August 2009, the MOHW introduced a new rule that reduced the drug price by up to 20 % if its manufacturer provided kickbacks to promote its sales [3]. Until then, however, there was no legal ground to impose a criminal penalty for receiving kickbacks in connection with drug transactions. This double standard of criminal penalty for kickback providers but no penalty for the recipients posed a constant dilemma for drug producers. While drug producers came to heed the MOHW warnings and became highly wary of using rebates (illegal kickbacks) as a marketing tool, they still faced expectations of rebates from some hospitals and doctors who had become accustomed to receiving them. Adding further to the quandary, three incidents of suicide by drug salespersons were reported in 2009 [4], which demonstrated that a crackdown on drug manufacturers (givers) alone would not put an end to the illegal rebate practices in Korea.

Thus, a new rule called “dual punishment” was drafted, rendering both the giving and receiving ends of illegal rebates punishable. In February 2010, the new policy of the Dual Punishment System (DPS) was publicly announced by the MOHW. This new legislation faced strong resistance from various stakeholders and the process of legislation was delayed. However, the DPS reform bill finally passed the Korean National Assembly in April 2010 and was officially implemented in November 2010. With this new legislation in place, the Korean government can now impose criminal punishment on healthcare professionals who are involved, voluntarily or involuntarily, in illegal pharmaceutical marketing. As of March 2012, a number of criminal charges have been imposed on healthcare

providers for receiving illegal kickbacks. It would be of interest to other countries to observe how such a policy can be processed and brought to contend with the challenges posed by stakeholders, in particular, the receiving end of illegal kickbacks. By looking at the background, objectives, outcomes, and potential issues of this reform, we hope that meaningful lessons can be learned from the recent Korean DPS experience.

2 Methods

A rather simple research methodology, collecting and interpreting related information, was used. A review of the literature between 2006 and 2011 was undertaken in MEDLINE using the following terms: “South Korea,” “pharmaceutical,” and “reforms.” This provided only a limited number of relevant peer-reviewed publications in English. Consequently, the search was supplemented by additional papers written in Korean, including an online search of websites of relevant authorities and organizations in Korea, internal country documents, and feedback from key stakeholder groups. Papers about ongoing reforms in other countries were also searched and included in the study. Any costs are presented in KRW and US dollars (US \$1 = 1,156 KRW, 2010).

3 Structure of Korean Pharmaceutical Industry

3.1 Pharmaceutical Market

Korea’s pharmaceutical market was ranked among the world’s top 15 and is worth US \$15.7 billion with a global market share of 1.7 % in 2009 [5, 6]. Although its share of the global market is not significant, the Korean market is growing fast and is recognized by the Intercontinental Marketing Services Health as one of the fast-growing emerging economies [5].

Drug expenditure in Korea tended to grow more rapidly than the rest of healthcare expenditure in the NHIC until 2006 (Table 1) [7]. In this context, a strong cost containment measure entitled the “Drug Expenditure Rationalization Plan” was introduced in December 2006, with the purpose of downsizing pharmaceutical expenditure and applying pressure to lower drug prices. Not only was the positive list system implemented in Korea in 2007, but Korea also officially adopted economic evaluation and budget impact analysis as a tool for drug payment decisions with the introduction of a drug price negotiation system and reevaluation of currently listed drugs [8, 9]. As a result, the increase in drug expenditure started to slow but still accounted for 22.5 % of total (including both NHIC and

Table 1 Percentage of pharmaceutical expenditure out of total Korean National Health Insurance (NHI) expenditure, 2002–2009

	2002	2003	2004	2005	2006	2007	2008	2009
Total NHI expenditure (billion US\$)	46	53	61	69	80	90	99	111
Percentage of total NHI outlay (%)	25.2	27.2	28.4	29.2	29.4	29.4	29.6	29.6

Source: National Health Insurance Corporation, Statistical Yearbook [7]

non-NHIC expenditures) healthcare expenditure, which was significantly higher than the average for OECD countries (16.9 %) in 2009 [10].

3.2 Pharmaceutical Pricing and Research and Development

Total pharmaceutical manufacturing output in 2009 was US \$12.8 billion, which corresponds to 1.39 % of Korean gross domestic product (GDP) [6]. The average annual growth rate of pharmaceutical production over the period 2005–2009 was 8.7 %, which was higher than the average annual growth rate of the global gross national product (GNP) of 5.3 % [11]. Pharmaceutical import into Korea has always exceeded its export since 1995. In 2009, for example, the trade deficit for pharmaceuticals was almost US \$2.48 billion, slightly lower than US \$2.80 billion of the previous year [12].

