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Analysis of the Korean generic medicine market: Factors affecting the market share of generic medicines

Dong-Sook Kim | Jihye Shin | Jusun Chung

Department of Research, Health Insurance Review & Assessment Service, Wonju, South Korea

Correspondence

Dong-Sook Kim, Department of Research, Health Insurance Review & Assessment Service, Hyeoksin-ro 60, Wonju, South Korea.
Email: ststone@hanmail.net

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Abstract

This study probed the market share of generic medicines by patients' age and sex, type of medical facilities, route of administration, number of generic brands, market size (drug expenditure), and therapeutic class and investigated factors associated with a high market share of generic medicines in Korea. We analyzed using national health insurance data between 2010 and 2019. The dependent variable was the generic medicine market share, measured as the number of prescriptions and expenditures. Multivariable regression analysis was conducted using the numbers of generic brands, market size by each ingredient and therapeutic class, relative price, the number of prescriptions, and therapeutic class. Total pharmaceutical expenditures have increased due to the high use of single-source drugs. The number of prescriptions and expenditures for generic medicines were 0.3 billion prescriptions and \$7.8 billion, respectively, accounting for 46.5% and 46% of the total market. Multivariate analysis showed that the number of prescriptions (>20 thousand) and the market size of main active ingredients (>\$1 million) were associated with an increased market share, whereas the number of generic brands (compared to <3) was associated with reduced generic medicine market share. In conclusion, we found that supply policies to promote the market entry of generic medicines by mandating price consistency between generic medicines and off-patent original medicines had limitations in increasing the generic medicine market share. Policy should be put in place both to ensure the timely market entry of generic medicines and to promote the use of cheaper generic medicines.

Study Highlights

WHAT IS THE CURRENT KNOWLEDGE ON THE TOPIC? Promoting the competition of generic medicines could be a core policy to reduce pharmaceutical prices and expenditures.

WHAT QUESTION DID THIS STUDY ADDRESS?

There is a need to investigate the factors associated with the market share of generic medicines.

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WHAT DOES THIS STUDY ADD TO OUR KNOWLEDGE?

Market size (as drug expenditures) by ingredient, price, the number of prescriptions, and therapeutic classes were all associated with an increased market share of generic medicines, whereas the number of generic brands was not a significant factor.

HOW MIGHT THIS CHANGE CLINICAL PHARMACOLOGY OR TRANSLATIONAL SCIENCE?

Policy should be put in place both to ensure the timely market entry of generic medicine, and to increase the market share of generic medicines.

INTRODUCTION

Generic medicines have improved patient compliance by reducing patients' out-of-pocket costs, while generating savings for the health care system by providing the same efficacy at lower prices.¹ Encouraging the market entry of generic drugs and promoting the use of generic medicines are crucial in terms of boosting accessibility and reducing costs.²⁻⁸ Therefore, the United States and many European countries are seeking growth of the generic medicine market as a tool for curtailing pharmaceutical expenditures, as pharmaceutical costs have been increasing faster than economic growth over the past decades.^{1,9,10} The prescription share of generics jumped from 57% in 2004 to 86% in 2013, and it has been reported that the expansion of the generic medicines market saved the US health care system a trillion dollars.^{11,12} Meanwhile, in some countries, the use of generic medicines or biosimilars has been reported to be limited despite demand-side policies targeted at pharmacists and patients.^{13,14}

In April 2012, Korea introduced a policy that mandated both the prices of generic drugs and off-patent original medicines to be set at 53.55% of the on-patent prices of the originals 1 year after entering the market to curb increasing medication expenses. This applied to products with three or more generic drugs with the exception of certain drugs. The principle of "same ingredients and same strength, at the same price" lowered drug prices and eliminated the price gap between brand-name drugs and generics.¹⁵ However, after a decade of enforcing this policy, which requires the same price for drugs, there is no mechanism to induce pharmaceutical companies to provide generic drugs at lower prices. Moreover, physicians have stated that they have no incentive to use generics because the out-of-pocket costs for patients remain the same.¹⁶

Although the above-described policy was appropriate to decrease pharmaceutical expenditures, it did not address other points to induce the market competition of generic medicines, and thereby to push down the prices of generic medicines spontaneously.^{17,18} Therefore, there is still a need to amend the pricing policy of generic medicines to achieve further price reductions. Moreover, the

use of generic medicines in Korea has not been properly documented in terms of the characteristics of patients and classes of medicines. This study intended to probe the market share of generic medicines by patients' age and sex, type of medical facilities, route of administration, size of market, competition level, and therapeutic class, and investigate factors associated with a high market share of generic medicines in Korea.

