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Different Policy Outcomes of the New Drugs and Currently Listed Drugs under the Positive List System in South Korea

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ABSTRACT

Four years have passed since the positive list system was implemented in South Korea. The system was received well because it has fulfilled its intended objective of enhancing the cost-effectiveness of new drugs. With regard to currently listed drugs, however, debate has lingered since the reevaluation of the cost-effectiveness by therapeutic group. This study intended to review the lessons learned and compromises reached in implementing an evidence-based national formulary. Currently listed drugs are very different from new drugs. In terms of effectiveness, the level of existing evidence tends to be lower for currently listed drugs. Also, the evaluation plan was quite delayed because of the vast amount of literature. In the political decision-making process, a coalition was formed by the pharmaceutical companies with physicians, and the government had difficulty responding because of the strong resistance against the reevaluation of currently listed drugs. Although idealistic, it was an attempt to apply the same standard of cost-effectiveness for currently listed drugs as that for new drugs. To successfully implement the system, however, some factors that need to be considered were limitation of available evidence on currently listed drugs and specific strategies employed against political resistance.

Keywords: drug expenditure, economic evaluation, positive list, reimbursement.

Background

On December 29, 2006, the positive list system (PLS) was implemented in South Korea as a part of the Drug Expenditure Rationalization Plan [1]1. After that, listing status and reimbursement price were determined through a relative comparison of the effectiveness and cost for the mostly widely used comparable drugs that can be substituted in the corresponding disease. This criterion for cost-effectiveness was applied not only to new drugs but to the currently listed drugs as well. Currently listed drugs were regarded as listed under the PLS but required reevaluation by therapeutic groups in accordance with the criterion of cost-effectiveness based on the government's 5-year plan from 2007 to 2011.

Five years have passed since the PLS was introduced in Korea. The system is being rooted without any major controversy for the new drugs. Currently listed drugs, however, have been mired in controversy ever since reevaluation was launched. Eventually, reevaluation of cost-effectiveness by therapeutic group was abandoned in July 2010, and an alternative, more straightforward approach of pricing reduction was adopted.

This article aimed to 1) present the listing status of new drugs and the reevaluation status of currently listed drugs following the introduction of PLS and 2) compare the scientific evaluation, evaluation infrastructure, and political decision making on cost-effectiveness as the reasons for the different policy outcomes applied to new drugs versus currently listed drugs.

Listing of New Drugs and Reevaluation of Currently Listed Drugs Under the PLS

Listing of new drugs under the PLS

With the introduction of the PLS, cost-effectiveness of new drugs is the fourth requirement to qualify for reimbursement by the national health insurance in addition to safety, efficacy, and quality. The first stage for evaluating the cost-effectiveness of new drugs is a review of clinical utility based on extensive literature review. In the event the clinical superiority of a new drug is confirmed, in comparison to that of a therapeutic alternative drug, a premium price may be applied. On the other hand, even for a new drug, if its clinical superiority is not proven, it is reimbursed at a price lower than those of the therapeutic alternatives currently in wide usage. Also considered are the impacts on the budget, reimbursement status, and price in foreign countries [2].

As illustrated in Table 1, the overall rate of drug listing has decreased since the PLS was in effect in 2007. The drug listing

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Table 1 – Listing of new drugs under the positive list system.

Year	Number of drug products			Number of drug ingredients*		
	Number of submissions	Decision to reimburse†	Price negotiation and listing‡	Number of submissions	Decision to reimburse†	Price negotiation and listing‡
2007						
N	40	25	17	33	20	11
%	100.0	62.5	42.5	100.0	60.6	33.3
2008						
N	89	67	55	67	49	37
%	100.0	75.3	61.8	100.0	73.1	55.2
2009						
N	80	62	54	49	33	28
%	100.0	77.5	67.5	100.0	67.3	57.1

Source: Health Insurance Review and Assessment Service (2010) [4].

* Drugs that have the same ingredients with different dosage were counted as one ingredient.

† The Health Insurance Review and Assessment Service reviews the submitted documents and the Drug Reimbursement Evaluation Committee (DREC) decides whether to reimburse based on cost-effectiveness.

‡ The National Health Insurance Corporation negotiates prices with drug companies for the drugs decided as reimbursable by the DREC.

rate before the PLS was 62.0% in 2005 and 76.0% in 2006 [3], whereas the rate dropped to 42.5% in 2007, 61.8% in 2008, and 67.5% in 2009 after the PLS. Meanwhile, according to data collected by the Health Insurance Review and Assessment Service (HIRA), reasons cited for rejection were obscure/unacceptable cost-effectiveness (60.6%) and obscure clinical utility (22.7%) [5]. The PLS is taking root as related to new drugs, and cost-effectiveness is playing a crucial role in the decision-making process.

Reevaluation of currently listed drugs under the PLS

The objective of applying the PLS to currently listed drugs is to accelerate the usage of cost-effective drugs under the health insurance system by conducting an objective evaluation of the relative value of various drugs included in the same therapeutic group. As of January 2007, the number of listed drugs was approximately 20,000. As the first step of delisting, drugs not produced or not having been claimed for reimbursement for the preceding 2 years, which numbered some 4000 drugs, were deleted from the list. Also, a 5-year (2007–2011) reevaluation plan was proposed for 49 therapeutic groups on the basis of impact on the health insurance budget [1].

In 2007, pilot projects for migraine and hyperlipidemia drugs were initiated by the HIRA research team. Results show that drugs that were not considered to be cost-effective were eliminated from the list. However, drugs remained on the list if pharmaceutical companies accepted the evaluation results and made voluntary price cuts. As demonstrated in Table 2, 89.5% of migraine drugs were maintained on the list while the remaining drugs were listed with restrictions or remained on the list with price cuts and none were delisted. Only 58.6% of hyperlipidemia drugs were maintained on the list, 39.3% remained on the list after instituting price cuts, and only 2.2%, or 7 products, were delisted. Such outcome triggered debate over whether the results corresponded with the basic delisting purpose of the PLS, because most were able to maintain their place on the list by adopting price cuts.

The first main wave of reevaluation was launched in 2009 with hypertension drugs. A university research team was entrusted with the evaluation as part of a research contract. The research team, however, faced great difficulty in evaluating hypertension drugs as they contained 131 ingredients of 1226 drug products. Strong controversies also arose over the uncertainty of evidence and data synthesis methodologies, which led to delay in meeting the deadline and resistance from pharmaceutical companies and prescribers.

Accordingly, to speed up the review process, the evaluation routine was shifted in July 2010 to a more concise process that did not provoke debate over methodology. Under the new method, drugs were supposed to be delisted when they failed to show a level of clinical usefulness or were priced higher than 80 percentile of the highest price among drugs containing the same ingredients. In the event the company accepted price cuts, however, the price was to be lowered to the level of 80 percentile within the following 3 years. Under the measure of overall price cuts following the shift in the system, 285 of the total of 1226 hypertension drugs were designated to institute price reductions.

With the shift in the reevaluation system of currently listed drugs, reassessment on the trade-off between effectiveness and cost for the substitutable drugs within the same therapeutic groups was abandoned. On the other hand, reevaluation was conducted through the drug price reduction approach for drugs containing the same ingredients.

Table 2 – Pilot project results for the reevaluation of currently listed drugs under the positive list system.

Therapeutic class	Maintain	Price cut	Delist	List with restriction	Total
Migraine					
N	51	2	0	4	57
%	89.5	3.5	0.0	7.0	100.0
Hyperlipidemia					
N	188	126	7	0	321
%	58.6	39.3	2.2	0.0	100.0

Source: Health Insurance Review and Assessment Service (2010) [4].