Evidence-Based Decision-Making in Asia-Pacific with Rapidly Changing Health-Care Systems: Thailand, South Korea, and Taiwan

Thidaporn Jirawattanapisal, MPharm,1 Pritaporn Kingkaew, BPharm,2 Tae-Jin Lee, PhD,3 Ming-Chin Yang, DrPH4

1International Health Policy Program, Ministry of Public Health, Muang Nonthaburi, Thailand; 2Health Intervention and Technology Assessment Program, Ministry of Public Health, Muang Nonthaburi, Thailand; 3School of Public Health, Seoul National University, Seoul, Korea; 4College of Public Health, National Taiwan University, Taipei, Taiwan

ABSTRACT

Objective: To review the use of evidence in the market approval process, reimbursement, and price control mechanisms for medicines and medical devices in Thailand, South Korea, and Taiwan.

Methods: Documentary reviews supplemented by interviews with senior policymakers of relevant public health authorities.

Results: Drug regulatory authorities play a vital role in the market authorization process by considering evidence on safety, efficacy and quality for new medicines, and bio-equivalence for new generic products of previously patented medicines. For the formulation of the reimbursement list, all three cases applied evidence on cost-effectiveness, to various degrees, with clear institutional structure, capacity, and functions. Only Thailand has specified an explicit benchmark on cost-effectiveness for inclusion in the reimbursement list. For price control, all have established mechanisms and processes for price negotiation. These mechanisms apply evidence on cost structure and relative prices in other countries to ensure affordable prices, especially with the patented drug industry. Thailand’s universal insurance schemes use a capitation payment model which proves effective in implicit price control. To increase access to essential medicines that have patents on and high price, Thailand applied Trade-Related Aspects of Intellectual Property flexibilities; “government use of patent,” for public noncommercial purposes to seven essential drugs in 2006 to 2008.

Conclusion: Rapidly increasing health expenditure and universal health insurance systems have created greater requirement for proof of “value for money” in the approval and funding of new medical technologies. All settings have established clear mechanisms to apply appropriate evidence in the processes of market approval, reimbursement, and pricing control.

Keywords: economic analysis, economic evaluation, economic outcome, health-care decision makers, health economics.

Introduction

One of the main targets of health policy formulation is to ensure the efficient use of limited resources, requiring efficient and transparent use of evidence to inform sound decision-making. This is particularly relevant to decisions relating to the approval and reimbursement of health technologies such as drugs, diagnostics, treatment procedures, and medical devices. In countries with large health insurance schemes, especially publicly funded universal ones, there is usually very strong demand to achieve maximum “value for money.” In Asia-Pacific, Thailand, South Korea, and Taiwan have health systems developed particularly rapidly to achieve universal health insurance, based on public policies and legislation. All are further characterized by the increasing reliance on scientific and economic evidence to inform decision-making within their health systems. Medical technologies, including medicines, medical devices, and diagnostics are subject to intensive formal review and assessment of their “value for money” before allowing their market approval and their reimbursement within the universal health insurance schemes.

In the 3rd Asia-Pacific Conference of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR), representatives of the three cases reviewed the mechanisms and the processes used to assess new health technologies. Many similarities as well as differences were evident. This article aims to compare and critically assess the national mechanisms and processes in generating and applying evidence to inform policy decisions on health technologies relating to: 1) market authorization; 2) price control; and 3) reimbursement and financial control policies of health technologies in three settings. It is expected that results from this study will be useful for international comparison and providing input for decision-makers who seek to reform or strengthen the use of evidence in decision-making.

Methods

This article was synthesized from three articles presented at the 3rd ISPOR conference in Seoul on September 6, 2008. Each article was developed based on extensive documentary reviews supplemented by interviews with senior administrators of relevant public health authorities.

In Thailand, information was collected from the Drug Control Division, Medical Device Control Division, Medium Price Setting Committee, and the Subcommittee for Development of the National List of Essential Drugs (NLED) which is under the Thai Food and Drug Administration (FDA), and from the Benefit Package Subcommittee of the National Health Security Board.

In South Korea, information was collected from the Korean Food and Drug Administration, the Health Insurance Review and Assessment Service (HIRA), and the National Health Insurance Corporation (NHIC).

