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## DECISION-MAKER COMMENTARY

## Drug Reimbursement Decision-Making in Thailand, China, and South Korea

Surachat Ngorsuraches, PhD<sup>1,\*</sup>, Wei Meng, MA<sup>2</sup>, Bo-Yeon Kim<sup>3</sup>, Vithaya Kulsomboon, PhD<sup>4</sup><sup>1</sup>Faculty of Pharmaceutical Sciences, Prince of Songkla University, Songkhla, Thailand; <sup>2</sup>China Health Insurance Research Association, Beijing, China; <sup>3</sup>Health Insurance Review & Assessment Services, Seoul, South Korea; <sup>4</sup>Faculty of Pharmaceutical Sciences, Chulalongkorn University, Bangkok, Thailand

## A B S T R A C T

**Objective:** To provide a comparison of national drug reimbursement decision-making, including an update of economic evaluation roles and barriers, in Thailand, China, and South Korea. **Methods:** Documentary reviews supplemented by experiences of policymakers. **Results:** National health insurance policy in all the three countries has been developed toward coverage for all. It leads to higher health-care expenditures and requires a good reimbursement system for health-care services, including drugs. Drug reimbursement decision-making in these countries is to develop a reimbursement list with the help of various committees having different roles. Primarily, they assess the clinical and safety evidence. Economic evidence, including budget impact and pharmacoeconomic evaluation, has also been very important for their reimbursement decision-making. This evidence is sometimes used in negotiation mechanism, which allows pharmaceutical companies to lower their drug prices and leads to

lower overall drug expenditures. Several common barriers, for example, human capacity and data availability, for obtaining economic evidence in all the three countries, however, still exist. **Conclusions:** Drug reimbursement decision-making in Thailand, China, and South Korea is in its transition period. It seems to run in the same direction, for example, guideline development and pharmacoeconomic evaluation agency establishment. Pharmacoeconomic evaluation plays important roles in the efficiency of drug reimbursement decision-making, even though there are several barriers to be overcome.

**Keyword:** drug reimbursement, health insurance, reimbursement decision-making.

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## Introduction

Health-care systems in the Asia-Pacific region have dramatically changed in the last 10 years. One of the major changes among countries in the region has been health insurance coverage. While their health insurance systems have aimed for an increase in access to health-care services, health-care policymakers need to ensure efficient resource allocation because of limited resources. These countries have established their own evidence-based mechanisms for making decisions in various processes, for example, approval and utilization of health technologies [1,2]. Among these processes, drug reimbursement is one of the most powerful tools formulated by policymakers because it financially affects providers and, in turn, could affect patients. It is a complex issue, however, because it always has two facets, increasing and restricting access. Therefore, this topic was chosen to be presented at the first plenary session of the ISPOR 4th Asia-Pacific Conference in Phuket, Thailand, on September 6, 2010. Thailand, China, and South Korea were selected as country examples because they had rapidly changing systems in the region. Senior policymakers were invited to represent their countries and were asked to review the

decision-making of health-care reimbursement, focusing on drugs. This commentary was synthesized from this specific plenary session and aimed to provide a comparison of national drug reimbursement mechanisms, including an update of economic evaluation roles and barriers, across all the three countries.

## Health insurance systems

Drug reimbursement mechanisms are part of health insurance systems. Thailand, China, and South Korea have their own unique health insurance systems, which tend to shape the reimbursement mechanism because of several factors, for example, employment type, source of funding, and payment mechanism.

## Thailand

Thailand has approximately 64 million people and had a gross national income (purchasing power parity) of approximately 180,000 Thai baht per capita in 2008 (approximately US\$5000) [3]. On average, Thai citizens spent approximately 4% of their annual income for health-care services. The country is one of the Asia-

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\* Address correspondence to: Surachat Ngorsuraches, Faculty of Pharmaceutical Sciences, Prince of Songkla University, Hatyai, Songkhla 90112, Thailand.

E-mail: [surachat.n@psu.ac.th](mailto:surachat.n@psu.ac.th).

