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#### MarketWatch

### Pharmaceutical Reform In South Korea And The Lessons It Provides

The reform's implementation, although well-intentioned and successful in some respects, was imperfect from the start.

#### by Hak-Ju Kim and Jennifer Prah Ruger

**ABSTRACT:** Through implementation of its 2000 pharmaceutical reform, the South Korean government expected to reduce the cost of medications and improve service levels, medical appropriateness of care, and drug effectiveness. However, despite the reform's lofty goals, unintended consequences have distorted the supply of medical services and spending. These consequences have included increasing the use of uninsured services, prescribing high-price drugs, and a growing market share for multinational drug companies. Further reforms are needed to reduce the measure's adverse effects. This paper examines the Korean mandatory prescription system and offers an analysis of Korea's reforms. [Health Affairs 27, no. 4 (2008): w260–w269 (published online 28 May 2008; 10.1377/hlthaff.27.4.w260)]

N RECENT YEARS, multinational pharmaceutical companies have focused in-Lecreasing attention on South Korea. This attention has resulted largely from the Korean Health Care System Reform Act of 2000, or Separation of Prescribing and Dispensing (SPD). The new system prohibits doctors from dispensing medications to outpatients, and it bans pharmacists from prescribing drugs.1 Under the old system, pharmacists were allowed to write prescriptions, while doctors were free to dispense medications directly to their patients. Consequently, both doctors and pharmacists made higher profits, while patients unknowingly abused prescribed drugs. Abuse of drugs, particularly of antibiotics, was a chief reason that health authorities introduced the reform. Since 1 July 2000, drug dispensaries at hospitals have been shut down, and patients must purchase medicines at pharmacies using prescriptions from their doctors. General pharmaceutical products, such as antacids and painkillers, remain freely available at pharmacies.

This reform represented a structural shift in Korea's health delivery system, because it not only altered patterns of medical services provided by doctors to patients, but also increased the average fee-schedule price, expanded foreign companies' share of the domestic pharmaceutical market, and added to the large deficit in the government's health insurance budget. The government argues that the reform has been successful, because the use of

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antibiotics and injections in Korea has declined under the new system, leading to an actual reduction in health care spending. For instance, hospitals prescribed antibiotics to 43 percent of patients on average in the third quarter of 2001, down from 49 percent in the previous year. In the same period, hospitals also wrote prescriptions for injections for an average of 6 percent of patients—a 47 percent decrease from 12 percent in the previous quarter.<sup>2</sup> Hospital insurance claims also reveal a

marked decline in medicines, including steroid use.<sup>3</sup> The number of different antibiotics and other drugs prescribed per episode also appears to have decreased after the dispensing restriction, although no obvious differences were found in these reductions between viral and bacterial illness.<sup>4</sup>

However, government

health spending has increased, and multinational pharmaceutical manufacturers remain upbeat about their prospects in this major Asian market, the eleventh largest in the world. For example, according to Korea's Health Insurance Review Agency (HIRA), since the reform, the market share of highprice drugs has increased from 36.2 percent to 54.3 percent and that of original brand-name drugs has increased from 11.35 percent to 14.82 percent.<sup>5</sup> In addition, a survey of consumers demonstrates that transportation difficulties and time costs have restricted public access to medical facilities and pharmacies.6 The government is currently intent upon reducing these expenditures and patient costs with various cost containment measures, such as Actual Transaction Pricing (ATP), and offsetting them with a tobacco tax.

The purpose of this paper is to provide an analysis of the reform and its effects on health care spending and the pharmaceutical industry, and to offer suggestions for strengthening the system.