About 4.55 % of Korean pharmaceutical sales were allocated for research and development (R&D) in 2008, which stands in significant contrast to that of 31 global pharmaceutical companies (16 %) [11, 13]. Korean data reveals that only 3 firms put more than 7 % of sales into R&D in 2007 [14]. Local manufacturers' development programs generally have focused on production of generics rather than development of innovative drugs. One of the reasons local companies focus on generics lies in the fact that the current drug pricing system guarantees relatively good prices for generic products. For example, under the current drug pricing regulatory system, a drug price falls to 70 % of the patent price in the first year of the patent expiration and to 53.6 % from the second year onward. The generics get 59.5 % of the patent price in the first year and 53.6 % (same as the off-patent originals) from the second year onward [15]. Therefore, it appears that drug producers are prepared to use aggressive promotional activities like drug rebates in return for relatively good mark-ups (compared to full market competition), while allowing R&D motivation to sink. Under the current generic pricing rule, it is evident that sales volume, not R&D itself, is the life-line of the pharmaceutical companies, rendering their R&D efforts greatly diminished as long as generic pricing remains sufficiently rewarding. This also partly explains the high number of local drug companies (over 580 in 2009) [11]. Moreover, because the drug companies' profits

are well protected domestically by the current regulatory pricing scheme, there exists little interest in exploring the competitive overseas market. The majority of capital in the industry is retained for vigorous promotional activities within Korea.

3.3 Characteristics of Market Structure

The Korean pharmaceutical industry can be characterized by a low entry barrier, no generic price competition, and heated sales promotions among a large number of small-sized drug suppliers, including manufacturers and wholesalers. The generous pricing of generics and the absence of price competition, coupled with the Korean FDA's moderately stringent new drug approval process, create an ever-inviting environment for new manufacturers to enter the market and produce generic products.

In the past decade, there has been a significant consolidation of pharmaceutical wholesalers in Europe. In many EU member states, more than two thirds of the pharmaceutical market is now supplied by the top three [16]. Relative to its pharmaceutical market size, however, there are still countless small-scale suppliers in Korea. There existed only 24 manufacturers with product value exceeding US \$86.5 million in 2009 [11] and the number of wholesalers providing drug distribution services was 1,245, 90 % of which had sales less than US \$8.6 million in 2008 [17]. Under such circumstances, intense competition among producers, among wholesalers, and between producers and wholesalers, is inevitable. The excessive number of producers and wholesalers and lack of specialization in business strategy could have led to unhealthy competitive behaviors by both rebate givers and receivers, negatively impacting the overall efficiency of the Korean pharmaceutical market.

4 Illegal Practices in Pharmaceutical Market

4.1 Current Situation

Illegal promotional activities are still not uncommon in the Korean pharmaceutical industry. Drug manufacturers and wholesalers have offered both extra payment and gifts to healthcare professionals and institutions in return for

prescribing and purchasing their products. As stated above, in December 2007, the KFTC reported consumer damage caused by illegal rebates in the pharmaceuticals market of approximately US \$1.8 billion, which accounts for about 20 % of total pharmaceutical sales that year [1]. In 2009, the KFTC made corrective orders against pharmaceutical companies that unduly lured customers or obstructed others' business activities, imposing total penalties of US \$17.6 million on seven manufacturers (five global and two local companies). In addition, KFTC financial penalties of US \$2.5 million in total were imposed on nine pharmaceutical companies for illegal rebates during 2006–2010 [18]. The KFTC revealed specific types of unfair luring of purchasers as follows: offering economic benefits in the form of advisory and consultation fees, fees for product presentation, supporting doctors' seminars and workshops, excessive fees for conducting postmarketing surveillance, or providing free goods and services including televisions, computers, medical devices, and monetary support [1].

4.2 Factors Involved in Illegal Marketing Practices

Unlike other products, medicines are unique in that the ultimate choice of a product lies in the hands of prescribing doctors and not with the patients taking the drugs or third-party payers who pay the bills. Thus, pharmaceutical companies have no choice but to target doctors and medical institutions rather than patients when marketing their products. As such, they have strong incentives to maintain positive relationships with the doctors and pharmacists involved in prescribing and dispensing their products.