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Pacific countries that have an emerging health insurance system. Major changes in national health insurance began in 2002, when a Universal Coverage (UC) health insurance policy was launched. Since then, the health insurance system in Thailand has three major schemes, the Civil Servant Medical Benefit Scheme (CSMBS), the Social Security Scheme (SSS), and the Universal Coverage (UC) scheme. The UC scheme covers about 75% of the country's population while the CSMBS and the SSS cover approximately 22%. Therefore, only about 2% of the whole population is still uninsured [1]. The CSMBS was established as a fringe benefit in 1978, to provide health-care services to all government employees, their dependents, and retirees. It is fully funded by general tax, and it is operated by the Comptroller General's Department, Ministry of Finance. The SSS was established in 1990, and it is a compulsory insurance scheme for employees in the private sector. It covers only the employees themselves. Its source of funds basically comes from employees, employers, and the government, and it is run by the Social Security Office (SSO). The UC scheme is a social welfare scheme by nature for people who are not eligible for the CSMBS and the SSS. It is primarily funded by general tax, and it is operated by the National Health Security Office [1].

### China

China has systematically carried out a series of reforms in medical security since 1990s. Now a multilevel medical security system, which is compatible with the socialist market economy of China, has been established. It plays an important role in securing and improving people's lives and stabilizing the social stability in China. Basically, there are three principal medical insurance schemes, Urban Employee Basic Medical Insurance, Urban Resident Basic Medical Insurance, and New Rural Cooperative Medical Care. For disadvantaged groups, Urban and Rural Social Medical Aid is also provided as a minimum security. Moreover, there are other supplementary schemes, including Enterprise Supplementary Medical Insurance, Commercial Health Insurance, Civil Servants Medical Subsidy, and Medical Security, for specific groups. The Urban Employee Basic Medical Insurance scheme, launched in 1998, covers urban employees and retirees, some urban residents with flexible employment, and rural migrant workers. In 2003, the Chinese government began to establish the New Rural Cooperative Medical Care scheme for rural residents while the Urban Resident Basic Medical Insurance scheme was initiated in 2007 to provide medical benefits to all urban residents, excluding those covered by the Urban Employee Basic Medical Insurance scheme. In some cities, the Urban Resident Basic Medical Insurance and New Rural Cooperative Medical Care schemes have been integrated into a unified scheme named the Urban & Rural Resident Basic Medical Insurance scheme. In 2009, the total medical insurance coverage rate in China reached 93%, with Urban Employee Basic Medical Insurance scheme insuring 17% (220 million), the Urban Resident Basic Medical Insurance scheme insuring 14% (180 million), and the New Rural Cooperative Medical Care scheme insuring 61% (830 million) of the residents.

### South Korea

Korean National Health Insurance (KNHI) was introduced as the first social insurance program for only corporate employees in 1977, and it covered the whole population of the Republic of Korea in 1989. Basically, the KNHI is funded by various sources, including premium, co-payment, tax, and employment funds. Fee-for-service is the major payment method of the KNHI while the diagnostic related group (DRG) method is used for seven types of medical procedures. Similar to any fee-for-service type of payment system, overutilization is a challenge for the KNHI. In 2009, the benefit coverage rate (rate of reimbursement for covered services) for inpatient care was approximately 80% and for outpatient care was

between 50% and 70%. There are various agencies in South Korean health-care system. For overall administration, the Ministry of Health and Welfare controls the KNHI program. While medical care institutions provide medical care, an agency called the National Health Insurance Corporation (NHIC) is responsible for reimbursement to health-care provider institutions. In addition, the Health Insurance Review and Assessment service (HIRA), which is a specialized governmental organization, is responsible for health insurance review and assessment processes. In these processes, medical care institutions need to submit claims to HIRA. HIRA then checks the input and error of claims, and the claims undergo an indicator review. The results of the review are eventually transmitted to the NHIC and provider institutions.

Even though these three countries have unique health insurance systems, they have developed toward universal coverage, which extensively increases access to health-care services, including drugs. The universal health insurance coverage, however, can be expensive, especially drug expenditure, if the reimbursement has not been set appropriately.

### Drug reimbursement systems

Drugs are what patients expect when they obtain health-care services. The drug reimbursement system itself has two facets because it can not only contain costs but also limit access. Therefore, the reimbursement system in each country has been carefully designed, especially the list of reimbursable drugs. Table 1 summarizes drug reimbursement systems across all the three countries.