### Context Of Pharmaceutical Reform In Korea

Successful implementation of its economic development plan enabled the Korean government to introduce a public medical insurance system (National Health Insurance, or NHI) in the late 1970s. To enlist public support, the government set low medical service charges for insured patients, a practice that did not change much until recently. The low premium

rates in the NHI scheme, along with limited coverage and benefits, left many people underinsured. To help stabilize its finances, the NHI system subsidized and reimbursed less than 50 percent of expenditures for health insurance in various regions. To compensate for lost income, doctors' clinics and hospitals turned to prescribing drugs and selling them,

d multinaers remain this major est in the to Korea's come, doctors' clinics and hospitals turned to prescribing drugs and selling them, for profit, directly to their patients at their dispensaries. They also charged custom fees for uninsured medical services. Meanwhile, pharmacists increased their incomes by influencing customers' self-medicating behavior and sup-

plying the products they prescribed.

These practices had long been a bone of contention between groups representing doctors and pharmacists.8 They had also been blamed for rampant misuse and abuse of pharmaceuticals. Moreover, critics blamed them and the fee-for-service (FFS) system for increasing the portion of the country's debt attributable to the NHI system. Additionally, except for some illegal items such as opiates, people could purchase special drugs without any prescription from either doctors or pharmacists. Korean doctors and pharmacists also were widely known for prescribing excessive doses of antibiotics, to boost their profits and respond to patients' expectations. The rate of antibiotic resistance among Koreans was among the world's highest before the reform.9 The overuse of drugs, especially antibiotics, increased the overall resistance of germs, render-

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ing medication less effective and diseases more virulent. Under the old pharmaceutical system, Korea was ranked highest in the world in penicillin resistance.<sup>10</sup> The country's high drug spending was another important factor prompting reform in this area. Drug costs accounted for approximately 31 percent of national health spending before the reform.<sup>11</sup>

These problems and the growing overlap between the roles of doctors and pharmacists prompted efforts to separate the two professions' functions and ultimately to separate medical institutions from pharmacies.<sup>12</sup> However, implementing the decision-making process envisioned in the reform had been postponed several times by politics and by stakeholders' delaying tactics.13 The first government discussion on separating prescribing from dispensing took place back in 1963, following numerous committee meetings. A broad blueprint emerged in the late 1980s. At that time, the beginning date was to be July 1991, but it was postponed in the legislature. In December 1993 the Ministry of Health and Welfare (MOHW) took new legal steps to separate the roles of doctors and pharmacists, setting 7 July 1999 as the final implementation date. But opposition from the Korean Medical Association (KMA) and the Korean Pharmacists Association (KPA) forced a further delay, and successful implementation continued to elude the government. The reform effort truly concluded 1 July 2000, with the SPD Act.

# Increase In National Medical Expenditures And Fee-Schedule Prices

Initially, the Korean government expected the reform to achieve the following major objectives: (1) to divide roles between physicians and pharmacists and to prevent unnecessary and incorrect prescriptions, therefore reducing total health spending; and (2) to prevent abuse and misuse of medications, and to reduce the damage that results. But doctors and hospitals intensified their opposition to the new system, fearing that it would severely cut their earnings because their businesses had be-

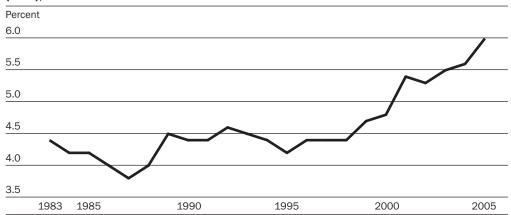
come heavily dependent on drug sales.<sup>15</sup> Members of the KMA threatened collectively to close their clinics unless the government abandoned the plan or increased consultation fees to offset lost income. Responding to doctors' demands for concessions in exchange for reform, and to avert the threat of hospital and clinic closures, the MOHW authorized a 72 percent increase in consultation fees for seeing outpatients and a fivefold increase in prescribing fees for the year 2000.<sup>16</sup> The legislation's final form incorporated these concessions.