In Taiwan, information was collected from the Bureau of Food and Drugs Analysis and the Center for Drug Evaluation (CDE), the Drug Benefit Committee and the Devices Benefit Committee under the Bureau of National Health Insurance (NHI).
Table 1  Characteristics of the three public health insurance schemes in Thailand

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>UC</th>
<th>SSS</th>
<th>CSMBS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feature</td>
<td>State welfare</td>
<td>Social insurance</td>
<td>Fringe benefit</td>
</tr>
<tr>
<td>Eligible population coverage</td>
<td>Anyone who is not covered by the SSS and CSMBS</td>
<td>All private employees and temporary public employees</td>
<td>All civil servants and permanent public employees, retirees, and their dependents</td>
</tr>
<tr>
<td>Population coverage in 2007</td>
<td>46,512,000</td>
<td>7,732,000</td>
<td>4,956,000</td>
</tr>
<tr>
<td>Source of finances</td>
<td>General tax revenue</td>
<td>Equal contribution from employers, employees, and the Government</td>
<td>General tax revenue</td>
</tr>
<tr>
<td>Payment mechanism for health services</td>
<td>Capitation based on hospital expenditure (Capitation contract model)</td>
<td>Capitation based on hospital expenditure (Capitation contract model)</td>
<td>Fee-for-service retrospective reimbursement model</td>
</tr>
<tr>
<td>Expenditure per capita (2007 Thai Baht)</td>
<td>2,089</td>
<td>2,200</td>
<td>8,462</td>
</tr>
</tbody>
</table>

Note: Approximately 2% of the population is covered by voluntary private health insurance systems and around 3% are not covered by any health insurance scheme. Source: Adapted from Thailand Health Profile 2005 to 2007 [19,20].

UC, Universal Health Insurance; SSS, Social Security Scheme; CSMBS, Civil Servant Medical Benefit Scheme.

Results

The National Health Insurance Systems

All settings have well-established National Universal Health Insurance systems. The benefit packages are extensive and include all high-cost health care and drugs. The differences lie mainly in the source of funding and in the provider payment mechanisms.

In Thailand, there are three public health insurance schemes cover the entire population. The Civil Servant Medical Benefit Scheme (CSMBS) covers 8% of the population, funded totally from tax revenue and pays providers based on a retrospective fee for service reimbursement system. The Social Security Insurance Scheme (SSS) covers private employees, 15% of the population, funded equally from the tax revenue, the employers and the employees. The Universal Health Insurance (UC) or the “gold card” scheme covers the rest of the population and is funded entirely by tax revenue. There is essentially no, or very little, co-payment in any of the three schemes. The SSS and the UC schemes pay providers based on a close ended pre-paid-capitation budgetary system. This payment system puts the financial risk on the providers, so drugs and medical devices are prescribed more cautiously. Nevertheless, it may result in underprescription and insufficient use of essential drugs and medical devices. Table 1 compares the key characteristics of each scheme.

South Korea and Taiwan are managed by a single National Health Insurance mechanism, funded either by premium contributions or tax revenue together with employment-based funding and co-payments by the patients. Providers are paid by a fee for services retrospective reimbursement system. There is a list of treatments that specifies those that are entitled to reimbursement, supplemented by substantial copayments by patients. Such fee-for-service systems tend to support extensive or over use of drugs and technologies, as the providers are not responsible for the cost, or may even further profit from its inflation.

Health expenditure in each case is increasing at a rate higher than economic growth. The universal health insurance systems are pushed to be more stringent in assessing the “value for money” of all medical technologies that are included in the benefit package of each scheme.

Mechanisms and Evidence Used in Market Authorization

All settings have well-established drug and medical device regulatory authorities that require evidence on quality, safety, and efficacy for market authorization, with few differences among them, the details of which are shown in Table 2. It is noteworthy that Thailand has a 2-year temporary market authorization of new drugs, pending the result of a Safety Monitoring Program [1–6]. In South Korea, there is no need for people involved in the process to declare their Conflict of Interest (COI). None currently require cost-effectiveness information for market authorization; however, in the Thai revised drug bill, there is an article that requires cost-effectiveness information for market authorization, for which approval is pending.