METHODS

Data source

This study used the Korean national health insurance claims data between 2010 and 2019. In Korea, there is a single-payer national healthcare system that pays for all inpatient and outpatient visits, prescriptions, and dispensations in pharmacies for all citizens on a fee-for-service basis. The captured variables included patients' demographic characteristics, disease, medical service use, and medication (ingredient name, dosage, price, number of days, and pharmaceutical cost). Out-of-pocket expenses were determined using both a fixed rate and a flat rate calculation, as well as a cap on out-of-pocket expenses.

We used the cumulative reimbursement medicine list managed by the Health Insurance Review and Assessment Service (HIRA) to review price and dosage changes.

Identifying generic medicines

Between 2010 and 2019, a total of 185,569 products and 6813 ingredients, doses, and formulations were cumulatively listed in the market. Medicines with the same active ingredient, dose, and formulation have the same active ingredient, dose, administration route, and formulation, whereas medicines with the same active ingredient formulation have the same active ingredient, administration route, and formulation, with a total of 3616 listed.

In this study, original and generic medicines were distinguished using the ingredient formulation standard,

according to which the active ingredient, administration route, and formulation are the same. The identification for the same active ingredient following the Anatomical Therapeutic Chemical (ATC) classification of the World Health Organization (WHO).¹⁹ For instance, the registered original drug for atorvastatin (ATC C10AA05) is Lipitor (20 mg) by Pfizer Korea and its generic drug is Tovast Tab (20 mg) developed by Hanmi Pharmaceutical. In the case of esomeprazole (ATC A02BC05), the original drugs are Nexium Tab (20 mg and 40 mg) and Nexium Inj. by AstraZeneca Korea, and its generics are Esozole Tab (20 mg and 40 mg) by Celltrion Healthcare. Meanwhile, Nexazol Cap (20 mg and 40 mg) developed by LG Life Sciences and Eso-DT ODT (20 mg and 40 mg) by Taejoon Pharm were not regarded as generics as they have altered the formulation of the original.

Definition of dependent and independent measures

An overall pharmaceutical market trend analysis was conducted for single-source medicines, off-patent multisource original medicines, and generic multisource medicines. Patient characteristics were analyzed according to the formulation (oral vs. injectable, dermal, and inhalant drugs), age (children, adults, and the elderly), sex (women), and type of medical facility to investigate the characteristics of the subgroups.

To examine the influence of various factors on the market share of generic medicine, we performed calculations according to the analytical unit of this study, which was medications (the same main active ingredient and same formulation). For each active ingredient, there can be multiple brand name products with different dosages and/or routes of administration, and we did not consider dosage.

The dependent variable was the generic medicine market share, measured as the number of prescriptions (referred to as volume) and expenditures. In this multivariate analysis, the number of prescriptions and drug expenditures were calculated, excluding single-source medications. Total spending included value-added tax using National Health Insurance (NHI) claims data from the entire population. The proportions of generic medicines with the same main active ingredients were measured as continuous variables. The explanatory variables were the formulation (oral vs. injectable, dermal, and inhalant drugs), the number of generic brands by ingredient (<3, 3–9, and 10 or more), price (less than \$20 vs. \$20 or more), the number of prescriptions by ingredient (<20 thousand vs. 20 thousand or more), market size measured as the amount of drug expenditures for each ingredient (less than \$1 million vs. \$1 million or more), and

market size of the therapeutic class (less than \$0.2 billion vs. \$0.2 billion or larger) based on the WHO ATC 2-level therapeutic classification, as selected from Organisation for Economic Co-operation and Development (OECD) Health Statistics.²⁰

Statistical analysis

Multivariate regression analysis was performed using the following factors: year, formulation, the number of generic brands by ingredient, price, the number of prescriptions by ingredient, market size (as pharmaceutical spending) for each ingredient and therapeutic class, and therapeutic class based on the ATC 2-level.

SAS Enterprise version 7.1 (SAS Institute, Cary, NC, USA) was used for all analyses. We considered a two-tailed value of $p < 0.05$ to indicate statistical significance.