There are some other significant reasons why illegal drug rebates are prevalent in Korea. First, as noted earlier, fierce competition among drug suppliers make the suppliers concentrate on marketing activities. Industry data reveal that sales and administrative spending in local pharmaceutical companies account for 40 % of their total sales, which is far greater than the average for manufacturers in other sectors (12 %) [19]. The Korean government has no control over visits by drug company representatives to doctors' offices, which aim to target doctors' prescribing choices, and there are no binding measures such as compulsory International Nonproprietary Name (INN) prescription or compulsory generic substitution by pharmacists that can effectively regulate doctors' prescription behaviors or patterns. Furthermore, because healthcare providers are reimbursed on a fee-for-service basis and the for-profit private sector dominates healthcare delivery in Korea, profit-maximizing behavior of healthcare providers is deemed as the rational norm. Although the Korean NHIC has a drug reimbursement formulary, it does not prevent a doctor's prescription choice from being influenced by

promotional marketing by a certain manufacturer; there are many drugs within a therapeutic group in formulary and doctors can change their prescriptions as they wish within a group. In general, the Korean government sets prices of drugs in the formulary at a rate that are higher than the actual transaction price (ATP). By NHIC law, medical institutions (hospitals and pharmacies) are reimbursed at the government-set prices. Therefore, the difference between the ATP and the government price is where the creative manipulation of illegal rebates occurs. Hospitals and pharmacies are supposed to report ATPs and ultimately not pocket the difference, but medical institutions simply have not been reporting ATPs. As a result, heavy price competition prevails in the form of illegal rebates, often disguised as sales promotions or in the form of hidden transactions involving money when there should be no price competition among pharmaceutical companies for the same products.

5 New Anti-Rebate Law

5.1 Previous Law

The 2007–2008 amendment of the Pharmaceutical Affairs Acts (PAA) [20] dictated that pharmaceutical manufacturers, importers, and distributors (wholesalers) shall not provide pharmacists and doctors in medical institutions with any free gifts for the purposes of sales promotions. This regulation, however, has been assessed to be insufficient in deterring kickbacks effectively. First, "free gift for sales promotion" was not well defined in the amendment and therefore failed to inform stakeholders which marketing activities were illegal. Second, there existed an imbalance of punishment between kickback providers and recipients. If manufacturers or wholesalers as givers were detected violating the regulation, they were subject to business suspension. On top of such administrative charges, criminal charges and fines of up to US \$2,600 or a maximum 1-year imprisonment could be imposed. Healthcare professionals as kickback receivers, however, faced a maximum 2-month business suspension as an administrative charge only, with no criminal penalty attached. In other words, under the 2007–2008 amendment, kickback providers were criminally penalized while receivers were not. Lastly, the degree of punishment assigned to law violators was still not harsh enough to serve as a disincentive in conducting illegal marketing activities. Under such a light and imbalanced penalty frame, gains from illegal rebates could easily outweigh the potential loss that offenders might be willing to pay in fines and even in business loss.

Table 2 Changes in anti-rebate legislation

Measure	Before DPS	After DPS
Healthcare provider: Doctor/Pharmacist/Hospital		
Administrative charge	2-month license suspension	1-year license suspension
Criminal charge	None	Fines of up to US \$26,000, or imprisonment less than 2 years
Manufacturer/Importer/Wholesaler		
Administrative charge	Manufacturer and importer: from 1-month suspension to revocation of operation permit Wholesaler: from 15 days to 6 months suspension	Same as before
Criminal charge	Fines of up to US \$2,600 or imprisonment less than 1 year	Fines of up to US \$26,000 or imprisonment less than 2 years

Source: Korean Food and Drug Administration, the Pharmaceutical Affairs Acts, 2010

DPS dual punishment system

5.2 Reform Process and the Resulting DPS

Facing the dilemma of weak regulation and continuing illegal rebates, the Democratic Party, which was the leading political party at the time, submitted the PAA amendment bill that proposed to impose criminal punishment for both parties (illegal rebate givers and receivers) under a DPS in August 2008. However, no practical discussion followed in the National Assembly regarding the DPS. The Democratic Party proceeded to submit two further versions of DPS legislation, and, finally, in February of 2010, all three previously submitted DPS-related bills were brought before the National Assembly's Health and Welfare Committee and the MOHW announced its intention of introducing the DPS.