Mechanisms, Processes, and Evidences Used in Decisions for Reimbursement

All three cases have established institutions to generate and apply evidence on cost-effectiveness in their decisions to include new technologies in the insurance schemes’ reimbursement list referred to as the “reimbursable list” in South Korea and Taiwan, and as the “benefit package” in Thailand [7]. This is because the health insurance systems in South Korea and Taiwan have pay providers based on a fee schedule for services, while Thailand pays providers based on a prospective capitation system.

South Korea has the most advanced capacity in generating and use of evidence on cost-effectiveness, while Taiwan and Thailand have been established in the last 2 years. There is no specific timeline to have advance pharmacoeconomic (PE) system of review; however, both cases have been generating PE activities; publishing PE guideline or submission guideline [8,9] and training for pharmacoeconomists.

Table 2  The market authorization process in Thailand, South Korea, and Taiwan

<table>
<thead>
<tr>
<th>Regulatory authorities that play a vital role in market authorization</th>
<th>Thai FDA, Korean FDA, Taiwan DOH, Bureau of Food and Drug Analysis and the Center for Drug Evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mandatory evidence required</td>
<td>• Safety, efficacy, quality for new medicines&lt;br&gt;• Bio-equivalence for generic products of new medicines&lt;br&gt;• Thailand: 2-year temporary license and SMP granted for all new drugs which provide market exclusivity, before granting a permanent license&lt;br&gt;• South Korea: 2 steps licensing for medical devices: article review and market approval by GMP accreditation</td>
</tr>
<tr>
<td>Noteworthy issues in the process</td>
<td></td>
</tr>
</tbody>
</table>

Thai FDA, Thai Food and Drug Administration; Korean FDA, Korean Food and Drug Administration; DOH, Department of Health; SMP, Safety Monitoring Program; GMP, good manufacturing practice.
Concluding remarks

All applied evidences on cost-effectiveness in the Taiwan Listing in the National Health Insurance formulary South Korea Medicines are assessed by HIRA for reimbursement considered by the Working Groups. The Health Economic where the latter was added in the revision of the NLED 2004 and declaration of COI during the development of the NLED. Health Economic Working Group. All parties involved require a Working Groups as well as health economists to work for the specialists throughout the country to work for 16 Specific The development also requires a number of outstanding medical cases Key features of the reimbursement systems

<table>
<thead>
<tr>
<th>Cases</th>
<th>Key features of the reimbursement systems</th>
</tr>
</thead>
</table>
| Thailand    | • Medicines previously selected in the NLED are included in the benefit packages of all three national health insurance schemes  
• The 2007 revision of NLED required cost-effectiveness evidence produced by the newly founded Health Intervention and Technology Assessment Program |
| South Korea | • Medicines are assessed by HIRA for reimbursement list based on clinical benefits, cost-effectiveness, budget impact, and price of similar medicines in other countries.  
• PE evidence for new medicines is mandatory for reimbursement |
| Taiwan      | • Listing in the National Health Insurance formulary requires evidence on effectiveness; cost-effectiveness is not mandatory  
• In 2007, the HTA Division was established under the Centre for Drug Evaluation to provide supporting information on cost-effectiveness to the Bureau of NHI |

Concluding remarks

All applied evidences on cost-effectiveness in the decision on reimbursement of medicines with clear institutional structure, capacity, and functions

Table 3 summarizes the key features of the reimbursement systems in the three settings.

Thailand. Under the regulation of Prime Minister Office B.E.2535 (1992) on public procurement, the NLED is a list of drugs, vaccines, radioactive substances, and disinfection agents that are necessary for prevention and control of all major health problems. The regulation mandates the Ministry of Public Health (MOPH) to develop the NLED and a “medium price” or “reference price” list of each drug in the NLED [10,11]. The NLED is about 50% bigger than the World Health Organization’s model list of essential medicine [12]. They tend to be the optimum list of medicines for basic health-care system including 673 items of active ingredients or 892 dosage forms followed 17 categories of British National Formulary [11]. All public health-care facilities are required to procure the drugs using government budget based on the NLED and within the medium price. The NLED constitutes the list of drugs that are reimbursable in the three public health insurance systems (Table 1). It also aims to be used as a tool to encourage the rational use of medicines [11].

The cost of prescribed drugs outside the NLED is born by individuals under the SSS and UC systems; under the CSMBS system, three attending physicians can approve the use of drugs outside of the NLED.