RESULTS

Overall market size and market share and the utilization of generic medicines

For generic medicines, the proportion of prescriptions increased, whereas the proportion of total pharmaceutical expenditures decreased. The number of prescriptions was 267 million in 2019, accounting for 46.5% of the total number of prescriptions. Although the number of generic prescriptions increased by three times in 2019 compared to 2010, the expenditures for generic medicines increased by less than two times. The pharmaceutical expenditures for generic medicines accounted for 46% of the market in 2019 (\$7.819 billion).

The market share of generic medicines by administration route showed that both the volume and value of injectable drugs increased sharply. For oral drugs, the value of expenditures for generic medicines increased from \$3.8 billion (92.7%) in 2010 to \$6 billion (81.21%) in 2019. For injectable drugs, the value of expenditures for generic medicines increased and the market share decreased from \$0.3 billion (7.3%) in 2010 to \$1.4 billion (18.8%) in 2019.

As shown in Table 1, the proportion of the 65+ age group and women in the share of generic medicines showed a slight increasing trend. The share of elderly users in the generic market increased from 38.2% in 2009 to 45.7% in 2019. The share of women in the generic market fluctuated, but increased slightly from 52.5% to 52.8% in 2019. The analysis of market share by type of medical facilities demonstrated that the share of clinics in the generic market decreased from 58.3% in 2010 to 53.3% in 2019.

TABLE 1 Overall market share and the utilization of generic medicine by subsector

| | No. of prescriptions, million (%) | | | Expenditures, million \$ (%) | | |
|------------------------|-----------------------------------|------------|------------|------------------------------|-------------|-------------|
| | 2010 | 2014 | 2019 | 2010 | 2014 | 2019 |
| Total | | | | | | |
| Single-source | 15 (6.6) | 19 (8.2) | 46 (8.1) | 783 (9.0) | 1257 (13.4) | 4142 (24.3) |
| Off-patent originators | 132 (60.0) | 124 (52.4) | 261 (45.5) | 3688 (42.6) | 3690 (39.3) | 5051 (29.7) |
| Generic medicines | 73 (33.3) | 93 (39.4) | 267 (46.5) | 4186 (48.4) | 4452 (47.4) | 7819 (46.0) |
| Generic medicine | | | | | | |
| Administration | | | | | | |
| Oral drugs | 54 (73.0) | 68 (72.3) | 95 (35.6) | 3816 (91.2) | 4009 (90.0) | 6049 (77.4) |
| Injectable drugs | 18 (24.3) | 22 (23.4) | 157 (58.8) | 302 (7.2) | 368 (8.3) | 1401 (17.9) |
| Dermal or inhalant | 2 (2.7) | 4 (4.3) | 15 (5.6) | 68 (1.6) | 75 (1.7) | 369 (4.7) |
| Age | | | | | | |
| Children (<7 years) | 3 (4.0) | 3 (3.5) | 15 (5.4) | 113 (2.7) | 96 (2.2) | 179 (2.3) |
| Adults (7–64 years) | 47 (64.2) | 58 (62.3) | 150 (56.3) | 2482 (59.3) | 2471 (55.5) | 4082 (52.2) |
| Elderly (≥65 years) | 23 (31.8) | 32 (34.2) | 102 (38.2) | 1591 (38.0) | 1885 (42.3) | 3558 (45.5) |
| Sex | | | | | | |
| Men | 34 (46.6) | 44 (47.3) | 123 (46.1) | 1988 (47.5) | 1942 (43.6) | 3690 (47.2) |
| Women | 39 (53.4) | 49 (52.7) | 144 (53.9) | 2198 (52.5) | 2510 (56.4) | 4129 (52.8) |
| Medical facilities | | | | | | |
| Tertiary hospitals | 25 (34.2) | 35 (37.6) | 107 (40.1) | 1334 (31.9) | 1376 (30.9) | 2709 (34.6) |
| General hospitals | 19 (26.0) | 28 (30.1) | 66 (24.7) | 410 (9.8) | 482 (10.8) | 940 (12.0) |
| Clinics | 29 (39.7) | 31 (33.3) | 94 (35.2) | 2442 (58.3) | 2595 (58.3) | 4170 (53.3) |

Market share of generic medicines by category

Table 2 shows the number of generic brands and the market share of generic medicines based on the number of prescriptions and expenditures by category.