#### Thailand

In Thailand, all three major insurance schemes have their own health service benefit packages listing reimbursable services and also have their own payment systems. Basically, the benefit packages are composed of two major health services, ambulatory and inpatient services, under different kinds of reimbursement methods. The CSMBS uses prospective payment (DRG) for inpatient services and fee-for-service type of payment for ambulatory services. It limits its beneficiaries to obtain any services only in public hospitals. While the SSS allows its beneficiaries to use health-care services at either public or private network hospitals, basically its payment type is capitation for both inpatient and ambulatory services. Similar to the CSMBS, the UC scheme provides similar coverage for inpatient health services under the DRG type of payment. It applies capitation type of payment, however, for ambulatory services [1].

Because the nature of provided inpatient services depends to a large degree on common medical and nursing procedures, the DRG for the CSMBS and the UC scheme and capitation for the SSS work efficiently. The DRG has been set for each health-care procedure or intervention, and the CSMBS and the UC scheme can allocate their resources accordingly. The SSS beneficiaries may sometimes suffer with the underutilization of provided services that could possibly happen from capitation. Its impact tends to be minor because most beneficiaries are in their working ages and rarely use the inpatient services. Recently, however, the SSS beneficiaries have raised a concern that their health benefit package is inferior to that offered by the CSMBS and the UC scheme. The ambulatory services rely heavily on prescription drug use. Decisions for drug reimbursement have a longer history, and it has been more systematically developed than other areas in health-care services. The mechanisms, processes, evidence used in decisions for drug reimbursement, and the role of health technology assessment on drug reimbursement in Thailand have been comprehensively presented in previous literatures [1,4]. Basically, the National Drug Committee develops the National List of Essential Medicines (NLEM), which is a list of drugs, vaccines, radioactive

**Table 1 – Comparison of drug reimbursement decision-making system across three countries.**

	Thailand	China	South Korea
<b>Structure:</b> Organizations involved in developing the reimbursement list			
• Central government agency	• Ministry of Public Health	• Ministry of Human Resources and Social Security and other related ministries	• Ministry of Health and Welfare
• Government authorities/committee	• Food and Drug Administration (FDA)	• Provincial authorities	• Health Insurance Review Agency (HIRA), e.g., Drug Benefit Coverage Assessment Committee (DBCAC)
	• Health Intervention and Technology Assessment Program (HITAP)		• National Health Insurance Cooperation (NHIC)
<b>Process:</b> Development of the reimbursement list	<i>Steps</i>	<i>Steps</i>	<i>Steps</i>
	• Industry submission of application	• Clinical benefit and safety assessment	• Industry submission of application
	• Clinical benefit and safety assessment	• Pharmacoeconomic evaluation and budget impact analysis	• Clinical benefit and safety assessment
	• Pharmacoeconomic evaluation and budget impact analysis	• Professional groups review and preliminary list formed	• Pharmacoeconomic evaluation and budget impact analysis
	• Price negotiation	• More than 2000 experts voting	• Price negotiation
	• Getting approval from ministry	• Suggestion of reimbursement limitation	• Getting approval from ministry
	<i>Decision-making criteria</i>		<i>Decision-making criteria</i>
	• Safety and efficacy score and cost index	• Getting approval from ministry	• Clinical benefit
	• Cost-effective threshold, e.g., gross domestic product (GDP) per capita for each quality-adjusted life-year	<i>Decision-making criteria</i>	• Cost-effective threshold, e.g., GDP per capita for each quality-adjusted life-year
	• Budget impact	• Safety, efficacy, and clinical needs	• Reimbursement status and price in other countries
		• Information of price and pharmacoeconomic evaluation in other countries	• Budget impact
		• Budget impact	
<b>Outcome:</b> Reimbursement list	National List of Essential Medicines (NLEM)	National Basic Medical Insurance Drug Formulary List	Positive List System

substances, and disinfection agents that are necessary for the prevention and treatment of all major health problems, to encourage rational drug use. It also works as a reimbursement list for all the three schemes. The Food and Drug Administration (FDA), under the authority of the Ministry of Public Health, plays an important role—the selection of individual experts or institutions across the country to work for the NLEM committee. Primarily, the NLEM committee is composed of two major groups—clinicians and health economists in several subcommittees. While the clinicians assess the clinical benefits and safety of all drugs by using the developed safety and efficacy score, and the cost index, the health economists evaluate some products. Finally, the NLEM committee collects all the evidence and endorses the list.