Figure 1 illustrates the development of the NLED. The National Drugs System Development Committee appoints senior decision-makers, health professionals, academics, and representatives of the public health insurance schemes as members of the NLED Subcommittee, and authorizes them to develop the NLED. The development also requires a number of outstanding medical specialists throughout the country to work for 16 Specific Working Groups as well as health economists to work for the Health Economic Working Group. All parties involved require a declaration of COI during the development of the NLED.

The evidence used includes safety, efficacy, and efficiency where the latter was added in the revision of the NLED 2004 and 2008. Evidences on drug safety and efficacy are synthesized and considered by the Working Groups. The Health Economic Working Group commissioned Health Intervention Technology Assessment Program (HITAP), an independent research institute under the MOPH, to conduct PE assessments. Results of these studies are subsequently considered by the Subcommittee for inclusion/exclusion of these drugs from the NLED. HITAP has also developed guidelines on PE studies which have been approved by the Subcommittee on the NLED of the Thai FDA, and the Benefit Package Subcommittee of the National Health Security Board [9]. These guidelines are therefore accepted as the Thai National Guidelines. The two subcommittees also agreed on a “benchmark” of cost-effectiveness to include new technologies in the benefit package. Any technology with a cost per quality-adjusted life-year gained below the average gross domestic product (GDP) per capita is considered acceptable for inclusion on the NLED.

There was no reimbursement list for medical devices in Thailand. The coverage of medical devices varies largely among the three public schemes. CSMBS post-paid almost all medical devices though a fixed rate fee-for-service payment while UC and SSS include the use of medical devices as part of their basic health packages and paid for based on prepaid capitation (Table 1).

South Korea. Since 2007, it has been mandatory to submit PE evidence on new medicines for the purpose of reimbursement. Depending on the extent of improved effectiveness of new medicines compared with that of their main comparator, different PE frameworks apply. If it is claimed that a new medicine shows improved effectiveness, cost-effectiveness or cost-utility analysis is required. In this case, the incremental cost-effectiveness ratio is a central criterion for the reimbursement decision. If the effectiveness of new medicine is similar or noninferior to that of the main comparator, then cost-minimization analysis suffices for the reimbursement decision.

Decisions on reimbursement of new medicines are made by the Pharmaceutical Benefit Assessment Committee (PBAC) of HIRA. A subcommittee can be commissioned to review effectiveness and cost-effectiveness on a scientific basis before PBAC’s decision. Decisions made by PBAC are based on a majority vote. Where this process fails to attain a clear decision, the Ministry of Health, Welfare and Family Affairs has the final say on the reimbursement of the medicine of interest.

Figure 2 shows the reasons for deciding not to reimburse new medicines between 2005 and 2007. Compared with year 2005, the percentage of medicines that were not reimbursed for lack of evidence on clinical effectiveness reduced significantly in 2007, while the share of medicines not reimbursed for lack of evidence on cost-effectiveness increased by 22 percentage points (to see these reasons).

Since the introduction of mandatory submission of PE evidence, academic societies concerned have been providing education programs for training pharmacoeconomists in both public and private sectors in line with the government’s policy. Thus, in spite of the current lack of experts in PE arena, the policy that requires PE evidence in the decision-making for reimbursement of new medicines is expected to keep its way.

Taiwan. When submitting the application to the Drug Benefit Committee of Bureau of National Health Insurance (BNHI), pharmaceutical companies have to provide evidence of effectiveness. Usually, this will include published articles on clinical trial results and technical reports. Occasionally, a pharmaceutical company will also provide results of local trials.

Currently, the BNHI does not require systematic reviews of effectiveness or PE information, or to conduct such local studies.
The only mechanism to control the expenditures of a new drug is the 3-year agreement policy applied to those drugs whose estimated budget impact is greater than 100 million NTD per year (about US$3.1 million). The review system for health technology under the NHI in Taiwan slightly differs for new drugs and for new devices/materials. The Drug Benefit Committee is in charge of drug listing, pricing, and prescribing guidelines. The Device Benefit Committee, on the other hand, is in charge of the listing, pricing, and usage guidelines for new devices.

Responding to the lack of PE data in the review process, the CDE added the health technology assessment (HTA) division to its services in October 2007 [13,14]. The CDE is a nonprofit organization established by the Department of Health (DOH). The HTA division will provide evidence to the Drug Benefit Committee/BNHI on comparative effectiveness and cost-effectiveness. It primarily uses secondary data and published literature to generate the relevant evidence.