Exhibit 1 shows an increasing trend in national medical expenditures (NME) as a percentage of gross domestic product (GDP).<sup>17</sup> NME in Korea was roughly 6.0 percent of GDP in 2005, up from 4.8 percent in 2000. Between 1983 and 1999, however, the NME share of GDP remained fairly consistent.<sup>18</sup> Exhibit 2 compares the annual percentage increases in Korea's GDP, NME, and average medical prices as established by the national fee schedule.<sup>19</sup> The rate of growth of NME was 27–28 percent annually in 1995–1996 and declined to 9 percent in 1999; GDP growth was anomalously high in 1995, about 17 percent, and then declined to below zero in 1998, rebounding to 10 percent in 1999. However, some specific trends in both indicators illuminate the relative impact of NME on GDP. For example, averaged out for the whole period 1991-2005, NME increased at an annual rate of 16 percent, compared with about 10 percent for GDP. Averaged across 1991 to 1995, the NME growth rate remained constant at around 15 percent. However, the economy declined sharply after 1996; in 1998, the GDP growth rate neared zero or worse. Moreover, with the exception of 2002, over the decade from 1995 to 2005 the NME growth rate remained higher than the GDP growth rate, and NME as a share of GDP increased (Exhibit 1). The rise in this indicator brought widespread concern that health care costs were out of control.

Since then, NME has appeared to increase continuously. Since the pharmaceutical reform was implemented, a steady rise in outpatient medical insurance fees has inflated the NHI's budget deficit. According to the Korean

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EXHIBIT 1
National Medical Expenditures (NME) As A Share Of Korea's Gross Domestic Product (GDP), 1983–2005



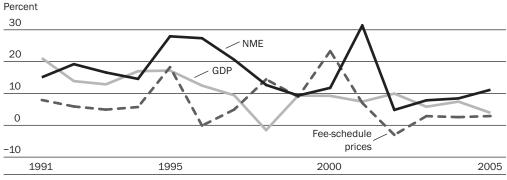
**SOURCES:** Korea National Statistical Office, Social Indicators in Korea 2007 (Seoul: NSO, 2007); and Organization for Economic Cooperation and Development, OECD Health Data 2007 (Paris: OECD, 2007).

Health Administration, total outpatient medical insurance fees were estimated at 9.8 trillion won in 1999 (before reform) and at 12.9 trillion won in 2001 (after reform)—a yearly increase of 1.5 trillion won.<sup>20</sup> Thus, the government's hope to lower costs has not yet borne fruit. MOHW budget figures reveal that spending on reimbursed drugs rose by roughly 25 percent to 4.5 trillion won (approximately US\$4.3 billion) in 2001, while the higher doctors' fees and substantial dispensing fees for

pharmacies (formerly included in doctors' margins) have raised the deficit in the MOHW insurance budget.<sup>21</sup>

Pharmaceutical spending in 2006 was 8.4 trillion won, which accounts for 29.4 percent of total health insurance payments (Exhibit 3).<sup>22</sup> Increasing medication costs may be explained by an increasing number of patients who take more expensive and diverse brandname drugs, driven by supply-side changes, such as fortified marketing efforts by pharma-

EXHIBIT 2
Annual Changes In Korea's Gross Domestic Product (GDP), National Medical Expenditures (NME), And Average Fee-Schedule Prices, 1991–2005



**SOURCES:** Korea National Statistical Office, Yearly Gross Domestic Product (GDP) Statistics in Korean Statistical Information System (Seoul: NSO, 2007); and Ministry of Health and Welfare, National Medical Expenditures and Fee-Schedule Prices Statistics (Seoul: MOHW, 2007).