The current practice of drug reimbursement decision-making in Thailand has been drastically changed in the past few years, and it is still very dynamic. Under limited resources, the practice has recently been based on pharmacoeconomics (PE) because it helps the Thai government make rational policies or allocate resources efficiently. PE has been applied in the decision process on the reimbursement of drugs listed on the NLEM with clear institutional structure, capacity, and functions [1]. A health technology assessment agency under the Ministry of Public Health, Health Intervention Technology Assessment Program (HITAP), is primarily responsible for conducting economic evaluation of some drugs, especially expensive ones. Its major mission is to efficiently and transparently appraise health interventions and technologies. Every year HITAP asks various stakeholders, for example, health-care providers, academicians, payers, and patient advocacy groups, across the country for potential drugs that should be evaluated. After the list of these drugs is finalized, HITAP assigns its own scientists to conduct economic evaluation. HITAP developed not only a national guideline for economic evaluation but also agreed with the World Health Organization guideline that average GDP per capita be considered as a cost-effective threshold. Sometimes, the results of economic evaluation show that particular drugs have higher cost per quality-adjusted life-years gained than the threshold; the evidence has been used to successfully negotiate drug prices with manufacturers before the drugs are listed on the NLEM.

Currently, the Thai FDA is developing a new NLEM. Pharmaceutical companies have been asked to voluntarily include PE information in their submitted dossiers for being listed in the NLEM. The economic evidence that the health economic working group members consider, however, is not only the PE but also budget impact analysis. Both of them help policymakers make better decisions on resource allocation and budget management. The pharmaceutical companies have also been more active in the preparation of the PE information. If they can prove that their drugs are cost-effective, as compared to those of their competitors, the PE information would be a surplus of the drugs and increase the chance of their being listed on the NLEM.

There have been several barriers for using the PE information in reimbursement decision-making. First, similar to other countries in the Asia-Pacific region, Thailand still lacks PE experts. Even though the current situation has been better than it was in the past several years, the experts in this area are still in demand. This problem led to another barrier, which is the transparency question. This transparency barrier works both ways for the Thai government and the pharmaceutical companies. While the government has a major concern on the validity of the PE information submitted by the industry, the pharmaceutical companies usually complain about the transparency of the PE information considering process. The companies also have a concern that the government would focus more on prices or expenditures than on the PE information and therefore are reluctant to invest in obtaining the PE information locally because the drug market in Thailand is relatively small. Recently, there has been a suggestion that third

party or external experts should be hired to audit the PE information. Because the number of experts in this area is small, this suggestion seems to be unrealistic.

The cost-effective threshold has become a critical barrier for adopting PE. The national guideline for economic evaluation developed by HITAP adopted the World Health Organization suggestion for the cost-effective threshold, and it has been applied to the development of the NLEM. Only those drugs that have a cost per quality-adjusted life-year gained below the average GDP per capita are considered cost-effective drugs [1]. Recently, the Thai GDP per capita has been less than 180,000 Thai baht (approximately US\$5000), and this threshold is usually applied across the board. Noticeably, a number of products, especially anticancer treatment and biological drugs, tend to be not cost-effective if this threshold is used. Some of them, however, were sometimes proved to be cost-effective for particular patient groups and were listed in the NLEM with recommendations. These recommendations were usually found violated. Therefore, an auditing system for expensive drugs has been used for the CSMBs and the UC scheme reimbursement process to ensure rational drug uses and to control costs.