The guiding principle for listing is the demonstrated effectiveness as shown in the literature. There are, however, a few conditions that may prohibit the intervention from being listed, such as when the budget impact is expected to be huge, where there are similar products on the list, or the existence of severe adverse effects.

Mechanisms, Processes, and Evidence Used in Decisions on Pricing

In each country, there are clear mechanisms to regulate prices of medicines listed on the “reimbursable list” or the “benefit package.” Evidence on cost structure, relative prices in other countries, and negotiations between health insurance funds are common mechanisms to ensure reasonable prices. Thailand also effectively introduced compulsory licenses, which is a flexibility measure allowed by the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS). This aimed to pursue generic competitions and price reductions of patented products.

Thailand. Several mechanisms have been used for price control of drugs and medical devices. Most goods available in the market are determined generally by market mechanisms driven by supply
and demand; however, different mechanisms have been applied for medicines. For the price labeling of over-the-counter (OTC) drugs, the control of the Ministry of Commerce over drug prices are mandatory under the Prices of Goods and Services Act B.E.2542 (1999). The evidence used for price setting of OTC drugs includes information on cost structures and international prices submitted by pharmaceutical companies.

On the other hand, prices of non-OTC drugs include in the NLED procured by public hospitals, controlled by the “Medicine Price Ceiling,” which is a list of maximum prices for each drug that sellers are allowed to charge from public hospitals [10]. The ceiling price is set by the Committee for Development of the Medicine Price List based on collective information on purchasing prices of similar drugs from all public hospitals [10]. The information collected by the committee is also used in the “Reference Prices of Medicines” database and is publicly available through the website of the Drugs and Medical Supplies Information Center (http://dmsic.moph.go.th/index.php) [10]. Public hospitals can use this information for negotiating with pharmaceutical companies before subsequent purchases. There was no price ceiling and reference set for medical devices, and prices are based entirely on market supply and demand.

In the case of bulk purchasing at the national and provincial levels, prices of drugs and medical devices are also controlled by other effective mechanism [15]. This is particularly with drugs and medical devices which are widely used in very high quantities and include antibiotics, diabetes, antihypertensive, condoms, and others.

Recently, the Thai MOPH endorsed the use of generic forms of seven patented drugs for public noncommercial purposes under article 51 of the Thai Patent Act B.E.2535 (1992), which complies with article 31(b) of the World Trade Organization Agreement on TRIPS and the Doha Declaration on Intellectual Properties and Public Health. These consisted of efavirenz, lopinavir/ritonavir, clopidogrel, imatinib, docetaxel, erlotinib, and letrozole. The policy allowed the Government Pharmaceutical Organization (GPO) to import generic products of the issued drugs from Indian pharmaceutical companies as well as producing them locally by the GPO resulting in a significant reduction in price of these particular drugs.

South Korea. In the case of medicines, a price-volume arrangement was introduced to control expenditures. Manufacturers or importers are required to submit the expected sales for their products when they apply for reimbursement in the NHI. Considering budget impact, NHIC negotiates a price for the medicine based on the expected sales amount. If actual sales exceed expected ones for a specified period after approval for reimbursement in the NHI, the price of the medicine of interest is reduced accordingly. For example, if actual sales exceed expected ones by more than 30% for 1 year after reimbursement, the price of the medicine is expected to be lowered by approximately 10%.

In 2007, as an additional containment measure for reimbursement by the NHI, a positive list system was instated to replace the negative one; all drugs that were previously eligible for reimbursement were initially placed on the positive list, with a 5-year timeframe for their reevaluation. The main criterion for keeping drugs on the list is cost-effectiveness. If a drug proves not cost-effective, in principle, it should be excluded from the list. Nevertheless, if its manufacturer wants to lower its price to the extent to which it becomes cost-effective, then the drug can remain on the list. In the case of migraines, for example, 3 out of 11 chemicals were found to be not cost-effective. As a result, one chemical was excluded from