The MOHW believed a driving force behind the DPS would be a political deal with the Korean Hospital Association (KHA). Since 2000, the KHA had demanded that the government recognize illegal rebates as an incentive for purchasing pharmaceuticals at lower prices so that the illegal rebates could be retained as legally approved revenues for hospitals. Such a demand for an incentive system, however, was strongly opposed by civic groups, in particular by a consumer advocacy group called Citizens' Coalition for Economic Justice (CCEJ). The pharmaceutical industry also opposed the suggested incentive program, arguing that the balance in bargaining power between hospitals and pharmaceutical companies would become even more skewed in the long run as hospitals push the companies for greater discounts and rebates.

A turning point for the DPS legislation came after some political effort from the KPMA. The entire pharmaceutical industry, represented by the KPMA, persuaded the National Assembly's Health and Welfare Committee to legislate the DPS in return for the incentive program if the political atmosphere of dialogue between the MOHW and KHA enforced the KHA-proposed incentive system to be

eventually introduced. The CCEJ also played an important role in accelerating the passage of the DPS. The CCEJ reported their survey results on lawmakers' potential votes (in favor vs not in favor) on the dual punishment structure in early April 2010, saying that 11 out of 24 committee members answered the question and all of them expressed support for dual punishment. The CCEJ strongly urged the lawmakers to pass the bill. As a result of public hearings and negotiations among stakeholders, the MOHW managed to introduce both the DPS and the incentive system simultaneously, making all stakeholders both gain and lose.

Parliamentary discussion on all the previously submitted DPS-related bills followed; the original one and a revised bill from the Democratic Party in late February 2010, and two revised bills from the Grand National Party (current ruling party) in March and April of 2010. Agreed upon by the MOHW and the National Assembly Committee, a new DPS bill was proposed and finally passed the Assembly in late April of 2010. The new anti-rebate law was officially introduced for general public hearing in May 2010 and it was subsequently implemented with an effective date of November 2010.

Changes brought by the implementation of the DPS are summarized in Table 2. According to the new legislation, a healthcare provider or medical institution shall not take any economic kickbacks beyond allowances. Also, the amended law allows criminal charges to be brought against doctors and pharmacists if they are involved in illegal transactions of any kind. It further specifies that physicians and pharmacists will have their licenses suspended for up to 1 year for the administrative charge and/or be sentenced to less than 2 years in prison for the criminal charge. The degree of punishment on manufacturers or wholesalers that provide kickbacks was also strengthened, as detailed in Table 2.

Another notable element of the DPS legislation is a highly generous financial reward for providing information

on undetected rebates. The legislation introduced rewards of up to US \$260,000 for reporting an illegal transaction between kickback providers and takers, with the reward paid to the informant when the crime is found to be true.

Various reactions were observed during the process of DPS legislation. The DPS introduction sparked strong opposition from doctors, who claimed they were offended by being treated like potential criminals and further argued that the government attempted to shift its responsibility onto doctors for the growth in pharmaceutical expenditure. Some doctors boycotted drugs from the local pharmaceutical companies that were known to have supported the government's decision on dual punishment policy [21]. Meanwhile, the pharmaceutical companies, although fearful that doctors' animosity would influence pharmaceutical sales negatively, supported the establishment of dual punishment by law. They pointed out that the MOHW anti-rebate campaign that targeted the companies alone in the past was not only unfair but also ineffective. Civic groups were doubtful of whether the new policy would effectively reduce the size of illegal rebates, because the level of criminal punishment was still low and various exemption clauses were newly introduced into legislation during the stakeholder negotiation process. They expressed concern that the low level of punishment along with the exemption clauses may nullify the reform.

5.3 Interim Outcomes of the DPS

There have been some tangible outcomes with the newly initiated DPS legislation during the past 2 years of implementation. In total, 23,092 physicians, 130 pharmaceutical companies, and 221 wholesalers have been detected and punished for illegal rebates since introduction of the DPS. From 2007 to 2009, only 17 pharmaceutical companies were reported for illegal rebates before the DPS. Increased reporting of illegal rebates seemed to be the result of a joint effort from the introduction of the DPS and strengthening governmental regulation; the Public Prosecutors' Office, the National Policy Agency, KFTC, KFDA, HIRA, NHIC, and other public offices, after the launch of the DPS, collaborated to establish the "joint governmental investigation on pharmaceutical rebates" in order to crack down on rebates [22]. On top of criminal charges on both the providing and receiving ends of illegal kickbacks, by the DPS law, the MOHW is obliged to cut the price of kickback-related drug items. To date, the MOHW has lowered prices of 130 drug items from 9 companies with the average price reduction of 9%, which was expected to achieve an annual NHIC budget saving of US \$48 million [22].

