

Current Pharmacoeconomic Issues and Drug Reform in South Korea

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In this issue's ISPOR Student Corner, we feature research from 1st year graduate student, Haesuk Park. Haesuk Park is pursuing a PhD degree at the University of Texas at Austin and completed her bachelor and master of pharmacy degrees in South Korea. The following editorial is for a project in a pharmacy administration seminar in Spring 2009 with her major professor, Dr. Karen Rascati PhD. Her research interest lies in cost-effectiveness studies in South Korea.

South Korea has the 11th largest share in the global pharmaceutical market, accounting for \$9.9 billion out of \$712 billion worldwide sales [1]. During the last three decades, two major health care reforms were realized in South Korea. The first was the integration reform, which merged multiple-insurers into a single entity in the form of the National Health Insurance (NHI) system in the late 1970s [2]. It took about 12 years until the NHI program started covering all citizens on a compulsory basis in 1989. The National Health Insurance Corporation, a single payer, collects premiums from the citizens and reimburses the health care expenses to the providers. Besides deductibles, patients pay coinsurance rates of 30% for clinic outpatient services, 50%-55% for hospital outpatient services, and 20% for inpatient services [3].

The second reform was the separation reform that took place in 2000. This reform designated the prescribing responsibilities to the physician and dispensing to the pharmacists [2]. The Korean government expected this reform to reduce the cost and misuse of drugs. However, the reform increased medical expenditures [4]. Consequently, the NHI has been faced with a deep financial crisis that has also been a major political issue in South Korea since 2001 [4]. Over the decade from 1995 to 2005, the average national medical expenditures growth rate (16%) remained higher than the gross domestic product (GDP) growth rate (10%). In 2006, South Korea spent roughly 6% of its GDP on health care, and pharmaceutical spending was \$6.7 billion, which accounted for 29.4 % of the total health insurance payments [4].

To moderate the ever-growing drug expenditures, a Positive List System (PLS) was introduced by the Ministry of Health Insurance and Welfare (MOHW). On January 1, 2007, the new reimbursement reform, Health Insurance and Healthcare Reimbursement Amendments Act of 2007 (Article 10 and 11), came into effect, aimed at a substantial amendment of the drug pricing and reimbursement [5]. The previous Negative List System was to be replaced by the PLS, where data on

the cost-effectiveness of drugs would be analyzed for reimbursement [6]. On April 2007, another reform was passed that directed a recalculation of the cost-effectiveness of drugs in 49 therapeutic classes, totaling 16,529 products over the next 5 years (MOHW notification No. 2007-116, enactment from April 2007) [7].

Pharmacoeconomic research conducted with the statins received considerable attention as it was the first pharmacoeconomic study conducted and published by the Health Insurance and Review Assessment (HIRA) in South Korea. A cost-utility analysis was performed to estimate and compare the effects of statins with no therapy for the primary prevention of a cardiovascular disease (CVD) event in males 55 years of age with a high risk of CVD. The cost per quality-adjusted life-year (QALY) gained was measured for both groups using Markov modeling during a life-time horizon. The results indicated that statin therapy produced an incremental cost-utility ratio of \$35,100 (approximately 44 million Korean won) per QALY gained compared to no statin therapy [7].

After completion of this pharmacoeconomic study, the HIRA announced its decision regarding pricing reform for statins. A \$24,000 (approximately 30 million Korean won) cost per QALY has been suggested as a threshold at or below which new medical interventions should be considered for adoption by the HIRA in previous analysis [7]. Therefore, a reduction in the price of statins by about 30% would be needed to achieve close to an incremental cost-utility ratio of \$24,000 per QALY gained. For example, a 32% reduction in the price of Zocor® (simvastatin) 20mg resulted in \$0.67 per tablet as the upper limit price of simvastatin. If generic versions of simvastatin were already below \$0.67 per tablet, their prices were not reduced, but if they were above this value they were included in the price deductions [8].

Much debate arose between pharmaceutical companies and the Drug Reimbursement Committee of the HIRA regarding the validity and credibility of pharmacoeconomic studies and pricing reform. The key issues brought by pharmaceutical companies included unrealistic study assumptions, inconsistent cost data, and skewed comparative effectiveness of statins [8]. However, the HIRA failed to explain or clarify their decision-making process. Eventually, on March 31, 2009, the MOHW announced the changes in the national drug formulary. The listing prices for statins were to be decreased by 12-36% over the next 2 years [8].

The MOHW planned to complete cost-effectiveness studies on drugs in 49 pharmaceutical classes within 5 years, yet only two classes have been completed thus far. As South Korea focuses on economic evaluations in its drug reforms, the number of pharmacoeconomic studies is expected to increase significantly. If the results of pharmacoeconomic analyses are used for reimbursement purposes, economic evaluations should be conducted accurately, and the results used in decision-making have to be fair and acceptable. Furthermore, it is important to develop a clear methodological guideline for pharmacoeconomic studies and establish a transparent decision-making process for the purpose of allocation of limited resources. ☺

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