<table>
<thead>
<tr>
<th>Year</th>
<th>NHI Exp. (Annual growth rates, %)</th>
<th>Drug costs (Annual growth rates, %)</th>
<th>Drug costs as % NHI exp.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1998</td>
<td>290.9 (11.4)</td>
<td>72.3 (12.9)</td>
<td>24.8</td>
</tr>
<tr>
<td>1999</td>
<td>316.6 (8.8)</td>
<td>80.4 (11.13)</td>
<td>25.4</td>
</tr>
<tr>
<td>2000</td>
<td>326.0 (2.9)</td>
<td>82.9 (3.1)</td>
<td>25.4</td>
</tr>
<tr>
<td>2001</td>
<td>341.7 (4.8)</td>
<td>84.7 (2.2)</td>
<td>24.8</td>
</tr>
<tr>
<td>2002</td>
<td>370.9 (8.5)</td>
<td>90.5 (6.9)</td>
<td>24.4</td>
</tr>
<tr>
<td>2003</td>
<td>383.9 (3.3)</td>
<td>94.5 (4.3)</td>
<td>24.6</td>
</tr>
<tr>
<td>2004</td>
<td>438.8 (14.1)</td>
<td>109.4 (15.7)</td>
<td>24.9</td>
</tr>
<tr>
<td>2005</td>
<td>452.4 (3.1)</td>
<td>112.1 (2.4)</td>
<td>24.8</td>
</tr>
<tr>
<td>2006</td>
<td>456.4 (0.9)</td>
<td>114.1 (1.8)</td>
<td>25.0</td>
</tr>
<tr>
<td>2007</td>
<td>473.8 (3.8)</td>
<td>117.0 (2.5)</td>
<td>24.7</td>
</tr>
</tbody>
</table>

Source: [16,17] (USD 1 = 32 NTD in 2005).
## Table 5  Summary of evidence-based decision-making in Asia-Pacific with rapidly changing health-care systems: Thailand, South Korea, and Taiwan

<table>
<thead>
<tr>
<th>Issues for decision</th>
<th>Evidence used</th>
<th>Evidence producers</th>
<th>Evidence users</th>
<th>Legal frameworks</th>
<th>Special notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval for market authorization</td>
<td>Drugs, chemical, biotechnological, safety, toxicology, product patent and, safety, efficacy information (BE study for the generics of all new drugs, PMS data for the market authorization revision)</td>
<td>Original and generic drug company and the FDA officer</td>
<td>Original and generic drug company, BPA, BFDA, and CDE Officers</td>
<td>KFDA, BFDA, and DBC</td>
<td>Certificate of free sales in country of origin is needed</td>
</tr>
<tr>
<td></td>
<td>Drugs Safety and efficacy</td>
<td>Drugs Safety, effectiveness, quality evidences and clinical trial data are applied for permit license</td>
<td>Subcommittee on drug evaluation under relevant Committees established in the three Acts</td>
<td>Therapeutic Subdivision of BPA, BFDA, CDE, DBC, HTA</td>
<td>NHTAC assess safety and efficacy of the New procedures, diagnostics before applying for listing of reimbursement to HIRA.</td>
</tr>
<tr>
<td>Medical devices</td>
<td>Medical devices quality, safety, and efficacy and assessment of social, economic and ethical impact</td>
<td>Medical device companies and the FDA officer</td>
<td>Medical device companies, NHTAC</td>
<td>KFDA, NHTAC, BPA, BFDA, and DBC, HTA, NHI, HTA division</td>
<td>Necessary for certification of free sales in country of origin.</td>
</tr>
<tr>
<td></td>
<td>1) Apply for permit license: Safety, efficacy</td>
<td>Medical devices Safety, effectiveness, quality evidences and clinical trial data are applied for permit license</td>
<td>Medical device companies, BPA, BFDA, and CDE, NHI, HTA division</td>
<td>Device BC of NHI Officers</td>
<td>Certificate of free sales in country of origin is needed</td>
</tr>
<tr>
<td></td>
<td>2) Apply for marketing: Safety, efficacy and GDP</td>
<td>Medical device companies and the FDA officer</td>
<td>Medical device companies, BFDA, HTA, NHI, HTA, NHTAC, BPA, BFDA, CDE, DBC, HTA, NHI</td>
<td>Medical Device Evaluation Subcommittee</td>
<td>NHTAC assess safety and efficacy of the New procedures, before applying for listing of reimbursement to HIRA.</td>
</tr>
</tbody>
</table>