Meanwhile, the decrease in illegal rebates can be linked to a decrease in sales and administrative spending of pharmaceutical companies. However, it is difficult to judge

the net effects of the DPS at present because (1) sales and administrative spending had been declining even before the introduction of the DPS, and (2) data from only 1 year (2011) are available for cross comparison [23].

6 Some Issues Anticipated

Although the new law has been successfully implemented, several issues have already been raised. The exemption-from-punishment clause within the new law has been a contested issue. The DPS policy both strengthened the level of punishment for rebate providers and introduced a new punishment rule against rebate takers. However, provisions were made for circumstances when both the givers and takers would be exempt from prosecution. According to the new law, for example, a drug salesperson is allowed to provide business entertainment of less than US \$87 in value or a promotional product valued less than US \$8.70 for marketing purposes. It further specifies that the number of these business receptions by a salesperson cannot exceed four times a month [24]. Civic groups, however, argue that these exemption-from-punishment clauses are improper because they make clearly illegal practices look legal. They have also expressed concerns that illegal rebates can easily be hidden in transactions that take place under the practices of legal marketing behaviors.

Another issue concerns the level of punishment for accepting illegal rebates. Once again, civic societies argue that the specified maximum penalty of 1-year suspension of license for physicians and pharmacists and/or less than 2 years imprisonment may not serve to deter expectations of kickbacks. When a low probability of detection of illegal practices is combined with a relatively insignificant level of criminal penalty, it is possible that the potential costs of receiving illegal rebates can be seen as being outweighed by expected benefits. Therefore, expecting effective control over illegal kickbacks through the new law may not turn out to be as effective as first thought.

Another significant issue concerns the question of who ultimately benefits from this legislation. The ultimate losers of any illegal rebates are the consumers/patients who end up paying higher drug costs either in the form of higher unit prices or greater quantity of consumption, or both. Net savings are expected when the new regulation becomes truly effective, but the question remains of whether the savings would be properly transferred to consumers, as is hoped, or retained by pharmaceutical companies. Unless the health authority becomes actively involved in the reallocation of the net savings from pharmaceutical companies to consumers in the form of price reductions, it is likely that the money will stay in the hands of the pharmaceutical companies.

Finally, there remains some concern regarding pharmaceutical companies and their funds that are freed up from not having to pay illegal rebates. It is expected that the new policy would allow pharmaceutical companies to channel their net savings from illegal rebates to R&D investment, which would enhance the competitiveness of the Korean pharmaceutical industry in both domestic and international markets. However, we believe that this optimistic view will remain unfulfilled as long as the government-set price of patent-expired generics remains as high as it is now (53.5 % of price of originals on average). Under such conditions, local pharmaceutical companies have little incentive to research and develop innovative products for the sake of market survival. In this sense, we feel that the new anti-rebate legislation will not likely function as was originally hoped.

7 Concluding Comments

Against accumulating annual budget deficits in the NHIC, the Korean government has been introducing various policies of managing pharmaceutical expenditure since 2006 [8, 9]. This process of policy reform and introduction is still ongoing, and eliminating illegal rebates that were deeply embedded in pharmaceutical transactions was a part of this large-scale reform. As in cases from other countries [25–27], the objective of pharmaceutical policy may not be attainable with a single intervention. In other words, the policy effect of the DPS may require other interventions to effectively improve doctors' prescription and transparency of pharmaceutical circulation, such as INN prescription, compulsory generic substitution by pharmacists, or price cutting of generic drugs.