Another major barrier of using the PE is the availability of necessary and relevant data. Even though data became more important for the health-care decision-making in Thailand, they are fragmented and gradually developed. Not only the comprehension of data but also their validities are still problematic. Only little health-care data are available at the national level, and most of them are for administrative purposes. The prospective price list of DRG is an example and has been used in a number of PE studies. Recently, data at the patient level have become more focused. In reality, most government hospitals have their own electronic patient records, which are primarily used for administrative purposes. Data sharing is very restricted because of major concerns about confidentiality. Therefore, primary data needed to be collected in most of previous PE studies. Generally, the pharmaceutical companies can hardly access patients' records collected by the government hospitals. Unlike conducting clinical trials, the industry has been reluctant to invest in collecting data for PE studies. It is concerned about how seriously the Thai government uses the PE evidence in its decision-making. Also, the pharmaceutical market in Thailand may not be large enough for the pharmaceutical companies to invest in this relatively new area. Frequently, the pharmaceutical companies have brought resources, including data, models, and experts, from their regional or headquarter offices. Only recently, local capacity has been built in several companies.

## China

Formulary is an accepted management of drugs for health insurance in China. Drugs listed in the formulary should be clinically needed, safe and effective, convenient to use, and reasonably priced and should have sufficient market supply. They must also meet some basic criteria, for example, listing in the *Pharmacopoeia of the People's Republic of China* (current edition), and meet the standard of the State FDA. Similar to other countries, imported drugs need to get approvals from the State FDA.

National, provincial, and local authorities have their own responsibilities in the formulary-making and implementing process. A primary reimbursement formulary in China is the National Basic Medical Insurance Drug Formulary List. It is codeveloped by the Ministry of Human Resources and Social Security and other related ministries. The National Basic Medical Insurance Drug Formulary List is composed of three parts, which are Western medicines, traditional Chinese medicines, and Chinese herbal pieces. They are handled differently in the reimbursement list. The positive reimbursement list is used for Western medicines and traditional Chinese medicines; on the other hand, the negative reimbursement list is applied to Chinese herbal pieces. Also, some

drugs and materials, for example, nutritional supplements, animals and animal organs, dried fruits and liquid preparations brewed with traditional Chinese medicines, fruit preparations and oral effervescent agents, blood products, protein products (except special indications, first aid, and emergency treatment), are not included.

Drugs in the positive reimbursement list have been divided into two classes, A and B, from several aspects, such as drug characteristics, authorization level, reimbursement rates, and usage limitation. Generally, drugs in class A are essential with broad applications, have good effects, and have lower prices, while those in class B are optional, have good effects, and have relatively higher prices. Drugs in class A are allowed to be reimbursed at specific rates with few limitations, while the costs of drugs in class B must be shared as co-payment by the insured.

The development of the drug formulary follows precise procedures. The first is to collect and compare drug data comprehensively. On the basis of all drugs approved officially in a certain period, experts review and consider their clinical benefits, price information, safety data, and international PE data. They then enter the second step, PE. In this step, pharmacoeconomists not only compare the drugs under pharmacoeconomic views and methods but also analyze the impact of these drugs on the funds of medical insurance, work injury insurance, and maternity insurance. Only those with pharmacoeconomic advantages and optimal impact on the funds are selected. All information is reviewed and discussed by professional groups to reach a consensus before a preliminary formulary is formed. The next step is voting, which is deployed at both national and provincial levels. More than 2000 experts are involved in this process. On the basis of voting results, consultation experts bring forward payment limitation suggestions to some drugs, which are expensive and abused easily. Finally, after related ministries consolidate and examine all the information and suggestions, they approve the formulary and then disseminate it. Since initiating national health insurance reforms in 1998, China has promulgated three versions of the drug formulary, which are State Basic Medical Insurance Drug Formulary (2000 version), State Basic Medical Insurance and Work Injury Insurance Drug Formulary (2004 version), and State Basic Medical Insurance, Work Injury Insurance, and Maternity Insurance Drug Formulary (2008 version). There have been great expansions in drug types and numbers. In the 2000 version, the formulary contained 725 Western medicines and 415 Chinese medicine preparations. In the latest version, the State Basic Medical Insurance, Work Injury Insurance, and Maternity Insurance Drug Formulary issued in 2009, the drug numbers increased to 1164 and 987 for the Western medicines and Chinese medicine preparations, respectively. This reflects higher medical scientific progress, greater insurance payment capacity, and more extensive benefit coverage.