### Notes
- BE, bioequivalence study; BFDA, Bureau of Food and Drug Analysis; BPA, Bureau of Pharmaceutical Affairs; CDE, Center for Drug Evaluation; CE, cost effectiveness; COI, conflict of interest; DBC, Drug Benefit Committee; Device BC, Device Benefit Committee; EMCI, Essential Medical Cost Index; FDA, Food and Drug Administration; HIRA, Health Insurance Review and Assessment Committee; HTA, Health Technology Assessment Program; ISAE, safety and efficacy; KFDA, Korean Food and Drug Administration; NHI, National Health Insurance; NHTAC, New Health Technology Assessment Committee; PE, pharmacoeconomic; PMS, Post Marketing Surveillance; WGs, Working Group.
the list while the other two were kept on it by lowering their prices.

Taiwan. The BNHI has introduced many strategies to control health expenditure. These strategies include price adjustment based on the prices of international products; existing products (inter-brands comparison) or market price and volume survey; delegation of financial responsibility to regional bureaus; co-payment for outpatient drugs; generic grouping (a reference pricing scheme based on chemical equivalence); a global budget payment system for clinics and hospitals; and reduction of flat daily payment rate of drugs for clinics.

After an increase in overall drug costs in the NHI from 62.2 billion NTD (about 1.9 billion USD) in 1996 to 94.5 billion NTD in 2003, Lee et al. [16] carried out a time-series analysis of the impact of the various price control strategies on the growth rate of drug costs. Recent information from BNHI as of May 2008 shows that drug costs reached 117 billion NTD in 2007 [16]. Three strategies, consisting of generic grouping, delegation of financial responsibility, and reduction on flat payment rate of clinics, were significantly associated with the reduction of drug costs. Hospital global budgets, however, offset partial savings from the above-mentioned three strategies.

Cumulative savings during the study period were estimated to be 25.4 billion NTD (about 0.80 billion USD) [16]. Of all the strategies, generic grouping had the most significant effects on all models except for outpatient clinics. Reduction of flat payments and delegation of financial responsibility were significantly associated with drug cost reductions in clinic and inpatient sectors, respectively. Nevertheless, neither drug co-payment nor price adjustment based on international or interbrand price comparison had significant impact on drug costs (Table 4) [16,17].

Discussion and Conclusion

The establishment of universal health insurance systems with rapidly increasing health expenditure poses considerable challenges to policymakers having to decide which interventions are to be authorized and funded in the formal health sector. This study reveals actors and processes involved in generating, using and applying evidence to inform policy decisions on the approval of medicines, with guidelines set by the government to ensure the quality of research. In Thailand, where HITAP is currently responsible for the gathering of PE data, the newly developed guidelines suggest a shift toward the Korean and Taiwanese systems where pharmaceutical industry or importers can submit economic evaluation data.

It is noteworthy that although evidence-based decision-making has been applied in all processes within the three settings with respect to drugs, this has not been the case with medical devices in the Thai setting. The enhancement of evidence-based decision-making is found throughout the health-care systems of Thailand, South Korea, and Taiwan. Table 5 summarizes the key areas where evidence-based decision-making has been established in the three countries. With the increasing use of evidence to inform their decision-making, the 3rd Asia-Pacific Conference of the ISPOR has recognized these three cases as having rapidly changing systems compared with other members of the Asia-Pacific region. The lessons learnt from this article might be useful for other nations that seek to enhance the use of the scientific-based data in general and economic evaluation data in particular in developing their health policy.

We acknowledge Dr.Suwit Wibupolprasert and Dr.Viroj Tangcharoensathien, Senior Advisor on Health Economics and Disease Control of the Thai Ministry of Public Health for giving us direction and crucial comments on this study; Dr. Yot Teerawattananon, program leader of HITAP, Ms. Zandra Z. Yin, Director, International Development (Asia, Pacific, Africa, and Europe) and International Society for Pharmacoeconomics and Outcomes Research (ISPOR) for full support. Dr.Yoel Lubell from HITAP for English language technical support and other suggestions on the manuscript.

Source of financial support: No funding was received.

Thidaporn Jirawattanapisal, Pritaporn Kingkaew, Tae-Jin Lee, and Ming-Chin Yang have no conflicts to declare.

References