EXHIBIT 3
Trends In Pharmaceutical Expenditure In Korea's National Health Insurance (NHI), Billions Of Korean Won, 2001–2006

	2001	2002	2003	2004	2005	2006
Total expenditure	4,180	4,801	5,583	6,354	7,229	8,404
Percent of total NHI outlay	23.5%	25.2%	27.2%	28.4%	29.2%	29.4%
Rate of increase	_a	14.85%	16.28%	13.80%	13.78%	16.26%

**SOURCES:** National Health Insurance Corporation, *Statistical Yearbook 2005* (Seoul: NHIC, 2006); and Ministry of Health and Welfare, *White Book on Health and Welfare 2006* (Seoul: MOHW, 2007).

ceutical companies. To resolve this problem, the MOHW recently introduced the so-called Positive List System (PLS), under which only medicines proven effective but also price-competitive are covered by the NHI.<sup>23</sup>

### **Reaction From The Health Care Market**

■ Increased incomes. Despite doctors' and pharmacists' fears about the reform's economic consequences, the average annual income per doctor's clinic increased from 299 million won in 1998 to 338 million won in 2001. The average annual income per pharmacy increased even more during the same period, from 60 million to 305 million won.<sup>24</sup> Estimated average annual profit increases related to reform ranged from 50 million to 83 million won per doctor's clinic and from 23 million to 87 million won per pharmacy.<sup>25</sup> The rapid growth in doctors' incomes is partly attributed to the reform's drastic increase in service fees, which in turn caused large-scale migration of doctors from hospitals to clinics. Medical fees for insured services in clinics rose (up to 33 percent) at a much higher rate than in hospitals, where increases (or decreases) were -4 percent at professional hospitals, -2 percent at general hospitals, and 10 percent at hospitals.<sup>26</sup> In addition, faced with profit loss from reform, hospitals decided to provide uninsured medical services, for which fees are not regulated, with higher margins to recover these losses. The percentage of patients' out-of-pocket expense burden for uninsured medical services increased greatly after reform, while the

growth rate of total medicine spending decreased slightly. From 1999 to 2001, the profit on average from uninsured services increased more than 8 percent in hospitals. For example, the percentage of total profits stemming from uninsured services in general hospitals has risen from 19 percent before SPD reform to 26 percent afterward; for regular hospitals, it rose from 21 percent to 30 percent.<sup>27</sup>

■ Prescribing patterns. Another factor that can greatly increase medical spending is doctors' prescribing patterns. Currently, doctors prefer to prescribe brand-name or imported products, which are relatively costly compared with domestic counterparts. The percentage of high-price prescriptions for outpatients increased from 26.01 percent (in March 2000) to 34.36 percent (in March 2001) at clinics, and from 59.37 percent to 73.21 percent at general professional hospitals.<sup>28</sup> As a result, sales by pharmaceutical companies rose consistently after the reform, particularly among multinational companies, by 138.8 percent in total from the second half of 1999 to the second half of 2002.29 With drugs accounting for roughly 30 percent of NHI spending, the government introduced Actual Transaction Pricing (ATP) in 1999 to control prices. ATP reimburses hospitals for the price they pay for a drug, rather than the official list price, thus eliminating profiteering when suppliers discount drugs. ATP cut reimbursement prices by an average of 31 percent between 1999 and 2000, and the MOHW subsequently reduced prices to discounted levels determined by regular market surveys.30

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<sup>&</sup>lt;sup>a</sup> Not recorded.

ATP combined with reform removed one (profit-based) incentive for doctors to prescribe drugs, by eliminating their profit from drugs, which had been the main source of their income. However, it still failed to offer economic incentives for providers to reduce total prescriptions and provide high-quality medicines at reasonable costs to patients. According to the Korea Institute for Health and Social Affairs (KIHASA), for example, the average number of prescribed medicines per case fell

only slightly, from 6.09 items in 1999 to 5.80 items in 2001. However, the cost of pharmaceuticals per episode has risen (by 11.80 percent) from 1,170.20 won to 1,308.30 won.31 These findings suggest that increases in health care costs might have resulted from price increases in pre-

scribed drugs rather than a decrease in quantities of prescribed drugs.