The mean proportion of generic medicine in volume was higher among oral drugs (oral 65.1% and injectable 63.9%), whereas in expenditure higher among injectable drugs (oral 65.0% and injectable 65.6%). The generic market share by number of generic brands was as follows: in less than three 82.8%, in three to nine 52.5%, in greater than or equal to 10 60.5% by volume; and in less than three 81.2%, in three to nine 50.5%, in greater than or equal to 10 61.3% by expenditure. The generic market share among medicines with a number of prescriptions less than 20 thousand was 61.4% in volume and 60.9% in expenditures, and among the 20 thousand or more group it was 61.0% and 68.7%.

The share of generic medicines showed somewhat different results for spending by main ingredient and spending by ATC 2-level class. In terms of drug spending for the active ingredient market size, the generic medicine share was lower in markets less than \$1 million (61.4% by volume and 60.9% by expenditures) and higher in those

more than \$1 million (70.2% by volume and 70.3% by expenditures). On the other hand, generic medicine share of ATC-2 level class market was slightly higher in markets less than \$200 million. The generic medicine market share was high for G03 (sex hormones), and was low for C10 (lipid modifying agents), N05 (antipsychotics), and L04 (immunosuppressants). The therapeutic class with the lowest generic market share was antipsychotic drugs (45.2% based on volume and 40.6% based on expenditures), followed by antihyperlipidemic agents (52.0% and 48.0%, respectively), and immunosuppressant drugs (52.9% and 54.8%, respectively).

Expenditure according to therapeutic ATC-2 level

The largest market for generic drugs among the ATC 2-level classes with a market size of \$200 million or more in 2019 was C10 (lipid modifying agents, plain), followed by J01 (antibacterials for systemic use), A02 (drugs for acid related disorders), and C09 (agents acting on the renin-angiotensin system). The highest rate of growth was found in C10, followed by N07 (other nervous system drugs) and N06 (psycho-analeptics; Figure 1).

TABLE 2 The number of generic brands and the market share of generic medicines by categories

| Categories | No. of products (%) | Market share based on prescription (%) | Market share based on expenditure (%) |
|---|---------------------|--|---------------------------------------|
| Administration type (oral) | 7192 (66.5) | 65.1 | 65.0 |
| Injectable drugs, dermal, inhalant | 3618 (33.5) | 63.9 | 65.6 |
| No. of medicines (<3) | 3848 (35.6) | 82.8 | 81.2 |
| 3–9 | 3931 (36.4) | 52.5 | 50.5 |
| ≥10 | 3031 (28.0) | 60.5 | 61.3 |
| Price (<\$20) | 10,393 (96.1) | 63.8 | 64.5 |
| ≥\$20 | 417 (3.9) | 74.8 | 75.0 |
| No. of prescriptions by ingredients (<20,000) | 6684 (61.8) | 61.4 | 60.9 |
| ≥20,000 prescriptions | 4126 (38.2) | 70.2 | 70.3 |
| Same ingredients market (<\$1 million) | 6565 (60.7) | 61.0 | 59.7 |
| ≥\$1 million | 4245 (39.3) | 70.6 | 71.8 |
| ATC–2 level class market (<\$200 million) | 5026 (46.5) | 65.7 | 65.9 |
| ≥\$200 million | 5784 (53.5) | 64.5 | 63.2 |
| ATC | | | |
| A02 (drugs for acid related disorders) | 5634 (52.1) | 64.4 | 65.0 |
| A10 (drugs used in diabetes) | 1360 (12.6) | 67.1 | 63.4 |
| C01 (cardiac therapy) | 191 (1.8) | 71.5 | 72.0 |
| C02, C03, C07, C09 (hypertensive drugs) | 865 (8.0) | 67.9 | 65.3 |
| C10 (lipid modifying agents) | 237 (2.2) | 52.0 | 48.0 |
| G03 (sex hormones and modulators of the genital system) | 112 (1.0) | 81.3 | 75.6 |
| J01 (antibacterials for systemic use) | 987 (9.1) | 66.5 | 67.3 |
| L01 (antineoplastic agents) | 224 (2.1) | 71.0 | 69.6 |
| L04 (Immunosuppressants) | 97 (0.9) | 52.9 | 54.8 |
| M01 (Anti-inflammatory and antirheumatic products) | 500 (4.6) | 66.6 | 65.6 |
| N02 (analgesics) | 188 (1.7) | 65.8 | 66.8 |
| N05 (antipsychotics) | 132 (1.2) | 45.2 | 40.6 |
| R03 (drugs for obstructive airway disease) | 283 (2.6) | 58.8 | 58.3 |

Abbreviation: ATC, Anatomical Therapeutic Chemical.