Currently, similar initiatives are being implemented in other countries. For example, pharmaceutical manufacturers have to report certain gifts and payments to physicians under the Physician Payment Sunshine Act from 2014 in the USA [28]. Sweden and Croatia have limited the number and the extent of contact between company representatives and physicians for strict controls over marketing activities. The adherence to these controls was enhanced through penalties or potential delisting of products [29, 30]. These initiatives are often coupled with multiple measures to further enhance the prescribing efficiency and to fully realize the resource benefits. The United Kingdom introduced the “M and W” scheme leading to lower generic costs and better transparency in generic pricing, which led to an appreciable fall in the reimbursed drug expenditure [27]. The Netherlands similarly increased the generic utilization through preference pricing policies [26]. Lithuania also has compulsory INN prescribing and pharmacists should display the cheapest generics [25]. In this regard,

for ultimate prescription efficiency in Korea, additional demand and supply side measures could be added to the current DPS.

Although it is too early to assess the success or failure of the DPS itself, particularly in terms of illegal kickbacks prevention, it is a meaningful step toward increased transparency in drug transactions in Korea. Every past governmental administration had showed strong interest in cracking down on drug-related illegal rebates, and stakeholders and civic groups at the heart of the issue have had countless heated debates on numerous aspects of it, but with little meaningful outcome in hand. Finally, Korean policy settled upon the DPS.

As with many other health policy issues, the DPS debate had its own politics and power struggles entangled with drug distribution and consumption. However, all stakeholders agreed to some level that punishment for illegal rebates had to be dual in nature, with criminal charges being imposed on both the providers and the receivers, which contributed to the passing and implementation of the DPS. The DPS itself may not be sufficient to bring about all the anticipated benefits but the message in this strengthened regulation is clear and promising. We do hope that the Korean experience with the DPS can provide a meaningful lesson to other health systems that face similar pharmaceutical market challenges.

Acknowledgments The study was conducted and prepared without any source of funding. The work presented here was carried out by collaboration of all authors; Yang B and Yu S defined the research theme, Yu S is the guarantor for overall content, while Yu S and Kim J collected the data and interpreted the results. All authors contributed to writing of the manuscript and have no conflicts of interest that are directly relevant to the content of this article. The opinions expressed in this manuscript are those of the authors.

References

1. Korea Fair Trade Commission. Corrective Measures against improper concerted acts by 10 pharmaceutical companies. [online]. http://www.ftc.go.kr/news/ftc/reportView.jsp?report_data_no=2819&tribu_type_cd=&report_data_div_cd=&currpage=1&searchKey=1&searchVal=10&startdate=&enddate=. Accessed 1 March 2013.
2. US International Trade Commission. US-Korea Free Trade Agreement: Potential Economy-wide and Selected Sectoral Effects, Chapter 3. Sector-specific assessment, 2007. p. 65–6.
3. The Ministry of Health and Welfare in Korea. Reducing price of a drug involved in rebates, [online]. [http://www.mw.go.kr/front/all/sal0301vw.jsp?PAR_MENU_ID=04&MENU_ID=0403&CONT_SEQ=218130&page=1&SEARCHKEY=TITLE&SEARCHVALUE=약가 인하\(price reduction\)](http://www.mw.go.kr/front/all/sal0301vw.jsp?PAR_MENU_ID=04&MENU_ID=0403&CONT_SEQ=218130&page=1&SEARCHKEY=TITLE&SEARCHVALUE=약가 인하(price reduction)). Accessed 12 July 2012.
4. SBS Newspapers, Continuous suicide of salesmen, Why? [online]. http://news.sbs.co.kr/section_news/news_read.jsp?news_id=N1000688080. Accessed 1 March 2013.
5. IMS Health. Pharmerging shake-up: new imperatives in a redefined world. [online]. http://libproxy.catholic.ac.kr/be022ed/_Lib_Proxy_Url/search.proquest.com/docview/1034409304/fulltextPDF/13CBE5FB1203B022CF2/9?accountid=10373. Accessed 1 March 2013.