**■ Effects on manufacturers.** Moreover, NHI reimbursement cuts affected domestic pharmaceutical companies more than multinationals: Korean firms' margins to wholesalers, which hold a monopoly over supply to hospitals with more than 100 beds, are kept in close check. Also, ATP has failed to halt discounting, which has been driven under the table, and the system does little to encourage price competition because hospitals have no incentive to choose lower-price drugs. In addition, foreign pharmaceutical companies now give sizable noncash benefits to doctors in hospitals and clinics as advertising, affecting doctors' prescribing practices.<sup>32</sup> The use of multinational and domestic brand-name products has soared, causing a shift away from cheaper generics.

■ Illegal prescribing. As another limitation, the reform did not clearly prevent pharmacists from supplying prescriptions illegally at patients' request, despite repeated pledges to the contrary. Although in the past several years only a few hospitals and pharmacists have been disciplined for unauthorized activity, the government should take this problem seriously and enact concrete measures to prevent it. Recent assessments of pharmacists revealed 400 irregularities in 2001, including dispensing substitute medicines without a doctor's consent and writing unauthorized prescriptions.33 The current system lacks sufficient means to control abuse by pharmacists.

■ Foreign competition. Another problem is the threat of foreign pharmaceutical companies' domination in Korea's drug market. For example, the change in the market share of do-

mestic pharmaceutical com-

panies before and after SPD reveals some interesting trends. It fell from 32.2 percent in 1999 to 23.7 percent in 2000 (a 26.4 percent decline) for small and midsize companies and from 58.3 percent to 53.6 percent (a 8.1 percent decline) for large companies

during the same period. For foreign companies, however, market share increased from 9.6 percent in 1999 to 22.7 percent in 2000, a 136 percent increase.34 The coverage provided by the NHI includes imported drugs, spurring drug imports. In 2001, multinational companies registered in South Korea increased their sales by 13 percent, to 4.9 trillion won (US\$4.7 billion).35 Of the top ten drugs prescribed in 2001, seven were produced by foreign companies or their local licensees, while just three came from local firms—Korea Green Cross, Dong A, and Il Dong.36

**Antibiotics.** In terms of antibiotic use, a major concern before SPD, according to the MOHW, the number of antibiotics and injections prescribed by doctors dropped two years after reform.<sup>37</sup> However, whether this improvement came mainly from the new division of labor between doctors and pharmacists is unclear. Indeed, the significance of improvement itself is disputed.<sup>38</sup> The MOHW evidence is not consistent with results from other government agencies. For instance, recent data from the Korea Food and Drug Administration indicated that antibiotic production and imports have increased steadily since the reform (Exhibit 4), which implies that antibiotic use

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might have actually increased. To evaluate changes in doctors' prescribing behavior accurately, more time must elapse, and the array of factors influencing doctors' prescribing behavior must be considered.

#### Lessons From The Pharmaceutical Reform

The results of Korea's reforms have revealed vulnerabilities in the current national health care system, including the public service delivery system, the inconsistent decision-making process, medical treatment abuses, and excessive inflation in health care costs.<sup>39</sup>

- Consumers' reaction. In the early days of the new system, some experts voiced concern that Korea was not ready for reform.<sup>40</sup> They argued that forced implementation would confuse and inconvenience the public, because no single pharmacy could possibly stock all of the drugs needed for every illness. Patients would have to visit many pharmacies to find prescribed drugs. However, recent surveys report that after an initial adjustment period, inconvenience is decreasing, and patients are adapting to the new system.<sup>41</sup> Antibiotic prescribing for patients also declined after the dispensing restriction, although there are ongoing debates in terms of data reliability and validity, as mentioned above.
- **Dispensing costs.** However, the reform, which was preceded by ATP, raised dispensing costs as a result of the loss of competitive price control, adding an unnecessary burden to the NHI budget. Prices of drugs prescribed by doctors rose rapidly, and dosing periods lengthened. Although the reform eliminated the economic incentive to prescribe medica-

tions, the current system offers little economic incentive to trim the overuse of high-price drugs. According to the MOHW, the percentage of patients using relatively high-price, brand-name drugs, when alternatives of equal quality are available, rose from 26 percent in May 2000 to 54 percent in May 2001.<sup>42</sup> Increases in the price and quantity of prescribed brand-name drugs have directly exacerbated the health insurance crisis.