Factors associated with generic medicine market share

Table 3 summarizes the results of the regression analysis performed to confirm variables that affect the generic medicine market share. The number of prescriptions (>20 thousand), price, and market size of main active ingredient (more than \$1 million) were significantly associated with an increased market share of generic medicine. However, the number of generic brands (3–10 and 10 or more compared to <3) and the market size of the same therapeutic class based on the ATC 2-level classification (\$200 million or more compared to <\$200 million) were associated with lower generic medicine market shares.

DISCUSSION

To our knowledge, this is the first study to describe the trend of competition and market share of generic medicines in Korea. The Korean government has implemented the policy of having the same price between generic medicines and off-patent original medicines since 2012. As a result, the timely market entry of generic medicines was successful. However, although the market of generic medicine was competitive and there was a high proportion of generic drug prescriptions, expenditures have not dropped to a meaningful extent.

Our analyses yielded four main findings. First, pharmaceutical expenditures increased considerably due to the more rapid introduction of new medicines than the

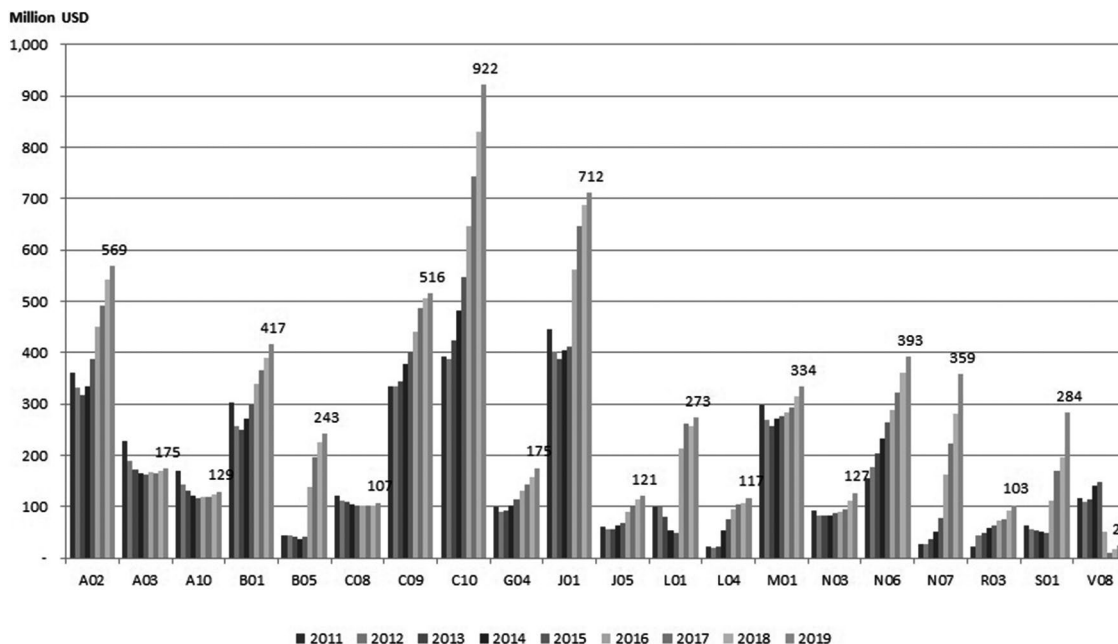


FIGURE 1 Expenditures for generic medicines in the Anatomical Therapeutic Chemical (ATC) 2-level class with a market of more than \$200 million