6. Hong SW, The current status and regulations on MRCT in Korea. Asia-Pacific Economic Cooperation. [online]. http://www.apec-ahc.org/files/tp201002/Session4_SoonWookHong.pdf. Accessed 1 March 2013.
7. National Health Insurance Corporation. Statistical Yearbook. 2010.
8. Yang B, Bae E, Kim J. Economic evaluation and pharmaceutical reimbursement reform in South Korea's National Health Insurance. *Health Aff.* 2008;27(1):179–87.
9. Lee H, Kim J. Delisting policy reform in South Korea: failed or policy change? *Value Health.* 2011;15:204–12.
10. OECD, Health Data. 2011.
11. Lim D, Choi H, Joung M, et al. The Study on Pharmaceutical Industry Analysis, Korea Health Industry Development Institute. 2010.
12. Korea Pharmaceutical Statistics. Korea Pharmaceutical Manufacturers Association. 2010.
13. Lee G, Seo K, Lim D, et al. Fact and analysis of the research and development in health industry. Korea Health Industry Development Institute. 2009.
14. Joung M, Lee B, Joung Y, et al. The study on pharmaceutical industry. Korea Health Industry Development Institute. 2008.
15. The Ministry of Health and Welfare in Korea. New Policy of Drug Price. [online]. [http://www.mw.go.kr/front_new/al/sal0301vw.jsp?PAR_MENU_ID=04&MENU_ID=0403&page=1&CONT_SEQ=258276&SEARCHKEY=TITLE&SEARCHVALUE=약가\(drug price\)](http://www.mw.go.kr/front_new/al/sal0301vw.jsp?PAR_MENU_ID=04&MENU_ID=0403&page=1&CONT_SEQ=258276&SEARCHKEY=TITLE&SEARCHVALUE=약가(drug price)). Accessed 1 March 2013.
16. Taylor D, Mrazek M, Mossialos E. Regulating pharmaceuticals distribution and retail pharmacy in Europe. In: Mossialos E, Mrazek M, Walley T, editors. *Regulating pharmaceuticals in Europe*. Maidenhead: Open University Press; 2004. p. 196–212.
17. Joung Y, Lee B, Joung M, et al. A study on the development of pharmaceutical wholesalers industry. Korea Health Industry Development Institute. 2010.
18. Daily Pharm. Heavy Penalty imposed on 9 drug companies for illegal rebates. [online]. <http://www.dreamdrug.com/Users/News/NewsView.html?ID=141670>. Accessed 1 March 2013.
19. The Ministry of Health and Welfare in Korea. The direction for transparency and enhancement of drug circulation. [online]. http://www.kpanews.co.kr/bbs/data/kpanews_.asp?show_idx=8301&table=bbs_data&category=1&page=6&search=&keyword=. Accessed 1 March 2013.
20. Korean Food and Drug Administration. The Pharmaceutical Affairs Acts. 2010.
21. Dailymedi. Doctors keep boycotting products from 5 pharmaceutical companies who are in support of the DPS legislation. [online]. <http://66.232.143.22/news/view.html?skey=%B0%A3%BE%CF&page=5§ion=1&category=4&no=457538>. Accessed 12 July 2012.
22. The Board of Audit and Inspection of Korea. Audit on Management of NHI drugs. 2012.
23. The Study on Pharmaceutical Industry Analysis, 2012, Korea Health Industry Development Institute. [online]. <http://www.bai.go.kr/>. Accessed 1 March 2013.
24. Korea Fair Trade Commission. Exposed illegal rebate by pharmaceutical companies. [online]. <http://www.ftc.go.kr/news/ftc/reportList.jsp>. Accessed 1 March 2013.
25. Garuoliene K, Godman B, Gulbinovic J, et al. European countries with small populations can obtain low prices for drugs: Lithuania as a case history. *Expert Rev Pharmacoecon Outcomes Res.* 2011;11(3):343–9.
26. Woerkom M, Piepenbrink H, Godman B, et al. Ongoing measures to enhance the efficiency of prescribing of proton pump inhibitors and statins in The Netherlands: influence and future implications. *J Comp Eff Res.* 2012;1(6):527–38.
27. McGinn D, Godman B, Lonsdale J, et al. Initiatives to enhance the quality and efficiency of statin and PPI prescribing in the UK: impact and implications. *Expert Rev Pharmacoecon Outcomes Res.* 2010;10(1):73–85.
28. Roehr B. Drug companies will have to report all payments to US doctors from March 2014. *BMJ* 2013;346. doi:10.1136/bmj.f826.
29. Godman B, et al. Multifaceted national and regional drug reforms and initiatives in ambulatory care in Sweden: global relevance. *Expert Rev Pharmacoecon Outcomes Res.* 2009;9(1):65–83.
30. Brkicic LS, Godman B, Voncina L, et al. Initiatives to improve prescribing efficiency for drugs to treat Parkinson's disease in Croatia: influence and future directions. *Expert Rev Pharmacoecon Outcomes Res.* 2012;12(3):373–84.