To give priority to the basic health needs of the population, China developed the National Essential Medicines List for Primary Healthcare Facilities. The most recent (2009) National Essential Medicines List for Primary Healthcare Facilities includes 307 items. Basically, these drugs must have higher levels of clinical benefits and safety with low costs. In addition, the central government allows the provincial governments to add more drug items if local needs exist. All drugs listed at the national and provincial levels are included in class A of the National Basic Medical Insurance Drug Formulary List to improve affordability and access to essential drugs.

Recently, another round of health system reforms in China has started, and it is aimed at developing basic medical insurance for all citizens. The reform has three primary objectives. The first objective is to consolidate and expand basic health insurance coverage. Specifically, the insured population of Urban Employee Basic Medical Insurance needs to reach 410 million and the coverage rate of New Rural Cooperative Medical Care needs to stabilize at

90%. The second objective is to reinforce and balance basic medical insurance benefits. The subsidy for citizens to enroll in New Rural Cooperative Medical Care or Urban Resident Basic Medical Insurance would be raised to 120 renminbi (RMB) per year per capita. The reimbursement rate of inpatient expenditures covered by Urban Resident Basic Medical Insurance or New Rural Cooperative Medical Care would be more than 60%. The third objective is to improve basic medical insurance fund administration. Prospective payment methods, especially capitation and paying according to diagnosis and global budget, are encouraged. The negotiation mechanism between medical insurance agencies and medical care and drug providers is also to be explored.

As a consequence of these reforms, drug management in medical insurance has been developed. PE is encouraged to be strengthened for use in the process of new drug approval and pricing. The exploration of a negotiation mechanism for drugs listed in the National Basic Medical Insurance Drug Formulary is suggested. Both national and local insurance agencies should work together to organize the negotiation team. The PE of clinically needed and expensive drugs with innovation and unlisted in the National Basic Medical Insurance Drug Formulary should be ready for the negotiation mechanism. Similar to many countries in the Asia-Pacific region, however, China needs to overcome some barriers to strengthen PE, including the number of pharmacoeconomists, comprehensive and valid database of drug price information, safety, professional agencies, and training. It is recommended that pharmaceutical companies provide the relevant data and participate in the negotiation process. Independent review experts will be in charge of submitting review proposals, checking data, and also conducting PE.

### South Korea

Total health-care expenditure in South Korea has been increasing as in other countries. By 2009, as the need for health-care services continued to grow, the total expenditure was almost three times the total expenditure for 2001. The rapidly increasing health expenditure has created a greater requirement for proof of "value for money" in the approval and funding of new medical technologies. Consequently, the South Korean government introduced the Positive List System in December 2006. Overall, the purpose of the Positive List System is to maximize the cost-effectiveness of drug use for health insurance benefit. The Positive List System selects drugs that are effective in both therapeutic and economic aspects for health insurance benefit coverage. Reimbursement and price decisions for new drugs are separated. HIRA is responsible for reimbursement assessment while the NHIC conducts price negotiations with pharmaceutical companies. In the Positive List System, the pharmaceutical company voluntarily submits applications for new drugs. The government opens the pathway to list necessary drugs by the authority of the Minister of Health and Welfare when needed. HIRA is also in charge of reviewing the reimbursement status of listed drugs. It regularly excludes drugs neither produced nor claimed for 2 years and reevaluates clinical benefits and the price of drugs that were listed before the Positive List System was introduced.

After a pharmaceutical company submits an application for a new drug to HIRA, HIRA performs an economic evaluation and assesses the appropriateness of the benefit of inclusion of the drug. These are done by working level and the Drug Benefit Coverage Assessment Committee (DBCAC) in HIRA. Based on HIRA's assessment results, the NHIC negotiates with the pharmaceutical company for pricing. If the negotiation fails, drugs are not placed on the list. Nevertheless, there is a Drug Reimbursement Coordination Committee that mediates necessary drugs that can be reimbursed. Finally, the Minister of Health and Welfare publishes the final price to the public after review by the Health Insurance Policy Review Committee within the ministry.