increase in the generic medicine market share. Even if generic medicines enter the market, prescribing behavior (e.g., continuing to use the off-patent original medicines or switching to new medicines) is likely to increase the overall drug cost. Second, we found that the expansion of the generic medicines market varied by market size (in terms of pharmaceutical spending), the number of generic brands, and therapeutic class. Third, the number of generic brands in the market varied by therapeutic class. A market size of the same therapeutic class with more than \$200 million was associated with a reduced generic market share, whereas a market size per ingredient of more than \$1 million was associated with an increased generic market share. The therapeutic class with the lowest generic market share was antipsychotic drugs, followed by anti-hyperlipidemic agents, and immunosuppressant drugs. Fourth, the therapeutic class with the lowest generic market share was antipsychotic drugs, followed by anti-hyperlipidemic agents. In general, there is a tendency not to use generic psychiatric drugs, even if bioequivalence has been demonstrated. In previous study, 73% of 105 patients responded that they would be unlikely to take a generic antipsychotic drug.²¹ Therefore, we thought that many psychiatric patients might prefer the original medicine brands. As expected, the market share of generic medicine in antipsychotic drugs was consistent with our hypothesis. However, the generic medicine market share was the second lowest for the therapeutic class of anti-hyperlipidemic agents; therefore, it is necessary to promote the use of generic medicines for chronic diseases. Last, a notable point

was that the generic market share was higher for therapeutic classes with fewer than three generic brands, a higher price (\$20 or more), and a larger market size (200 million or more). We expected that a higher number of generic brands would be associated with a lower price of generic medicines, and that a larger market size of the same therapeutic class would increase the market share of generic medicines; however, the opposite results were found. This trend is inconsistent with previous studies conducted in other countries. However, some studies in Korea reported findings consistent with these results.

In several previous studies, competition by the entry of generics has been shown to place a downward pressure on the prices of medicines. Previous studies reported that competition among generics medicines caused reductions in prescription drug prices,^{12,22–24} but some researchers reported a decrease in market competition over time, thereby leading to a lack of an effect on drug prices.¹² Most research in other countries has shown that generic price competition has been a successful strategy for lowering prescription drug prices, but some research has reported that this strategy did not work in Korea.²⁵ In contrast with previous studies, our study found that the competition in the market became excessively fierce as more generics entered the market. Although this fixed pricing policy at 53.55% of on-patent original medicines contributed to a higher level of competition, it did not have a large impact on market prices and expenditures. The manufacturer has no incentive to lower the price of medicines. Therefore, the price of

TABLE 3 Multivariate regression analysis of factors affecting the market share of generic medicines during 2010–2019

| Factors | Market share based on no. of prescriptions | | | Market share based on expenditures | | |
|---|--|--------|----------------|------------------------------------|-------|----------------|
| | β | SE | <i>p</i> value | β | SE | <i>p</i> value |
| Intercept | 489.5 | 231.63 | 0.0346 | 932.0 | 239.4 | 0.0572 |
| Year | −0.2 | 0.1 | 0.0747 | −0.4 | 0.1 | 0.0004 |
| Administration type (oral) | Ref. | | | Ref. | | |
| Injectable drugs, dermal, and inhalant | −1.3 | 0.8 | 0.0996 | −1.3 | 0.8 | 0.0979 |
| No. of medicines (<3) | Ref. | | | Ref. | | |
| 3–9 | −35.2 | 0.8 | <0.0001 | −34.5 | 0.8 | <0.0001 |
| ≥10 | −38.8 | 1.0 | <0.0001 | −39.7 | 1.0 | <0.0001 |
| Price (<\$20) | Ref. | | | Ref. | | |
| ≥\$20 | 3.5 | 1.9 | 0.0651 | 5.5 | 1.9 | 0.0038 |
| No. of prescriptions by ingredients (<20,000) | Ref. | | | Ref. | | |
| ≥20,000 prescriptions | 9.9 | 0.8 | <0.0001 | 11.6 | 0.8 | 0.0165 |
| Same ingredients market (<\$1 million) | Ref. | | | Ref. | | |
| ≥\$1 million | 21.7 | 0.9 | <0.0001 | 17.7 | 0.9 | <0.0001 |
| ATC–2 level class market (<\$200 million) | Ref. | | | Ref. | | |
| ≥\$200 million | −4.2 | 0.8 | <0.0001 | −2.0 | 0.8 | 0.0165 |
| ATC | | | | | | |
| N05 (antipsychotics) | Ref. | - | - | Ref. | - | - |
| A02 (drugs for acid related disorders) | 4.1 | 1.8 | 0.0259 | 1.6 | 1.9 | 0.3757 |
| A10 (drugs used in diabetes) | −2.7 | 2.4 | 0.2632 | 1.8 | 2.9 | 0.3757 |
| C01 (cardiac therapy) | −2.2 | 2.5 | 0.3805 | −2.4 | 2.5 | 0.342 |
| C02, C03, C07, C09 (hypertensive drugs) | 3.2 | 1.3 | 0.0145 | 4.3 | 1.3 | 0.0012 |
| C10 (lipid modifying agents) | −7.3 | 2.3 | 0.0016 | −5.5 | 2.4 | 0.0246 |
| G03 (sex hormones and modulators of the genital system) | 8.4 | 3.2 | 0.0093 | 11.7 | 3.4 | 0.005 |
| J01 (antibacterials for systemic use) | 6.7 | 1.3 | <.0001 | 4.3 | 1.3 | 0.009 |
| L01 (antineoplastic agents) | 5.1 | 2.5 | 0.0383 | 4.5 | 2.5 | 0.077 |
| L04 (Immunosuppressants) | −3.3 | 3.5 | 0.3431 | −7.6 | 3.6 | 0.0361 |
| M01 (anti-inflammatory and antirheumatic products) | 5.9 | 1.7 | 0.0004 | 4.4 | 1.8 | 0.0128 |
| N02 (analgesics) | 1.2 | 2.5 | 0.6332 | −0.1 | 2.5 | 0.9727 |
| R03 (drugs for obstructive airway disease) | −0.5 | 2.1 | 0.8045 | −1.7 | 2.2 | 0.4399 |