■ Implementation challenges. The reform's implementation, although well-intentioned and successful in some respects, was imperfect from the start. For instance, the MOHW bars hospitals and pharmacies from occupying the same building, but that rule is neither binding nor backed by disciplinary action. Government negotiators have even given in to doctors' demands for the right to sell prescribed intravenous medicines. In fact, they have made many concessions to doctors, including a 69 percent hike in prescription charges. Thus, insurance premiums had to be raised by 9 percent in 2000 to meet increased costs.<sup>43</sup>

Because the reform transformed entrenched customs, however, it could require several years to take full effect. Koreans should be ready to endure some transitions. The government must clarify its role and its ability to establish transparent drug transaction procedures. By granting concessions to enact reform, the government appears to have frustrated its own goals. There is a real possibility that the reform will not succeed without further appropriate modifications.

■ Threats to reform. First among the key factors that threaten the reform is the political

EXHIBIT 4
Drugs Imported Into Korea That Contain Antibiotics, 2000–2003

	2000	2001	2002	2003
Number of imported drugs containing antibiotics	42	60	67	80
Cost (billions of U.S. dollars)	19.636	29.041	34.771	34.690

**SOURCE:** Korea Food and Drug Administration, "Annual Statistics on Antibiotics Production and Import from Overseas," National Assembly's Inspection Report by Congressman M.O. Ahn (Seoul: National Assembly Secretariat, 4 October 2004).

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strength of the health services sector, which is primarily dependent on private institutions. Reform might have been more successful if the government had provided economic incentives to doctors to select medical products appropriately and cost-effectively.<sup>44</sup> The government also might have expanded its role as a major provider of medical care to the public. These limitations have exacerbated market functioning and raised concerns about government leadership.

Second, the process by which the reform was developed and implemented was affected by a number of political realities, and it proceeded without evidence based on carefully testing the effects of its interventions in Korea's private and public health economy. Government regulations need to be implemented more effectively, to prevent subsequent failures.<sup>45</sup>

Third, inside the domestic pharmaceutical market, the reform combined with ATP is forcing Korean pharmaceutical companies, which traditionally have depended on domestic markets, into a situation similar to their Japanese counterparts. Japanese companies are going through mergers and acquisitions to survive pharmaceutical reform because of intensifying competition with multinational companies in their home market. Many academic experts and nongovernmental organization (NGO) leaders expect that Korean drug makers will do the same in coming years. 46

The Korean Government expected the pharmaceutical reform to reduce the cost and misuse of medications and improve drug efficacy. In January 2008 it implemented a drug formulary (the PLS) that lists relatively cheap alternatives of the same quality as brand-name drugs. It will penalize doctors and consumers who still prefer expensive brand-name products, by limiting benefits to hospitals and increasing patients' out-of-pocket expenses. Some argue, however, that trying to reduce the demand for high-price items will thwart physicians' duty to choose the best medication for each patient.<sup>47</sup>

Despite its lofty aims, the pharmaceutical reform has resulted in unintended distortions in the supply of medical services and expenditures, increasing the use of uninsured services and high-price drugs, and expanding market share for multinational companies. It also is resulting in the full separation of medical institutions and pharmacies for outpatient care. 48 Further reform bills are needed to reduce these unintended adverse effects. Introducing recommended drug formularies and restricting insurance benefits for those not on the list may help restrict unnecessary growth in medical spending. Thoughtful consideration of evidence-based incentives and disincentives for health care providers will be crucial in future reforms.

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