The DBCAC is composed of several specialists, including representatives of the Korean FDA, consumers, medical experts, and HIRA. Under the DBCAC, as a subcommittee, HIRA has an economic subcommittee composed of five members, two medical, one statistical, and two health technology experts. This subcommittee reviews the appropriateness of the economic model and the cost-effectiveness. HIRA itself also has two clinical advisory committees, the Healthcare Review and Assessment Committee and the Serious Illness Review Committee. The Healthcare Review and Assessment Committee is a group of medical specialists who advise on the medical feasibility and coverage restriction while the Serious Illness Review Committee is composed of some specialists from the Korean FDA, medical experts, and specialists from HIRA and is in charge of advising on coverage restrictions for drugs prescribed to patients with cancer. For the Positive List System, there are five criteria for decision-making—clinical benefits, cost-effectiveness results, impact on health-care budget, reimbursement status and prices in other countries, and potential impact on other aspects of public health. There are, however, some exceptions. These are collectively known as “rules of rescue,” which are no alternative treatments, no alternative drugs for severe or life-threatening diseases, and drugs for rare diseases and necessary to treat these patients.

It is mandatory to submit PE evidence on new medicines to prove their cost-effectiveness for the purpose of reimbursement. If a pharmaceutical company wants to launch a new drug with improved effectiveness but with a higher price compared with that of a main comparator, it has to submit the cost-effectiveness or cost-utility analysis of the drug to be reimbursed. In this case, incremental cost-effectiveness ratio is a central criterion for the reimbursement decision. HIRA does not have an explicit incremental cost-effectiveness ratio threshold. It will be accepted or rejected, however, in reference to GDP per capita, considering the incremental cost-effectiveness ratio in regard to disease severity, societal burden, quality of life, and innovations. For this process, HIRA developed assessment guidelines such as the Pharmacoeconomic Evaluation Guideline, Submission Guideline, and the DBCAC assessment criteria. Also, HIRA provides Presubmission Consulting Services and opens the assessment results to the public on its homepage ([www.hira.or.kr](http://www.hira.or.kr)) where assessment content, schedules, and related references can be found. In addition, HIRA provides information such as the annual average weighted price of individual ingredients and claims data. Regular education programs about any change in guidelines and laws for companies are also provided.

HIRA has excluded drugs that have not been produced or claimed for 2 years since the Positive List System was introduced. Consequently, listed drugs have decreased from 20,775 items in 2006 to 15,091 items in 2010. HIRA performed a “Reevaluation of listed drugs” to review the reimbursement status of drugs that were listed before the Positive List System by the therapeutic groups. The therapeutic groups of the pilot project were migraine and hyperlipidemia, and 378 drugs were reviewed. As a result, 239 drugs were maintained, 128 drugs had prices lowered, and 11 drugs were excluded from the list. Overall, after the Positive List System was introduced, the annual growth rate of drug expenditure decreased from 14.6% during 2001 and 2005 to 11.5% during 2007 and 2009.

As in Thailand and China, PE demands much time and great efforts. Lack of relevant evidence such as local costing data and head-to-head randomized controlled trials with relevant comparators presents a challenge. For instance, relevant local cost data

were used in about 60% of submissions and randomized controlled trials comparing directly with comparators were used in 64% of PE submissions. Various efforts are being made to overcome these barriers. For instance, the development of guidelines for conducting indirect treatment comparison is under active discussion in South Korea. The revision board of the guidelines for PE is currently gathering the opinions from pharmaceutical companies.

## Conclusions

In conclusion, drug reimbursement decision-making in Thailand, China, and South Korea is in its transition period; however, all the three countries have a similar structure, process, and outcome. Also, they seem to run in the same direction, for example, guideline development and PE agency establishment. Each country has established more than one committee that is responsible for drug reimbursement decision-making. Basically, pharmaceutical companies are asked to submit clinical, safety, price, and PE evidence. Thailand and South Korea have a specific agency to support PE evidence. All the three countries have similar decision-making criteria, even though those in Thailand and South Korea seem to be more explicit in the case of PE. China and South Korea also consider drug prices in other countries. China designs its drug reimbursement lists to match both national and local needs, while both Thailand and South Korea have a drug reimbursement list only at the national level. Apparently, PE gradually plays important roles in the efficiency of drug reimbursement decision-making. Similar to many countries in the Asia-Pacific region, the number of PE scientists is one of the major barriers for adopting PE in the reimbursement decision-making. It also leads to other barriers, including the controversial issues of cost-effective threshold and the availability of relevant data, which still require future improvements.

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