Abbreviation: ATC, Anatomical Therapeutic Chemical.

generic medicines converges at 53.55% of the price of the corresponding on-patent original medicines.

The major implications of this study are as follows: first, we analyzed trends in the total pharmaceutical market. We found that the market size of single-source drugs grew considerably with the introduction of new generic drugs. Therefore, pharmaceutical expenditures showed substantial growth even as patents expired. Korea maintains a positive reimbursement list using health technology assessments that address factors, such as cost-effectiveness. This study showed that generic price regulations had a limited effect and could

not prevent shifts in prescribing behavior to high-cost new drugs. Second, pharmaceutical expenditures were not falling as they should be, compared to the number of prescriptions of generic drugs and the growing share of generics in the off-patent market. This suggests that Korea needs a policy roadmap that can incentivize generic manufacturers to reduce prices while simultaneously encouraging medical institutions to use cheaper generics. According to a study of successful policies for introducing generic drugs in Japan, the keys to success were the government's promotion of the use of generic drugs, price adjustments for drugs that stayed on the

market for a longer time, and a generic-replacement incentive system offering JPY 60 for 20% or higher compounding fees for generics.²⁶ Third, the cumulative number of manufacturers tends to be higher in the off-patent market, implying that generics are more likely to enter larger markets.

Our study has some limitations that should be kept in mind. In many cases, original medicines first developed by multinational pharmaceutical companies are not registered on the patent list in Korea, as the product patent system was only introduced in 1987. For example, in the case of ranitidine (ATC A02BA02), Zantac Tab (30 mg) by GlaxoSmithKline was re-registered in 2016 after issues with distribution rights, whereas a product by Dong-A ST was listed as the first patent product. We could not analyze why pharmaceutical companies entered markets with a sufficiently large number of generic manufacturers. To address this question, future research would need to combine this data with information on the profitability of individual pharmaceutical companies.

In conclusion, the number of generic brands is 10,810 and the spending on generic medicines has increased during the 10-year period analyzed herein. These results suggest that supply policies that mandate price equivalence between generic medicines and off-patent original medicines have ensured the timely market entry of generic medicines. According to trend analysis, total pharmaceutical expenditures increased, and the market share of generic medicines decreased due to the introduction of new drugs. Of particular note, we found that a higher number of generic brands (compared to <3) was not associated with an increased generic medicine market share. Policy should be put in place both to ensure the timely market entry of generic medicines, and to promote the use of generic medicines by physicians, pharmacists, and patients.

CONFLICT OF INTEREST

The authors declared no competing interests for this work.

AUTHOR CONTRIBUTIONS

D.-S.K. wrote the manuscript. D.-S.K. designed the research. J.S. and J.C. performed the research. J.S. and J.C. analyzed the data.

ETHICAL APPROVAL

The studies involving human participants were reviewed and approved by the Institutional Review Board by Health Insurance Review and Assessment Service (HIRA). Written informed consent for participation was not required for this study in accordance with the national legislation.

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